Correlates of Patient Retention in HIV Care and Treatment Programs in Nigeria

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Background: Long-term retention is a crucial component of HIV care because treatment success can only be measured among retained patients. However, poor retention has continually challenged long-term HIV management. Understanding of determinants of retention will inform proactive retention strategies particularly in developing countries where poorly-developed geographic mapping systems have hampered patient tracking. We evaluated the correlates retention in a large HIV program in Nigeria.

Methods: In March 2011, we conducted a retrospective quality of care evaluation for 5320 randomly selected HIV-positive adults aged ≥15 years (64.2% female; median age: 35 years) enrolled in 37 treatment facilities in our program. Eligible patients were enrolled 15 months prior to the evaluation or earlier. Retention was described as having one or more clinic visits in the review year (2010). Patient-related correlates of retention were determined using logistic regression.

Results: 144 patients died/transferred in the review year. In total, 3231 (62.4%) of 5176 patients were retained (65.6% female; median age: 36.5 years). 75.8% of patients on ART, and 23.4% pre-ART patients were retained. Correlates of retention were: Age 30-60 years (OR=1.37, 95% CI:1.22-1.57) versus <30years; Gender (OR=1.79, 95% CI:1.65-1.93) versus males; Baseline CD4 cell count (100-350 cells/mm 3 OR=1.25, 95% CI: 1.08-1.46 vs <100cells/mm 3); Baseline WHO stage (WHO Stage 1-2:OR=1.76, 95% CI:1.52-2.05) vs WHO stage 3-4; Being on ART (OR=10.3, 95% CI:1.88-11.9) vs non-ART; Later year of enrollment (2008-09 OR:1.21, 95% CI:1.08-1.34 vs 2005-07); Later year of ART initiation (2008-09 OR:1.73, 95% CI:1.49-2.01 vs 2005-07); In a multivariate model, gender, age, ART Status, baseline CD4 counts and WHO stage remained significant correlates of retention in our study.

Conclusions: 3 out of 4 pre-ART patients and 1-in-4 ART patients were not retained in 37 HIV treatment facilities in Nigeria. Pre-ART status, male gender, age <30, baseline CD4 counts <100 cells/ml and baseline WHO stage23 were the strongest predictors of poor retention. It is imperative that HIV programs proactively identify high-risk patients and intensify retention efforts in their early stages of care.
Improving HIV Counseling and Testing Services for Men who have Sex with Men in Nigeria

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Introduction: Despite HIV Prevention initiatives by stakeholders in Nigeria, MSM are highly discriminated in Health settings. These experiences limit their demand for HIV (HTC), and consequently force them to conceal their sexual orientation and health issues which in turn increases the risk associated with HIV. The objectives of this analysis was to understand MSM preference for HIV (HTC), and to improve service delivery.

Methods: An analysis was conducted for a year in 6 councils of the FCT. Two (2) mobile HTC models were used in this study (A and B). Model A involved MSM trained HTC officers, while Model B, non-MSM health personnel who were recruited to provide HTC in both drop in center, and at outreaches. Outreaches were conducted at 3 months intervals with help from community mobilizers. Refreshment was provided for clients during HTC as a means of motivation, and clients were allowed to choose either Model A or B. Consent forms during pre-test counseling and structured questionnaires were administered after post-test counseling.

Results: 768 MSM, between the ages of 18-41 years, were counseled and tested. 595 were counseled and tested by Model A and 173 by Model B, respectively. These respondents gave the following reasons for the overwhelming turn outs in Model A: 399 said they shared the same sexual Orientation with Model officers, while 196 were comfortable because there was no fear of stigma or discrimination. In Model B, MSM gave the following reasons: 138 said the HTC seems more confidential and their HIV status was not going to be disclosed to other familiar MSM, while 35 responded that B officers were qualified medical personnel who provided professional health services.

Conclusions: Many MSM clients preferred model A to B. Thus, for rapid breakthrough in HIV/AIDS prevention and OIs (opportunistic infections) management, MSM should be trained and recruited as HTC officers. Also, stakeholders must continue to collaborate with the Nigerian government to completely eliminate the discrimination of MSM.

The Art of Adherence: Using Body Mapping Methodologies to Explore HIV-Positive Women’s Relationships with their Medications

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Background: Optimal adherence to HAART (> 95% of prescribed medication) is critical to maintaining health and preventing adverse health outcomes like resistance to HIV medications, immune system collapse, and death. Most medical research on adherence examines the degree to which HIV-positive people follow prescribed medical advice. Missing from this approach is an understanding of how medical information about adherence is incorporated into the health practices of people living with HIV/AIDS and the gendered nature of such practices. In response to this, we conducted a qualitative study with service providers and women and men with histories of poly-substance drug use to explore how gender and ideas about the body impact medication practices.

Methods: We completed semi-structured interviews with providers and HIV-positive participants (n=25) and body mapping with six women participants, a unique methodology that allowed participants to communicate their experiences with HAART through art-based practices. These activities, which are the focus of this paper, included two workshops, follow-up interviews, and a community-based art show.

Results: The women identified many factors that make it difficult to take HAART consistently, including fatigue with complex medical regimens, a desire to avoid daily reminders of their disease status, and incomplete knowledge of their medications. However, they did not focus exclusively on these struggles and placed equal importance on explaining, through symbols, words, and colors, how their relationship with their medications has evolved within the context of their on-going 'journey' of living with HIV.

Conclusions: Our body mapping data provide new and important insights regarding the ideologies and practices that inform how HIV-positive women approach taking HAART. Of particular importance are the socio-emotional and physical impediments to taking their medications consistently, along with the complex and often ambivalent position these medications occupy within the unique and courageous journeys these women travel as they live with HIV.
Self-Reported Adherence to Antiretroviral Treatment and Its Correlates among AIDS Patients in Hunan Province of China

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Background: Optimal adherence to antiretroviral treatment (ART) is critical for suppressing drug-resistant, delaying the disease progression, reducing the death rate, and improving the quality of life among AIDS patients. With the comprehensive adherence intervention from the health care organizations, national and international research foundations, how is the situation of adherence to ART in Hunan Province is unclear nowadays.

Methods: A cross-sectional survey was conducted in two major CARE sites of Hunan from July 2010 to Oct 2011 by face-to-face interviews. Adherence measures included direct questioning regarding the number of doses taken in the 7 days prior to interview, the Community Programs for Clinical Research on AIDS (CPCRA) Adherence Self-Report questionnaire, and a 30-day visual analogue scale (VAS).

Results: The mean age of the 418 subject was 38 years old (SD=9.7), with 293 (70%) were male, 305 (73%) were from city, 244 (58.4%) were educated from high school or lower, and 117 (28%) were active or former heroin users. The average ART time was 18 months (range: 1,73). According to the 30-day-VAS, 72% (301/418) of subject maintained more than 90% adherence, but during past 7 days, 90% (375/418) reported more than 90% adherence and 78% (325/418) reported 100% adherence. The three measures of self-reported adherence were highly correlated. On multivariate analysis, heroin abuse (odds ratio [OR] =1.7; 95%confidence interval[CI]=1.1, 2.7; p<0.05), less educated (OR=1.3; 95%CI=1.0, 1.7; p<0.05) and lack of remind from family members (OR=1.5; 95%CI=1.0, 2.4; p<0.05) were associated with 90% or less adherence.

Conclusions: The adherence to ART among AIDS patients in Hunan was improved compared to that of 5 years ago by the same measurement. Strategies for future intervention should consider how to help drug users or less-educated people (such as farmers) to maintain optimal ART adherence, and family involved in Chinese culture might be a choice.

Pediatric Resistance to Antiretroviral Therapy: The Role of the Caregiver

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Background: The success of antiretroviral therapy (ART) in the treatment of HIV relies predominantly on optimal adherence to daily medication taken at prescribed times with appropriate nutrition. For children under 5 years, caregivers are responsible for administration of medication doses and reporting of doses to clinicians at monthly clinic visits. Suboptimal adherence to treatment may cause compromised immune suppression and drug resistance. Yet, various factors limit optimal adherence. The aim of this study was to qualitatively ascertain caregivers’, doctors’, nurses’, ARV counselors’, and traditional healers’ perspectives of the barriers and facilitators to caregivers’ treatment administration practices (TAP’s).

Methods: Doctors and nurses providing ART to children in rural KZN participated in in-depth interviews. ART counselors, traditional healers and primary caregivers participated in focus groups. The focus groups and interviews were conducted in isiZulu with the assistance of an isiZulu speaking translator. Interviews and focus groups were recorded and transcribed. Transcripts were translated into English where necessary and back translated to ensure accurate interpretation. Analysis was conducted using Atlas.ti 7 a qualitative data management tool.

Results: Barriers to caregivers’ administration practices as reported by doctors, nurses, counselors and traditional healers were (1) poor caregiver knowledge of TAP’s and (2) multiple persons administering treatment. Many caregivers reported not receiving the compulsory counseling sessions before their child was initiated on treatment and were thus unable to understand the importance of accurate and timely doses. Caregivers reported that poor palatability of treatment was the main characteristic of the child that inhibited caregiver administration practices. The main facilitator to TAP was the frequent monitoring of caregiver knowledge of administration practices by clinicians and counselors.

Conclusions: Continual monitoring of the caregiver by clinicians and counselors is necessary to ensure favorable treatment outcomes, such as suppressed viral loads, in young children receiving ART.
Depressive Symptoms and Correlates among People Living with HIV in Hunan, China

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Background: Depressive symptoms are common among people living with HIV (PLWH) and are associated with poor treatment outcomes and nonadherence to antiretroviral treatment (ART). Data regarding the prevalence of depression among Chinese PLWH are limited and inconsistent.

