



7th International
Conference on
**HIV TREATMENT
AND PREVENTION
ADHERENCE**

June 3-5, 2012 • Miami



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Postgraduate Institute
for Medicine



79403 Tolerability of Atazanavir-versus Darunavir-Based Combination Antiretroviral Therapy among US Medicaid HIV Patients

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Objectives: No large, randomized head-to-head comparison of the tolerability of atazanavir (ATV) and darunavir (DRV) for first-line treatment of HIV-1 is currently available. This study compared the tolerability of ATV- versus DRV-based combination antiretroviral therapy (cART) among US Medicaid patients receiving routine HIV care.

Methods: Retrospective study using Medicaid claims data from 15 US states. Subjects were HIV patients 18-64 years of age initiating ATV- or DRV-based cART from 1/1/2003 to 7/1/2010, with continuous enrollment for 6 months before (baseline) and 6 months after (evaluation period) cART initiation, and at least 1 evaluation period medical claim. Outcomes were the incidence of new-onset medically attended (ICD-9-CM-coded or treated) tolerability issues during the evaluation period. Five specific issues were selected from published literature: gastrointestinal; lipid abnormalities; diabetes/hyperglycemia; rash; jaundice. ATV and DRV patients were propensity score matched (ratio 3:1) using demographic, clinical, and treatment covariates. Statistical analyses consisted of Kaplan-Meier survival analyses and multivariable Cox proportional hazards models adjusting for covariates lacking post-match statistical balance.

Results: Matched study sample included 1848 ATV and 616 DRV patients; mean age 41 years, 50% female, 69% black. Incidence rates per 1,000 patient-months of observation were: gastrointestinal - ATV 43, DRV 60 ($p = 0.01$); lipid abnormalities - ATV 17, DRV 27 ($p < 0.01$); diabetes/hyperglycemia - ATV 8, DRV 8 ($p = 0.61$); rash - ATV 87, DRV 111 ($p = 0.007$); jaundice - ATV 1.1, DRV 0.3 ($p < 0.01$). After multivariable adjustment, hazard ratios for DRV (reference = ATV) were: gastrointestinal - 1.25 ($p = 0.04$); lipid abnormalities - 1.38 ($p = 0.07$); diabetes/hyperglycemia - 0.84 ($p = 0.55$); rash - 1.11 ($p = 0.23$). Too few instances of jaundice (12) occurred to support multivariable modeling.

Conclusions: Medication tolerability can play a major role in the success or failure of cART. In this study, ATV patients had a significantly lower hazard of gastrointestinal issues and a lower hazard of lipid abnormalities that trended toward significance ($p = 0.07$).

79404 Falling Through the Cracks: The Gaps between Depression Prevalence, Clinical Recognition, Treatment, and Response in HIV Clinical Care

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Background: Depression is prevalent among people living with HIV/AIDS (PLWHA), goes clinically unrecognized in a majority of cases, and when identified is often untreated or undertreated. Untreated or ineffectively treated depression reduces success at multiple points along the HIV treatment continuum of HIV diagnosis, engagement, treatment, adherence, and virologic suppression, and thus likely influences overall community viral load (VL). Successful treatment of depression in PLWHA requires its own treatment continuum: clinical recognition, initiation of treatment, adequacy of treatment, and achievement of remission. Our goal was to quantitatively describe the depression treatment cascade in HIV patients and to estimate the overall proportion of depressed HIV patients who are being effectively treated.

Methods: We reviewed the literature to estimate the proportion of depressed HIV patients who are clinically recognized as depressed, receiving any mental health treatment, receiving adequate treatment, and achieving depression remission.

Results: Based on the literature, we estimate that approximately 25% of PLWHA have had a major depressive disorder in the past year; of those with a disorder, 45% are recognized clinically, 23% receive any treatment, 8% receive adequate treatment, and 6% achieve remission. Thus, 77% of PLWHA with depression are not receiving any treatment, 92% are not receiving adequate treatment, and 94% have not achieved remission. Simulations suggest that only by targeting multiple steps along the depression treatment continuum can overall remission rates for PLWHA be substantially improved.

Conclusions: While effective medical treatments for depression are well established, the successful treatment of depression in HIV patients is a rare event due to shortcomings in clinical recognition, treatment initiation, and treatment adequacy. Mental health care models for HIV patients that address these gaps will be critical both to improve quality of life and to mitigate depression's impact on community VL.



79425 Task Shifting to Community Health Workers: Evaluation of the Performance of a Peer-Led Model in an Antiretroviral Program in Uganda

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Background: Task shifting to community health workers (CHW) has received recognition. We examined the performance of community antiretroviral and tuberculosis treatment supporters (CATTS) in scaling up antiretroviral therapy (ART) in Reach Out Mbuya, a community-based ART program in Uganda.

Methods: Retrospective data on home visits made by the CATTS were analyzed to examine the CATTS ability to perform home visits based on the model's standard procedures. Qualitative interviews were conducted with 347 randomly selected patients and 47 CATTS to explore their satisfaction with the model.

Results: The CATTS ability to follow up with patients worsened from patients requiring daily, weekly, monthly, to three-monthly home visits. Only 26% and 15% of them correctly home visited patients with drug side effects and a missed clinic appointment, respectively. Additionally, 83% visited stable pre-ART and ART patients (96%) more frequently than required. Of the 3650 patients, 680 (18%) were lost to follow up (LTFU) during the study period. The mean number of patients LTFU per CATTS was 40.5 who were male, ($p = 0.005$), work for longer durations ($p = 0.02$), and had lower education ($p = 0.005$). An increased number of patients ($p = 0.01$) were associated with increased LTFU. Ninety-two percent of the CATTS felt that the model could be improved by reducing the workload. CATTS who were HIV positive, female, not residing in the same village as their patients, more educated, married, on ART, and spend less time with the patients were rated better by their patients.

Conclusions: The Reach Out CHW model is labor-intensive. Triaged home visits could improve performance and allow CATTS time to focus on patients requiring more intensive follow-up.

79427 Socioeconomic Support Reduces Non-Retention in a Comprehensive, Community-Based Antiretroviral Therapy Program in Uganda

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Background: The benefits of socioeconomic support (SE support), composed of various financial and nonfinancial services that are available based on assessment of need, in reducing mortality and lost to follow-up (LTFU) at Reach Out Mbuya (ROM), a community-based ART program in Uganda, were evaluated.

Methods: Retrospective observational cohort data from adult patients enrolled between May 31, 2001, and May 31, 2010, were examined. Patients were categorized into none, 1, and 2 or more SE support based on the number of different SE support services they received. Using Cox proportional hazards regression, we modeled the association between SE support and mortality or LTFU. Kaplan-Meier curves were fitted to examine retention functions stratified by SE support.

Results: In total, 6645 patients were evaluated. After 10 years, 2700 (41%) were retained. Of the 3954 not retained, 2933 (74%) were LTFU and 1021 (26%) had died. After 1, 2, 5, and 10 years, the risks of LTFU or mortality in patients who received no SE support were significantly higher than those who received some SE support. In adjusted hazard ratios, patients who received no SE support were 1.5-fold (1.39-1.64) and 6.7-fold (5.56-7.69) more likely to get LTFU compared with those who received 1 or ≥ 2 SE support, respectively. Likewise, patients who received no SE support were 1.5-fold (CI: 1.16-1.89) and 4.3-fold (CI: 2.94-6.25) more likely to die compared with those who received 1 or ≥ 2 SE support, respectively.

Conclusions: Provision of SE support reduced LTFU and mortality, suggesting the value of incorporating such strategies for promoting continuity of care.



79428 Return to Normal Life after AIDS as a Reason for Loss-to-Follow-Up in a Community-Based Antiretroviral Treatment Program

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Background: Understanding the reasons for loss-to-follow-up (LTFU) from a community-based antiretroviral therapy (ART) program in Uganda is important.

Methods: Retrospective cohort of patients LTFU between May 31, 2001, and May 31, 2010, was examined, and a representative sample of 579 patients was traced to ascertain their outcomes. Qualitative methods were used to explore reasons for LTFU. Using a Cox proportional multivariable model, we examined risk factors for stopping treatment.

Results: Of 579/2933 patients sampled for tracing, 32 (5.5%) were untraceable, 66 (11.4%) were dead, and 481 (83.0%) were alive. Of those found alive, 232 (40.0%) stopped treatment, 249 (43.0%) self-transferred, and 61 (12.7%) returned to care at Reach Out Mbuya (ROM). In adjusted hazard ratios, born-again religion, originating from outside Kampala, resident in Kampala for 1-5 years, having school-age children who were out of school, non-HIV disclosure, and pre-ART were associated with increased risk of stopping treatment. Strict enrollment, follow-up procedures, pre-ART eligibility criteria, catchment area restrictions, return to work and family, religious beliefs, and long waiting times were cited as main barriers to retention.

Conclusions: Many patients on ART have an improved quality of life and return to normal life. These factors are main reasons for discontinuation of care. HIV care should therefore be normalized and managed as a chronic disease, with the patients taking a central role in the management of their health. Efforts should be made to identify those in need of close follow-up, improve referrals, and develop mechanisms to track patients who transfer to different treatment sites.

79429 Strategies for Optimizing Clinic Efficiency in a Community-Based Antiretroviral Treatment Program in Uganda

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Background: Antiretroviral therapy (ART) scale-up is challenged by increasing caseloads, health worker shortages, and labor-intensive care models.

Methods: Using a before and after study design, time and motion studies, and qualitative methods, we evaluated the impact of triage and longer intervals between clinic visits on clinic efficiency in a community-based program.

Results: Overall time spent at the clinic was reduced from 206 minutes (range: 159-250) to 85.5 minutes (range 59-116) ($Z = -1.996$; $p = 0.046$). The total time waiting to see providers was reduced from 94 minutes (range: 58-131) to 82 minutes (range: 55-109) ($p = 0.000$; $Z = -14.032$). Patients undergoing ART preparation waited longest to see providers and stable non-ART and stable ART patients spent less time with providers during both periods. Patient and provider satisfaction improved and waiting times were reduced, allowing better service delivery to more patients using the same staff.

Conclusions: Improving clinic efficiency is a continuous process, and there is the need to train providers and to integrate quality improvement techniques into routine clinic operations.



79458 Supporting Adolescents Living with HIV/AIDS (ALHIV) to Live Positively through Peer Support Groups

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Background: Reach Out Mbuya (ROM) is a community-based non-governmental organization (NGO) that started in 2001. ROM provides care, treatment, and support to adults, children, and adolescents. In addition, services have been provided to orphans and vulnerable children (OVCs) in 7 core program areas. In 2008, the Friends' Forum Club (FFC), a peer support group (PSG) for adolescents living with HIV/AIDS (ALHIV), was established at ROM HIV/AIDS Initiatives. The mission of the FFC is "to empower HIV-positive adolescents to build a positive self image, adhere to antiretroviral therapy, establish healthy relationships, improve their self-esteem, and acquire life skills through adolescent peer mentorship and adolescent-led structured activities, ultimately leading to improved care and well being."

Methods: FFC monthly meetings typically run every first Saturday of the month throughout the year. The members are counseled in individual and small group therapy sessions that consider pressing needs among other variables. The FFC also incorporates educational components including topics on reproductive health, antiretroviral adherence, disclosure, life skills, college preparation, personal finance management, and goal-setting.

Results: The FFC currently has 300 participating ALHIV. Eighty percent of the participants report being better at handling daily life, 70% report getting along with family and peers, 80% have improved class attendance and are performing well academically, 60% are coping well with issues of stigma and accepting their HIV status, and 95% report improved medical adherence, practicing life skills, and having more hope for the future. Eighty-five percent have developed the capacity to share their personal life experience with other peers. ALHIV who are well informed about their illness (HIV/AIDS) can make healthy decisions concerning their medication, choose to live positively, and avoid treatment failure.

Conclusions: Peer-to-peer education and support have made significant contributions to the attitudes and behavior of ALHIV and to the prevention of further infections. Adolescent involvement in the planning and programming of intervention is key in the peer-to-peer model of care and support, and it has a great impact compared to the adult-led model.

79923 Behavioral Interventions to Promote Linkage to Care and Retention in Care among People Diagnosed with HIV in the United States: A Qualitative Systematic Review, 1996-2011

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Background: Early entry into HIV care and better retention in care have been shown to improve the health and quality of life of HIV-diagnosed persons. Keeping HIV-diagnosed persons in continuous HIV care is likely to reduce viral load levels, thereby reducing the risk of HIV transmission. We conducted a qualitative review of interventions that promoted linkage to care, retention in care, and health care utilization in HIV-diagnosed persons in the United States.

Methods: Comprehensive searches included electronic databases, hand searches of journals, reference lists, and listserv. Studies were included if they were conducted in the United States after 1996 and had data on linking, retention in care, or health care utilization.

Results: Fourteen studies met the selection criteria, and all addressed patient-level barriers. There was great heterogeneity in target population, study design, intervention component, analysis approach, and outcomes measured. Four studies specifically targeted newly diagnosed persons, and 3 targeted those falling out of care. Eight studies used 1-group designs and 6 used controlled trials. For outcomes, 3 studies reported data on linking newly diagnosed individuals to care, 5 reported retention in care, and 10 reported general health care utilization. Despite heterogeneity, several strategies showed potential in successfully promoting positive outcomes, including providing counseling, education, and support; using a coordinator who is actively involved in a client's care activities; offering co-located care or transportation; and providing ancillary services.

Conclusions: Emerging strategies identified in this review could be considered for implementation and further evaluated in real-world settings with more rigorous study designs. Standardized measures of linkage and retention in care should also be established to facilitate comparison across studies and identification of best practices. More research is needed to examine the added effect of multidimensional interventions that not only address individual factors but also system and structural factors associated with barriers to health care utilization.



79936 Evaluation of Antiretroviral Treatment Adherence in People Living with AIDS in an Infectious Diseases Clinical Care Unit at Amazonas State, Brazil

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Introduction: Brazil has 600,000 people living with AIDS, with 75% of them using first-line antiretroviral therapy (ART) regimens. Amazonas has about 5000 people using ART. This is the first study about their perceptions of adherence and the limitations of their treatment.

Objectives: To learn about the difficulties related to adherence to ART, allowing for a better understanding of non-adherence to treatment and helping to improve local adherence monitoring.

Methodology: A cross-sectional sample of 94 people with AIDS taking ART in the unit. Data were obtained through interviews conducted at the hospital and the pharmacy. Adherence was estimated based on the number of tablets taken in the 7 days preceding the interview. Good adherence was defined as taking at least 95% of the tablets.

Results: Eighty-two percent of patients reported adherence to treatment, and 18% reported non-adherence. About 83% of non-adherent patients were male. People with elementary education made up 88% of patients in the non-adherence group. When asked to classify the support they receive from friends/family as good, fair, or poor, 29% reported "bad" in the non-adherence group, while only 6% said the same in the adherence group. All of the patients in the non-adherence group had side effects; 53% reported that they did not know about any of these effects beforehand. The average CD4 cell count at diagnosis showed no difference between the groups; however, the current median CD4 cell count was 242 cells/mm³ in the non-adherence group and 333 cells/mm³ in the adherence group.

Conclusions: The presence of side effects (SEs) when taking ART and lack of information about SEs could be related to non-adherence to treatment. Non-adherence was associated with an increased hospitalization rate. Receiving good support from family was related to greater adherence. Adherence to treatment showed better laboratory results, with higher CD4 cell counts in the adherence group than in the group without satisfactory adherence.

79942 Budget Impact Analysis of HIV Screening and Counseling in the VA Healthcare System

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Background: Screening for HIV is cost effective relative to many interventions, but uncertainty about costs of organizational interventions to encourage screening can impair adoption. Our objective was to conduct a budget impact analysis of an effective intervention to aid managers considering implementation of an HIV screening and testing program.

Methods: We modeled the effects of the intervention on the quarterly costs of antiretroviral therapy (ART), outpatient and inpatient utilization, and staff expenditures in the VA over a 2-year period of increasing HIV testing rate. We used the estimates of HIV prevalence, screening and counseling rates, test return rates, positive test rates, and treatment rates as inputs. We tested the model on a national cohort of 20,000 patients with HIV risk factors over a 2-year period.

Results: Expanding HIV screening from 3% to 15% per year identified an additional 21 cases of HIV infection over a 2-year period at an estimated total cost of approximately \$290,000, over 60% of which was due to the provision of ART to newly diagnosed patients. While the quarterly costs of the testing per se decreased over time as fewer persons required testing, the cost of ART increased from \$10 to more than over \$60,000 over a 2-year period as more infected patients were identified. In sensitivity analyses, the rate of serodiagnosis and the annual rate of HIV testing had by far the greatest impact on programmatic costs.

Conclusions: The fixed direct facility cost to support an HIV testing program during the initial phase is most expensive during the first quarter of operation. Budget impact models like these can be given to managers so that they may conduct sensitivity analyses guiding implementation decisions.



79943 Implementing a Rapid HIV Testing/Linkage to Care Project among Homeless Individuals in Los Angeles County: A Collaborative Effort between Federal, County, and City Government

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Background: The homeless population, though vulnerable to HIV infection, traditionally lacks access to HIV testing diagnostics and linkage to care (LTC). This project, an ongoing collaborative effort involving Gilead Sciences, the US Department of Veterans Affairs (VA), the County of Los Angeles, Department of Public Health, Office of AIDS Programs and Policy, and the City of Los Angeles AIDS Coordinator's Office, is evaluating barriers and facilitators to 1) providing HIV rapid testing to homeless shelter clients; 2) linking HIV-positive individuals to care through a) the VA, or b) the Los Angeles County Department of Health Services, depending on veteran status.

Methods: HIV oral rapid tests are offered by HIV counselors. In cases with (preliminary) positive test findings, a confirmatory test and clinic appointment is arranged, and a taxi voucher is provided. Summary sheets are kept, including tests conducted and client's veteran status. Data analysis is ongoing to review performance. Upcoming qualitative interviews will elucidate barriers and facilitators regarding the success and potential sustainability of this outreach effort.

Results: A year of data indicates significant progress in testing: 733 clients tested (31 veterans); 7 confirmed positive (1 client did not receive confirmatory results); LTC confirmed for 5 clients; 1 client did not return for confirmatory results and was not LTC; another client refused LTC. Challenges included development of confirmatory test procedures, gap between confirmation and LTC, and LTC follow-up.

Conclusions: This collaboration between governmental agencies has been successful and can be used as a model for future collaborative efforts of this type. Efforts are ongoing to better track clients by the use of a new LTC model.

79944 Implementation of a Nurse-Initiated Rapid HIV Testing Intervention at High Prevalence Primary Care Sites within the US Department of Veterans Affairs Healthcare System

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Objectives: The Centers for Disease Control and Prevention (CDC) and the US Department of Veterans Affairs Healthcare System (VHA) have recently adopted policies that support routine HIV testing of all those between the ages of 18-64, regardless of risk profile. Nurse-initiated routine HIV testing has been previously shown to increase testing and receipt of results significantly more than other traditional testing methods. We implemented and subsequently evaluated the implementation of a nurse-initiated model of routine HIV rapid testing in the primary care clinics at 2 geographically distinct, urban VA hospitals: 1 in the mid-Atlantic, and the other in the Southwest United States.

Methods: Study nurses at both sites were trained in HIV rapid testing and VA electronic medical record data entry techniques prior to commencement of the project. HIV rapid testing rates were monitored weekly by local project staff. The original intervention period was originally slated as 6 months at both study sites; due to the strong uptake of our testing program at our Southwest United States site, the study period had to be curtailed to 4 months. Descriptive HIV testing statistics were culled from the VA Corporate Data Warehouse (CDW) for purposes of site comparison.

Results: At our mid-Atlantic United States site, 2364 HIV rapid tests were conducted at our targeted clinics during the 6-month intervention period. At our Southwest United States site, 2522 tests were conducted during an abbreviated 4-month study period. At site 1, we identified 5 previously undetected HIV-positive veterans during our study period and 2 after the study period. At site 2, we identified 9 HIV-positive veterans and 2 after the study period.