Methods: Data were collected from 496 PLWH between July 5th 2009 and July 31st 2010 at two HIV treatment sites in Hunan, China. Depressive symptoms were assessed using the Center for Epidemiological Studies Depression scale (CES-D).

Results: The prevalence of depressive symptoms was high, with 309 (62%) subjects reporting a CES-D total score equal to or above 16. Independent predictors of a CES-D equal to or above 16 included active heroin use (OR = 1.83, 95% CI 1.08 - 3.12), female gender (OR = 1.66, 95% CI 1.04 - 2.64), low level of social support (OR = 0.91, 95% CI 0.88 - 0.94), and lack of stable job (OR = 0.53, 95% CI 0.34 - 0.83).

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

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: Homeless individuals are at increased risk for negative health outcomes. HIV rates are high among the homeless, and are of special concern, given the transient nature of the homeless population, coupled with traditional HIV testing methods which impose a significant gap between testing and receipt of results. Same-day HIV rapid testing can mitigate this gap. We organized and implemented an HIV rapid testing/linkage-to-care initiative in homeless shelters via a multi-agency collaboration between federal and local government in Los Angeles County.

Methods: Mixed methodology; HIV testing data was collected on-site; qualitative data was collected by telephone. Post-intervention interviews conducted with stakeholders evaluated barriers and facilitators.

Results: A total of 817 homeless individuals were tested as part of this effort. Seven HIV-positives were identified; five of seven were linked to long-term care. Mean testing cost was $48.95 per client; cost per-positive was $5,714.

Conclusions: Costs were highest initially, and declined over time. This effort was viewed positively by participants. Results suggest that the high HIV seropositivity found among homeless shelter residents warrants project costs. This collaboration was successful, both programmatically and based on key stakeholder responses.
**36 An Evaluation of Post-Incarceration Linkage to Care for HIV/Hepatitis C-Infected Veterans in Los Angeles County**

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**Background:** Correctional institutions offer opportunities to identify Veterans with Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV), and for the US Department of Veterans Affairs Veterans (VA) to link them to medical care upon release.

**Methods:** This study provides the first description of barriers and facilitators that HCV and/or HIV-infected Veterans face in seeking medical care after community re-entry from Los Angeles County (LAC) jails. Semi-structured interviews of two cohorts: 1) clinical/non-clinical VA/LAC jail staff; 2) Post-incarcerated Veterans with self-identified HIV and/or HCV. Sixteen interviews were completed from cohort 1 and 9 from cohort 2.

**Results:** Although some characterized current efforts positively, barriers were highlighted. Veterans and staff described insufficient strategies for identifying eligible Veterans, ineffective outreach, and inadequate staffing. Strategies for improving linkage, including routine in-take identification of Veteran status, greater program dissemination and increased staff were noted.

**Conclusions:** Results highlight existing gaps for Veterans transitioning to VA healthcare from LAC jails. Findings can guide future efforts to strengthen gaps in care between local and federal government.

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**40 Quality Assurance Investigation of Antiretroviral Adherence in an Outpatient HIV Clinic**

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**Background:** Adherence to antiretroviral (ARV) medication is important for viral suppression and to avoid the development of resistance in patients with Human Immunodeficiency Virus (HIV). The primary objective was to describe and compare ARV adherence using two methods: patient reported and provincial claims database information.

**Methods:** All consecutive patients attending an appointment at The Ottawa Hospital (TOH) Immunodeficiency Clinic from February 13 until March 9, 2012 were approached for enrolment. 210 patients were enrolled and each patient completed the Medication Adherence Self-Report Inventory (MASRI), a self-reported adherence questionnaire. Adherence was also calculated for each patient using the Ontario Drug Benefit (ODB) Drug Profile, a provincial drug claims database. Patient characteristics were collected from clinic patient records.

**Results:** The adherence results were heavily skewed in favor of excellent adherence. The median MASRI reported adherence was 100%, and the median ODB reported adherence was 98%. When adherence data was organized in 25% interval groups, MASRI and ODB adherence weakly correlated (r = 0.188, p = 0.042). Characteristics associated with ARV adherence less than 75% were female gender (OR 2.73, 95% CI 1.62-4.61, p=0.005) and non-men who have sex with men (OR 1.96, 95% CI 1.71-2.25, p=0.004). History of missed appointments was associated with a discrepancy between MASRI and ODB adherence score (OR 2.56, CI 1.18-5.56). No characteristics were found to correlate with virologic failure and adherence, because of the limited number of therapy failures (n=3). However, past treatment failure was found to correlate with detectable viral load (OR 2.79, CI 1.20-6.51).

**Conclusions:** Patients in our clinic had excellent adherence when measured by the MASRI and ODB database. The MASRI and ODB calculated adherence were weakly correlated with each other. Interventions towards improving adherence should target women living with HIV.
Physical Activity and Health Outcomes among HIV-Infected MSM: A Longitudinal Mediation Analysis

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Background: Low physical activity is associated with depression, which may in turn, negatively impact antiretroviral therapy (ART) adherence among HIV-infected individuals; however, prior studies have not investigated the relationship between physical inactivity and ART non-adherence. Thus, the purpose of the current study is to examine the association of physical inactivity, depression, ART non-adherence, and viral load in HIV-infected men who have sex with men.

Methods: The sample (N = 860) was from a large, multicenter cohort of HIV-infected patients engaged in clinical care (the Center for AIDS Research Network of Integrated Clinical Systems; CNICS).

Results: Longitudinal mixed-level modeling revealed that across time, depression mediated the relationship between physical inactivity and ART non-adherence, γ = .075, and the relationship between physical inactivity and viral load, γ = .05. Furthermore, ART non-adherence mediated the relationship between depression and viral load, γ = .002, and the relationship between physical inactivity and viral load, γ = .009.

Conclusions: Low levels of physical activity predicted increased depression and poor ART adherence over time, which subsequently predicted higher viral load. Promoting physical activity as part of treatment programs for individuals living with HIV and mood difficulties may be worthy of further investigation.

Appearance Concerns, Depression, and ART Non-Adherence in HIV-Infected Individuals with a History of Injection Drug Use: Prospective Analyses

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Background: Appearance concerns are common among HIV-infected individuals, and previous cross-sectional and longitudinal data indicate that these concerns are associated with antiretroviral therapy (ART) non-adherence. However, to date, no known longitudinal data have examined the mechanism behind this relationship. Thus, the aim of the current study was to test depression severity as a longitudinal mediator of the relationship between appearance concerns and ART non-adherence in HIV-infected individuals with a history of injection drug use (IDU).

Methods: Participants were 89 HIV-infected individuals with a history of IDU who participated in a prospective, randomized controlled trial of cognitive behavioral therapy for depression and medication adherence. Clinician-administered measures of depression severity and appearance concerns, along with electronic monitoring of ART non-adherence were used. Data were analyzed via longitudinal linear mixed-level modeling, and mediation was tested with the Monte Carlo Method of Assessing Mediation (MCMAM).

Results: Appearance concerns were predictive of depression severity, γ = .31, SE = .076, 95% CI [.16, .46], t = 4.1, p = .0001, and depression severity was predictive of ART non-adherence, γ = 3.3, SE = 1.3, 95% CI [1.8, 5.8], t = 2.6, p = .01. The effect of appearance concerns on ART non-adherence, however, was significantly mediated by depression severity, γ = 1.02, 95% CI [.21, 2.1].

Conclusions: Appearance concerns are associated with depression severity, which subsequently is associated with ART non-adherence. Integrative interventions addressing appearance concerns, depression and ART adherence are needed, as this is one potential pathway towards worse health outcomes in HIV-infected individuals.
Stimulant Use is a Significant Risk Factor for Poor Engagement in HIV Medical Care

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Background: Stimulant (e.g., cocaine, methamphetamine) use is a recognized risk factor for poor prognosis among people with HIV, however little is known of its impact on engagement in HIV medical care. The purpose of this study is to assess: 1) the attitudes toward HIV medical care among stimulant-using men who have sex with men (MSM); (2) whether recent stimulant use is associated with poorer HIV medical care engagement.

Methods: MSM (n=276) living in the US and diagnosed with HIV for at least 1 year completed an online survey in 2009. Participants self-reported demographics, stimulant use (past month), engagement in HIV medical care (past year), and attitudes toward HIV medical care.

Results: Men were on average 42 years old, White (71%), and highly educated (43% with a college degree). Most (84%) reported no recent stimulant use, while 16% reported using one or more types of stimulants. In the past year, 69% of men attended all of their HIV medical appointments, 22% missed at least one appointment, and 9% had not attended any HIV medical appointments. Stimulant users (57%) were significantly less likely than non-stimulant users (85%) to report that HIV medical care is a high priority (p<.01). Nearly half (46%) of stimulant-using men reported having low confidence in attending all HIV medical appointments in the next year. Stimulant use was significantly associated with not attending any HIV medical appointments in the past year in the unadjusted model (Relative Risk Ratio=2.84, 95%CI[1.07,7.58]), as well as in models adjusted for demographic (RRR=3.16, 95%CI[1.13,8.84]) and psychosocial (RRR=3.44, 95%CI[1.17,10.15]) factors (p<.05).

Conclusions: Stimulant use was significantly associated with not engaging in HIV medical care in this sample of MSM. Interventions that address the importance of HIV medical care and increase stimulant user’s confidence in attending appointments may be critical to fully engage this difficult-to-reach population in care.
Perceived Infectiousness and Beliefs About Treatment as Determinants of ART Use and Adherence among High Risk, HIV-Infected Patients in Chiang Mai, Lusaka, and Rio de Janeiro: Qualitative Results from HPTN 063

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Background: The availability of ART (antiretroviral therapy) for treatment is rapidly expanding in developing world settings, and recent data (HPTN052) support treatment as a biomedical prevention strategy. However, the potential value of ART as prevention may be limited by poor adherence or uptake leading to uncontrolled virus. HPTN 063 is an observational mixed-methods study of high-risk HIV-infected patients in Chiang Mai, Thailand, Lusaka, Zambia, and Rio De Janeiro, Brazil to obtain data to optimize integrating HIV prevention into HIV treatment.