Conclusions: Nurse-initiated HIV rapid testing was successfully implemented at both study sites. Although data entry of HIV test results did present a potential barrier to long-term sustainability, HIV testing continued to occur at varying levels at both sites, post-intervention.



79945 Qualitative Assessment of Re-Entry into Care for Previously Incarcerated HIV/HCV-Infected Veterans

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Objectives: Veterans are overrepresented in incarcerated populations, making up to 10% of all inmates. Incarcerated veterans are at higher risk for HIV and hepatitis C virus (HCV) and in addition, confront challenges to obtaining post-release medical care (e.g., perceived unavailability of civilian health services and poor discharge planning). This VA-funded study, currently ongoing and in collaboration with the Los Angeles County Office of AIDS Programs and Policies (OAPP), is evaluating the barriers, facilitators, and gaps in care that exist regarding linkage to VA medical services for recently incarcerated HIV and/or HCV-infected veterans from the perspective of clinical and social service providers, as well as newly released veterans themselves.

Methods: We are recruiting and interviewing 29 participants. These participants consist of 20 VA outreach and LA County jail staff charged with linking recently released veterans to care as well as 9 recently released veterans who self-report a history of HCV or HIV to the VA Outreach Specialists (VAOS).

Results: Although the study has recently begun, barriers to linkage and care have already been identified. Results show that VA providers do not have access to the veterans' records while incarcerated; consequently the treatment plan veterans receive in jail is self-reported and usually incomplete. Our other major finding is that the VAOS are solely present in the men's jails and access the women's jail only upon request, but many women veterans are unaware of the VAOS service.

Conclusions: Initial data suggest that veterans who are released from jail should be given a discharge summary of their treatment plan and have the VAOS enter their history into the patients' VA electronic medical records. In addition, with the growing number of women veterans, we should have VAOS active in both the men's and women's jails.

79948 Acceptability of Fingerprint Scanning for Personal Identification among Patients Seeking HIV/STI-Related Services, Los Angeles, 2011

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Background: Easily collected and reliable unique digital personal biometric identification may allow for simplified monitoring of HIV testing, linkage, and retention in care. Fingerprint scan identification is inexpensive and increasingly used in the private sector and in research studies. We determined the potential acceptability of using fingerprint scan identification among clinic patients in Los Angeles, California, with particular attention to differences in acceptance among racial/ethnic groups.

Methods: In November 2011 we administered a 10-question survey to a convenience sample of consecutive patients at an urban HIV/sexually transmitted infection (STI) clinic. Acceptance was defined as "likely" or "very likely" to agree to provide a future fingerprint scan for personal identification. "Unsure" participants were excluded. We entered data into Excel and used STATA12 for statistical analyses.

Results: Of 191 survey respondents, 147 responses were complete and analyzable. Except for female sex, participant characteristics of included responses were similar to those not included. Among those 147, 96% (n = 141) were men, and 94% (n = 132) were men who have sex with men (MSM). Overall acceptance was 72%. Within MSM, acceptance was 76% among white MSM (n = 55), followed by 70% among Hispanic MSM (n = 46), 70%, mixed MSM (n = 10), and 67% among African-American MSM (n = 12). African American and Hispanic MSM were not less likely to report intended acceptance compared with white MSM (risk ratio (RR) 0.9, 95% CI 0.6, 1.3; RR 0.9, 95% CI 0.7, 1.1, respectively). Acceptance among women (n = 3) or transgender (n = 3) persons was 67% and heterosexual men (n = 8) was 63%.

Conclusions: The potential use of fingerprint scan identification was very acceptable among persons seeking HIV/STI testing and care in an LA clinic. While our modest sample size limits inferences about racial/ethnic differences, acceptance was essentially similar across subgroups. Fingerprint scan identification could be a powerful way to facilitate monitoring in testing and linkage-to-care programs.



79960 Lessons Learned from an HIV Medication Adherence and Quality of Life Intervention for Persons 50 Years and Older: PRIME

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Introduction: The number of people living with HIV (PLWH) aged 50 years and older is growing, and the CDC projects this age group may represent half of the US HIV population by 2015. HIV programs have traditionally targeted younger populations or have not been tailored for this age group. However, PLWH who are 50 years and older have a different peer group, particular socioeconomic concerns, unique health needs such as increased rates of chronic health problems, multiple medication adherence issues, and health-related quality of life (QOL) concerns.

Description: This presentation will describe the experience of a telephone-delivered trial of a self-management intervention to improve treatment adherence and QOL among 452 older PLWH. Participants were recruited from AIDS Service Organizations (ASOs) from 9 geographic areas across the United States. Participants were randomized to 1 of 3 interventions: 1) control (self-management book only); 2) group conference calls; and 3) individually tailored telephone counseling. All participants received a book on self-management and living well with HIV. Targeting medication adherence and QOL, the intervention arm was holistic in nature and covered topics including: personal values, readiness to change health behaviors, HIV treatment knowledge, problem solving, medical self-monitoring, symptom management, stress and depression, physical and social activity, health-related communication, prioritizing health problems, and accessing care resources.

Lessons Learned: Retention rates were high for the research survey, but there were significant differences in attendance between the group and individual arms. Lessons learned and recommendations will be described including intervention delivery and content considerations, recruitment and retention tips, medication adherence challenges, treatment tailoring, and common health-related goals in this population.

Recommendations: Telephone counseling that is individually tailored and holistic, and recognizes the unique needs of this population appears to be a feasible and acceptable mode for supporting self-management among older PLWH.

79970 Adherence and Quality of Life in HIV-Infected Patients after 9 Months of Receiving HAART at a Northern Nigerian Hospital

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Background: Improved adherence to antiretroviral therapy (ART) should improve clinical outcomes and health-related quality of life (QOL). This study aims to evaluate the effect of adherence on QOL among treatment-naïve HIV infected individuals receiving ART in an adherence study in Kano, Nigeria.

Methods: A review of self-reported QOL measures for 600 HIV-positive patients initiating ART and enrolled into the first phase of an adherence intervention study in Kano, Nigeria, (August 2006 and January 2008) was conducted. Patients' QOL was measured at ART initiation and 9 months thereafter using a validated 10-item SF-12 survey. Responses were grouped into 8 QOL domains, and a paired Student's T test was used to compare mean scores. Changes in aggregate physical health (PCS) and mental health (MCS) summary scores and associations between patient characteristics were examined. HRSA's 3-question-adherence measure was used to determine self-reported adherence (scores of above 10 were considered good) at Month 9.

Results: Of 600 study participants, 259 (43%) were male with a mean age of 33 years. Median baseline CD4 lymphocyte count was 165 cells/mm³, and HIV-1 viral load (VL) was 94,487 copies/mL. Baseline PCS and MCS scores were 41.9 and 57.0, respectively. Participants experienced significant improvement in all QOL dimensions; namely general health perception, physical functioning, physical pain, mental health, physical health, emotional health, energy, and social functioning ($p < 0.0001$). Participants reporting good adherence achieved higher general health perception Z scores at 9 months compared to those with suboptimal adherence (0.42 vs -0.06 $p = 0.07$). Four hundred and twenty-one participants (70%) completed this study phase, (70 were terminated from the study, 75 were lost-to-follow-up, 31 died, and 3 transferred). Analyses of QOL measures beyond 9 months of follow-up (Phase II) are in progress.

Conclusions: The relationship between treatment adherence and QOL in resource-limited settings should be further explored.



79971 Providing Access to CD4 Testing among HIV-Positive Pregnant Women through an Outreach System: A Case of Northern Uganda

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Introduction: In 2009, the Ministry of Health (MOH) formulated a preventing mother-to-child transmission (PMTCT) scale-up plan with a target of 80% HIV-positive mothers assessed for antiretroviral therapy (ART) eligibility through CD4 cell count testing and/or WHO clinical staging. Eighty percent of those eligible were initiated on highly active antiretroviral therapy (HAART). The Northern Uganda Malaria and Tuberculosis Programme (NUMAT) supported the efforts to increase the identification and initiation of these mothers on ART using an outreach model. Apac District with 14 PMTCT Sites was selected for the pilot phase.

Description: Starting March 2010, NUMAT partnered with the district and CNAPSIS, a Canadian Medical logistics company, to extend CD4 cell count services to all the 14 sites. CNAPSIS bikers were facilitated on bi-weekly basis to visit the sites, carry out phlebotomy, transport samples from the facilities, test, and return results. A joint team from the partners visited facilities quarterly to review progress, address challenges, and mentor the health workers. Those found eligible were referred to NUMAT-supported ART clinics for initiation.

Lessons Learned: Over a period of 15 months, 318 HIV-positive mothers were enrolled. A total of 275 (86%) had their CD4 cell count tested and obtained results, while 240 had complete records of clinical staging and drug regimens prescribed. The median CD4 cell count test result was 418 cells/mm³. A total of 121 mothers had CD4 cell count <350 cells/mm³, and of these 55 were initiated on ART while the rest were put on prophylaxis regimens. It was found that the WHO staging, while useful in deciding eligibility for ART, showed a high specificity (95%), but a low sensitivity (50%).

Recommendations: An outreach model is feasible for CD4 cell count access in resource-limited settings, especially if backed by rigorous follow-up of mothers into the community and close supervision of health workers. Utilizing the CD4 cell count test for deciding on PMTCT drug regimen is a more reliable approach than WHO clinical staging. CD4 cell count testing for pregnant mothers should be scaled up for a more effective PMTCT intervention.

79974 The Impact of Case Management from a Men's Only Group on CD4 Cell Counts, Viral Loads, and ART Adherence in a Pilot Study of HIV-Positive Men

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Background: Research has not adequately addressed the impact of case management in HIV-positive men alone, or if there is a difference in their antiretroviral therapy (ART) adherence. Developed and led by a case manager in September 2006, the "Men's Only Group" met once a month. At these meetings, HIV-positive men in the practice could openly discuss topics about their disease with other HIV-positive men. Our study determined the impact of case management in a non-formal setting in HIV-positive men who attended the "Men's Only Group" compared to those who did not. Adherence to ART, CD4 cell counts, and viral load (VL) were compared.

Methods: This was a retrospective, case-matched study in which men who were 18 years or older were eligible if they were "Men's Only Group" participants for a minimum of 6 total sessions and had at least 3 measurements of CD4 cell counts and HIV VL. Exclusion criteria included attendance of less than 6 total sessions, hepatocellular carcinoma, or treatment with interferon or chemotherapeutic agents. Thirty cases were matched on a 1:3 ratio with controls by baseline characteristics of age and race. At various follow-up intervals, ART, change in CD4 cell counts, VL, and adherence scores were assessed.

Results: By the third follow-up visit, the case group had higher mean CD4 cell counts (620 vs 526 cells/mm³), lower mean VL (3047 vs 20,461 copies/mL), a higher percentage of undetectable VL (80% vs 69%), and a higher adherence percentage score (96% vs 94%).

Conclusions: There was a trend in improved CD4 cell counts and VLs in HIV-positive men who attended the "Men's Only Group." Men who attended these sessions regularly may have a higher likelihood of adherence with ART. In our study, case management in an informal setting showed an impact on ART adherence.



79978 A Counseling Package for Reintegrating Patients into Care after Loss to Follow-Up: Return to Care Counseling and the Self-Care Course

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Introduction: Retention to antiretroviral therapy (ART) is a challenge for programs and recent data show that rather than withdrawing permanently, patients tend to cycle in and out of care. This has deleterious effects on ART outcomes. Returning to care can be difficult for patients who must “reintegrate” into a system that may have multiple penalties for treatment interrupters. Interventions that use re-entry into care as an opportunity to promote retention are needed. To address reintegration in resource-limited settings and prevent additional interruptions in care, we developed a theory-based comprehensive reintegration package to improve and monitor retention in care.

Description: The intervention approach uses motivational interviewing and draws from situated application of the Information, Motivation, Behaviour Skills (IMB) model to retention in care. The two-part intervention includes Return to Care Counseling (RTCC) and a group Self-Care Course (SCC). RTCC is an 8-step, 15 minute, one-to-one discussion, exploring facilitators and barriers to retention that defines a personalized clinic attendance-related goal and strategizes on the realization of that goal. Additionally, coping and resilience for reintegration into the clinic system is addressed. The SCC is an education and counseling group which uses discussion and exercises to assist participants in developing their own self-care plan. The intervention has been translated into an SOP and supportive documents.

Lessons Learned: Intervention mapping generally structured the development approach. The development of RTCC and the SCC was informed by staff experiences and review of clinic-based data. Throughout this development process, current standard of care, potential areas for improvement, and need for patient support that is culturally competent and sensitivity to local clinical care environment and resources were considered.

Recommendations: The package will be pilot-tested in an ART clinic in Cape Town, South Africa. Patients and staff will complete evaluation surveys assessing feasibility and acceptability and identifying areas for improvement. Chart-abstracted data will be reviewed for retention and treatment outcomes. A pre-/post-implementation assessment of clinic staff attitudes will examine changes in perceptions of patients returning to care.

79979 Racial and Ethnic Differences in Adherence-Related Dialogue in HIV Care

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Background: Disparities in quality and outcomes of care for people with HIV negatively affect black and Hispanic patients. Differences in provider-patient communication could be involved.

Methods: Using the Generalized Medical Interaction Analysis System (GMIAS), which codes for both topic and speech act category of all utterances in a visit, we analyzed 415 routine outpatient visits by people with HIV, with 45 different providers in 4 practice settings.

Results: There were few differences in communication patterns related to patient race/ethnicity. A previous observation that black patients make fewer utterances than others was replicated. A new observation, possible only with the GMIAS, is that in a model with physician as a random effect and adjusting for site, patient age, gender, log₁₀ HIV RNA, CD4 T-cell count, and self-reported adherence, there was more dialogue concerning antiretroviral adherence with black and Hispanic patients than with white patients ($p = .02$). There was not more “problem solving” dialogue about specific strategies to improve adherence; the increased dialogue consisted only of physician inquiries and general advice to be more adherent. Speech act patterns were similar for all 3 groups, with strong provider verbal dominance and directiveness.

Conclusions: Although black and Hispanic patients did tend to have higher viral loads, there was more discussion of adherence after controlling for the difference. Perhaps providers are less confident that their black and Hispanic patients are adherent, regardless of indications; or perhaps black and Hispanic patients have a greater need or desire to discuss adherence, or to discuss it at greater length. Whether this is beneficial to patients, or represents a misallocation of time or misdiagnosis of need, is unclear. It is possible that adjusting for clinical variables and self-reports does not fully capture a patient’s need for adherence counseling. Further research on how these discussions are initiated and maintained is needed.



79981 ART Adherence and Psychological Distress among English- and Spanish-Speaking PLWHA on the US-Mexico Border

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Background: People living with HIV/AIDS (PLWHA) suffer from disproportionate rates of psychological distress, which negatively impacts antiretroviral therapy (ART) adherence. Furthermore, racial/ethnic minorities, including Latinos, have been found to have lower levels of ART adherence. We evaluated the extent to which psychological distress predicted ART adherence among English- and Spanish-speaking adults.

Methods: We recruited a nonprobability sample of 300 HIV-positive adults (80% male; 51% Spanish speaking; 82% of Mexican descent) at an HIV primary care clinic on the US-Mexico border. A cross-sectional survey assessment included a 30-day visual analog scale (VAS) assessing adherence, the Hospital Anxiety Subscale (HAS), the Beck Depression Inventory IA (BDI-IA), and the Post-Traumatic Stress Disorder Checklist-Civilian Version (PCL-C). Latent path analysis was used to model associations.

Results: Overall, English speakers reported lower levels of VAS adherence (84.3%) than did Spanish speakers (90.1%) and higher BDI-IA, PCL-C, and HAS scores ($\beta = .18-.28$; all p 's $<.05$). All lower-order factors (BDI-IA, PCL-C, and HAS subscales) loaded onto the higher-order factor of psychological distress ($\gamma = .69-.92$, all p 's $<.05$). Greater latent mean levels of psychological distress were associated with less adherence ($\gamma = -.17$, $p <.05$). Our full model showed that both English language and psychological distress were associated with worse adherence (chi-square = 1921, $p <.05$, RMSEA = .05, CFI = .98, NNFI = .97).

Conclusions: Lower levels of psychological distress and better ART adherence among Spanish speakers suggest that language may be a proxy variable for a protective effect of culture (i.e., familial cohesion or social support) consistent with the Mexican health paradox. Future research should aim to identify these specific protective mechanisms for improving adherence and reducing psychological distress, especially in more acculturated Mexicans in the US-Mexico border region.

79982 Barriers and Enablers to Retention in HIV Care among Patients Not Yet Eligible for ART: A Qualitative Assessment in Rural Tanzania

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Background: Most research on retention in HIV care has focused on patients who are eligible for, or have initiated, antiretroviral therapy (ART). We examined barriers and enablers to retention among patients not yet eligible for ART, or of unknown eligibility due to incomplete clinical immunological assessments.

Methods: We conducted 10 in-depth interviews (IDI) with health care providers, and 25 IDI and 4 focus group discussions with pre-ART patients in 2 public-sector HIV clinics supported by ICAP in Kagera, Tanzania.

Results: Enabling factors to retention in care included participation in people living with HIV/AIDS (PLWHA) support groups or informal community networks that provided emotional and practical support for regular clinic attendance. Specifically, patients reported these supports motivated them to keep clinic appointments, and often provided assistance with transportation costs or home and work responsibilities. Additionally, being a parent inspired greater engagement in care, as parents felt a responsibility to stay healthy for their children. Barriers to retention included non-disclosure of one's HIV status to family, particularly among women. Without admitting they needed to attend the HIV clinic, women faced difficulties obtaining money for transportation and explaining their time away from home. Both non-disclosing men and women also expressed concern that they would be recognized at the HIV clinic. Other barriers to pre-ART retention were patients' conflation of HIV and AIDS and expectations from the HIV clinic. Indeed, some patients believed an HIV diagnosis required immediate ART initiation regardless of disease stage, and were frustrated when deemed ineligible, while others struggled to accept the necessity of regular checkups without medication or other treatment.

Conclusions: Social context, interpersonal interactions, and beliefs regarding HIV/AIDS, ART, and the health care system appear to exert a strong influence, both positive and negative, on patients' motivation and ability to remain engaged in care before they initiate ART



79983 Characteristics of PLWHA Seeking and Not Seeking HIV Care in 2 Russian Cities

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Background: Curtailing the explosive HIV epidemic in Russia will require provision of antiretroviral medications (ARVs) on a large scale. Ascertaining why ARVs are not available to or acceptable by people living with HIV/AIDS (PLWHA) is important in increasing coverage.

Methods: Secondary analysis of data collected from PLWHA not in care in Orenburg and St. Petersburg (N = 551) allowed comparison of the characteristics of those who had not sought treatments (N = 478), refused ARVs (N = 29), or halted ARV therapy (N = 44). The questionnaire included scales on neuropsychological maladaptation and coping strategies validated within the Russian context.

Results: PLWHA who tried to access care were older ($p < 0.001$), more likely to have a constant partner ($p < 0.01$), and more likely to be an active drug user. However, they also experienced negative outcomes, including losing employment or education ($p < 0.01$) and broken relationships ($p < 0.01$). On the other hand, even unproductive interactions with the health care system were associated with reporting sufficient knowledge to make informed treatment decisions and more positive attitudes toward initiating therapy ($p < 0.01$). These individuals also reported more active social-support seeking, including discussions on HIV treatments with uninfected friends ($p < 0.01$) and relatives ($p < 0.01$). Those never seeking care demonstrated higher scores for depression ($p < 0.05$). The sample as a whole had higher-than-average rates of anxiety and other characteristics of psychological maladaptation relative to the general Russian population and displayed emotional rather than problem-oriented coping strategies using the Lazarus scale.

Conclusions: Efforts to initiate and maintain PLWHA in ARV therapy need to be improved, focusing first on attracting those diagnosed with HIV to present at specialized clinics and thereafter convincing them to initiate and maintain ARV therapy.