Methods: From May 2010-June 2012, semi-structured qualitative interviews were conducted with 80 in-care, HIV-infected individuals who reported current transmission risk behavior. The qualitative interview explored knowledge about HIV, experiences taking ART, and psychosocial factors that potentially influence adherence to ART. Interviews were recorded, transcribed, translated to English and examined using thematic-analysis.

Results: Equal numbers of heterosexual men and women (n=30) participated across the sites and 20 men who have sex with men (MSM) were enrolled, equally, in Thailand and Brazil. While responses were shaped by the socio-cultural contexts unique to risk groups and geographic locations, several broad themes pertaining to ART use and transmission risk behavior emerged across settings: 1) confusion about criteria for ART initiation; 2) perceiving an undetectable viral load to be both an HIV risk reduction strategy and personal health benefit; 3) reporting that ART adherence was connected to their perceived level of HIV infectiousness; and 4) concerns about drug resistance resulting from non-adherence.

Conclusions: Perceptions of HIV transmission risk are linked with patterns of ART utilization and notions of ART effectiveness across settings. Treatment as prevention efforts may benefit from addressing perceptions of how HIV treatment influences self-perceived transmission risk and ART initiation/adherence. Some patients’ confusion about starting ART highlights the need for myriad prevention efforts (i.e., PrEP, behavioral interventions, and ART as treatment for prevention).
48 Adherence To HIV/AIDS Antiretroviral Therapy In a Tertiary Hospital In North Central Nigeria

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**Background:** Suboptimal medication adherence rates to antiretroviral therapy poses serious problems to the control of HIV/AIDS. This study aims to assess the treatment adherence rate among HIV positive patients receiving treatment in a Nigerian Tertiary Hospital.

**Methods:** This was a descriptive, cross-sectional study conducted at the HIV clinic of the University of Ilorin Teaching Hospital, Kwara State. Self-reported treatment adherence rate was assessed among adults accessing drugs for the treatment of HIV over the preceding 7 days to minimize recall bias. Systematic random sampling method was used to select 550 participants out of a population of 2200. Data was collected using semi-structured interviewer administered questionnaire and analysis was done using SPSS.

**Results:** A total number of 550 HIV patients were studied and the age range of the respondents was 18 to 65 years with the mean age of 39.9±10 years. Mean duration of treatment period is 1.2±0.5 years. Pretreatment adherence instruction was given to 99.8%. More than three quarter (86.9%) of the patients did not miss their drugs in the last 3 months while 89.8% did not miss their drugs in the last 7 days. The highest proportion (36.1%) of the patients who missed their drugs in the last three months did so for 7 days and above and the mean duration of missing drug among the patients was 4.6±2.5 days. The treatment adherence rate of HIV patients was 92.6%. Reasons patients gave for non adherence included: travel (44.4%), felt sick and depressed (25%), ran out of drugs (33.3%), felt better (19.8%), lack of money for transportation (50%), side effects (37.5%), forgetfulness (41.7%), perceived stigma (30.5%).

**Conclusions:** The adherence rate is still less than optimal despite advancements made in treatment measures. Adherence monitoring plans such as home visiting and care should be sustained and home based care should be encouraged.

49 Prospective Memory and Antiretroviral Adherence in Youth Living with HIV

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**Background:** Neurocognitive impairment has been linked to lower rates of adherence as well as higher rates of substance use, and both of these behaviors are highly prevalent in youth living with HIV (YLH). Emerging evidence suggests that prospective memory (PM) could represent an important piece of the puzzle and explain why “forgetting” is the most commonly cited reason for nonadherence. PM is defined as the neurocognitive capacity to successfully form, maintain, and execute an intention at a particular point in the future in response to a specific cue. To date PM has not been examined in YLH. We present baseline data from a randomized clinical trial to evaluate the relationship between PM and adherence in YLH.

**Methods:** 100 participants (ages 16 to 29) in Chicago completed self-report measures of adherence (visual analogue scale) and PM including the Prospective and Retrospective Memory Questionnaire (PRMQ assessing PM complaints) and Prospective Memory for Medications Questionnaire (PMMQ assessing PM-based strategies to support adherence). Both measures include subscales for high-demand (self-cued PM complaints and internal strategies such as making plans to take medications) and low-demand (environmentally-cued PM complaints and external strategies such as an alarm clock).

**Results:** The sample was 95% ethnic minority and 80% male (Mean age= 23). Mean reported adherence over the last 30 days was 66%. In univariate analysis, higher adherence was associated with fewer self- and environmentally-cued PM complaints and greater use of internal PM strategies. In regression analysis controlling for psychological distress and substance use, only internal PM strategy use was significantly predictive of higher adherence with the entire model accounting for 19% of the variance.

**Conclusions:** PM is associated with adherence in YLH. The use of internal strategies may be particularly important for youth-specific adherence interventions. We present a new NIDA-funded translational PM intervention development initiative.
50 Trends in Single-Tablet ART Regimen Use and Association with Increased Adherence in the Women’s Interagency HIV Study, 2006-2012

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Introduction: Single-tablet ART regimens (STRs) were developed to improve adherence. Their uptake has not been well-described among U.S. HIV-infected women, who often have contraindications for certain formulations and competing factors resulting in lower adherence.

Methods: Participants were enrolled during 1994/1995 or 2001/2002 in the Women’s Interagency HIV Study (WIHS), a longitudinal cohort of HIV-infected and -uninfected women in 5 U.S. cities. We examined semiannual trends during 2006-2012 in STR use and ART adherence, defined as 95% adherence in the past 6 months via self-report. We tested for time trends using Poisson regression with generalized estimating equations. In a subset of women who switched from a preexisting regimen to an STR, we tested for a post-switch increase in adherence and virologic suppression among those remaining on an STR for two visits, using conditional logistic regression.

Results: 13,675 person-visits (N=1,500 ART-treated women, 53% black, 28% Hispanic, 27% IDU, mean age 41 years, 80% male, 33% IDU, median age 44), were included. STR use increased from 7% in 2006 to 20% in 2012 (p<0.001), while adherence increased from 75% to 80% (p<0.04). After taking into account use of STRs, the secular increase in adherence was no longer statistically significant (p=0.29), suggesting that improved adherence is largely due to their uptake. Among those who switched regimens (N=200), the STR was associated with increased adherence (80% to 87%), adjusted odds ratio [OR] 2.23, 95% CI 1.08-4.60) and virologic suppression (72% to 80%, OR 1.78, 95% CI 0.86-3.68).

Conclusions: In this largely treatment-experienced group of women, STR use increased to one-fifth of the population, with adherence increasing significantly during the same period. Our findings provide support that STRs are effective in improving adherence and clinical outcomes. Despite this, 20% prescribed ART were still not fully adherent; additional work is still needed to better understand the conditions that optimize adherence and therapeutic benefits in women.

51 Association of Time-Varying Adherence to ART on Rates of AIDS/Death: Cross-Cohort Analysis

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Background: The association between adherence and viral suppression has been well characterized, but its direct effect on morbidity and mortality is less well understood.

Methods: We examined data from three North American cohorts that collect prescription refill data. Percentage treatment adherence over one year was calculated for each subject for up to three years of antiretroviral therapy (ART). Adherence was categorized as low (<70%), medium (71-80%) and high (>80%). Associations between adherence and AIDS or death were estimated using Cox models with time-varying adherence, adjusted for cohort, age, gender, transmission risk group, baseline CD4 count, baseline AIDS, and further adjusted for time updated virological suppression. Virological suppression was defined as viral load <500 copies/ml on the most recent viral load measured within the same time period as the adherence measurement.

Results: Data were available on 4,535 patients (mean age 41 years, 80% male, 33% IDU, mean baseline CD4 count 249 cells/mm3). There were 124 AIDS events and 237 deaths in 10,390 person-years of follow-up. 62% of patients had high adherence after year 1 and 64% after years two and three. In adjusted models, the hazard of AIDS or death increased with increasing non-adherence (compared to >90% adherence: ≤70%, hazard ratio (HR) 5.72, 95% confidence interval (CI): 4.32-7.58; 71-90%, HR 1.99, 95% CI: 1.41-2.92). These HR were only modestly attenuated after further adjusting for virological suppression (≤70%, HR 3.59, 95% CI: 2.56-5.05; 71-90%, HR 1.65, 95% CI: 1.14-2.38).

Conclusions: Greater levels of adherence to ART are associated with reduced rates of AIDS or death, even after adjusting for viral suppression. This implies that adherence is not only a strong predictor of clinical success via viral load, but also an early indicator of declining health status making it a valuable tool for clinicians in daily practice.
Implementing Behavioral Activation and Life-Steps for Depression and Antiretroviral Therapy Adherence in an HIV Community Health Center: Evaluating a Modular, Group Approach

Jessica Magidson (presenting), Christopher Seitz-Brown, Steven A. Safran, Lance Morgan, Carl Lejuez, Stacey Daughters

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Introduction: Depression is highly prevalent among individuals living with HIV/AIDS and associated with poor adherence to antiretroviral therapy and worse disease outcomes. Empirically-supported cognitive behavioral interventions exist to address improvements in depression and adherence in this population; yet, these techniques have been designed for individual treatment in mental health settings. Dissemination and implementation studies are needed to examine how to adapt these techniques in medical settings where many individuals receive treatment.

Description: Primary aims of this study were to implement empirically supported cognitive behavioral techniques for depression (behavioral activation; BA) and HIV medication adherence (Life-Steps) for delivery in an outpatient community health center in a modular, group format that did not rely on sequential session attendance. Feasibility was examined over eight weeks (n = 13). Preliminary effects on depression, health-related quality of life, and medication adherence were examined and exit interviews were conducted with a subset of participants (n = 4) to inform future modifications.

Lessons Learned: It was feasible to implement this evidenced-based intervention into the HIV care setting. Mean changes over 8 weeks demonstrated clinically significant reductions in depressive symptoms, improvements in physical and mental health-related functioning, and antiretroviral therapy adherence. Exit interview feedback revealed the importance of peer-led contributions, difficulties utilizing homework in this format, and positive effects of structure and goal-setting for improvements in both mood and adherence.

Recommendations: Findings demonstrated the initial feasibility of adapting BA and Life-Steps for delivery in a modular, group format in outpatient HIV care. Future directions include testing the modified intervention in a larger sample with a comparison control.

Assessing Adherence in a West African Cohort in Guinea Bissau (the AssAiA Project)

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Background: Non-adherence is a major barrier to antiretroviral therapy (ART). Low adherence is a threat to ART programs and it is therefore crucial to address the factors leading to non-adherence. We have previously found in a qualitative study that HIV patients in Bissau have insufficient knowledge about HIV and ART. We showed that the experience of treatment benefits and social support facilitated adherence, whereas the main barriers were: lack of HIV-knowledge, and treatment-related costs.

Methods: We pilot tested a questionnaire designed for assessment of adherence and description of barriers and facilitators to adherence based on our previous findings. From October 2012 to March 2013, 350 HIV patients in the in the Bissau HIV cohort at the HIV clinic on Hospital National Simao Mendes in Bissau, were enrolled in the study. Patients were interviewed by a local trained nurse.

Results: Twenty-two percent were men, 34 % were illiterate. Forty one per cent were married and only 17% of these had disclosed their HIV-status to their partner. Non-adherence is a problem, as 25% did not take the medicine during the last 4 days and 20% skipped their medicine during weekends. The main barriers were lack of knowledge about ART/ HIV (40%), and disclosure-related difficulties (70%). The most frequent reasons for not taking medicine were side-effects (30%), simply forgetting (12%), too ill to attend the clinic (8%), lack of food (7%).

Conclusions: In a mobile urban West African population of HIV patients, one quarter have not taken their medicine at least one of the past 4 days, mainly because of perceived side effects and forgetting to take the drugs, non-adherence was strongly associated with lack of basic knowledge about HIV. There is an urgent need to improve HIV knowledge if adherence rates are to be improved.
59 Home Intervention Improves Adherence in Hunan, China

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Background: Free ART (antiretroviral therapy) is available through the China CARES program, but treatment adherence remains an issue. A Freirian home-nursing intervention improved ART adherence in the United States, but has not been tested elsewhere.

Methods: A culturally adapted home-nursing adherence intervention (Ai Sheng Nuo) was evaluated in a randomized pilot study among 110 patients in Hunan Province, China. All subjects self-reported less than 90% adherence to prescribed ART or pre-ART medications and had detectable viral load. Subjects were randomized to the 6-month intervention (N=55) or usual care (N=55). Data were collected at baseline, 6 months, and 12 months. Adherence was measured with a visual analogue scale.

Results: At 6 months, 69% of the control group and 90% of the intervention group were adherent. At 12 months, 64% of controls and 87% of the intervention group were adherent. Controlling for baseline adherence score and whether the subject was ARV naïve, the intervention group had higher adherence compared to the control group (p<.016). Adherence did not differ significantly between 6 and 12 months in either group (p=.415). There were no significant differences in detectable viral load between groups or over time. In both groups, the proportion of those with an undetectable viral load increased at 6 months (52% in the control group; 59% in the intervention group), and 12 months (70% in the control group; 73% in the intervention group).

Conclusions: Adherence improved for all subjects participating in the study. The intervention group had significantly higher adherence at 6 months and the effect was sustained after the conclusion of the intervention.

60 Defining Self-Reported and Prescription Measures of Adherence to ART: Multi-Cohort Analysis

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Background: Early identification of poor adherers to ART could facilitate interventions to prevent treatment failure. However, cohorts collect adherence data in diverse ways and defining levels of adherence is not straightforward. We examined how different measures may be used to identify those at risk of viral failure.

Methods: 6/19 cohorts collaborating in the ART Cohort Collaboration (ART-CC) contributed adherence data: 3 from prescription refills (3 North American cohorts) and 3 from self-report questionnaires (2 European, 1 North American cohort). For prescription data, we derived 1-year percentage adherence and viral suppression (≤500 copies/ml) using the viral load closest to the 1 year time point. For self-report data, we derived percentage adherence in the last 28 days and viral suppression using the closest viral load measure after but within 6 months of the questionnaire. We plotted Receiver Operating Characteristic (ROC) curves to assess discrimination of percentage adherence for diagnosing viral suppression, and estimated the area under the ROC curve (AUROC); 0.5 corresponds to no and 1 to perfect discrimination.

Results: Adherence and viral load data were available from 13276 patients: 9591 and 3685 with prescription and self-report data respectively. Greater proportions of patients were virally suppressed and had ≥95% adherence in cohorts with self-report compared with prescription data. AUROCs varied from 0.56 to 0.85 between cohorts and were systematically higher in cohorts with prescription data, likely due to the categorical rather than continuous nature of the self-report data.

Conclusions: Cohorts were heterogeneous in terms of viral suppression and adherence. Prescription and self-report data measure different aspects of adherence. Self-report items may provide a better snapshot of current adherence enabling identification of inadequate adherence before viral loads begin to climb. This real-time reporting advantage of self-report questionnaires may constitute an intervention which may explain the apparent lower discriminatory power compared with prescription data.
Adherence Intervention Reduces Depressive Symptoms in Hunan, China

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Background: Free ART (antiretroviral therapy) is available through the China CARES program, but medication adherence remains an issue and mental health services are lacking. Depression has been associated with suboptimal adherence in a number of cohorts.

Methods: As part of a pilot study of the efficacy of a culturally adapted home-nursing adherence intervention (Ai Sheng Nuo), depressive symptoms were measured among 110 patients receiving ART in Hunan Province, China. All subjects self-reported less than 90% adherence to prescribed ART or pre-ART medications and had detectable viral load. Subjects were randomized to the 6-month intervention (N=55) or usual care (N=55). Data were collected at baseline, 6 months, and 12 months. Adherence was measured with a visual analogue scale. Depressive symptoms were measured with the CES-D (Chinese).

Results: At baseline 71% of controls and 58% of intervention subjects reported symptoms suggestive of depression (i.e., CES-D score ≥ 16). The proportion of subjects in each group with CES-D of 16 or greater decreased to 60% of control subjects and 50% of intervention subjects at 6 months. Differences at baseline and at 6 months were not statistically significant. However, the proportion of intervention subjects with a symptom score of 16 or greater continued to decrease at 12 months (38%), while returning to baseline in the control group (71%). In multivariate analyses, controlling for whether a subject was ART naive, there was a significant difference in overall CES-D scores between the two groups (p=.001), with the control group having a higher proportion of people with a score of 16 or greater. There was no association between adherence and CES-D scores.

Conclusions: In this cohort, depressive symptoms were prevalent and not significantly related to self-reported adherence behavior. However, receipt of the adherence intervention was associated with reduced depressive symptoms at the long-term follow-up visit.

Every Dose Every Day: A Preview of a New e-Learning Training Toolkit for HIV Care Providers to Improve Adherence to Antiretroviral Medications

Kathleen Green (presenting), Rhondette Jones, Janet Van Ness

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Introduction: Adherence to anti-retroviral therapy (ART) is critical to the success of HIV treatment and treatment as prevention. However, despite ART advances, more than 800,000 of the estimated 1.2 million people living with HIV in the U.S. do not have a suppressed viral load. In order to prevent treatment failure and drug resistance and to see the prevention benefits of treatment, patients must have greater than 95% adherence. Thus, an important challenge for providers is to support patients’ adherence to HIV treatment.

Description: In Fall 2013, the CDC’s Division of HIV/AIDS Prevention Capacity Building Branch will launch an e-learning training toolkit for HIV care providers featuring four evidence-based behavioral intervention strategies that were found to improve HIV adherence among ART-naïve and/or experienced patients. These four strategies include - Project HEART (Helping Enhance Adherence to Anti-retroviral Therapy); Partnership for Health - Medication Adherence; Peer Support; and SMART (Sharing Medical Adherence Responsibilities Together) Couples. These interventions were identified as “good evidence” according to the CDC’s HIV/AIDS Prevention Research Synthesis (PRS) Project. The e-learning training toolkit includes an overview of each strategy, theoretical underpinnings, staff roles and responsibilities, session content, videos demonstrating sessions in action, and comprehensive guides for integrating the strategy into an agency/clinic. Finally, downloadable brochures, manuals and posters are available to assist providers and staff with successful implementation.

Lessons Learned: The development of an e-learning training facilitates swifter movement in disseminating evidence-based interventions into practice for intended users. The original researchers play a critical role in transferring knowledge of their research into practice.

Recommendations: This e-learning training toolkit will be pilot-tested among HIV clinical providers. Continuing education will be given to learners who complete the training. This training will assist HIV providers in assessing and better understanding their patients’ challenges to achieve and support optimal adherence.
**Stages of Change and Adherence to Antiretroviral Therapy**

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**Background:** Research has consistently demonstrated the inability of clinicians to predict non-adherent patients. The stages-of-change model, originally described to understand smoking cessation, has been widely applied to cessation of harmful behaviors. The objective of the current study was to determine whether phases in the model (i.e., pre-contemplation, contemplation, planning, action, and maintenance) predicted adherence to antiretroviral therapy (ART).