79986 Adherence, Substance Abuse, HIV Status Disclosure, and Risk Taking among PLWHA in Ivanovo and Novosibirsk, Russian Federation

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Background: Adherence to highly active antiretroviral therapy (HAART) is central to reducing the HIV epidemic, especially in a country such as Russia, which has one of the fastest growing epidemics in the world. We explored the interactions of alcohol and drug use with HIV diagnoses and adherence.

Methods: A survey of patients at AIDS centers conducted in 2010 in the cities of Ivanovo (n = 100) and Novosibirsk (n = 103) explored substance use and correlates of adherence using a measure for self-report of adherence that was completed by both the patient and their infectious disease physician.

Results: More than 9 in 10 (93%) reported a history alcohol consumption, which declined or was eliminated in 29% of patients following their HIV diagnosis. More than half (52%) reported a history of drug injection, and 56% stopped drug use after learning their HIV status. One-third of patients (34%) were on HAART. On average, patients on HAART (N = 69) estimated their adherence at 87%, and 60% reported 90%-100% adherence. Physician appraisal supported those from patients in most cases. Self-reported high adherence was significantly associated with higher frequency of disclosure of HIV-status to non-specialist physicians, social workers, and drug-using but not sexual partners, with more frequent visits to the doctor, stronger belief in patients' ability to use condoms even when consuming alcohol, increased sense of responsibility in reducing the risk of infecting their sexual partner, and reduced belief that uninfected people feel disgust when encountering PLWHA. Increased adherence was also associated with fewer negative outcomes due to alcohol use, including financial difficulties, absenteeism, jobs loss, interruption of relationships, conflicts at work/schools, doctors' warnings, and feelings of withdrawal the morning after drinking.

Conclusions: Alcohol and drug use influence adherence, but in this population alcohol use seems more closely tied to poor performance.



79987 Community Pharmacy Adherence Support Services: Patient and Pharmacist Perceptions

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Background: Adherence support can be provided in tandem with monthly antiretroviral therapy (ART) dispensing at community pharmacies. To maximize the impact of pharmacy adherence interventions, it is important to understand factors that may facilitate or hinder implementation of such programs.

Methods: Qualitative study of HIV-positive patients in San Francisco and pharmacists who serve them. Patient-participants were included if they were HIV-positive, taking ART for ≥ 3 months, and picked up medication at their pharmacy within the last 7 days. Pharmacists serving a substantial HIV-positive clientele were included. Semi-structured interviews were digitally recorded and analyzed using a grounded theory approach.

Results: 19 HIV-positive participants and 9 pharmacists were interviewed. Patient-participants were aged 42-59 years (mean = 50.8), predominantly female (79%), and black (63%). Pharmacist-participants were predominantly Caucasian (55%), males (66%), practicing in pharmacy approximately 10 years (range: 3-28). From the patient's perspective, facilitators to adherence counseling interventions included having a "personal relationship" and feeling "cared for" by pharmacy staff. Stress, illness, environment, and perceiving that the pharmacist was too busy limited receptiveness to adherence counseling. From the pharmacist's perspective, facilitators to adherence interventions included having more time to spend with patients, and having good interpersonal skills to develop strong relationships. Barriers included having to juggle multiple responsibilities, patient co-morbidities (e.g. substance abuse) that may limit intervention effectiveness, and patients' lack of interest in adherence services. Most pharmacists assessed adherence via refill dates and provided support through counseling, automatic refills, provision of reminder devices, and facilitating insurance issues. However, patients often did not recognize that adherence support was being provided by the pharmacist unless counseling was performed.

Conclusions: Patient receptiveness to pharmacy adherence interventions is highly dependent upon the staff's ability to forge a personal relationship. Pharmacies can improve promotion of adherence services to increase patient understanding of the ways pharmacists assist them with adherence.

79990 HIV Testing by Black Frontline Physicians in the United States: Treatment and Referral Patterns for Newly Diagnosed Patients Differ According to Physician Characteristics and Patient Demographics

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Background: Limited data exist on HIV referral and treatment behaviors of black frontline physicians in the United States.

Methods: A physician survey was conducted at the 2010 NMA Convention and via email. Eligibility criteria: black race; practicing at least 1 year; practice composed of at least 60% adults and 20% black patients; Internal/General Medicine, Obstetrics/Gynecology (OBGYN), Family Practice, or Emergency (ER)/Urgent Care specialties.

Results: 502 surveys were completed (>34,000 invitations). Comparisons are physician-reported averages ($p < 0.05$). Physicians who were male, Internal/General Medicine, and had more male, black, and HIV-positive patients were more likely to treat patients for HIV themselves. ER/Urgent Care physicians were less likely than others to have conversations with patients after a positive HIV test (78% vs 98%). Physicians who treated more HIV themselves were more likely to ask how the virus may have been contracted vs physicians who treated less HIV (90% vs 77%). Physicians with more female patients were more likely than those with fewer to have discussions with patients following a positive HIV test (89% vs 75%); OBGYNs were more likely than others to refer HIV-positive patients to an HIV specialist (95% vs 87%) and less likely to take direct action by treating/monitoring the virus (36% vs 51%). Female physicians were also more likely than males to refer patients to a specialist (95% vs 87%; 91% overall). Younger and female physicians were more likely to report a lack of knowledge as the reason for referring patients to a specialist. Male physicians were more likely than females to report that HIV-specific training (60% vs 46%) and contact with other HIV-treating physicians (35% vs 24%) would help them treat more HIV themselves.

Conclusions: The majority of black frontline providers did not treat patients for HIV themselves. Significant HIV-specific training may be required to more uniformly prepare black frontline physicians to manage HIV-infected patients.



79991 A Multi-Dimensional Intervention Improves Retention in HIV Care

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Background: Retention in care is a necessary aspect of adherence to HIV treatment, in order to obtain prescriptions for medications and regular monitoring of HIV-related values. Recent data obtained by the National Quality Center In+Care campaign found that only 60% of individuals seen in HIV clinics in the past 2 years had a medical visit in each half of those years, indicating less than optimal adherence.

Methods: A total of 99 HIV-positive individuals who had documented difficulties with medication and/or appointment adherence were randomly assigned to an intervention based on the Information-Motivation-Behavioral Skills model, or standard of care. The intervention consisted of 2 face-to-face sessions for HIV education, motivational interviewing (MI), and training on medication strategies and patient-provider communication; 6 telephone calls to continue MI and education; and provision of adherence-enhancing devices, including pillboxes, reminder watches, and calendars. Outcomes included self-reported medication adherence and pharmacy refills, and appointment retention as measured by a visit in each 4-month block of the year on study.

Results: While outcomes did not show significant improvements for medication adherence, for those who were not fully retained in care in the 12 months prior to enrollment (<1 visit in each 4-month block; n = 60), significantly more of those who had at least 3 of the 8 intervention contacts were fully retained on study as compared to those in the control group ($X^2 = 7.70$, $p = .05$).

Conclusions: Minimal exposure to HIV education, enhancement of motivation to engage more fully in HIV treatment, training on patient-provider communication, and receipt of adherence-enhancing devices improved retention in care as seen by a visit in each third of the year on study for individuals who had previously been not fully retained. Further research is needed to understand the component(s) of the intervention that are most important in supporting appointment adherence.

79992 A Qualitative Inquiry of Technology Use to Support Linkage to HIV Care for Jail Reentrants: A Formative Research Study

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Background: Innovative strategies to address linkage to HIV care and adherence for correctional populations returning to the community are needed. Information and communications technology (ICT)-based tools (including computerized counseling and cell phone texting support) have shown efficacy in supporting linkage to care in various populations, but have not been studied in correctional populations. We conducted a formative exploration regarding acceptability and usability of ICT tools to support linkage to community care among HIV-positive reentrants.

Methods: Twenty-four semi-structured qualitative interviews were conducted in Washington, DC, and Rhode Island among HIV-infected persons with a recent history of incarceration. Participants were asked to use a computer-counseling tool and answer questions about their perceptions of acceptability and usability of ICT within and outside the jail setting. Interviews were recorded and transcribed, and data were analyzed using Atlas.ti. Major themes were identified.

Results: Jail reentrants' perceptions regarding the use of a computer-based intervention and text messaging to support HIV care linkage were favorable. The issue of maintaining confidentiality regarding serostatus emerged as an important concern, and participants felt that the use of ICT versus a counselor would provide confidentiality in jail. Other participants suggested that live pre- and post-intervention counseling be available to address any questions not addressed by the ICT. Addressing main barriers to care, such as housing and substance abuse, was identified as being a necessary component for this population. Participants responded positively about receiving appointment and medication reminders via text message and felt they would be useful. Most participants were amenable to developing and receiving customized text messages.

Conclusions: Jail reentrants in Washington, DC, and Rhode Island felt positively about the use of innovative technological tools to support HIV education and linkage to care upon reentry. Future studies will focus on the customization of currently existing ICT tools for use with criminal justice populations.



79994 Antiretroviral Adherence Interventions: A Review of Reviews Since 2005

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Introduction: Since the authors' first qualitative review of interventions to promote antiretroviral adherence in 2005, the field has grown exponentially. There have since been more than 400 additional publications and 324 ongoing National Institutes of Health (NIH)-funded studies (according to an NIH RePORTER search with the terms adherence, HIV, and intervention).

Description: We searched PubMed with the terms HIV adherence (review or synthesis or meta) and the internet for all reviews, syntheses, or meta-analyses of adherence interventions targeting adults published in any language in peer-reviewed journals since 2005. We identified 11 syntheses, including 5 targeting a general adult population (3 meta-analyses and 2 reviews); one each on sub-Saharan Africa, reminder devices, technology-based interventions, community health workers; and 2 on directly observed therapy (DOT) interventions.

Lessons Learned: The reviews yielded new information on promising strategies in resource-limited settings, including treatment supporters, DOT, mobile phone and text support, diary cards, and food rations. There were conflicting results regarding DOT. The 2 meta-analyses concluded that there were small but significant effects of interventions on adherence and viral load. The review of education and counseling interventions suggested that information and skills development programs, delivered over a period of at least 12 weeks, appeared to produce more positive outcomes in adherence. Across reviews, authors underscored the need for multicomponent, individually tailored approaches that address the myriad reasons and contexts that precipitate non-adherence among people living with HIV/AIDS. Increasingly, the need to best match intervention approaches to the needs and recourses of a particular patient or subgroup in a given context has been recognized.

Conclusions: Providers or interventionists should adopt an approach that allows for candid discussions with patients about antiretroviral therapy adherence experiences that promote the identification of specific needs and circumstances of the individual and that leverage clinic-based, community, or individual resources to address these.

79995 Adherence as a Predictor of the Development of Class-Specific Resistance Mutations

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Background: Non-adherence to therapy is one of the strongest predictors of therapeutic failure of antiretroviral therapy (ART). Virologic failure with subsequent emergence of resistance reduces future treatment options and therefore long-term clinical success of HIV treatment.

Methods: Prospective observational cohort study including patients starting a new class of ART regimen between 2003 and 2010. Participants were naive to class of ART and completed ≥ 1 adherence questionnaire prior to resistance testing. The outcome was development of class-specific drug resistance mutations. Logistic regression (LR) models were used to estimate the effect of adherence on resistance stratified by ART class.

Results: Of 299 included individuals, 155 started a nonnucleoside reverse transcriptase inhibitor (NNRTI) and 144 a boosted protease inhibitor (PI/r) regimen. Adherence was similar between the 2 groups with 85% reporting adherence $>95\%$. For those on NNRTI regimens, the number with new IAS-USA mutations increased with higher levels of non-adherence (29.5% with 100% adherence, 44.4% with 95%-99% adherence, 56.5% with $<95\%$ adherence). LR models indicated a significant increase in the odds of developing a class-specific mutation when adherence was $<95\%$ (odds ratio [OR] 2.97, 95% confidence interval (CI): 1.10-8.05). Adherence was slightly higher in the PI/r group compared to the NNRTI group (73.6% vs 67.7% with 100% adherence); however, the number of new IAS-USA drug mutations was considerably lower in the PI/r group (9.7% vs 36.1%). Adherence $<95\%$ was only significantly associated with emergence of M184V (OR 21.58, 95%CI: 1.50-310.05) and not IAS-USA or PI-specific mutations in LR models.

Conclusions: Therapies containing PI/r seemed more forgiving to incomplete adherence compared with NNRTI regimens, which allowed higher levels of resistance emergence, even at adherence levels above 95%. However, even in failing PI/r regimens good adherence may prevent accumulation of further resistance mutations and therefore help to preserve future drug options.



79997 Potential Interventions to Support Adherence to HIV Pre-Exposure Prophylaxis (PrEP): A Systematic Review

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Background: Adherence is critical for maximizing the effectiveness of pre-exposure prophylaxis (PrEP) in preventing HIV infection. Systematic reviews have been published on strategies to support adherence to antiretroviral medications in HIV-infected individuals. Whereas adherence to antiretroviral therapy for treatment has received considerable attention, potentially effective strategies for promoting the use of prophylactic medications have not been well characterized, yet could provide much needed guidance in the development of interventions to support PrEP adherence. To address this gap in the literature, we conducted a systematic review across prevention fields to characterize promising adherence support interventions that could be applied in the PrEP context.

Methods: Using the PubMed, Cochrane, and WHO Global Health Library databases, we searched for randomized controlled trials evaluating interventions to promote adherence to daily prophylactic medications, including oral contraceptives, osteoporosis prevention, malaria prophylaxis, latent tuberculosis, post-exposure prophylaxis for HIV, hyperlipidemia, and hypertension.

Results: A total of 50 randomized controlled trials published between 1979 and 2011 were identified; 9 tested multiple interventions, yielding 66 separately evaluated strategies. Adherence measures included self-report, pill counts, electronic monitoring, and clinical outcomes, with over half (38/66; 57.6%) of studies using multiple measures. Interventions were categorized as education-based (13), telephone support (8), counseling (7), provision of adherence/clinical feedback (7), incentives/contingency contracts (6), peer-based (6), multi-modal (5), pill delivery-based (5), text messages and interactive voice response systems (4), electronic monitoring of adherence (3) and self-monitoring (2). Overall, two-thirds (44/66; 66.7%) reported statistically significant improvements in adherence. All (5/5; 100.0%) multimodal interventions were associated with improvements. Counseling, telephone support, and feedback also appeared to be effective, with 71%-86% of those studies reporting improvements.

Conclusions: Based on this review across several prevention fields, promising adherence approaches included multimodal, counseling, feedback, and telephone-based support interventions. These strategies may be particularly valuable in guiding the development of interventions to support PrEP use or the use of other prophylactic medications.

79998 Effect of a Pilot Clinic-Wide Social Marketing Campaign to Improve Adherence to ART

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Background: Social marketing campaigns have been used in public health but have not been tested to improve adherence to antiretroviral therapy (ART). This pilot study tested the effectiveness of a 5-month clinic-wide social marketing campaign at improving adherence to ART at an HIV clinic in Houston, TX, USA.

Methods: The intervention was developed based on patient preferences and included a video, posters, pens, mugs, and lapel buttons with the campaign slogan "Live the Solution: Take Your Pills Every Day." Participants were interviewed before and >30 days after the intervention to assess change in self-reported adherence over the last 4 weeks, the primary outcome, with a visual analogue scale.

Results: Pre- and post-intervention surveys were completed by 141 participants (mean age 46 years; 60% male; 65% black, 30% Hispanic). Ninety-six percent of the participants received at least some dose of the intervention and 86% reported positive impressions of the intervention. Adherence did not change over time (mean change -2.02, paired t-test $p = 0.39$). Self-reported dose of intervention did not predict change in adherence. Among the 39.7% of participants who correctly identified the campaign slogan on the post-intervention survey, adherence increased by 3.3%, while it decreased in the other participants by 5.5% (paired t-test $p = 0.07$).

Conclusions: The social marketing campaign did not increase adherence to ART in spite of being well received by the patients. Adherence tended to increase in patients who were more engaged with the intervention. Future interventions need to engage patients more completely and have a more potent effect on adherence.



80003 Cross-Cultural Adaptation of Pediatric Adherence Measurement in Kenya

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Background: Without adaptation for cultural differences, the reliability and validity of measurement items may diminish. Cognitive interviewing is a respondent-centered research technique to study understanding and processing of questionnaire items. We report on cognitive interviewing to adapt antiretroviral therapy (ART) adherence measurement items for use in a resource-limited setting.

Methods: We first compiled a battery of adherence measurement items based on a systematic literature review and qualitative work in Kenya. We conducted cognitive interviews assessing the items with adolescents and caregivers of HIV-infected children enrolled in Kenya. Item evaluation used verbal probing and guided “thinking aloud” to evaluate understanding, memory of relevant information, and decision/judgment/response processes. Analysis followed a systematic sequence of review, compiling data by item, and coding responses.

Results: We interviewed 21 Kenyan parents and guardians of HIV-infected children (mean age 6.5 years, SD 2.8) on ART for a mean of 1.7 years and 10 adolescents (mean age 15 years, SD 1.8) on ART for a mean of 3.6 years, with good thematic saturation. Cognitive interviews optimized item-response options, wording, and content. Some participants demonstrated difficulty with “think aloud” processes, but verbal probes were easily answered. Key findings for response options included difficulty describing specific ART information, such as drug names; differences among responses to various recall periods, with preferences for the shortest (one 24-hour day) and longest recall periods (one month); benefits for including normalizing statements before asking for sensitive information; and challenges processing Likert scales. Wording changes were needed for key topics, such as the meaning of “missed doses,” having “side effects,” and describing traditional treatments. Important content areas for inclusion were queries about dose timing, disclosure, stigma, and food insecurity.

Conclusions: Cognitive interviewing is a productive strategy for increasing the face validity and understandability of adherence measurement items, particularly across cultures. Interviews in Kenya suggested changes for item response options, wording, and content that may have relevance for other resource-limited settings.

80004 Adapting Adherence Measurement Tools for Cross-Cultural Use

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Introduction: Cross-cultural measures of health behavior are integral to measuring adherence in various populations. Culture permeates health behaviors, and a single assessment of these behaviors is often not universally applicable. Appropriate cross-cultural adaptation can reduce cultural differences in how adherence assessments perform.

Description: Our objective is to describe a systematic approach to the cross-cultural adaptation of adherence measurement strategies and tools. By systematically reviewing methods of measuring health behaviors, examining how these assessments may be affected by cross-cultural differences, and drawing examples from how the cultural profile of a sample population (Kenya) influences assessment of adherence, we will elucidate a systematic approach for adapting adherence measurement tools for cross-cultural use.

Lessons Learned: Assessing adherence behaviors in Kenya or any cross-cultural setting requires careful attention to the choices among measurement methods, awareness of issues specific to cross-cultural health measurement, employment of techniques to address these challenges, and a close understanding of the culture of interest.

Recommendations: Based on our review of health measurement literature and analysis of the relevant cultural factors in Kenya, the following recommendations would be made for assessing adherence:

- When possible, assessment tools for each context should be developed in parallel, following best standards for item construction.
- Development of all assessment tools should include members of the targeted group, considering ethnicity, language, and socioeconomic factors. These collaborators should also participate in cognitive interviewing for revisions.
- Best possible translation processes should be employed, including back-translation, de-centering, committee review, and field-testing.
- All elements should be pilot-tested in a representative sample to investigate cultural equivalence and psychometric properties (reliability and validity).
- Investigators should consider broadly the methods of measurement available, with priority placed on limiting literacy demands, using items tailored to cultural values, and respecting vulnerable populations.



80005 Factors Associated with Adherence to Antiretroviral Therapy among Perinatally Infected Children and Adolescents in Brazil

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Background: As of July 2011, 14,329 cases of perinatally acquired AIDS have been reported in Brazil.

Methods: Multicenter study with children/adolescents and caregivers, including chart review, standard adherence questionnaire (answered by children's caregivers and adolescents), WHOQOL-BREF, assessment of misuse of alcohol/other substances. Children/adolescents with no missed dose in the last 3 days (100% adherence) and viral load (VL) <50 copies/mL. Statistical analysis comprised contingency tables and respective statistics and multi-variable logistic regression.