**Methods:** Data for the current analysis comes from a randomized trial of a provider-focused intervention. Individuals were eligible if they were taking ART and had detectable HIV-RNA at the baseline visit. Adherence was measured using MEMS (Medication Event Monitoring System) and self-report. Data from 503 follow-up visits from 141 individuals using MEMS were used. Descriptive statistics characterized the sample and the stages-of-change over time. Linear mixed models were used to determine the impact of stages-of-change on repeated measures of adherence after controlling for potential confounders.

**Results:** The sample was 23% female, 50% white, 26% African-American, with a mean age of 42 years. The overall average MEMS adherence was 73% and 17% were in the pre-contemplation, contemplation, or planning phases for taking ART. Those in the pre-contemplation, contemplation, or planning phase had significantly lower MEMS adherence (-18.4%, p<.0001) compared to those in the action and maintenance phases, after adjusting for age, sex, race, education, depression, and alcohol and substance use. No demographic characteristics predicted adherence. Similar results were observed for self-reported adherence.

**Conclusions:** The stages-of-change model may offer a potential screening tool for clinicians to discover patients at-risk of non-adherence to ART. Similar to prior research, demographic characteristics did not distinguish ART adherence in this study, reinforcing the need for clinicians to engage in dialogue with patients about their adherence behaviors. Future research is needed to test the use of this model as a screening tool in the clinical setting.

**Disclosure of HIV Status and Enrollment in HIV Care in Western Kenya: Findings from a Home-Based Counseling and Testing Initiative**

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**Background:** Early identification and enrollment in care of HIV-positive individuals is crucial to the success of antiretroviral treatment (ART) programs. While home-based counseling and testing (HBCT) identifies individuals early in the course of disease progression, linkage to HIV care is inadequate in many resource-limited settings. The objective of this study was to determine the proportion and correlates of enrollment in HIV care among a population-based sample of individuals who had previously tested positive for HIV in western Kenya.

**Methods:** As part HBCT, all households within 6 USAID-AMPATH (Academic Model Providing Access to Healthcare) catchments were visited. Of the 5,558 individuals identified as HIV-positive between July 2009 and August 2011, 1,048 (19%) were previously known infections. Logistic regression analysis determined factors associated with self-reported enrollment in HIV care.

**Results:** Sixty-six percent of the sample was female, with a mean age of 35 years. On average, HIV testing occurred 2 years prior to HBCT. Seventy-five percent (n=786) reported enrollment in HIV care. Characteristics associated with enrollment in multivariate analysis included: female sex (odds ratio (OR) = 1.57, 95% confidence interval (CI): 1.04, 2.39), age over 26 years (OR=2.87, 95% CI: 2.46, 3.34), and monthly income ≥3000 Kenyan Shillings (OR=1.34, 95% CI: 1.03, 1.74). Those who had disclosed their HIV status to at least one other person were nearly 7 times more likely to report enrollment in HIV care (OR=6.66, 95% CI: 5.06, 8.77) compared with those who had not disclosed.

**Conclusions:** One-quarter of individuals previously known to be HIV-positive were not enrolled in care. Women, older adults, those with higher income, and those who disclosed their HIV status were more likely to enroll in care following HBCT testing. Additional efforts to engage men, young people, and those of lower income are urgently needed to ensure the individual and population effectiveness of ART.
Both patients (n=25, 40% female, mean age 32 years) and More clients at the sub-acute primary care sites Programs to link HIV-infected IDUs in addiction treat-

To end the epidemic, clients must be engaged in

We conducted 3 focus groups with HIV-infected IDUs and

In Russia, HIV-infected injection drug users (IDUs) in

Clients engaged in primary care have a positive meas-

Clients' 2012 laboratory values extracted from electron-

97 semi-structured in-depth interviews with their clinical providers in St. Petersburg, Russia; interviews were in Russian and audio-record-
ed. We analyzed data directly from audio recordings to identify essential themes.

Results: Both patients (n=25, [40% female, mean age 32 years]) and staff (n=7) identified lack of motivation as a significant barrier to accessing HIV care among IDUs. Other internal barriers stated by IDUs included mistrust of HIV providers, fearing stigmatization due to their drug use, lack of psychological support, and misperceptions about HIV care per se. External barriers cited were transportation difficulties, lengthy registration procedures, and lack of HIV-related information. Consistently, IDUs equated HIV care with dispensing of antiretroviral therapy. Poor health was infrequently mentioned as a motivation to seek care.

All study participants liked the idea of using peer case management to improve engagement of IDUs in HIV care. Most IDUs perceived peer case managers as sources of psychological support and HIV-related information; learning about peers’ positive HIV care experiences was identified as a useful facilitator.

Conclusions: Programs to link HIV-infected IDUs in addiction treat-

ment to HIV care must focus on reducing logistical barriers and moti-
vating participants to access care. Peer case management might have the potential to deliver education regarding the benefits of HIV care and to provide examples of peers’ positive experiences with such care. Exploratory qualitative research helped tailor a standard HIV-care linkage intervention to one potentially helpful for Russian HIV-infected drug users.

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Comparing the Utility of Substance Use Measures in the Prediction of Medication Adherence: Quantity, Severity, or Pattern?

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Introduction: The CDC estimated that by 2015 more than half of those living with HIV will be age 50 and older. The link between substance use and reduced adherence to HIV medication is well-established in samples of younger adults; this association is less understood among older adult populations. One challenge faced by researchers in this area is appropriately quantifying substance use in a manner that permits an accurate representation of use as well as the associations between use and outcomes of interest, such as HIV medication adherence.

Methods: HIV-positive men and women over age 50 from the New York City area (n=540) completed survey interviews via telephone about their demographic information; self-reported immunologic functioning (viral load); recent (past 30 days) HIV medication adherence and drug and alcohol use. Respondents also completed the AUDIT and DAST-10.

Results: Three measures of substance use were obtained: amount of use (the sum of the number of days each drug was used); severity of use (scores above the clinical cutoff on the AUDIT and/or DAST-10); and use pattern (determined empirically using Latent Class Analysis). Number of missed medication days was regressed simultaneously on these three measures. Severity was uniquely and positively associated with missed medication days. Substance use pattern was uniquely associated with non-adherence for heterosexual women, but not heterosexual or gay men. Quantity of substance use was not significantly associated with non-adherence after accounting for pattern and severity.

Conclusions: Measures of quantity, severity, and pattern differ in their predictive utility as well as their ability to inform the tailoring and targeting of intervention. These results indicate the need to explore multiple methods of operationalizing substance use. They also suggest that the predictive utility of measures may vary across demographic factors.

Developing a Mobile HIV Adherence App, While Keeping a Homeless Population in Mind

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Introduction: Adherence to HIV medication (ARVs) can be challenging - exceptionally so for people who are homeless. Many have "competing priorities," such as finding food or shelter, that interfere with taking medication. A plethora of smart phone applications (apps) exists to assist with adherence. Boston Health Care for the Homeless Program (BHCHP) participated in the development of one such prototype app - hiVIVA. Though most BHCHP patients do not currently have access to smart phones, in all likelihood this technology will be in the hands of even the most disadvantaged populations within a few years. It behooves their care providers to learn about apps such as hiVIVA.

Description: BHCHP participated in MIT Media Lab’s 2013 Health and Wellness Innovation event to help develop a prototype adherence support app. BHCHP’s focus was assuring the app’s relevance for people who are homeless. The team produced hiVIVA, a multifaceted app which includes: real-time adherence support/reinforcement, visual simulation of ARVs working in the body which changes depending upon lab values and adherence, patient/provider communication, and gamification and social connection capabilities.

Lessons Learned:
• The “competing priorities” of team members presented a challenge. Participants had varying agendas and it took time to develop a common focus.  
• This writer was initially skeptical about the app’s relevance for BHCHP patients, given their lack of smart phones. Yet it became clear that the app could be particularly relevant for this population. hiVIVA’s social connection and gamification aspects might provide the social support that these transient patients often don’t have outside of their care providers. Furthermore, hiVIVA’s innovative HIV education/support components can be a useful office-based tool.

Recommendations: The homeless HIV+ population should beta test hiVIVA so their feedback is incorporated into the final product. Care providers of people who are homeless should familiarize themselves with health-related mobile app technology.
76 HIV/AIDS Treatment at a Tertiary Hospital Clinic in Ghana - Where are the Men?

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Background: In resource-limited settings, men may face formidable barriers to accessing HIV care as early diagnosis and treatment interventions tend to focus on women through antenatal care. This study seeks to investigate gender differences in entry to care in a large urban HIV clinic in Ghana, a country where men account for almost half of the HIV epidemic.

Methods: We performed a retrospective chart review of all adults who initiated care at Komfo Anokye Teaching Hospital (KATH) HIV clinic in Kumasi between January 1 and December 31, 2011. Charts were abstracted for demographic, medical, and behavioral variables of interest. Differences between men and women were analyzed using a correlations matrix in which covariates with p<0.05 were considered significant.

Results: Of the 1,127 patients who initiated care during study period, 895 charts were available for review comprising of 279 (31.2%) men and 616 (68.8%) women. Men were more likely than women to be older (p<0.001), married (p<0.001), and more highly educated (p<0.001). An equal proportion of men (n=54, 19.4%) and women (n=121, 19.6%) did not return for CD4 assessment (p=0.92). CD4 count at entry to care was lower for men compared with women (261 versus 312; p=0.02). Over 51% of men and 44.6% of women had a CD4 count below 200 (p=0.09). Men were more likely than women to use their spouse for emotional support (p<0.001), to use alcohol (p<0.001), and to be sexually active (p=0.01).