Results: A total 260 vertically infected subjects receiving ART and caregivers were enrolled, 79% of them children and 21% adolescents. 57% of children and 49% of adolescents had VL <50 copies/mL; 93% children's caregivers and 77% adolescents reported 100% adherence. No significant statistical association was found between VL <50 copies/mL and 100% adherence ($p = 0.34$). In bivariate analyses, gender, AIDS at admission, current antiretroviral therapy (ART) with protease inhibitors (PIs) or nonnucleoside reverse transcriptase inhibitors (NNRTIs), former shifts of ART, HIV status of caregiver and depression among caregivers were not associated with the outcomes. History of HIV diagnosis motivated by symptomatic condition, lower caregiver scores for anxiety, and higher scores at the physical and psychological domains of WHOQOL-BREF were significantly associated with 100% adherence ($p = 0.04$; 0.01; 0.04, and 0.00, respectively). Shorter intervals between pharmacy visits were found to be associated with VL <50 copies/mL ($p = 0.002$). Multivariate logistic regression showed that "no need for intervention for misuse of alcohol/other drugs among caregivers" (OR = 0.49; 95% CI 0.27-0.89) and "shorter interval between pharmacy visits" (OR = 0.97; 95% CI 0.95-0.98) are independently associated to VL <50 copies/mL; "caregivers without anxiety" (OR = 2.57; 95% CI 1.27-5.19) and "HIV test for children's symptomatic condition" (OR = 0.45; 95% CI 0.22-0.91) were independently associated to 100% adherence.

Conclusions: Pediatric HIV programs should consider a comprehensive assessment of caregivers and improved pharmacy reports in order to improve adherence. Continuous surveillance of perinatal exposition favors early diagnosis and may contribute to better adherence in the pediatric population before development of symptomatic condition.

80006 Psychosocial Influences on Medical and Laboratory Visits for Routine HIV Care

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Background: Studies to date evaluating routine HIV appointment adherence have focused almost exclusively on visits with a clinical provider. HIV care also requires regular laboratory visits to collect blood samples to obtain clinical markers of disease. Compliance with laboratory appointments improves the provider's available arsenal of information to effectively plan and treat patients. Therefore, this study measured risk and protective factors associated with adherence to both medical and laboratory visits.

Methods: Baseline and 28-week follow-up interviews plus medical record abstraction (MRA) were conducted with HIV-positive patients receiving care in South Florida. Assessments included demographics, substance use, depression, perceived HIV stigma, attitudes toward provider, and use of social support. The proportion of medical and laboratory appointments attended were calculated from MRA data. Variables significantly associated with medical and laboratory appointments in bivariate analyses were included in the final logistic regression models.

Results: Of 210 HIV-positive patients enrolled, 197 completed the 28-week follow-up, and MRA was completed on 206. Most participants were African American (83%) and nearly half were men (47%). Adequate appointment attendance was established at 75% through correlation with suppressed viral load ($N = 157$). Individuals who attended >75% of their laboratory appointments had a 2.51 greater odds of an undetectable viral load (VL) at follow-up. Medical appointment attendance was unassociated with VL. Logistic regressions revealed older age and use of social support each had a 1.06 greater odds of attending >75% medical appointments ($X^2 = 14.50$, $p < .001$) while moderate-severe depression indicated a 1.87 greater odds of attending <75% lab appointments, controlling for cocaine use ($X^2 = 8.75$, $p < .05$).

Conclusions: Findings show different rates of adherence, relations to VL, and disparate potential influences on attendance to medical versus laboratory appointments. Further study is needed to determine the effects of structural factors or perceived importance of the visit on attendance rates.



80007 How Adherence Research on ART Can Inform PrEP: Lessons from Our Missteps and Success

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Introduction: Research on the use of antiretroviral therapy (ART) for prevention (pre-exposure prophylaxis or PrEP) has also had dramatic but conflicting outcomes. Specifically, CARPISA 004 (1% tenofovir vaginal gel in heterosexual women; Abdool, et al., 2010); Partner's PrEP trial (once-daily tenofovir/emtricitabine or tenofovir in heterosexual men and women with HIV-positive primary partners; Baeten and Celum, 2011); iPrEx (once-daily tenofovir/emtricitabine among MSM; Grant, et al., 2010, 2011); and TDF-2 (once-daily tenofovir/emtricitabine in heterosexual men and women; Thigpen, et al., 2011) demonstrated significant reductions in HIV-infections (39%-63%). However, expected fertility led to early closure of the FEM-PrEP study and 2 of the 3 study arms in the VOICE trial. Importantly, reductions in HIV acquisition were more likely among participants demonstrating optimal adherence to the product.

Description: Some challenges to PrEP are unique, such as concern PrEP users will be misidentified as HIV-positive. Others are common to ART as treatment, including management of start-up side effects, daily dosing, and the burden of indefinite treatment course. Interventions to promote PrEP use are presently under investigation and the next several years should provide much needed insights into the factors that most influence consistent PrEP use in the "real world."

Lessons Learned: The extensive literature on adherence to ART as treatment (see Amico, et al., 2006; Pearson, et al., 2007; Simoni, et al., 2006a; 2006b; Simoni, Amico, et al., 2010) provides valuable information on ways to conceptualize the barriers to and facilitators of adherence; the most psychometrically sound self-reported adherence assessment methods; technological means to monitor adherence, methods of directly measuring adherence in bodily fluids, and effective strategies to promote adherence. These are presented in terms of successful strategies that might be replicated as well as missteps to be avoided in future PrEP studies and roll-out.

80008 Poor Quality of Life Is Associated With Stigma, Drug Abuse, and Lack of Social Support among HIV-Positive Individuals at Risk for ARV Non-Adherence in Hunan, China

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Background: Quality of life (QOL) is associated with both medication adherence and clinical outcomes among people living with HIV/AIDS (PLWHA). As China CARES continues to provide treatment to a growing number of PLWHA, it is important to understand factors associated with QOL among the diverse populations of PLWHA in China.

Methods: A cross-sectional study to describe QL and identify associated factors among PLWHA at risk for non-adherence in Hunan, China. Subjects were PLWHA self-reporting adherence <90% to prescribed antiretroviral (ARV) or to pre-ARV medications (TMP-SMX, multivitamins) between July 2010 and August 2011. A visual analogue scale was used to establish non-adherence in the previous 21 days. QOL was measured using the MOS-HIV. Other instruments included the Social Support Rating Scale (SSRS) and the HIV/AIDS-Related Stigma Scale.

Results: Subjects included 114 individuals (57 self-reported non-adherent to ARV and 57 to pre-ARV medications). Mean level of adherence was 77% (Med 86%) to ARV and 76% (Med 85%) to pre-ARV medications. Among those prescribed ARV, mean time on ARV was 3 months (Med 2; R = 1-13). For those already prescribed ARV, mean MOS-HIV score was 63 (+/-16) compared to 54 (+/-16) for those on pre-ARV medications (p = -0.002). Controlling for treatment group, HIV-related stigma (p = 0.0001), less social support (p = 0.03) and history of drug abuse (p = 0.03) were each independent predictors of lower QOL.

Conclusions: The low level of QOL among PLWHA and at risk for non-adherence in Hunan, China, is of concern. The association of QOL with stigma, drug abuse, and social support suggests potential points of intervention to improve QOL, medication adherence, and clinical outcomes in this vulnerable population.



80009 Assessment of Caregivers' Adherence to ARV Drugs Administration in HIV-Infected Children

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Background: Achievement of optimal adherence ($\geq 95\%$) to antiretroviral therapy (ART) administration poses more challenge in children as adherence is dependent on the caregivers. Few studies have been carried out in Nigeria to assess children's adherence to ART, hence the aim of this study.

Method: This was a cross-sectional study carried out using 37-item questionnaires randomly administered in the form of interview to 115 caregivers. One hundred and two (88.7%) properly filled and returned questionnaires were analyzed using SPSS version 15.0.

Results: Eighty-three (81.4%) of the caregivers were married, 88 (86.3%) females, 94 (92.1%) educated with a mean age of 36.54 ± 10.41 . Fifty-six (54.9%) of the children were male, 91 (89.2%) in school with a mean age of 6.98 ± 7.36 . Assessment of the caregivers' relationship with the children showed that 93 (91.2%) were their parents and 69% also HIV positive. Regimen assessment showed that 81 (17.7%) of the children were on a fixed-dose combination of AZT+3TC+NVP. Eighteen (17.7%) were already on second-line drugs. Only 7 (6.9%) of the children were on liquid only medication, most 79 (77.5%) were on tablet dosage form only. Many (63.73%) caregivers reported administering the children's medications at 7 AM and 7 PM daily with 84 (82.3%) using alarms as reminders. Eighty-seven of the caregivers agreed "haven been" [having been] taught how to correctly administer the medication. Caregivers' one-week self-report adherence assessment showed 68.6% adherence level. Reasons for non-adherence given by the non-adherent caregivers were: "child's refusal" (27), "I forgot" (18), "busy with other things" (12), "I fell asleep" (10), change in daily activity of caregiver and child got sick with another illness (6 each), lack of privacy (4), "the other caregiver missed administering the medication" (3), and "I ran out of medication" (2).

Conclusion: The adherence level was 68.6%, underscoring the need for adherence intervention studies targeted at caregivers to ensure optimal adherence in HIV-infected children on ART.

80010 High Prevalence of Depression among HIV-Positive Individuals at Risk for ARV Non-Adherence in Hunan, China

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Background: In China, antiretroviral (ARV) regimens are limited and adherence is critically important. In the United States, depressive symptoms are common among people living with HIV/AIDS (PLWHA) and are associated with non-adherence. Data regarding the prevalence of depression among Chinese PLWHA are limited.

Methods: A cross-sectional study to describe the prevalence and predictive factors for depressive symptoms among PLWHA at risk for nonadherence in Hunan, China. Subjects were PLWHA self-reporting adherence $< 90\%$ to prescribed ARV or to pre-ARV medications (TMP-SMX, multivitamins) between July 2010 and August 2011. A visual analogue scale was used to establish non-adherence. Other instruments included the Social Support Rating Scale, the Center for Epidemiological Studies Depression Scale (Chinese), and an HIV/AIDS Related Stigma Scale.

Results: Subjects included 114 individuals (57 self-reported non-adherent to ARV and 57 to pre-ARV medications). Mean level of adherence was 77% (Med 86%) to ARV and 76% (Med 85%) to pre-ARV medications. Among those prescribed ARV, mean time on ARV was 3 months (Med 2; $R = 1-13$). Overall, 66% scored 16 or higher on the CES-D, indicating significant depressive symptomatology. Forty-four (77%) in the pre-ARV phase scored 16 or greater compared to 31 (54%) of those already prescribed ARV (OR = 2.8; 95% CI = 1.3, 6.4; $p = 0.01$). Controlling for treatment group, independent predictors of depressive symptoms included a history of drug use (OR = 4; 95% CI = 1, 15; $p = 0.03$), a high level of stigma (OR = 1.06; 95% CI = 1.02, 1.09; $p = 0.001$), not having a stable job (OR = 3; 95% CI 1, 10; $p = 0.05$), and less social support (OR = 1.1; 95% CI 1, 1.2; $p = 0.02$).

Conclusions: The very high prevalence of depressive symptoms among PLWHA in Hunan, China, is of concern. Interventions to address depression are called for to fully realize the benefits of ARV provided by China CARES.



80014 The Effect of Sexual Minority Stigma on Antiretroviral Treatment Adherence among HIV-Infected Young Men who have Sex with Men

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Background: Among adolescents, nearly two-thirds of diagnosed HIV infections are from male-to-male sexual contact. HIV-infected young men who have sex with men (YMSM) experience stigma related to both their sexual orientation and HIV status. Recent data indicate that individuals with higher levels of experienced stigma are >3 times more likely to be non-adherent to their antiretroviral therapy (ART).

Methods: From August 2010 to June 2011, 30 semi-structured qualitative interviews were conducted with HIV-infected adolescents. Interviews addressed topics relevant to treatment adherence, including interpersonal relationships, living situations, access to care, mental health, and substance use. This analysis focused on the 7 self-identified YMSM compared to their heterosexual counterparts.

Results: Participants' ages ranged from 14 to 24 years (M = 20.2, SD = 2.6); 50% were black and 37% Latino. Of the 7 YMSM in the sample, all identified as gay or bisexual and reported acquiring HIV through male-to-male sexual contact. Although stigma impacted ART adherence for heterosexual and sexual minority participants, 2 domains of stigma were specifically described by YMSM: 1) self stigma -self-blame for behavioral acquisition of HIV; and 2) felt stigma self-imposed social avoidance stemming from perceived sexual minority stigma. For many, these unique manifestations of felt and self stigma translated into careful efforts to avoid disclosure of serostatus and ART medications. Such behavior was reported as a barrier to ART adherence as it often led to small social support networks, active concealment of medication, and unwillingness to take medication in non-private spaces.

Conclusions: Findings suggest that for YMSM, individual manifestations of stigma are distinct to their status as sexual minorities. Self-blame and social avoidance represent a process of shame that may uniquely affect their ability to carry out specific medication-related tasks. Interventions aimed at improving ART adherence among adolescents more broadly may need to address these distinct concerns of YMSM.

80018 Cultural and Linguistic Adaptation of a Computerized Counseling Tool for Persons Living with HIV in Western Kenya

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Introduction: Computerized counseling can support healthy behaviors and may be particularly useful in high-volume HIV clinics with constrained counseling staff. However such tools need to be adapted to new settings and populations before use.

Methods: We adapted a computerized-counseling tool ("CARE+"), tested in the United States, for use in western Kenya at USAID-Academic Model Providing Access to Healthcare Partnership. CARE+ occurs on audio-narrated touch-screen tablets containing evidence-based antiretroviral therapy (ART)-adherence and positive-prevention elements. We adapted the tool using an Expert Panel (providers and people living with HIV/AIDS (PLWHA), n = 5), HIV-client interviews (n = 40) and 2 provider focus groups (n = 33) to ensure culturally-appropriate content and English-Kiswahili translation, prior to a randomized controlled trial (RCT). We created new media ("avatars," medications, videos, voiceovers). CARE+-Kenya comprises risk assessment, tailored messaging, skill-building videos, personal health plan, and summary printout. Software usability-testing (n = 30) revealed that >80% did not own a computer, that most (n = 23/30) preferred text (vs icon) printouts, and most (87%-93%) said the tool met expectations. Average usability session was 25 (rural)-29 minutes (urban). The CARE+ Kenya RCT has now enrolled about 150 HIV-client participants.

Lessons Learned: There was congruence between themes identified by clients, providers, experts and eventual "CARE+ Kenya" content. These in-depth, multi-source exercises to support software localization also highlighted discrepancies between priorities and concerns of providers, HIV clients, and experts. Finally, it illustrated that what can be provided in a brief computer-counseling session can cover many but not all client needs, many of which can only be addressed by staff or socioeconomic services. Little computer orientation has been needed, as even rural participants have learned quickly how to use the tablets.

Recommendations: Computerized counseling tools can be successfully adapted for use in diverse cultural and linguistic settings, ideally using multiple inputs. Self-administered computerized-counseling can fill health workforce deficits, and appears feasible and acceptable even with low-computer-experienced populations.



80020 Lessons Learned from Modifying Software for a Computer-Delivered Prevention Intervention

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Introduction: The Test, Link to Care, Plus Treat (TLC-Plus) (HIV Prevention Trials Network Study 065 [HPTN065]) study has 5 components: Expanded HIV Testing, Linkage to Care, Viral Suppression, Prevention for Positives (PPF), and Patient and Provider Surveys. The PPF component is a 2-arm randomized trial to assess effectiveness of a computer-delivered prevention intervention (CARE) in addition to standard of care prevention counseling for reducing unprotected sex in HIV-infected participants. All participants will complete a computer-assisted assessment of risk behaviors at each visit. A total of 1320 subjects will be enrolled at 12 HIV care sites in Washington, D.C. and the Bronx, NY (about 110 subjects/site). Participants receive the intervention at months 0, 3, 6, 9, 12; an assessment at month 18 will assess durability of effect (6 months post-intervention). The primary end point is proportion reporting unprotected sex in preceding 3 months. CD4 cell count and viral load will be chart-abstracted to enable analyses of virologic responses.

Description: CARE provides an intervention delivered by computer tablets and headphones, tailored to participant responses, to support antiretroviral therapy (ART) adherence and prevention behaviors for HIV-positive patients, audio-narrated in English or Spanish. CARE was modified for HPTN 065 to focus on PPF content, and to administer the Patient Survey before first- and 12-month PPF sessions.

Lessons Learned: Pilot testing by study staff revealed inconsistencies in content and between text, video, and audio. Software modifications affecting either content conditional to previous answers or requiring synchronized text/video/audio are especially time-consuming and costly. Changes that appear relatively minor might require complex programming revisions followed by extensive logic-testing and additional audio-recording sessions.

Recommendations/Next Steps: Pilot testing of revised software is essential. The second revision of CARE will undergo pilot testing with prospective participants during early 2012. Site training and implementation of the PPF component is anticipated in Spring 2012.

80021 Qualitative Comparison of Barriers and Facilitators of Antiretroviral Therapy Adherence among Self-Reported Adherent versus Non-Adherent HIV-Positive Youth

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Background: Youth aged 13-24 years account for 25% of those living with HIV in the United States. Treatment adherence remains a significant challenge in this population. Antiretroviral therapy (ART) adherence among HIV-positive youth ranges from 28%-69% of doses prescribed, well below the >90% thought necessary for viral suppression. We qualitatively explored adherence in a diverse population of adolescents aged 14-24 years. Because there has been little research on facilitators of adherence in this population, we specifically explored differences between those who self-report high (>85%) versus low (<85%) ART adherence.

Methods: We conducted semi-structured qualitative interviews with 30 HIV-positive youth aged 14-24 years and diverse with respect to race/ethnicity, gender, and sexual orientation. Twenty-three participants were actively taking antiretroviral medication; of these, 13 reported adherence greater than 85% (adherent) and 10 reported adherence less than 85% (non-adherent). Participants were asked questions relevant to their treatment adherence, including their living situation, education/employment, interpersonal relationships, experience with taking antiretroviral medications, and perceived barriers to adherence. Interviews were recorded, transcribed, and examined using thematic and categorical analysis.

Results: Adherent and non-adherent participants reported similar barriers to adherence, including lack of social support, irregularity of daily schedules, lack of disclosure, HIV stigma, depressed and anxious mood, substance use, and side effects. Adherent participants described more independent management of HIV and a greater sense of personal responsibility/agency regarding their diagnosis and adherence than did their non-adherent counterparts. In contrast, non-adherent participants described lower risk perceptions regarding long-term consequences of non-adherence and greater reliance on parents/other family members for management of their HIV.

Conclusions: Fostering an internal locus of control regarding HIV and the management of a chronic illness among HIV-infected youth may facilitate improved adherence in this population. Creatively engaging youth about long-term consequences of non-adherence may also be an important tool for improving treatment adherence and continued engagement in HIV care.



80022 Baseline Findings of a Randomized Controlled Trial of Spanish-Language Computerized Counseling

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Background: HIV disease in the United States disproportionately affects Latinos, yet antiretroviral therapy (ART) adherence or positive prevention interventions are rarely delivered in Spanish.

Methods: A randomized controlled trial (RCT) of a Spanish-language computerized-counseling tool (CARE+ Spanish) to reduce ART non-adherence and transmission risk behavior, in 3 busy HIV clinics in New York City. Peer research assistants recruited Spanish-speaking adults on ART who were randomized to intervention 0, 3, 6, 9, 12 months (Group A), versus computer-collected risk behavior-only control arm 0, 3, 6, 9 months; at 12-months this control arm (Group B) received an intervention session. Linear and generalized linear mixed effects models will assess RCT intervention impact on 7- and 30-day ART adherence, clinic visit adherence, HIV-1 viral load and sexual/parenteral transmission risks, and assess whether any Group A changes are sustained at Month 12, among study participants.