Conclusions: Efforts to test and link men to care should be intensified. Men account for 45.5% of HIV positive adults in Ghana but only 31.2% of KATH’s patients. Men may not be seeking care consistently in Ghana and are accessing treatment at a later stage of their disease than women. Further research needs to be aimed at improving factors impacting late diagnosis and access to care.

77 Risk Perception, Risk Reduction, and Adherence to PrEP for Ugandan Serodiscordant Couples: A Qualitative Analysis

Monique Wyatt (presenting), Norma Ware, Jared Baeten, Connie Celum, Elioda Tumwesigye, Jessica Haberer, David R. Bangsberg

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Background: Pre-exposure prophylaxis (PrEP) is a promising new strategy for HIV prevention. As with antiretroviral treatment for HIV, adherence to PrEP is critical for effectiveness. A central yet largely unexplored question is how perceptions of HIV risk influence risk reduction behaviors, including adherence. Using qualitative data, this presentation examines the dimensions and dynamics of risk perception among serodiscordant couples participating in the Partners PrEP Study clinical trial in Uganda.

Methods: In-depth interviews on adherence were carried out with 95 HIV-1 uninfected individuals randomized to PrEP or placebo and 26 of their HIV-1 infected partners. A subset of 24 uninfected partners was asked directly about perceptions of risk. Interview data were content analyzed for the meaning of risk, and categories characterizing risk perception were developed.

Results: Uninfected partners understood the risks of acquiring HIV and were aware of multiple strategies to reduce risk. Risk reduction strategies used by participants included abstinence, reduction in frequency of sex or number of partners, and condoms. Perceptions of higher HIV risk in study participants were largely shaped by engaging in unsafe sexual practices, i.e., lack of condom use. Reasons for not feeling at risk included self-reported condom use, repeated confirmations of HIV negative status both prior to and during the study, “trust in God,” and “high hopes in the medicine.” Although PrEP was expected to protect against HIV, participants did not directly associate adherence with protection against risk. Perception of risk was frequently not reflected in risk reduction behaviors.

Conclusions: The relationship between risk perception, adherence to biomedical HIV prevention strategies, and risk reduction is complex, and warrants further study. Individuals who perceive themselves to be at risk compete weighing priorities that may ultimately interfere with risk reduction efforts. Understanding how risk perception motivates risk reduction and adherence will contribute to PrEP implementation success.
Factors Associated with Late Enrollment in HIV Care among HIV-Positive Individuals in Odessa Region, Ukraine

Oleksandr Neduzhko1, Ihor Perehinets2, Oleksandr Postnov3, Jack A. DeHovitz4, Robert Kaplan5, David Odegaard4, Michael A. Joseph5, Tetiana Kiriazova6 (presenting)

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Background: Despite 3.3 million HIV tests performed in 2011 in Ukraine, only 60% of those testing positive have been seen for HIV care at specialized AIDS Centers. Late enrollment in care results in higher HIV-related morbidity and mortality. This study’s objective was to identify barriers associated with delayed enrollment in HIV care among HIV-positive individuals in Odessa region, Ukraine.

Methods: A cross-sectional survey of 200 patients newly registered at Odessa Regional and Municipal AIDS Centers was conducted from September-November 2011. Independent factors associated with late (more than 3 months since positive HIV test result) vs. timely (3 months or less since positive HIV test result) enrollment in HIV care were evaluated using multivariable logistic regression.

Results: Of 200 subjects (mean age 35±8.2 years, 47.5% female, 42.5% had experience of injection drug use, 24% unemployed), 110 (55%) entered HIV care late. Odds of late enrollment were greater for those not feeling ill (aOR: 2.9, 95% CI: 1.49-5.77), having high school or less education (aOR: 2.3, 95% CI: 1.16-4.75), having disabilities unrelated to HIV infection (aOR: 5.2, 95% CI: 1.37-19.39), and feeling ashamed in front of health care providers (aOR: 6.3, 95% CI: 1.29-31.22). No association between drug use experience and delayed enrollment in HIV care was found.

Conclusions: Programs to link HIV-positive persons to medical care should focus on reducing barriers to accessing care. Strategies targeting individuals and communities in Ukraine should include education about benefits of HIV care at every stage of the disease, linguistically appropriate counseling and referral services, additional support for persons with disabilities, and stigma reduction campaigns.

People who were Traced After Being Lost to Follow-Up During Pre-ART Care are More Likely to Stop Care than Self-Transferring to Another Health Facility

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Background: Few studies have traced people who were LTFU during pre-ART care. This population was established from a prospective cohort of 348 persons newly diagnosed with HIV infection receiving care at Connaught Hospital in Freetown, Sierra Leone. Pre-ART care was described as the period from HIV diagnosis to ART initiation. LTFU was defined as not having attended a clinic visit in the last 150 days. People who were LTFU during pre-ART care were traced as per standard of care, which involved ascertaining their vital status and reasons for being LTFU. A purposive sample of tracing visits included 21 tape-recorded interviews. Interviews were transcribed and thematically coded by two independent readers.

Results: 130 of 348 (37.4%) patients were LTFU during pre-ART care. 90 of 130 (69.2%) patients were traced, and vital status was ascertained in 87 of these persons (96.7%). 22 of 87 (25%) were dead. Of the 65 persons who were alive, additional outcomes and reasons for LTFU were determined in 38 persons. 12 of 38 persons self-transferred their care to another health facility, and 26 (68.4%) stopped care. 15 of the 21 (71.4%) interviews were conducted with persons who stopped care. Multiple themes emerged from interviews and explained why people were LTFU: 1) financial constraints limit their ability to take transportation to clinic, 2) competing demands such as child care, school studies, work, and food security are prioritized over their HIV care, and 3) internalized stigma, hopelessness, and mental distress make patient perceive clinic attendance as a risk.

Conclusions: The majority of patients who were LTFU during pre-ART care stopped care rather than self-transferring to another health facility. Financial constraints, competing demands, and mental distress were barriers to care.
**82 Greater Cleveland HIV Health Information Project**

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**Introduction:** Optimizing patient engagement in the HIV care continuum will be more effective and efficient if coordinated at a community level rather than just at a clinic level.

**Description:** The Greater Cleveland HIV Health Information Project (CHHIP) is a provider-initiated collaborative created to improve the quality and utilization of HIV care in the Greater Cleveland area. Initial partners include five health systems, a standalone supportive service provider and the local health department. CHHIP leverages widespread use of electronic medical records (EMRs) to extract data elements across systems to inform community-wide practice. Partners selected data to be collected; the data storage framework has been developed and beta tested. On a quarterly basis, all partners will submit coded patient-level data. In addition to HIV related labs and office visits, providers will also submit data related to insurance coverage, primary language, mental health treatment, substance use, ED and inpatient visits, participation in support groups and outreach efforts.

Data sharing between the two largest providers has begun. A standardized unique identifier is used to allow for merging of records and account for patient movement between facilities. Using quality measurements consistent with HRSA, NQF and other nationally recognized guidelines, community, practice level and provider level quality reports will be generated. Providers meet regularly to discuss progress and share best practice.

**Lessons Learned:** EMRs are not static storage units, some elements are not stored as readily exported variables and changes to the EMRs affect secondary uses of data. In order to extract, store and merge data from different EMRs, data manipulation or recoding is often needed.

**Recommendations:** EMR data from remaining partner institutions will be collected and merged into the data system. Analyses of the local HIV care cascade by co-morbid conditions will allow for deeper understanding of community needs.

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**84 Comparative Effectiveness of Darunavir 1,200 mg Daily and Approved Dosing Strategies for Protease Inhibitor-Experienced Patients**

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**Background:** The HIV protease inhibitor (PI) darunavir, when dosed with ritonavir, is approved for twice daily use in treatment-experienced patients and once daily use in patients without darunavir resistance-associated mutations. Patients who failed a PI regimen in the past due to suboptimal adherence may find twice daily dosing a barrier to treatment success. We present data on the rate of virologic suppression achieved with darunavir 1,200 mg once daily in PI-experienced patients.

**Methods:** This retrospective, observational study included all patients treated with darunavir 1,200 mg daily, 600 mg twice daily or 800 mg daily after documented use of another PI at an urban immunodeficiency clinic. Data collection from inception of darunavir use in August 2006 through March 2012 included demographics, viral loads, CD4+ cell counts, and resistance test results. The primary outcome was defined as <50 HIV RNA copies/mL at 24 weeks according to the time to loss of virologic response algorithm. Baseline characteristics and virologic outcomes were analyzed across dosing groups via one-way analysis of variance.

**Results:** 135 patients were included in the intention to treat analysis. Demographics were similar across dosing groups. Patients treated with 600 mg twice daily had a lower baseline CD4+ cell count (mean 259 cells/mL vs. 343 across all groups; p=0.003). Most patients had no darunavir mutations at baseline. At 24 weeks, virologic suppression was reached by 53.6% of patients on 1,200 mg daily, 52.3% on 600 mg twice daily and 42.9% on 800 mg daily (p=0.568).

**Conclusions:** Darunavir 1,200 mg daily achieved similar virologic suppression to approved dosing regimens. Advantages to this novel dose include a lower pill burden, once daily dosing, and decreased exposure to ritonavir. Randomized controlled trials, including adherence and pharmacokinetic monitoring, are needed to determine the best use of darunavir 1,200 mg daily.
Engagement and Retention in Care for High-Risk Populations in Oakland, CA - Challenges and Opportunities

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Introduction: Biomedical human immunodeficiency virus (HIV) prevention education for high-risk populations in Oakland, California, including Black men who have sex with men (MSM), Latino MSM, and Women of Color, is a key component in normalizing HIV testing, reducing stigma, improving entry into and retention in care and antiretroviral (ARV) adherence, optimizing health outcomes, and reducing HIV-related health disparities, ultimately increasing the proportion of people living with HIV/AIDS (PLWHA) with an undetectable viral load.

Description: Oakland-specific challenges to retention and adherence were explored during a train-the-trainer workshop conducted for front-line staff and peers from community-based organizations (CBOs) using the International Association of Providers of AIDS Care/National Minority AIDS Council curriculum for extending the peer educator’s role to patient navigation. Workshop participants included staff and peers from AIDS Project of the East Bay, La Clinica de La Raza, and Women Organized to Respond to Life-threatening Diseases (WORLD).

Lessons Learned: Creating opportunities for agency staff to access up-to-date information on biomedical HIV prevention interventions, local research studies, and appropriate client referral options is more important than ever due to the pending implementation of the Patient Protection and Affordable Care Act. Increasing inter-agency coordination and collaboration has shown potential for facilitating re-entry into HIV care and improved ARV adherence; however, retention and adherence issues may be CBO-specific and should be addressed as such.

Recommendations: A series of training opportunities designed increase community and provider knowledge of biomedical HIV prevention interventions (including how to access PrEP), local research studies, and the most current HIV prevention and treatment science is necessary to help people complete each step in the HIV treatment cascade - both to improve individual health outcomes and to achieve the public health goal of an AIDS-free generation.

Optimizing Adherence Assessment among Adolescents: Who? How? When?

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Introduction: Youth and caregiver self-reports of perinatally HIV-infected (PHIV+) youth’s adherence to antiretroviral treatment (ART) may be the only option for providers, given the significant costs of objective measures (e.g., electronic monitoring devices). Using HIV RNA Viral Load (VL) as a gold standard of ART-response, this study compared its association to different adherence questions, informants, and time points to optimize assessment of adolescent ART adherence.

Methods: PHIV+ youth (n=194) and their caregivers participated in a 4-site longitudinal study (CASAH) in New York City. Data came from baseline (mean age=12), follow-up-1 (mean age=14), and follow-up-2 (mean age=17). Adherence variables included youth, caregiver, and youth-caregiver combined responses to: a) a single-item on the last time medications were missed (dichotomized <1 month vs. >1 month), and b) a procedure to assess percentage of missed pills adapted from a standardized questionnaire assessing medications, dosing, and missed doses in past 2-7 days (% Nonadherence). VL data closest to interview date was abstracted from medical charts.

Results: Agreement between youth and caregivers on all questions was generally poor across time points (kappa=.104-.354), with moderate agreement only on %Nonadherence at follow-up-1 (kappa=.513). Using Fisher’s exact test, the association between VL (<400 copies/ml) and adherence reports was variable. At baseline, the combined youth-caregiver response on the single item was the only item significantly associated with VL. At follow-up-1, youth, caregiver, and their combined reports on the single item; and their combined report on %Nonadherence were associated with VL (rho=.08). At follow-up-2, VL was only associated with youth report on the single item.

Conclusions: Results suggest that one adherence item focused on a longer timeframe may be more accurate than multistep assessments focused on shorter time periods. Using adherence data from both youth and caregivers may be optimal for understanding adherence in younger adolescents. With age, older youth alone may be better informants.
Street HIV Testing of Youth Is Persuasive Prevention Technique

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Introduction: With adolescent HIV rates still climbing, novel techniques for prevention must be used to stem new cases. The advent of home HIV test kits for over the counter sales in the U.S. is an efficacious way to test youth publicly in a quick and easy manner. The result is an underutilized tool that works as a deterrent to unprotected sex.

Description: Beginning in November 2012 after the introduction of home HIV test kits in pharmacies, a Harvard-trained youth AIDS expert began testing teens on the streets and at their favorite public gathering spots in Norfolk, Virginia, the city with the highest HIV/STI rates in the state. Because the oral swab technology is easy to administer with results in 20 minutes (no CLIA lab work necessary), the testing is popular among curious youth. No AIDS stigma to testing exists among peers when done outside hospital/clinics.

Lessons Learned: Over 45 public tests were administered to at least one person among groups of teens at parks, malls, beaches and on the streets. During the 20 minutes waiting for test results, the tester provided medically accurate information and counseling to the teens that asked probing questions of peer concern. Youth were surprised how easy the process was and that it could be done in private with a sexual partner. In the case of two HIV-positive tests (a 16- and a 17-year old), they were immediately taken for a confirmatory blood test.

Recommendations: Youth were impressed that tests were available without a doctor’s visit, a prescription, the need to be tested in a hospital or importantly, without parents’ knowledge. In every group of three or more, one adolescent was willing to be publicly tested. Immediately cell phones were sending texts and pictures to a wider audience using favorable descriptions.

Treatment Outcomes in a Decentralized Antiretroviral Therapy Program: A Comparison of Two Levels of Care In Nigeria

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Background: Decentralization of antiretroviral therapy (ART) services is a key strategy to achieving the millennium development goal of providing universal access to ART services for people living with HIV/AIDS. However, as small concentrated programs expand and scale out to increase utilization of services and improve coverage, there are concerns about maintaining adequate quality of care and treatment outcomes. Our objective was to compare ART treatment outcomes in a decentralized ART program in Plateau State, Nigeria

Methods: The APIN Plus/Harvard PEPFAR program used the hub-and-spoke model to decentralize ART services to 13 LGAs in Plateau State from 2007-2011 from a tertiary hospital (Prime site) to 13 secondary-level hospitals (Satellites) using national and program guidelines. We obtained socio-demographic, clinical and immuno-virologic data on patients aged >15 years who received HAART for at least 6 months and compared treatment outcomes between the Prime and Satellite sites

Results: Out of 14,418 patients, 7060(49.0%) were enrolled at the Satellites. At baseline, the Satellites had more females (70.8% vs 65.5%, p=0.0001), younger patients (33+9 vs 34+9, p<0.001), higher rates of TB-co-infection (6.4% vs 1.4%, p<0.001), and higher CD4 counts (218 vs 197cells/mm3, p=0.001) but viral loads were similar at both sites (25,770 vs 26,983c/ml, p=0.12).

While on HAART, Prime site patients achieved better immune restoration at 24 (365 vs 285cells/mm3, p<0.001) and 48 weeks (343 vs 304cells/mm3, p=0.001) and higher rates of viral suppression (<400c/ml) at 24 (41.9 vs 39.7%, p=0.08) and 48 weeks (50.9 vs 43.8%, p=0.01). Mortality was 2.3% vs 5.0% (p=0.001) at Prime and Satellites sites, while transfer rate was 8.7 vs 5.5% (p=0.001) at Prime and Satellites.

Conclusions: Our data shows that ART decentralization is feasible in resource-limited settings but efforts have to be intensified to maintain quality of care as we scale out to secondary and primary facilities.
The Effect on Treatment Adherence of Administering Drugs as Fixed-Dose Combinations versus as Separate Pills: Systematic Review and Meta-Analysis

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Background: Fixed dose combinations (FDCs) have been proposed as a strategy to simplify medication regimens with the purpose to enhance treatment adherence. The question to what extent FDCs lead to better adherence than the same active drugs administered as separate pills has nowadays become highly relevant. Decoupling of FDCs, from which patents have expired, into separate generic and branded drugs could result in considerable cost savings but possibly at the expense of lower adherence.

Methods: We searched the PubMed database from inception to December 2012 for randomized controlled trials (RCTs), comparing a FDC with the same active drugs administered as separate pills, with an oral administration route, medications being self-administered, and the endpoints of the study including a quantitative estimate of treatment adherence. We used the odds of non-adherence with FDCs versus separate pills as common effect size. We used a random effect model with Mantel-Haenszel odds ratio to aggregate findings into a pooled effect estimate with 95% confidence limits using Review Manager 5.2.

Results: Of the 1258 unique papers identified only 6 RCTs fulfilled inclusion criteria. A total of 3 RCTs reported use of FDCs in the treatment of tuberculosis, 2 RCTs in the treatment of HIV infection and 1 RCT in the control of hypertension. Use of FDCs did not result in significantly lower odds of non-adherence than separate pills (pooled OR; 95% CI: 0.89; 0.71 to 1.12). Despite the variety in medical conditions and adherence assessment methods concerned, we observed low and insignificant statistical heterogeneity (I² = 20%).

Conclusions: We observed a remarkable paucity of RCTs investigating the effects of FDCs on adherence. Based on the results of only 6 RCTs the general assumption that FDCs improve medication adherence was not supported. Further research is strongly recommended to clarify the effect of FDCs on medication adherence.
Predictors of Non-Adherence and Virologic Failure in a Large Scale Multi-National Non-Inferiority Trial of Three ARV Regimens in Diverse and Resource-Limited Settings: Data from the ACTG A5175/PEARLS Trial

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Background: PEARLS recruited from four continents (nine countries; N=1,575) showing that an antiretroviral regimen of ATV+DDI-EC+FTC, but not EFV+FTC/TDF, was inferior to EFV+3TC/ZDV.

Methods: Outcomes were nonadherence assessed via pill count (PC=missed any pills), ACTG self-report questions (SR=score derived via principal-components analysis) at regular intervals; and weeks to virologic failure. Predictors were quality of life (QOL; ACTG SF21), substance use, binge drinking, social support, sexual behaviors, and weeks since initiation. Life-Steps adherence counseling was provided. Logistic and linear regression was used for analyses of adherence at initiation (week 2), mixed-effects regressions for longitudinal analyses, and cox proportional hazards for virologic failure analyses.