Results: A total of N = 512 eligible patients were enrolled in the RCT (n = 44/556 initially enrolled were screen fails). Gender distribution was 361 (64.9%) male, 132 (23.7%) female, 11 (1.9%) transgender. Half (52%) had high school diploma or less. Mean age was 46.9 years (range 19-72 years), living with HIV for mean 13 years. Two-thirds (65%) said only a few or none knew their HIV status, and said they do not disclose to all sex partners (67%). One-third (34%) say they use condoms consistently, or take their ART consistently (31%). One-fifth abuse alcohol, and 17% scored as having severe depression by PHQ-9. Mean ART adherence by 30-day visual analog scale (VAS) was 87.2% (SD 22.3). 472 (92.2% retention) enrollees have been retained by 12-month study end.

Conclusions: A computerized counseling tool delivered in Spanish has been successfully delivered to over 500 patients in a high-volume HIV setting, over the course of one-year follow-up. If efficacious in this population, such a tool will expand the available linguistically-relevant adherence and positive prevention interventions for this vulnerable population.

80023 "Damaging What Wasn't Already Damaged in Me": Psychological Tension and Antiretroviral Adherence in HIV-Infected Methadone-Maintained Drug Users

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Background: Among HIV-infected persons, active drug use is often associated with poor adherence to highly active antiretroviral therapy (HAART). Addiction has also been associated with negative psychological states, including guilt, shame, and a sense of isolation.

Methods: Within a randomized controlled trial evaluating the efficacy of directly observed HAART delivered in methadone maintenance treatment programs, 15 participants completed semi-structured qualitative interviews regarding their experiences both with HIV and its treatment, and with drug use and its treatment. All interviews were recorded, transcribed, and thematically analyzed.

Results: Negative and positive cyclical psychological themes emerged regarding the meanings associated with antiretroviral adherence. All participants reported tension between a negative cycle (denial, guilt, shame, perceived isolation, and poor adherence) and a positive cycle (acceptance, motivation, empowerment, perceived connectedness, and improved adherence). Movement from negative to positive cycles was associated by many participants not only with increased HIV medication adherence, but also with decreased drug use.

Conclusions: Participants' descriptions of how movement between negative and positive psychological cycles influences HAART adherence mimics the cyclical nature of drug use and sobriety. Sustained antiretroviral medication adherence may require increased emphasis on longstanding psychosocial patterns experienced by persons with co-morbid substance abuse and HIV diagnoses.



80024 Ongoing Substance Abuse Worsens Decline in Adherence over Time: Results from MACH 14

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Background: Although active substance abuse is associated with worse adherence, few studies have examined its impact on changes in adherence over time. We sought to determine how ongoing, active drug or alcohol use affect adherence over time, and tested the hypothesis that ongoing active use is associated with a steeper decline in adherence over time than any use.

Methods: We analyzed data from the Multi-site Adherence Collaboration on HIV (MACH14), which included 16 studies of electronically monitored adherence. MEMS data were collected during 4 weeks prior to each of 2-7 visits, and substance use in the 30 days prior to each visit was also assessed. We used only data from observational studies or from control arms of intervention studies, and truncated follow-up at 180 days. To assess effects of ongoing substance use on adherence over time, for each substance we constructed 3 separate mixed effects linear models, all including a subject-level random effect (accounting for multiple observations per subject) and adjusting for age, gender, race, and study site. Separate models assessed the effect of time (measured in months) on adherence, stratified by use versus nonuse of the specific substance in the prior 30 days, and an additional model assessed significance of the interaction of substance use and time. We also assessed the effect of ever use of any substance use during the observation period on adherence over time by comparing mean adherence between subjects who did not use at all versus any use. We repeated all models for cocaine/stimulants, heroin, and alcohol.

Results: Among 753 subjects from 11 studies, adherence declined significantly over time, but the decline was worse among persons with ongoing cocaine use (-4.69% per month) versus those without (-0.59%, $p = 0.01$ for interaction between cocaine use and time), among those with ongoing heroin use (-1.64%) versus not (-1.22%, $p = 0.01$), and among those with ongoing alcohol use (-4.33%) versus not (-0.36%, $p = 0.24$). Persons with any substance use during the observation period had lower adherence than those without, but rates of adherence decline over time were similar between ever- and never-users, and interactions between history of any use of each substance and decline in adherence over time were not significant.

Conclusions: Adherence declined over time among all subjects, but this decline was associated with ongoing active substance use (particularly cocaine) and not with history of any substance use.

80032 An Electronic Medication Monitoring System for Patients on Antiretroviral Treatment in a Resource-Limited Setting in South Africa

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Background: Electronic medication monitoring systems are known to accurately record container opening patterns, quantify information and identify problems in antiretroviral therapy (ART) adherence. The main objectives of this study were to evaluate the e-MuM electronic monitoring system (electronic microprocessor, reminder unit [a specialized wristwatch] and software program) for practicality, impact, and effect on ART adherence.

Methods: A 4-phase, prospective, experimental study was conducted over an 8-month period at the Tshepang Antiretroviral Clinic, Dr George Mukhari Hospital in Ga-Rankuwa, South Africa, using 210 volunteer patients, randomized into test and control groups, balanced according to gender and time on treatment. Both groups received lamivudine tablets in an e-MuM container. Test group interventions included a reminder unit (end of Phase 1 to Phase 4), with added visual (e-MuM generated graphs) and verbal feedback (end of Phases 2, 3 and 4).

Results: "Strict" adherence included doses within one hour of the correct time and doses taken any time on correct day marked "lenient" adherence. The most significant increase in mean strict adherence ($p < 0.05$) was from Phase 2 to Phase 4 (after 2 verbal and visual feedback sessions), 18.8% for test group and 14.3% for control group. The difference between the 2 groups in terms of changes in adherence did not reach statistical significance.

Conclusions: The e-MuM system could be integrated in a normal resource-limited clinic setting with additional staff and facilities (hardware) for effective and sensitive feedback to patients on adherence patterns. A smaller, sturdy e-MuM system could be particularly helpful during ART initiation to ensure new patients are adherent to their treatment, and for suspected non-adherent patients.



80034 Monthly Assessments of Stressful Life Events in HIV-Positive Patients Participating in an Adherence Trial

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Introduction: Stressful life events, such as financial difficulties, deaths or illnesses in the family, or sexual or physical assault are common in people living with HIV and AIDS (PLWHA) and negatively affect adherence and risk behaviors. Other studies have measured recent stressful life events in PLWHA, but usually either cross-sectionally or with long recall periods. Few have conducted repeated monthly assessments and looked at the frequencies and specific types of events.

Methods: As part of a randomized controlled trial testing the effect of depression treatment on adherence (the SLAM DUNC Study), participants complete monthly unannounced phone-based pill counts, during which they complete a structured Stressful Life Events inventory querying events in the past month.

Results: To date, 94 participants have completed 278 monthly assessments (mean: 2.9 months/participant; range: 1-6) and reported a total of 900 individual stressful life events (mean 3.2 events/person-month; range 0-11); ≥ 1 event was reported at 87% of assessments. Financial stressors were the most frequently reported (mean 1.5 events/person-month), followed by relationship, work-related, and health-related stressors (mean 0.3 events/person-month each). Among individual financial stressors, lacking money for basic necessities was reported at 43% of monthly assessments. More stressful events on average were reported by women than men (3.5 vs 3.0, $p = 0.05$) and African Americans than whites (3.5 vs 2.5, $p < 0.01$).

Conclusions: Medication adherence among PLWHA is important to keep PLWHA healthy and prevent development of drug resistance. Therefore it is imperative that we understand possible predictors of non-adherence including the impact of stressful life events. The present study with repeated monthly assessment of both stressful events and adherence will eventually provide unique insight into the relationship between specific stressful events and HIV medication adherence in depressed patients with HIV.

80035 Short-Term Changes in Adherence and Neurocognition among Cocaine and Heroin Users with HIV Infection

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Background: A significant percentage of HIV-positive individuals in the United States use cocaine or heroin. Ongoing drug use is associated with non-adherence to antiretroviral therapy, as well as decreased neurocognitive function. It is thus important to understand the course of neurocognitive changes in these individuals.

Methods: Participants were HIV-positive individuals with a history of cocaine or heroin dependence and use within the previous 12 months. Standardized neuropsychological (NP) testing was completed at baseline and 6 months and NPZ-8 scores derived to measure global functioning. Medication adherence was measured with electronic monitoring (MEMS) at 4-week intervals.

Results: One hundred subjects were enrolled between 2005 and 2009. Of these, 66 subjects completed both NP evaluations and were retained for this study. NP completers were 58% male, 86% non-Hispanic black, 76% heterosexual, and 50% completed some high school but no diploma. Participants had HIV for a median of 10.5 years, and 50% were currently on antiretroviral therapy (ART). The median viral loads and CD4 cell counts were 6567 copies/mL and 369 cell/ μ L, respectively. Forty percent reported some cocaine use during the study period and heterosexual participants were more likely to report use (X^2 (df = 1) = 6.688, $p = 0.010$). No heroin use was reported. Multilevel-linear (MLM) models indicated that percent dose adherence declined significantly from baseline (F (5, 245.705) = 3.484, $p = 0.005$). Overall changes in cognition were non-significant (t (df = 65) = -0.745, $p = 0.459$); however, they were weakly correlated with changes in adherence ($r = -0.219$, $p = 0.095$) and significantly associated with cocaine use (t [df = 61.624] = -2.254, $p = 0.028$). Cocaine users' NPZ scores declined by -0.11 (SD 0.32) points, whereas non-cocaine users' NPZ-8 scores increased by +0.14 (SD 0.56) points.

Conclusions: Adherence decreased over the study period in this sample of current and former substance users; subjects with ongoing cocaine use experienced decrease in neurocognitive performance. Findings suggest a multidirectional influence of cocaine use, neurocognition, and adherence that warrants further study.



80036 Is Traditional Medicine a Barrier to Antiretroviral Therapy (ART)? Women and Men in Durban, South Africa, Reflect on Traditional Medicine and Antiretroviral Drugs (ARVs)

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Background: Despite scale-up of antiretroviral therapy (ART) in South Africa, evidence suggests traditional medicine (TM) use remains common among HIV clients. However, motivations for using TM (or not) for HIV, in addition to or instead of antiretroviral drugs (ARVs), have not been investigated. Such exploration is important because confusion or belief in benefits of TM over ARVs could lead to non-adherence to treatment.

Methods: As part of formative research for a prospective cohort study of newly diagnosed HIV individuals in Durban, we conducted semi-structured qualitative interviews with 15 women and 9 men testing or returning for HIV care in public-sector clinics and a prevention trial site. We asked about beliefs surrounding and experiences with TM for HIV and knowledge and opinions about ARVs.

Results: Most participants believed TM could not cure HIV and thought ARVs were more effective in suppressing HIV (and less expensive). Some thought TM could cure other diseases but not HIV because it is "modern" and requires Western medicine. Many were confused about whether TM used with ARVs helps or harms HIV-positive clients. Some believed TM could enhance health; others thought they were a bad option because they discourage ARV use or are harmful. Skepticism about traditional healers' motives was common; many believed healers trick people to buy medicines to make money. One HIV-positive participant decided to try TM when he learned he was ineligible for ARVs.

Conclusions: In this clinic-based population, we found strong support for ARVs, despite some confusion around the value of supplementing ARVs with TM. Some evidence suggests those ineligible for ART or who experience delays in accessing treatment may opt for TM. Given TM's cultural value, providers should openly discuss TM use and intentions with HIV-positive clients. Further research examining TM commonly used by HIV clients would assist providers in giving information about potential interactions with ARVs.

80041 Caution for Test-and-Treat: Higher Baseline CD4 Count Predicts Incidence of Treatment Interruptions among Patients Initiating ARVs in Rural Uganda

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Background: Little is known about adherence to antiretrovirals (ARVs) when initiating treatment at relatively high CD4 cell counts in resource-poor settings, where a test-and-treat strategy of HIV prevention would have the greatest public health impact. We hypothesized that those with higher CD4 cell counts might have lower adherence.

Methods: We estimated an association between baseline CD4 cell count and ARV adherence in the first 90 days of therapy for participants enrolled in the Ugandan AIDS Rural Treatment Outcomes study, a prospective cohort of persons initiating ARV. ARV use was measured using MEMS. Outcomes were 1) adherence <90%; 2) any treatment interruptions >72 hours; 3) number of treatment interruptions greater >72 hours; and 4) viral load (VL) >400 copies/mL at the next visit (until 120 days from baseline). Our primary exposure of interest was baseline CD4 cell count >250 cells/mm³. We fitted multivariable regression models (logistic models for binary outcomes; negative binomial model for the count outcome) to estimate these associations, while adjusting for age, sex, marital status, educational attainment, employment, socioeconomic status, travel time, Hopkins Depression Symptoms Checklist score, AUDIT-C alcohol-use screen, and ARV regimen.

Results: Four hundred seventy-three participants were enrolled from June 2005-April 2010. Median CD4 cell count at baseline was 132 cells/mm³ (IQR 76-200); 12.7% of participants had a CD4 cell count >250 cells/mm³. In multivariable analysis, higher baseline CD4 cell count was associated with an increased risk of any treatment interruption >72 hours (OR 2.21, 95% CI 1.01-4.83), follow-up VL >400 copies/mL (OR 2.62, 95% CI 1.08-6.40), and a non-significant increase in number of treatment interruptions >72 hours (IRR 2.45, 95% CI 0.95-6.30). There was no association with average adherence <90% (OR 1.44, 95% CI 0.78-2.64).

Conclusions: In patients initiating ARVs in Uganda, baseline CD4 cell count >250 cells/mm³ was associated with increased treatment interruptions and a VL >400 copies/mL in the first 90 days of treatment. Further study to determine reasons for this finding (eg, differences in clinical status) is needed. Interventions to support adherence in patients with higher CD4 cell counts should be considered as drug availability to this patient population increases.



80045 Psychosocial Factors Influencing Early Engagement and Retention in Pre-ART Clinical Care in KwaZulu-Natal, South Africa

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Background: To identify information-, motivation-, and behavioral skills-based strengths and deficits for retention in pre-antiretroviral therapy (ART) HIV care among HIV-positive patients initiating care in KwaZulu-Natal, South Africa.

Methods: An interviewer-administered survey was conducted among patients 18 years of age or older, newly entering care (diagnosed within the last 6 months), and ineligible for ART in one of 4 primary health clinic sites. Self-reported information, motivation, and behavioral skills specific to retention in pre-ART HIV care were characterized by categorization of responses into those reflecting potential strengths and those reflective of potential deficits. Deficits sufficiently prevalent in the overall sample (ie, >30% prevalent) were identified as areas in need of specific attention through intervention efforts adapted to the clinic level. Gender-based differences were also evaluated.

Results: A total of 310 patients (76% female) completed structured interviews. The average number of information deficits per participant was 4 of 12 items, motivation deficits encompassed 5 of 23 items, and behavioral skills deficits averaged 6 of 18 items. Across the sample, 8 information-, 9 motivation-, and 8 behavioral skills-deficit areas were identified as sufficiently prevalent to warrant specific targeted attention. Gender differences did not emerge.

Conclusions: Deficits in pre-ART HIV care-related information, motivation, and behavioral skills suggested that efforts to improve accurate information, to facilitate the development of social support, including positive interactions with clinic staff and decreasing community-level stigma, and to decrease structural and resource-depleting demands of HIV care may be particularly valuable to facilitate retention in pre-ART HIV care.

80046 Impact on Emergency Department (ED) and Hospitalization Utilization among Optimized Multidisciplinary Care Teams (MDCTs) Associated with Maximal Antiretroviral Therapy (ART) Adherence

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Background: Health care system level factors influence patients' ART adherence. We previously determined, through observational cohort and regression tree analyses, which MDCTs compared with HIV/ID Specialist only, were most associated with improved adherence. We now explore if these MDCTs are associated with less ED and hospital utilization.

Methods: We analyzed all new regimen starts (n=10,801; 7,071 ART-naive, 3730 ART-experienced) among HIV-positive patients in Kaiser Permanente California from 1996-2006, followed through 365 days post-ART regimen initiation. Employing pharmacy refill methodology and including patient-, regimen-, and provider level factors, via regression tree and mixed linear regression analyses, 5 MDCTs were associated with maximal ART adherence. We used mixed logistic (odds ratio; OR) and Poisson (incidence-rate ratios; IRR) regressions clustered by provider and medical center (adjusting for gender, age, race/ethnicity, HIV risk, ART experience, and prior ED/hospital utilization) to test which MDCT optimized for adherence were associated with decreased odds ED or hospitalization visit and fewer counts ED visit or days hospitalization.

Results: We found decreased odds of ED visits among these MDCTs compared to HIV/ID Specialist Only (Specialist): nurse (RN) plus social worker (SW) plus non-HIV primary care (PC) (OR = 0.60, p = 0.003), Specialist plus mental health worker (MH) (OR = 0.51, p = 0.01) and clinical pharmacist (pharmacist) plus SW plus non-HIV primary care (OR = 0.73, p = 0.03). Only teams RN plus SW plus PC (IRR = 0.74, p = 0.04) and pharmacist plus SW plus PC (IRR = 0.78, p = 0.05) were significantly associated with decreased counts ED. Only the pharmacist plus SW plus non-HIV primary care MDCT (OR = 0.75, p = 0.03) was significantly associated with decreased odds hospitalization. However, if hospitalized, this MDCT (IRR = 1.59, p <0.001) and MDCTs pharmacist plus PC (IRR = 1.83, p <0.001), pharmacist plus PC plus non-RN care coordinator (IRR = 2.10, p <0.001), and RN plus SW plus PC (IRR = 2.03, p <0.001) have greater days rate hospitalization than Specialist.

Conclusions: HIV MDCT associated with maximal ART adherence also can be associated with decreased odds ED visits and total ED counts rate. However, only pharmacist plus SW plus PC was associated with lower odds hospitalization although higher total days rate hospitalization. These data should be considered when HIV MDCT is being formed.



80049 The HIV-HL: A Brief Computer-Administered Measure of HIV-Related Health Literacy

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Background: Low levels of health literacy are related to lack of knowledge about HIV and poor medication adherence in persons treated for HIV infection. Current assessments of health literacy require clinician time for administration and scoring and do not assess several important aspects of health literacy, such as listening comprehension. To address this we developed a computer-administered measure of health literacy that is brief and is automatically administered and scored. Content is related medication taking and treatment of HIV infection. The new measure assesses listening comprehension through questions about a brief video of a simulated clinical encounter. The purpose of this study was to evaluate the validity of the new measure in relation to cognitive and health literacy measures.

Methods: As part of a study of a computer-based intervention to promote health literacy in those treated for HIV infection, 120 persons with HIV infection completed the computer-administered measure. One month after completing a battery of cognitive and psychosocial measures that included a standard measure of health literacy, participants responded to the 20-item multiple choice test. The validity of the new measure (the HIV-HL) was evaluated in relation to a standard measure of health literacy (Test of Functional Health Literacy in Adults, or TOFHLA) and to other cognitive and psychosocial measures and to electronically assessed medication adherence.

Results: The HIV-HL showed adequate internal reliability (Cronbach's alpha = 0.69). Scores on it significantly correlated with TOFHLA total and subscale scores even after correction for cognitive status (all p's <0.01). Performance on the new measure was related to self-reported HIV knowledge, as well as to general health-related self-efficacy. Scores on the HIV-HL also correlated with medication adherence, and in receiver operating curve (ROC) analysis effectively differentiated persons with and without adequate health literacy defined by TOFHLA scores. The ROC analysis provided cutoff scores with known sensitivities and specificities.

Conclusions: A computer-administered measure may be an efficient technique for assessing HIV-related health literacy while reducing the assessment burden on patients, clinicians, and researchers. With ROC-derived cutoff scores, it may be useful as a screening instrument.

80050 Impact of Herbal Remedies on Adherence to Antiretroviral Drugs in Zimbabwe

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Background: Traditional herbal remedy use in Zimbabwe among HIV-infected people on antiretroviral therapy (ART) is widespread amid resource limitations for patients looking to manage the disease. This outcomes research study was done to ascertain the impact of traditional herbal remedy use on adherence to ART when concomitantly used.

Method: A cross-sectional study was conducted at Parirenyatwa Hospital Family Care Clinic, which provides HIV treatment services. Eighty-three participants were enrolled and interviewed using a structured questionnaire to measure their adherence levels to antiretrovirals and herbal drug use; this was confirmed by pharmacy refill records and clinic records. All patients in the study were taking the single-tablet formulation of stavudine, lamivudine, and nevirapine for treatment of HIV infection. Adherence comparisons were made between patients taking ART only and those taking ART and traditional herbs at the same time.

Results: The concurrent use of herbal remedies did not have a significant effect on adherence to antiretrovirals (OR = 0.87; p = 0.81). Gender (OR = 1.4; p = 0.6), disclosure of HIV status (OR = 1.3; p = 0.6), and length of time on ART (OR = 1.1; p = 0.8) were not significantly associated with adherence in a univariate model.

Conclusion: Use of herbal remedies did not have an effect on adherence to antiretroviral drugs within this study setting. The use of single-tablet formulations has greatly improved adherence to therapy. Co-drugs or supplements are unlikely to affect overall adherence to treatment.



80051 Timing of Loss to HIV Care Differs by Sociodemographic Factors for Patients Initiating Care at an HIV Clinic in the Southeastern United States

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Background: The timing of loss to HIV care (LTC) is not well defined. We describe differences in when LTC occurs among patients at a Southeastern HIV clinic.

Methods: Eligible patients were HIV-infected, ≤ 18 years, and initiated care at Vanderbilt's Comprehensive Care Clinic from 2004-2006. Sociodemographic data and dates of HIV provider visits were analyzed using a 2-year follow-up period. Patients who were pregnant or died were excluded. LTC was defined as >365 days without a provider visit. Patients were categorized as immediate LTC (no provider visit following intake), early LTC (last provider visit ≤ 3 months from intake), late LTC (last visit >3 months), and not LTC. Adjusted risk ratios (RRs) and 95% confidence intervals (CIs) were calculated for associations of sociodemographic factors with immediate, early, and late LTC compared to patients not LTC.

Results: Among 855 patients, 82% were male, 36% African American, 4% Hispanic, 56% reported male-to-male sex (MSM) and 8% reported injection drug use (IDU); the median age was 38 years. Eighty-five (10%) were immediate, 137 (16%) early, and 157 (18%) late LTC, totaling 44% LTC during the follow-up period (median 64 days to LTC). Compared with patients 35-44 years of age, early LTC was more likely for patients aged 18-24 years (RR = 1.58 [95% CI: 0.99-2.51]) and less likely for patients aged 45-55 years (RR = 0.42 [0.22-0.79]). Age was not associated with immediate LTC. African Americans had RRs of 1.81 (1.12-2.94) and 1.41 (1.02-1.94) for immediate and early LTC, respectively, compared to Caucasians; late LTC was more common among Hispanics (RR = 1.48 [0.84-2.63]). LTC was more common at all times among the IDU risk group compared to heterosexuals; MSM were not associated with LTC.

Conclusions: LTC is common and primarily occurs ≤ 3 months from intake. Interventions to improve retention should target and account for differences in timing of LTC by age, race, and HIV risk.

80053 Do Dose-Timing Measures Improve Prediction of Detectable HIV RNA?

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Background: Medication Event Monitoring System (MEMS) enables investigation of how the timing of antiretroviral therapy (ART) doses impacts viral outcomes among patients with HIV. We hypothesized that measures of dose-timing error (DTE) would improve prediction of HIV RNA beyond average adherence among those with moderate adherence.

Methods: The MACH14 study includes data pooled from 16 studies across the United States. We restricted the study to individuals who were ART-naïve at baseline. Detectable HIV RNA was defined as >400 copies/mL. Measures of DTE over the previous month included: net timing error (cumulative error from standard dosing schedule) and mean net timing error (average error). Average adherence was defined as the percentage of doses taken/prescribed and split into 2 categories: moderate (30%-80%) and high ($>80\%$). We examined DTE measures in combination with average adherence within each adherence strata. Area under the curve analysis (AUC) following multivariate logistic regression models provided measures of discrimination. Models were adjusted for study site, age, gender, race, and education.

Results: Of the 282 individuals in the sample, the mean age was 38 years, 76% were male, and 39% were African American. The average monthly adherence was 59%. Of the 1378 HIV RNA measures, 29% were detectable. The AUC was not higher when DTE measures were added to models with average adherence among those with high adherence; however, among those with moderate adherence, there was a significant improvement in prediction when net timing error was included compared to average adherence alone (AUC = 0.73 vs AUC = 0.77, $p < 0.05$).

Conclusions: Among those with moderate adherence to ART, DTE may play an important role in understanding viral suppression beyond average adherence among patients who are treatment-naïve. Further research is required to determine how DTE varies by ART regimen and how it relates to other clinical outcomes. Clinicians should also encourage on-time dosing to help patients optimize treatment outcomes.



80059 Strategies to Improve Treatment Adherence in Human Immunodeficiency Virus (HIV) Patients at a Pharmacist-Supported Urban Outpatient Clinic

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Introduction: Adherence to antiretroviral therapy (ART) is linked to viral load (VL) suppression and increase in CD4 cell count resulting in positive patient outcomes. Having a clinical pharmacist (CP) available on-site allows for more face time between the patient and a clinician. This is in addition to the following CP duties: screening for drug-drug interactions; following up on adverse drug events; identifying and addressing barriers to adherence through treatment adherence interviews; and provider education. The CP is also able to closely follow up with refills of ART to assist with monitoring adherence and preventing medication waste resulting in reductions in cost to government-assisted programs [i.e., D.C. Medicaid and the AIDS Drug Assistance Program (ADAP)].

Description: Incorporating CPs into a multidisciplinary team allows for close monitoring of medication for HIV in addition to other comorbidities. A rapport is established with the patient fostering trust and personal motivation. The CP is able to focus on the medications and identify necessary adjustments. This frequent contact establishes a line of communication to instill a sense of comfort within the patient in reaching out to the health care team if there are any issues or questions, etc. The success of this approach is evidenced by the outcomes of the following 2 patients: 1) VL reduction (3.77 log) of 655,000 to 110 copies/mL over 5 months in a substance-abuse patient; 2) inconsistently adherent and sickly patient with a CD4 cell count increase from 44 cells/mm³ to 213 cells/mm³.

Lessons Learned: Patients have improved outcomes when a CP is part of a multidisciplinary team focusing on adherence and medication efficacy. It allows more time for patient counseling, education, and closer comorbidity monitoring.

Recommendations: Clinical pharmacists should be utilized as an integral part of the health care team for increased patient/clinician contact, provider education, and use of their clinical expertise.

80060 Dual Management of Livelihoods and ART Adherence: Results from a Mixed Methods Study of People Receiving Integrated ART and Food Supplementation in Bolivia

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Background: Integrated HIV and livelihoods programs (IHLs) are increasingly promoted to support the economic well-being and food security of people living with HIV, improve antiretroviral therapy (ART) adherence and outcomes, and serve as a sustainable transition from food supplementation in treatment settings. However, few studies in resource-poor settings explicitly investigate the livelihood experiences of people on ART who are beneficiaries of food supplementation and explore in-depth the dual management of ART adherence and livelihoods to inform interventions.

Methods: We implemented a mixed methods study with a sample of urban, food-insecure ART patients (N = 211) in Bolivia. Study participants were all beneficiaries of a clinic-based food supplementation pilot project, sponsored by the World Food Project. The purpose of the pilot was to support ART adherence by alleviating household food insecurity, and an IHL was being considered to serve as a transition strategy. Study instruments included a closed-ended questionnaire and a semi-structured qualitative interview.

Results: Study participants reported complex economic lives characterized by multiple livelihood activities, ranging from the formal to the informal. Women reported high rates of informal activity, piecing together small, inconsistent economic activities, such as washing dishes or clothes. Dual management of treatment and livelihoods emerged as a salient theme. Negotiating permission for time off to attend the clinic, as well as taking daily antiretroviral medications at work, provoked conflict and were the most universally cited problems. To avoid this conflict, many people made economically suboptimal livelihood decisions in order to have the flexibility to accommodate ART schedules. Health care barriers also exacerbated this conflict, such as limited clinic hours, staffing, or unavailability of medicines during critical times that participants took time off work to attend to their health care needs.

Conclusions: As ART turns HIV into a chronic condition, it is essential to understand how people integrate their livelihoods and ART to maintain adherence. A meaningful IHL should not take a "one-size-fits all" approach (eg, microfinance, training). Rather, it should first assess the current set of economic activities, skills, and barriers experienced by potential participants, and then provide a range of solutions that address both livelihoods and ART adherence concerns.



80062 Sleep Quality is Related to Medication Adherence in Persons Treated for HIV Infection

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Background: Sleep disturbances are common in those with HIV infection. Insomnia is a common patient complaint and is related to fatigue and immune dysfunction. Sleep disturbances in HIV may result from immune responses, drugs used to treat the infection, or psychological factors, such as depression and anxiety. Sleep disruption in the general population has been shown to have a negative impact on cognitive function, especially the same higher-level executive functions associated with medication adherence, while depression is related to both adherence and sleep. The purpose of this analysis was to assess the relation of sleep quality, cognition, and mood to medication adherence in persons treated for HIV infection.

Methods: As part of a larger study of an intervention to improve health literacy among persons treated for HIV infection, a subset of participants (n = 37) completed the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS). Participants' medication adherence over the following month was assessed using electronic monitoring (Medication Event Monitoring System, or MEMS). The relation of sleep quality to medication adherence was assessed in a Poisson regression model for count data that corrected for age, gender, race, education, depression assessed by the Center for Epidemiological Studies Depression scale (CES-D), and executive function assessed with Trail Making Test, Part B.

Results: After correction for age, gender, race, education, depression, and executive function, PSQI score (chi-square = 18.61, p < .001) but not ESS (chi-square = 0.91, p = 0.34) score was inversely related to MEMS-measured adherence, suggesting that sleep quality may have a negative effect on adherence independent of mood. Age, education, and depression were also related to adherence.

Conclusions: Results show that poor sleep quality may be related to lower levels of medication adherence, even after taking the effects of mood and cognition into account. A larger sample size might allow the evaluation of mediating effects of sleep on adherence via mood and cognition.

80065 Is Percentage Adherence Enough? Correlation of the Various Adherence Metrics from the MACH14 Study

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Background: Adherence to antiretroviral drugs is a major determinant of treatment success, but few studies have used a metric other than percentage adherence. We hypothesize that more summary metrics may offer advantage over simple percentage adherence. An initial step to assessing this is to determine the extent to which other metrics provide information above and beyond percentage adherence.

Methods: We used the Multi-Site Adherence Collaboration in HIV (MACH14) database. A total of 949 individuals who had at least 30 days of electronic monitors (MEMS) and viral load (VL) at the beginning and within 30 days of a monitoring period were included for these analyses. We summarized adherence in 3 ways as percentage (percent), the duration of the maximal gap between doses (max), and the coefficient of variation (coefficient) which is computed as the standard deviation of the time between doses divided by mean time between doses. We measured correlations among these 3 metrics.

Results: The subjects were 70% male, median age of 40 years (IQR: 35-46), 45% African American and 30% naive to therapy at baseline. The median duration of a period was 185 days (IQR: 118-283). The median adherence percent was 64% (IQR: 30%-91%), the median max was 14 days (IQR: 3-50), and the median coefficient was 1.28 (IQR: 0.55-3.1). Percent was moderately correlated with coefficient [r = -.57, (95%CI: -0.61 to -0.52) p < .001] and max [(r = -.64 (95%CI: -0.68 to -0.60), p < .001)] while coefficient and max were more strongly correlated [(r = .73, (95%CI: 0.70 to 0.76) p < .001)] with each other.

Conclusions: The results demonstrate that percentage adherence measured by MEMS is not strongly associated with other relevant metrics. In further analyses we will investigate how these different metrics are associated with virologic responses, and explore whether an appropriate metric is regimen dependent. Investigators as well as clinicians should consider looking at other facets of adherence behavior besides percentage in their evaluation of patients on antiretroviral therapy.



80067 Individually Tailoring a Health Information Technology Adherence Intervention Using Patient-Reported Web Survey Responses

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Background: Increasingly, Web-based and electronic messaging technologies are features of daily life among people living with HIV (PLWH), in the United States and abroad. Leveraging these methods of communication to support antiretroviral therapy (ART) adherence outside of the clinical-care visit offers numerous advantages, but also requires sensitivity to the potential for messages to be considered a burden or too general to have personal relevance. The Patient Portal intervention was developed as a theory-based adherence support approach that uses messages optimized for personal relevance to adherence-related strengths and barriers. We detail the Information-Motivation-Behavioral Skills (IMB)-model based assessment used, associated frequency of reported deficits among participants, and the library of messages developed to target identified information, motivation, and behavioral skills deficits.

Methods: 304 PLWH were randomized to receive either 9 tailored adherence-related secure messages from a study nurse/ pharmacist through an online electronic medical record (EMR) system [Intervention] or 9 emails about general services available through their health plan patient Website [Control]. Intervention messages were tailored to the theory based adherence deficits identified by baseline web survey responses to the LifeWindows IMB ART Adherence Questionnaire.

Results: Across all participants, commonly endorsed adherence barriers included deficits in (1) Information: how ART works (52%), ART interactions with alcohol and drugs (40%), health consequences of skipping medication (37%), ART side effects (26%); (2) Motivation: side effect concerns (49%), frustration with lifelong treatment (46%), disclosure concerns (43%), concerns about ART hurting health (42%); (3) Behavioral Skills: adapting to changes in routine (65%), managing side effects (53%), taking medications when busy (47%) and when not feeling well physically (41%) or emotionally (39%). Messages delivered to intervention arm participants in response to deficits within each IMB domain are also provided.

Conclusions: This study is among the first to use a web-based EMR platform to deliver a tailored adherence intervention. While the intervention is under evaluation for efficacy, the tailoring strategy and theory-based message library developed provide useful tools for targeting intervention content. Given the increasing prevalence of Web and mobile technology use, Patient Portal offers a novel approach for leveraging technology to deliver targeted and tailored adherence support.

80068 Patient Perspectives and the HIV Engagement in Care Cascade

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Background: HIV care has been conceptualized as a treatment cascade in which each step is contingent on the prior one. However, little is known about patient experiences at each step of the cascade in the era of "routine" HIV testing, where individuals may receive a new HIV diagnosis when seeking medical care for other reasons. We sought to understand more about the barriers and facilitators of successful engagement in care for this population.

Methods: In-depth interviews were conducted with in-care individuals whose HIV diagnosis occurred in the emergency department or urgent care clinic at least 6 months prior (n = 20), as well as hospitalized patients who had been out of outpatient HIV care for at least 6 months (n = 10). The latter group was chosen to gain a more complete understanding of challenges to engagement in care. Both inductive and deductive approaches were used to analyze the data and identify salient themes.

Results: Participants acknowledged the fear of death and stigma as major concerns at the time of HIV diagnosis and emphasized the importance of HIV knowledge in the linkage process, specifically immediate education on the biological processes of HIV, treatment options, and expectations for treatment. Participants well engaged in HIV care described shifts in perspectives on HIV, including acceptance of HIV as a chronic disease and the creation of daily routines to manage health. Positive aspects of provider relationships were experienced through phone calls, emails, and home/hospital visits in addition to scheduled clinic appointments. Out-of-care participants largely valued prior HIV care and often did not perceive themselves as out of care, citing competing priorities as interfering with appointments.

Conclusions: Barriers and facilitators of engagement in care change at different points in the treatment cascade. Interventions to support engagement in care should account for the changes that occur in patient perspectives over time.



80069 Household Food Supplementation is Associated with Improved Food Security and Nutritional Knowledge: Results from a Pilot Study to Improve ART Adherence in Honduras

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Background: The deleterious effects of food insecurity and malnutrition on a range of HIV-related outcomes, including antiretroviral therapy (ART) adherence and retention in care, are now well recognized in resource-limited settings. However, scientific evidence on how to best improve and sustain food security and nutrition among people living with HIV remains underdeveloped, particularly for populations with high levels of both food insecurity and overweight/obesity.

Methods: A pilot study was implemented in Honduras to investigate the impact of clinic-based household food supplementation on ART adherence, as well as intermediate outcomes hypothesized to affect adherence. Food supplementation plus nutritional counseling were randomly assigned to 2 clinics (n = 202), with the other 2 clinics receiving nutritional counseling only (n = 198). We used multivariate longitudinal linear regression models with individual fixed effects to estimate the association between food supplementation and intermediate outcomes, including change in food security (using a scale-based measure validated for the Latin American context), anthropometric measures (eg, weight, body mass index, waist circumference), and nutritional knowledge score, over the 12-month intervention period.

Results: We found that food supplementation plus nutritional counseling is associated with improved household food security (p <0.01), especially among women (p <0.01), primarily in the dimension of improved food quantity (p <0.01), with a lesser effect on dietary quality (p <0.05). Food supplementation was also associated with improved nutritional knowledge scores compared to the nutritional counseling group alone (p <0.05). Meanwhile there was an (adjusted) trend of improved weight and body mass index (p <0.05) for overweight or obese participants, regardless of intervention group.

Conclusions: Food supplementation improves household food security but does not appear to be associated with changes in nutritional status, including such adverse effects as weight gain among overweight participants. Thus, food supplementation is likely to improve adherence via an economic pathway rather than a nutritional one, ie, alleviating household economic constraints to treatment, including having sufficient food to take medications. However, valid concerns over the sustainability of food supplementation to support long-term treatment adherence have been raised and must be addressed.

80070 Translating Evidence-Based Interventions into e-Learning Trainings for HIV Providers in Clinical and Non-Clinical Settings to Improve HIV Medication Adherence

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Background: Growing evidence shows that optimal antiretroviral therapy (ART) reduces infectiousness and lowers the risk of transmission to others, demonstrating that ART is an essential weapon in the fight against HIV. In May 2011, 8 evidence-based interventions to support HIV medication adherence were reviewed and identified as good-evidence by the Prevention Research Synthesis Project at the Centers for Disease Control and Prevention (CDC). Traditionally at CDC, the road from HIV intervention research to science-based practice is typically 2 years. With an evolving domestic HIV epidemic and ambitious National HIV/AIDS Strategy goals, a swifter response in translating new evidenced-based interventions to its intended users was needed. Thus, the CDC selected 5 HIV medication adherence interventions for translation into e-learning trainings for clinical providers and community partners serving people living with HIV (PLWH). This presentation will provide a preview of the development and content of these e-learning trainings and share CDC's next steps for dissemination.

Methods: The e-learning development team comprises staff members from CDC and John Snow, Inc. At least, twice-monthly meetings were held with subject matter experts of each medication adherence intervention and other key stakeholders to facilitate accurate knowledge transfer to develop content for the e-learning modules. Online searches were conducted utilizing subscriptions through several databases to gather supplemental resources related to HIV medication adherence.

Results: The e-learning course consists of a media-rich and interactive learning environment to meet the needs of diverse experiences in the HIV/AIDS care system. The user is provided with an overview of the intervention and video scenarios with a provider and patient to illustrate the components of the intervention sessions in action. Downloadable tools are available to assist the provider with successful implementation.

Conclusions: Web-based trainings may be instrumental in facilitating a swifter movement from translating evidence-based interventions into practice for intended users.



80071 Do Neighborhoods Matter in HIV Management?

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Background: With encouraging success in terms of reduced mortality, new challenges have emerged in HIV management. Specifically, secondary prevention efforts have proven inadequate to reduce the estimated incidence of new HIV infections. Epidemiologic data suggest that geographic clustering of new HIV infections is a common phenomenon, particularly in urban areas with populations of low socioeconomic status. This study aims to assess the role of constructs associated with the social disorganization theory and its relationship to behaviors that cause the transmission of HIV and affect health outcomes of individuals with HIV.

Methods: This cross-sectional study assessed the associations between neighborhood conditions and HIV-related factors (virologic suppression, CD4 cell count, depressive symptoms, receipt of HIV medication) and engagement in risk behaviors (unprotected sex, alcohol use) among an HIV clinic population in metro St. Louis, Missouri. We used individual-level data that were abstracted through medical records and census-tract level data to assess neighborhood conditions (poverty rate, percentage of African American population, and unemployment rate).

Results: The sample was male (67.2%), African American (74.6%), and unemployed (58.3%). Among a sample of 762, we found that 74.0% had current antiretroviral therapy prescriptions and 65.8% experienced virologic suppression. Multilevel analyses did not indicate associations between neighborhood conditions and HIV management.

Conclusions: These findings suggest that although our sample differed by age, gender, race, and income, their engagement in HIV care was consistent and a small proportion of the sample experienced challenges with their HIV management. Neighborhood characteristics may not be an identifying challenge among individuals with HIV in managing their care. They may experience challenges in other aspects of their lives that influence HIV in a manner that was not measured. Future studies should incorporate in-depth risk behavioral assessments with other neighborhood characteristics.

80073 A MACH14 Study Comparing Self-Report and Electric Drug Monitoring Antiretroviral Adherence Estimates: Methodological Considerations

Nancy Reynolds¹ (presenting), Julia Arnsten², David Bangsberg³, Judith Erlen⁴, Kathy Goggin⁵, Carol Golin⁶, Robert Gross⁷, Honghu Liu⁸, Robert Remien⁹, Marc Rosen¹, Neil Schneiderman¹⁰, Jane Simoni¹¹, Glenn Wagner¹², Yan Wang⁸, Ira Wilson¹³

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Background: There is general agreement in the literature that self-report (SR) overestimates antiretroviral (ARV) adherence. SR adherence is typically considerably higher and only modestly associated with electronic drug monitoring (EDM) adherence. The discrepancy is attributed to respondent subjective bias (eg, recall bias, social desirability) that produces systematic additive error in the SR data and an inflated group mean. Little consideration has been given to other factors that may account for the discrepancy (eg, analyses compare estimates calculated with non-equivalent combinations of ARVs or intervals of time).

Methods: This MACH14 (Multi-Site Adherence Collaboration in HIV) study examined whether SR and EDM estimates would compare more closely if differences in ARV and time intervals were controlled in the analyses. A series of analyses were conducted with pooled, individual level longitudinal data from 14 independent studies with a trial period averaging 15.7 months (range 6 to 60). Each measurement event with both 3-day SR and matching 3-day EDM data for a specific ARV were included in the analyses and equivalent mean percentage adherence analyzed as a continuous variable in the comparisons across 23 different ARVs.

Results: The mean SR adherence ranged from .84 to .99 (mean = .91, median = .90) and EDM from .47 to .86 (mean = .72, median = .72). The SR and EDM adherence estimates were positively correlated (range, $r = .09$ -.76; mean, $r = .33$). SR adherence was higher than EDM in each comparison, but the mean difference between SR and EDM estimates varied widely across the ARVs (range, .01-.47; mean = .19; median = .19; $p < 0.001$ for 87% of the comparisons).

Conclusions: These analyses comparing SR and EDM adherence with time-ARV equivalent estimates showed the level of agreement differed substantially by ARV type. In ongoing analyses we seek to gain insight that will explain this unexpected finding and implications for research measuring and drawing inferences about ARV adherence behavior.



80076 Social Determinants of Late Presentation to HIV Care

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Background: In recent years, more focus has been placed on social determinants of health and understanding how community, environment, and health care system factors affect health outcomes. HIV policies and guidelines emphasize the importance of earlier HIV diagnosis and presentation for care. This study evaluated the role of patient and community-level factors in late presentation to HIV care.

Methods: HIV-infected patients newly initiating outpatient HIV medical care at an academic HIV medical center between 2005 and 2010 were included. The address each patient reported at their first clinic visit was geocoded using geographic information systems software to the appropriate US census block group. Using the 2005-2009 American Community Survey data collected by the US Census Bureau, community-level data ("social determinants") was recorded for each patient's census block group. Multivariable logistic regression was used to evaluate associations between individual- and community-level factors with late presentation for HIV care (initial CD4 cell count <350 cells/mm³).

Results: Among 609 patients (age = 36, 67% male, 47% white), 339 patients (56%) had an initial CD4 cell count <350 cells/mm³. In multivariable logistic regression, late presentation was correlated to living in a census block group with between 33% and 67% African Americans and with fewer residents who were linguistically isolated. At an individual level, older patients were more likely, while white females were less likely, to present with a CD4 cell count <350 cells/mm³. Higher percentages of males, intermediate percentages of African Americans, and fewer linguistically isolated families in their census block group were correlated to late presentation among male, but not female patients.

Conclusions: Both individual and community-level characteristics were associated with late presentation for HIV medical care. Percentages of African Americans and linguistically isolated families in a census block group may reflect disparities in HIV diagnosis, access to care, and stigma associated with the diagnosis.

80077 Binational Pilot Study of Directly Observed Therapy for Tuberculosis Treatment: A Potential Model for Monitoring HIV Treatment Adherence

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Background: Careful monitoring has been shown to improve patient adherence to HIV antiretroviral therapy (ART), which is necessary for viral suppression and preventing drug resistance. While directly observed therapy (DOT) has been used successfully for monitoring tuberculosis (TB) treatment to assure high adherence, and small studies have shown potential efficacy for ART adherence, DOT is labor intensive, costly, and potentially stigmatizing. Findings from an ongoing pilot study assessing the feasibility and acceptability of "Video-DOT" using cell phones for TB treatment adherence may provide a model for new methods of assuring high treatment adherence for HIV.

Methods: We conducted focus groups with TB patients, providers, and health officials to explore their perceptions about Video-DOT - a method used by case managers to observe patients taking daily medications by having patients video-record themselves and forward videos via cellular phone to the case manager's office computer. Subsequently, we pilot tested the Video-DOT application among TB patients. To identify cultural and economic barriers to Video-DOT use internationally, we conducted the study in San Diego, CA, and Tijuana, BC, Mexico.

Results: Focus groups included 14 patients and 14 providers/officials in San Diego; 8 patients and 33 providers/officials in Tijuana. Emerging Video-DOT related themes were 1) strengths: technology easy to use, increases patient mobility and confidence, decreases DOT-worker time constraints, improves patient privacy, lowers program costs, increases adherence, and eliminates travel constraints; and 2) weaknesses: less patient-provider interaction, less individualized care, symptoms or side effects possibly missed, and confidentiality concerns. Of 47 patients on Video-DOT (mean age = 40 years; range = 18-86), only one preferred in-person DOT. All completers to date (n = 5) reported that they would recommend Video-DOT for other patients.

Conclusions: Video-DOT is feasible and acceptable for TB treatment monitoring. Video-DOT could provide a novel tool for HIV care providers to monitor adherence among newly initiating or poorly adherent patients.



80079 Routine Clinical Care Adherence Assessments Provide an Update of the Current State of Adherence and Key Predictors during the Evolving and Aging HIV Epidemic

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Background: The HIV epidemic and its treatments continue to evolve with older patients and simpler regimens, etc. This leads to a crucial need for ongoing assessment of the state of adherence and key predictors over time.

Methods: The CNICS assessment has been implemented at multiple clinical sites across the United States. Patients presenting for routine care are asked to complete a touch-screen-based assessment including adherence, depression, drug/alcohol/tobacco use, and sexual risk behavior measures. Data from 4 sites (Seattle, Boston, Birmingham, San Diego) from 11 months of 2011 are included. We used chi-squared tests and Spearman correlations.

Results: 3,104 clinical assessments were completed by patients receiving antiretroviral medications (ARVs) in 2011, 34% were ≥ 50 years, 14% women, 29% black, and 14% Hispanic. Current illicit drug use reported was amphetamine/crystal/speed 7%, cocaine/crack 5%, and opiates 2%; current at-risk alcohol use was reported by 21%. Rates of ever using illicit drugs were not different by age, but current drug use was lower among those ≥ 50 years ($p < 0.001$). Patients ≥ 50 years had fewer sex partners ($p < 0.001$) (eg, 9% with ≥ 4 partners within 6 months vs 13%) than younger patients but no differences in condom use. Moderate-to-severe depression was reported by 23%. The most recent CD4 cell count was < 350 cells/mm³ for 26%. Adherence was reported as very good/excellent by 85%. Viral load (VL) was inversely correlated with self-reported adherence (0.24, $p < 0.001$). Among those ≥ 50 years, adherence was better ($p = 0.005$) and CD4 cell count nadir (but not current CD4 cell count) was higher ($p = 0.04$) than younger patients. Rates of detectable VL were almost half among patients ≥ 50 years (5.2 vs 9.2%, $p < 0.001$).

Discussion: Understanding the current state of adherence, transmission risk behaviors, and adherence predictors in clinical care is needed to target interventions and further efforts to improve clinical outcomes. Routine assessment of adherence enables us to track and predict this important predictor of mortality at this stage of the evolving and aging HIV epidemic in America.

80083 Differential Changes Over Time of RNA Viral Load with Heterogeneity among MACH14 Studies

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Background: Few studies have been able to model how the relationship between antiretroviral therapy (ART) adherence and viral load (VL) suppression change over time. To accomplish this we analyzed pooled data from 12 out of the 16 studies from the Medication Adherence Collaboration in HIV study (MACH14), each of which used the Medication Event Monitoring System (MEMS) to assess ART adherence.

Methods: The outcome was log₁₀ VL (copies/mL), and predictors were ART adherence (percent of prescribed doses taken), treatment nave, regimen type, and age. We modeled changes in VL over time using repeated measures linear mixed effects models (RMLMEM). To explore the possible nonlinearity of VL change over time, we also used generalized additive mixed models (GAMM) with a cubic spline with 12 knots. The variation across studies was evaluated using study-specific parameter estimates assessed by interaction between study and time.

Results: The subjects' mean age was 41 years, 35% were female, 79% had a high school education or less, and most were African American (45%) with white (26%) and Hispanic (19%). RMLMEM showed that VL declines with time, and that the lower VL is related to better adherence, older age, longer time of observation, and being treatment naïve. The GAMM showed that the VL decline was non-linear, with considerable study-to-study variability. As in the RMLMEM model, in the GAMM model VL declines were associated with longer time of observation, better ART adherence, and being treatment naïve.

Conclusions: Meta-analysis with only aggregated data could hide important study level variation. Studies to identify clinical, organizational and policy factors associated with these different variations are warranted. Models for changes in virologic and clinical outcomes over time should take into account site effects as well as possible non-linear effects.



80099 The Impact of a History of Sexual Abuse on Medication Adherence

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Background: We identified 54 patients, out of a patient population of 156, at the LSU Bogalusa Medical Center HIV Clinic, who reported a history of past sexual abuse. We hypothesized that adherence to antiretroviral medications would be less in this group of patients due to mental health issues, versus a cohort with no history of past sexual abuse. We further postulated that this would be reflected in the immunologic and virologic status of the 2 groups.

Methods: A retrospective analysis of 140 charts was undertaken. Data consisting of CD4 cell count, HIV viral load, and a history of past sexual abuse as reported by patients were obtained on 102 patients on highly active antiretroviral therapy.

Results: Forty-eight patients in the group with no history of sexual abuse had an average CD4 cell count of 514 cells/mm³ versus 443 cells/mm³ in the cohort with a past history of abuse. The median CD4 cell count values were 434 cells/mm³ versus 406 cells/mm³, respectively. The number of patients not virologically suppressed, >50 copies/mL, was 14 in the cohort with no history versus 20 in the group who reported a past history of abuse.

Conclusions: Medication adherence is a complex subject, influenced by many factors. We suggest that a history of past sexual abuse is possibly one of those factors.

80300 Positive Affect Predicts Engagement in Care following HIV Diagnosis

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Background: Revised Stress and Coping Theory proposes that positive affect serves important adaptive functions and its beneficial effects are heightened during stressful periods. The present study examined the prospective relationship between positive affect and health-related behavior change in the 18 months following an HIV-seropositive diagnosis.

Methods: The Coping with HIV Affect Interview (CHAI) cohort study enrolled 153 individuals who had recently received an HIV-seropositive diagnosis. Using logistic and linear regression, we examined whether baseline positive affect predicted linkage to HIV care, anti-retroviral therapy (ART) persistence (ie, remaining on ART medications following initiation), and decreased stimulant (i.e., cocaine, crack, and methamphetamine) use.

Results: Most participants were men who have sex with men (67%), middle-aged (M = 38, SD = 9), and Caucasian (47%). After controlling for negative affect, higher baseline positive affect independently predicted increased odds of linkage to HIV care (adjusted OR [AOR] = 2.09; 95% CI = 1.08 - 4.05) and ART persistence (AOR = 1.89; 95% CI = 1.23 - 2.89) as well as decreased frequency of stimulant use ($\beta = -0.24$, $p < .05$).

Conclusions: Consistent with Revised Stress and Coping Theory, findings from the present investigation indicate that increased positive affect during stressful periods promotes health behavior change. Interventions to increase positive affect following HIV diagnosis could boost the effectiveness of "test and treat" approaches to HIV prevention.



80302 Adherence and Early ART for Prevention: A Qualitative Study with French HIV Experts

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Background: The finding that early antiretroviral therapy (ART) almost eliminates the risk of heterosexual HIV transmission supports novel approaches to prevention including “Test and Treat” (T&T). This study aims to better understand how and whether this approach may be applied in France from the viewpoint of French HIV experts and to build knowledge on prevention efforts using early ART.

Methods: In 2011, 19 experts participated in a semi-structured interview on the application of T&T in France. Expertise was typically defined on the basis of contribution to the 2010 French HIV guidelines. Specializations represented include clinical care, epidemiology, virology, and community activism. Interviews lasted on average one hour, exploring experts’ position on T&T, issues of who and how to test and treat, and what public health discourses and evaluations should accompany it. Analyses of material concerning who and how to treat are presented here. Thematic analysis of the transcribed interviews was aided by Atlas.ti 5.2.

Results: Results highlight the important role of adherence, a consideration in both the decision to treat early for prevention and the desired features of ART for this purpose. In general, pervading discussion of the decision to treat earlier than current recommendations (CD4 count >500 cells/mm³) was uncertainty and, by extension, a process of weighing the risks and benefits in terms of patient health, the risk of transmission, patient choice, population health, and cost. Key considerations in the desired features of an ART for prevention varied but centered clearly on adherence but also toxicity/side effects, efficacy, simplicity, resistance, diffusion (in genitals) and customization, features that were often also linked with adherence.

Conclusions: Despite strong evidence-based medicine (eg, HPTN 052), concerns about adherence in “real life” added to experts’ uncertainties about the effects of early ART. ART that is initiated early for prevention should favor optimal and long-term adherence.

80408 Alcohol Consumption among MSM in Primary Partnerships is Associated with Decreased Adherence to Antiretroviral Therapy and Elevated HIV Viral Load

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Background: Alcohol use among HIV-positive adults is associated with decreased adherence to antiretroviral therapy (ART) and potentially hastened HIV disease progression. Building on prior research suggesting that alcohol use is associated with poorer HIV treatment-related outcomes, this study examined the associations of individual alcohol use and ART adherence and HIV viral load.

Methods: In total, 356 HIV-positive men who have sex with men (MSM) and their male primary partners completed a baseline visit for a longitudinal study examining the role of couple-level factors in HIV treatment. We used the Alcohol Use Disorders Identification Test (AUDIT) as the primary predictor variable and calculated both the individual’s total score and absolute value of the difference in partners’ scores. Primary outcome variables included: self-reported ART adherence, ART adherence self-efficacy (ASE Integration and Perseverance scales) and HIV viral load (using peripheral venous blood samples). Generalized estimating equations (GEE) were used to fit the regression models in these multilevel analyses which adjusted for relationship length, time on ART, and couple serostatus.

Results: For every one unit increase in the individual’s AUDIT score, the HIV-positive partner had a significantly lower odds of 30 (Adjusted Odds Ratio (AOR) = .93, $p = .04$) day adherence, significantly less self-efficacy in his ability to integrate ART into his daily life ($\beta = .045$, $p < .001$) and to persevere in HIV-treatment (standardized $\beta = .03$, $p = .003$), and a 2.84% higher viral load ($\beta = .03$, $p = .01$). The deviation in the couple’s mean AUDIT scores was only associated with a higher odds of 100% three-day adherence (AOR = 1.18, $p = .04$).

Conclusions: Alcohol consumption is associated with lower adherence to ART, less confidence in one’s ability to manage ART regimens, and elevated viral load among HIV-positive MSM in primary relationships. Interventions that address individual drinking patterns could boost the effectiveness of “treatment as prevention” with MSM.



80440 Initiation of Substance Abuse is Associated with Decline in Adherence Over Time: Results from MACH14

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Background: Though active substance abuse is associated with worse adherence, few studies have examined how changing substance use patterns affect changes in adherence over time. We examined how changes in drug or alcohol use affect adherence over time, and tested the hypothesis that substance use initiation is associated with a decline in adherence over time while discontinuation is associated with improvement.

Methods: We analyzed data from the Multi-Site Adherence Collaboration in HIV (MACH14), which included 16 studies (14 sites) of electronically monitored adherence. MEMS data were collected during 4 weeks prior to each visit, and studies included 2-7 visits. We used data from observational studies or from control arms of intervention studies, and truncated follow-up at 180 days. To assess effects of changing substance use on adherence over time, for each substance we categorized each pair of consecutive visits in one of 4 ways: non-use at both visits (never), use at 2nd visit only (initiate), use at 1st visit only (discontinue), or use at both visits (persistent). Our outcome was change in adherence from 1st to 2nd visit. We then constructed mixed effects linear models for each substance, including a subject-level random effect (accounting for multiple observations within each subject over time) and a fixed time effect (accounting for decline in adherence over time across all subjects). For each substance, separate models compared the impact of initiating (initiate v. never) or discontinuing (discontinue vs persistent) substance use on change in adherence.

Results: Among 753 subjects from 11 studies, we observed that adherence declined among persons who initiated substance use from one visit to the next compared to persons who remained abstinent (adjusting for decline in adherence over time). Declines (mean, 95% CI) attributable to substance use initiation were: alcohol: -3.7% (-8.8, 1.3); cocaine: -0.9% (-0.2, 6.4), marijuana: -10.3% (-19.4, -1.2) and heroin: -2.6% (-21.1, 15.9). In contrast, among persons who discontinued substance use compared to persons who used substances persistently, changes attributable to discontinuation were: alcohol: 0.6% (-3.8, 5.0); cocaine: 1.8% (-6.3, 10.0), marijuana: -2.9% (-10.0, 4.2) and heroin: 6.5% (-7.5, 20.4).

Conclusions: Substance use initiation was associated with decline in adherence over time, while discontinuation of substance use was associated with improvement or less marked decline.

80445 Adherence to Antiretroviral Therapy among Commercially Insured, HIV-Infected Women of Childbearing Age in the United States

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Background: Advances in antiretroviral therapy (ART) have led to more favorable reproductive outcomes among women with HIV (WWHIV). Presently, 83% of WWHIV in developed nations can expect to live through their child-bearing years. When treated according to ART guidelines, vertical transmission is <1%. Data on adherence to ART for WWHIV is limited, especially during pregnancy and for specific ART. The purpose of this study was to examine adherence for selected ART among commercially insured pregnant and non-pregnant WWHIV.

Methods: Women (aged 15-45 years) with HIV ICD-9 codes were extracted from the MedStat MarketScan claims data for 2000-2010. Pregnancy was defined as 270 days prior to the date of an infant delivery claim. Adherence was measured as medication possession ratios (MPR), which were calculated for all ART. Drug-specific MPRs were calculated for patients who had at least one prescription claim (Rx) for lopinavir/ritonavir (LPV/r), atazanavir (ATV), darunavir (DRV), and efavirenz (EFV).

Results: A total of 10,160 WWHIV were identified within the study period, of which 4,345 (42.8%) received ART. Mean follow-up time after HIV diagnosis was 2.7 years, and a total of 1,774 deliveries occurred. MPRs could not be reliably calculated during pregnancy because the majority of women with infant delivery claims (n = 1161, 65.4%) had no evidence of ART Rx during pregnancy in the database, even though most (69.9%) had other non-ART Rx claims. Of all WWHIV on ART (including pregnant women with recorded ART claims and non-pregnant women), the overall adherence was good: The percent with an MPR >95% ranged from 92.3% (while on EFV) to 95.1% (LPV/r). The proportion of individuals with poor adherence (MPR <80%) was small, with the highest observed frequency of individuals with MPRs <80% occurring while on EFV (1.8%).

Conclusions: Results from this database of commercially insured individuals suggest that non-pregnant WWHIV of child-bearing age are highly adherent to ART, with >90% having MPRs at the ideal level. The lack of ART Rx claims during pregnancy for many women requires further examination in order to determine whether they are either not treated according to guidelines, or are accessing ART Rx through sources alternative to their commercial insurer.



80451 Adaptation of a Computerized Tailored Information Intervention to Improve Health Literacy and Adherence in Spanish-Dominant Hispanics Living with HIV

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Background: Lower levels of health literacy have been related to poor medication adherence in persons treated for HIV infection. Critical factors in promoting adherence in some groups may not be the same in Spanish language dominant Hispanics (SDHs), particularly those born outside of the United States. The purpose of this study was to culturally-linguistically adapt a computer-delivered health literacy intervention based on the Information-Motivation-Behavioral Skills (IMB) model, initially developed for English-speaking HIV-positive persons, so it can be effectively used with HIV-positive Hispanics with limited English proficiency.

Methods: In January 2012, we conducted in-depth audio-taped interviews with 15 HIV-positive SDHs recruited from a community clinic serving low-income Hispanics to identify factors related to the elements of the IMB skills model (elements of motivation, problem-solving, information about specific medications) that act as facilitators or barriers to medication adherence in this group. Written questionnaires were used to collect data on acculturation, HIV medication knowledge, and adherence practices. Using a grounded theory approach (Glaser & Strauss, 1967), qualitative data were divided by emergent themes and coded.

Results: 67% (n = 10) of the participants were men; 33% (n = 5) were women. Ninety-two percent of participants were born outside the United States, 73% were unemployed or unable to work, 53% reported having less than a high school education, 67% were single/living alone, and 92% have a primary care physician. Emergent themes included the role of family, social support, substance use, stigma and discrimination, depression, and language of health care providers.

Conclusions: This study has identified several relevant themes within cultural contexts relevant to delivering a tailored, computer-based health literacy and adherence intervention to HIV-positive SDHs. The findings elucidate HIV-positive SDHs' knowledge of HIV disease and treatment, layers of decision-making for adhering to medication regimes, and the influence of language and culture in these decisions from an HIV-positive Hispanic person's perspective.

80454 Non-Adherence and the Spread of HIV Conspiracies in Social Networks among African Americans Living with HIV

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Background: Prior research suggests that misconceptions about HIV and antiretroviral therapy (ART), also known as HIV conspiracy beliefs (about the human origin of HIV and mistrust of ART), are high among African Americans and related to non-adherence. We examined whether such beliefs spread in social networks of African Americans living with HIV, as well as implications of network members' beliefs for non-adherence.

Methods: A total of 136 HIV-positive African Americans (74% male) participated in this ongoing longitudinal study. Participants listed 20 alters (people with whom they interacted in the past year) and indicated alters' characteristics, relationships among alters, and whether each alter discussed and agreed with the participant regarding 8 different HIV conspiracies. Participants were asked open-ended questions about the discussion of conspiracies in their networks. Medication adherence was measured electronically for 6-months post-baseline.

Results: Over half (53%) agreed with at least one conspiracy belief, 38% reported discussing at least one conspiracy belief with alters, and 58% reported having at least one alter who agreed with a conspiracy belief. Participants who perceived that a higher percentage of alters endorsed conspiracies were more likely to believe conspiracies themselves. Participants who showed better adherence had a higher level of trust in alters for HIV-related information, and had discussed ART-related conspiracies (eg, ART is poison) with a greater percentage of alters. In qualitative responses, participants who were adherent to 100% of their medications described open and analytic dialogue about conspiracies in networks, especially with others living with HIV and medical and social service providers. In contrast, participants who were non-adherent described less discussion of any HIV-related information in their networks.

Conclusions: Findings suggest that candid discussion of conspiracies may help to reduce the impact of mistrust on non-adherence. Results can be used to guide development of social-network-based interventions to improve adherence among African Americans living with HIV.



80456 Self-Reported Adherence, Clinical, and Laboratory Findings in Brazilian Adolescents on HAART: The ADOLIANCE PROJECT

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Background: The primary goals of antiretroviral therapy (ART) can be achieved only if patients have high adherence to schedules at all stages of life. Particularly during adolescence, adherence emerges as a major challenge. The objectives of this study are: 1) to assess the self-reported adherence among Brazilian adolescents receiving highly active antiretroviral therapy (HAART), and 2) to evaluate the association between optimal adherence and clinical and laboratory parameters.

Methods: As part of the multi-centric study Adoliance Project, the present cross-sectional study evaluated 81 adolescents followed at Federal University of Sao Paulo. The study population was receiving HAART and being followed in a regular basis for at least 6 months. During the inclusion visit the participants completed a questionnaire with demographic data, a 1-month recall instrument for symptoms evaluation (20 items) and self-reported adherence assessment, laboratory tests [CD4 cell counts and HIV viral load (VL) at inclusion]. Optimal adherence was considered when the adolescents had taken $\geq 90\%$ of drugs prescribed.

Results: Of a total of 81 participants, 59 (72.8%) reported optimal adherence to HAART and 35 (43.2%) showed viral suppression (VL < 50 copies/mL). Optimal self-reported adherence was significantly associated with both viral suppression [odds ratio (OR) 10.6, 95% CI 3.3-34.8; $p = 0.001$] and having CD4 cell counts > 500 cells/mm³ (53/81, 65.4%) [OR 3.07, 95%CI, 1.6-5.7; $p = 0.027$]. Of a total of 20 symptoms, only 2 were significantly associated with optimal adherence: "loss of memory" [OR 0.156, 95%CI, 0.026-0.939, $p = 0.043$] and "sleep disorder" [OR 0.157, 95%CI, 0.032-0.761]. There was no significant association between being adherent and age, ethnicity, education or type of HAART.

Conclusions: A combination approach of self-reported adherence, CD4 cell count and VL estimation seems to be a practical way of assessing adherence. In this cohort, an optimal adherence is associated with a lower risk of symptoms such as sleep disturbance and memory impairment.

80458 Evaluating Factors that Impact Loss to Follow-Up among Postpartum HIV-Infected Women in Mississippi

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Background: Retention in HIV care is imperative to improved long-term outcomes in HIV-infected patients. Significant disparities persist in accessing health care for HIV-infected women in the Southern United States, a population with a disproportionate burden of the HIV epidemic. As more HIV-infected women are deciding to have children, the perinatal period offers a unique opportunity to understand barriers and facilitators to regular HIV care in this growing population.

Methods: All pregnant and postpartum HIV-infected women seen by the Perinatal HIV Service at the University of Mississippi Medical Center in Jackson, MS from December 2010 onwards are asked to participate in a small pilot study which includes completion of a demographic questionnaire as well as assessments of depression (EPDS scale), intimate partner violence (WEB scale), stigma (HIV Experiences), and substance abuse (ASI-Lite), and dates of postpartum obstetrics and HIV visits.

Results: To date, 32 women are enrolled in this study: 15 during pregnancy, and 17 postpartum; mean age is 27 years (range 18-44); 90.6% are black ($n = 29$), 87.5% are single ($n = 28$), 81% report an income $< \$10,000$ ($n = 26$), 61% ($n = 14$) are uninsured, and 72% report a high school diploma/GED or higher ($n = 23$). Median CD4 cell count either at presentation to prenatal care for pregnant women, or near delivery for postpartum women, is 378 cells/mm³ (range 20-720 cells/mm³). 12 women (37.5%) had EPDS scores > 10 suggestive of depression; 12.5% ($n = 4$) screened positive for battering with WEB score > 20 . Only 3 women reported recreational drug use (marijuana). Eight (25%) women reported limited disclosure due to stigma concerns. Eighteen of the 25 women (72%) with known HIV infection prior to pregnancy reported seeing their HIV provider at least once in the previous year. Of the 27 women who are at least 6 months postpartum, 2 (7%) and 10 (37%) missed their postpartum HIV and OB visit, respectively.

Conclusions: HIV-infected perinatal women in Mississippi experience depression, intimate partner violence, and stigma, which may impact their adherence to postpartum medical care. Further research to assess their impact in order to develop cost-effective interventions is needed.



80460 Barriers to Engagement and Retention in Care among People Living with HIV in Rural Areas: A Review of Domestic Research and Health Care Models

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Background: Prevalence rates of people living with HIV (PLWH) in rural areas of the United States have been increasing since the start of the epidemic particularly in the South. Historically, availability of health care in rural areas has been lacking and specialized care for people living with HIV is especially problematic. In addition to availability of health care, rural PLWHA are faced with substantially greater barriers than their urban counterparts.

Methods: A systematic review of empirical studies was conducted focusing on barriers to care among PLWHA in rural areas of the United States. Data were extracted to identify the most common barriers to care among rural PLWHA. These barriers were then compared to rural health care models to examine the correspondence of barriers present in the patient population to those addressed by the models.

Results: The systematic review yielded 15 viable articles for analysis. Among the 27 barriers identified, the most commonly discussed barriers were transportation needs, provider discrimination and stigma, confidentiality concerns, and affordability and lack of financial resources. When mapped onto the rural health care models, several barriers were not addressed by any of the models, particularly the barrier of community stigma.

Conclusions: Barriers to care must be dealt with in conjunction with one another in order to alleviate their impacts. At present there are very few models that adequately address most major barriers to care for rural PLWHA in the United States. In particular, reduction of community stigma as a mechanism for increasing retention in care should be included in future health care models.

80463 Prevalence and Risk Factors of Non-Adherence among HIV-Positive Patients in Enugu, Southeast Nigeria

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Background: The alarmingly high rate of recurrent and/or new opportunistic infections among HIV-positive patients on antiretroviral therapy (ART) and the consequent switch to second-line therapy has been attributed to various factors, including non-adherence to therapy. We sought to find out why, despite intense treatment preparation prior to the commencement of therapy, non-adherence remains a critical problem with regards to treatment outcome.

Methods: We conducted follow-up visits with controlled interviews and questionnaire sampling among 300 HIV-positive patients on therapy at the Enugu State University Teaching Hospital, to collect data on factors that influenced non-adherence to medication. The incidence of opportunistic infection was monitored with clinical and microbiological methods, and the improvement in health was monitored by immunological parameters using difference in CD4 cell count during initiation, treatment default/documentated non-adherence, and confirmed treatment failure.

Results: Among several reasons that were presented as causes of non-adherence, 72% cited religious beliefs, while 50% cited cultural practices as reasons for stopping or interrupting medication. Eighty percent of patients on second-line therapy attributed failure of adherence to faith-based patronage. Twenty percent of patients had treatment failure despite claims of strict adherence. Significant depletion in CD4 cell count among patients that defaulted from therapy ($p = 0.005$) was noted, and new and complicated opportunistic infections, such as tuberculosis (15%) and cryptococcosis (3%), were also noted. Recurrence of malaria, urinary tract infection, and acute respiratory infection was high among this group.

Conclusions: Despite the rigorous efforts made by ART clinicians to stem the rate of treatment failures among HIV patients across board, the trend has remained on the increase due significantly to unwholesome influences by spiritual leaders. It should thus be noteworthy that winning the war against non-adherence may involve taking the battle to new frontiers vis-à-vis leading advocacy to faith-based and traditional institutions, particularly those noted to lay claims to the cure for HIV/AIDS.



80468 Pill Count Adherence as a Predictor of Antiretroviral Treatment Failure in Children

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Background: The most accurate method for monitoring adherence among children and adolescents is unknown. The Botswana-Baylor Children's Clinical Centre of Excellence records pill count-based adherence at every clinical visit. Viral load (VL) is assessed every 3 months. We retrospectively assessed whether pill count adherence thresholds could discriminate between patients who did and did not have virologic failure (VF).

Methods: VF was defined as failure to suppress the VL to <400 copies/mL by 6 months on treatment or 2 consecutive VL >400 copies/mL after initial suppression. Adherence was defined as: (# pills taken in interval/# pills prescribed for interval)*100 and capped at 100%. Subjects were classified as non-adherent if ≥2 pill counts were below various thresholds (see chart below). Unadjusted odds of failure, sensitivity, specificity and percent correctly classified were determined at each cut point.

Results: A total of 902 subjects (0-16 years) who initiated treatment with a nonnucleoside reverse transcriptase inhibitor (NNRTI)-based regimen, with an average of 48 pill counts/subject were included. Twenty-two percent of measurements were >100% and 7% were >105%. After capping adherence at 100%, median adherence was 100% both for those with (81 [11%]) and without (821 [89%]) VF (Wilcoxon rank sum p >0.2). The table displays the test characteristics at adherence thresholds ranging from 50%-100%. Correct classification was maximized at <50%, but the sensitivity for VF was poor.

Adherence Threshold	Number (%) with Failure	Failure Odds Ratio (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	% Correctly Classified
<50%	26 (32.1)	9.5 (5.4-16.7)	0.32 (0.22-0.44)	0.95 (0.94-0.97)	89.6
<75%	51 (24.6)	7.3 (4.5-11.8)	0.63 (0.52-0.73)	0.81 (0.78-0.84)	79.4
<80%	54 (21.5)	6.3 (3.9-10.3)	0.67 (0.55-0.77)	0.76 (0.73-0.79)	75.2
<90%	65 (15.2)	5.1 (2.9-9.0)	0.80 (0.70-0.88)	0.56 (0.52-0.59)	58.0
<95%	73 (11.3)	4.0 (1.9-8.3)	0.90 (0.81-0.95)	0.30 (0.27-0.33)	35.6
<100%	81 (10.3)	Ref	1 (0.94-1)	0.04 (0.03-0.06)	12.7

Conclusions: Pill count adherence among children and adolescents in Botswana is very high, even among patients with VF. Because a relatively small percent of patients have low adherence values and those patients are significantly more likely to have failed their treatment, in areas where VL tests cannot be regularly performed, triaging of VL based on suboptimal pill count adherence could help to identify pediatric patients with VF while maximizing resources.

80471 Acceptability of Coded Substance Use Assessment in a Bidirectional Mobile Phone Intervention for HIV-Positive Substance Users

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Background: Advances in HIV care have drastically reduced morbidity and mortality in people living with HIV, however, near perfect adherence is needed in order to effectively suppress the virus. Active substance users are significantly more susceptible to HIV treatment non-adherence. Rural environments and minority status are associated with high rates of social stigma, isolation, and further barriers to adherence. Interactive mobile phone interventions with real time adherence and substance use queries and prompts have the potential to promote healthy behaviors. Mobile phone interventions are especially attractive because they could reduce health disparities by reaching underserved populations.

Methods: As formative steps toward treatment development, patients reporting recent or past substance use from 2 semi-rural community HIV clinics in central Virginia participated in semi-structured interviews with the research team. Interviewers discussed the tenets of a novel bidirectional SMS mobile health application to promote treatment adherence and reduce substance use and elicited participants' views on barriers to adherence and to answering queries in a text-messaging application. The current analysis focuses on participant comfort with and skills for receiving and answering text queries about their substance use using a specified code. Interviews were transcribed and analyzed using NVivo software to identify relevant themes.

Results: Eighteen participants completed semi-structured interviews. Participant demographics: average age 47.7 years, SD = 8.02, 72% (13/18) were non-white, and 56% (10/18) were female. Initial analysis indicates themes of acceptability related to bidirectional substance use text messaging by the majority of participants. Participants had positive views of the use of coded messages related to substance use. Many interviews revealed that participants would be more receptive to the texting intervention if they were actively seeking help for substance use.

Conclusions: Bidirectional substance use assessments are acceptable to rural HIV-positive substance users. Participants responded positively to receiving coded messages related to substance use, and they believed such an intervention will be useful for individuals open to assistance in substance use. Our novel bidirectional text message intervention is being finalized based on our findings.



81492 The PillStation™ Medication Monitoring System: Feasibility of a Telemonitoring Device to Improve Adherence in HIV-Infected Patients

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Background: Suboptimal adherence to antiretroviral therapy (ART) has long been recognized as a roadblock to achieving virologic control. Research suggests that innovative approaches are needed to increase ART adherence. Telemonitoring is a novel strategy that captures and transmits a patient's adherence data using electronic technology. We piloted a telemonitoring PillStation™ in HIV-infected patients at a monitoring cost of \$60/month in Bronx, New York. The main objectives of this 3-month study were to assess: 1) patient acceptance; 2) device feasibility; and 3) changes in adherence.

Methods: The PillStation™ Medication Monitoring System is a multi-component intervention that combines the use of an electronic pillbox with a remote tele-monitoring call center. A built-in scanning system sends images, over a secure HIPAA-compliant platform server, to the call center to verify medication setup and monitors patient interactions with the device. Scans allow the call center to monitor adherence and provide telephone reminders when doses are missed. During a 6-month period, 100 patients were asked to participate, and 1 out of 10 accepted home installation for 3 months of monitoring. Telemonitoring was conducted in patients' homes in a low-income, inner-city area. Questionnaires were used to assess device acceptance and feasibility

Results: The majority of patients (88%) declined home installation due to 1) lack of phone/internet access; 2) confidentiality issues (i.e., concerns about device visibility resulting in HIV-status exposure); and 3) unstable housing. Ten participants agreed that the PillStation: 1) helped with adherence; 2) offered friendly telephone reminders; and 3) device display/sounds were helpful. The following challenges were identified: 1) technical challenges limited scanning with phone/internet connection, requiring router installations; 2) untimely scans/repeating reminders; 3) poor device portability; 4) device reloading issues; and 5) one device went missing.

Conclusions: Since more than half of HIV-infected patients use pillboxes as an adherence strategy, a usable telemonitoring pillbox should be researched. In this pilot, while adherence seemed to improve with telemonitoring, technical issues precluded widespread use. As technology improves, smaller, portable, secure reminder devices with built-in scanners/routers that address confidentiality and safe data transmission should be further developed.

81740 Among Women with HIV, Interaction between Childhood Sexual Abuse and Denial Predict Medication Adherence and Quality of Life

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Background: Among HIV-positive women this study investigated how a history of childhood sexual abuse (CSA) interacted with the coping strategy of denial to predict quality of life and highly active antiretroviral therapy (HAART)/antiretroviral therapy (ART) adherence.

Methods: Participants were 87 HIV-positive women from the Women Interagency HIV Study (WIHS) Chicago site (93.3% were African American, mean age = 44.75 years, and median income = \$6000-\$12,000). Women were asked whether they were sexually abused prior to age 18, to which they had the option to respond yes or no. Brief Coping Inventory measured denial and the Medical Outcome Study-HIV form assessed quality of life (QOL). Two WIHS self-report measures were used to calculate mean HAART/ART adherence across biannual visits.

Results: Of the 87 women, 23 reported CSA and 64 did not. T-Tests indicated that women with and without CSA did not significantly differ in their use of denial, nor did they differ on QOL or HAART/ART adherence. Hierarchical multiple regressions controlling for age, education, and income indicated that denial predicted lower quality of life ($\beta = -.26, p = .02$) but not HAART/ART adherence and that CSA and denial significantly interacted to predict mean adherence to any ART ($\beta = .26, p = .01$) and HAART ($\beta = .21, p = .05$) and QOL ($\beta = .24, p = .03$) so that only for women without CSA higher levels of denial significantly predicted lower QOL ($\beta = -.39, p = .002$) and only for women with CSA higher denial significantly predicted higher ART adherence ($\beta = .54, p = .03$) and tended to predict higher HAART adherence ($\beta = .41, p = .10$).

Conclusions: It is essential for researchers and providers working with HIV-positive women to consider the role of CSA and coping strategies together because a coping strategy such as denial that may be maladaptive for women without CSA, might be adaptive in promoting medication adherence for women with CSA.



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