Results:

Initiation: Unique predictors of PC nonadherence were: QOL-health (AOR=.99, p=.046), frequent binge drinking (AOR=2.12, p = .008), and region (p=.037). Unique predictors of SR nonadherence were Asia (b=.42, p=.04), and hard drug use (b=1.59, p=.002), a trend for unprotected sex (b=.51, p=.053), and assignment to the ATV-based regimen (b=.34, p =.01).

Longitudinal: Unique predictors of PC nonadherence were weeks (AOR=.015, p<.0001), QOL-health (AOR=.59, p<.0001), assignment to either once-daily regimen (ATV+DDI-EC+FTC or EFV+FTC/TDF) (AOR=.062, p<.0003, AOR=.494, p<.0001), Africa (AOR=.52, p=.0002), and hard drug use (AOR=.232, p=.045). Unique predictors of SR nonadherence were weeks (b=.063, p<.0001), QOL-health (b=.077, p<.0001), assignment to either once-daily regimen (ATV+DDI-EC+FTC or EFV+FTC/TDF (b=.223, p=.008, b=.185, p=.028), Africa (b=.298, p=.020), and soft drug use (b=.248, p<.0001), which decreased over time (b=.065, p<.001).

Weeks to virologic failure: Controlling for regimen, both PC (HR=1.64, p=.0004) and SR (HR=1.102, p<.0001) were significant. In models including either PC or SR, QOL-health, age, and region were significant (all p’s < .01).

Conclusions: Even in the context of a clinical trial, there were some variations in adherence, with variables such as QOL-health, regimen, drug-use, and region playing a role. Some psychosocial variables, such as adherence, and QOL-health, associated with virologic failure.
103 Translating a Theoretically Derived, Evidence-Based Adherence Intervention for Electronic Training and Wide-Spread Dissemination via the Web: The Long and Winding Road of Project HEART (Helping Enhance Adherence to antiRetroviral Therapy)

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Introduction: Evidence-based adherence interventions (EBIs) have been identified (http://www.cdc.gov/topics/research/prs/ma-chapter.htm) but not yet packaged or disseminated. To bring adherence EBIs to a wider audience at potentially lower cost, CDC contracted to package several EBIs using e-learning (i.e., web-based) trainings to train interventionists and support use. This presentation describes issues encountered in creating a web-based curriculum to teach the HEART intervention to providers.

Description: HEART was designed in the late 1990s for patients with multiple adherence barriers initiating antiretroviral therapy. A multi-component intervention, the core of HEART was based on the 5-stage model of problem-solving and social problem-solving therapy, employing a systematic approach to identifying adherence barriers and generating and implementing adaptive solutions. Patient-identified support partners (SPs) were integrated into this process to provide adherence support outside the clinic. Translating HEART for current-day use and electronic training required: (1) identifying the intervention’s unique components (i.e., strategies that have not become standard-of-care [e.g., medication education, regimen tailoring]) so that new tools and techniques to expand the armamentarium of adherence counselors could be created, (2) developing essential training materials, assessment instruments and patient tools, and (3) scripting and filming vignettes that demonstrate the problem-solving process – and the integration of SPs – using different patient-SP pairs addressing different adherence barriers. The intervention was also adapted to include patients changing regimens due to prior adherence challenges.

Lessons Learned: Demonstrating interaction with patients and SPs in the problem-solving process without in-person modeling, practice and correction presented the greatest challenge. Close attention to the wording of scripts was required and comprehensive implementation guides developed. Feedback from pilot testing with providers will be presented and incorporated into the final iteration.

Recommendations: Uptake, implementation barriers and need for additional technical assistance will be monitored following web-launch in 2013, and best approaches and venues for providing continuing assistance determined.

104 Evaluation of an HIV Adherence Counseling Program in La Romana, Dominican Republic

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Background: The impact of adherence to antiretroviral therapy (ART) has been well studied, demonstrating both reduction in human immunodeficiency virus (HIV)-1 viral load and lower rates of resistance, morbidity, and mortality associated with HIV infection. Adherence is particularly challenging in resource-limited settings; thus implementation and evaluation of adherence intervention programs is critical.

Methods: A retrospective cohort study was designed to evaluate the adherence counseling program for treatment-naïve patients ≥18 years of age at Clinica Familia in La Romana, Dominican Republic (CFLR). Adherence to appointments and biological markers of disease progression were assessed in cases and controls to determine whether counseling had an impact on adherence rates and clinical outcomes. Data were collected at baseline and monthly through 12 months.

Results: In total, 101 subjects were included for analysis, with 61 controls and 40 cases. Mean age was 40.6 years. Baseline CD4 lymphocyte count was 162 and 157 cells/mm³ in controls and cases, respectively. In a 9-month follow-up period, cases showed a 15-fold increase in CD4 count compared with a 2.5-fold increase in controls (p=0.0578). Cases were more likely to adhere to scheduled appointments with adherence rates of 86% vs. 76% in controls (p=0.035). No difference was found in days late for appointments (0.91 in cases vs. 0.57 in controls, p=0.18). There was no significant difference between rates of abandonment of treatment (7.5% in cases vs. 18% in controls, p=0.13), but all cases re-entered care within 12 months, compared with 3 of 14 controls. There was no difference in rates of transfer of care, death, or alive/in treatment at 12 months.

Conclusions: Short-term evaluation markers including CD4 count and appointment adherence improved, demonstrating the program’s beneficial impact. Long-term outcomes (e.g. abandonment, transfer of care, death) did not show changes within 1 year. Continued observation is necessary.
105 An Intervention to Optimize Uptake and Adherence to Pre-Exposure Prophylaxis (PrEP) in High-Risk MSM

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Introduction: To support pre-exposure prophylaxis (PrEP) adherence for high-risk MSM, we developed, tested the feasibility and acceptability of, and solicited feedback from participants on a CBT-based intervention to maximize PrEP adherence.

Description: Modeled after “Life-Steps,” an antiretroviral therapy (ART) adherence intervention used both for treatment and prevention, we developed a modular intervention to be completed in four weekly visits and two booster sessions. Intervention content included CBT-oriented adherence problem-solving skills, brief motivational interviewing, and sexual risk-reduction strategies. Optional modules addressed mental health and substance-use barriers to adherence. Adherence to PrEP was measured daily via Wisepill and sexual risk taking was assessed via daily text messages. The open-pilot included six high-risk seronegative MSM (mean age 35) who reported at least three unprotected anal intercourse (UAI) acts with at least two sexual partners and/or any UAI with a seropositive partner in the previous three months.

Lessons Learned: Mean self-reported UAI acts at enrollment was 10.8 (SD=10.3) for the prior three months. Participants’ average daily adherence for the first week on PrEP was 100%. Between months one and two, and two and three, average adherence was 91% (SD 10.3) and 94% (SD 1.97) respectively. For the same time points, average UAI for the first week on PrEP was 43 (SD=48), and 1.07 (SD=1.03) and 1.94 (SD=1.87) respectively. Results indicate participants took PrEP consistently in the context of continued HIV risk exposures. Exit interviews revealed participants responded well to intervention flexibility and suggested providing optional modules on disclosing PrEP use to health providers and sexual partners.

Recommendations: Providing PrEP adherence counseling in the context of continued high-risk sex among MSM may be a way to optimize PrEP adherence. It is recommended that PrEP prescription be accompanied by a flexible intervention for those who engage in high-risk behaviors but may have difficulties with consistent adherence.

108 Association of Quality of Sleep with Antiretroviral Therapy Uptake and Adherence in HIV-Positive Individuals

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Background: Over 73% of HIV+ individuals report quality of sleep (QOS) disturbances, versus 10-35% of the general population. QOS reductions may result in antiretroviral (ARV) non-adherence, leading to treatment failure, drug resistance, and increased HIV transmission. Therefore, recognition and treatment of poor QOS may benefit personal and public health. Our study aims were to: 1- examine time to ARV uptake based on QOS, 2- estimate QOS changes after ARV initiation, and 3- assess the association between QOS and non-adherence.

Methods: QOS in the past 30 days (range=0-28) was estimated quarterly for 12 months using nine questions assessing number of sleep hours/night, QOS rating, use of sleep aids, trouble staying awake/falling asleep, nocturnal awakenings, experience of night terrors/pain, and daytime concentration. Self-reported non-adherence (range=0-100%) was calculated using a visual analog scale in past 30 days. For aims one and two, we used proportional hazards and mixed model analysis, respectively. For aim three, we modeled percent non-adherence as a function of QOS using zero-inflated Poisson regression, clustering on repeated subject ID, and adjusted for demographics, homelessness, IVDU, alcohol use, CD4+, viral load, time since HIV diagnosis, and number of cigarettes/day.

Results: Data from 219 participants with mean age=44.3, 83% male, mean baseline CD4+=246 cells/mm³, 3.7% with baseline undetectable viral load, and mean baseline QOS=12.4 were examined. In 12 months, 64% had initiated ARVs. QOS was not associated with ARV uptake (HR=1.00, p=0.99). Mean QOS did not change after ARV initiation (p=0.62). Worse QOS was marginally associated with lower odds of perfect adherence (aOR=0.91, p=0.06). Among those who had any level of non-adherence, for every one unit worsening of QOS, there was a 4% increase in mean non-adherence (p=0.03).

Conclusions: We observed a significant association between poor QOS and non-adherence. Interventions designed to enhance QOS among HIV+ individuals may lead to improved adherence.
A Pilot Study to Engage HIV-Positive Black-American Youth via Telehealth Technology

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Background: Non-adherence is a strong determinant of virologic failure and correlated with survival. Black individuals have higher rates of HIV infection, enter care later in course of disease, are less likely to initiate antiretrovirals, and report lower antiretroviral adherence than other populations. Innovative interventions to improve access to medication counseling, treatment knowledge, and treatment engagement are needed to address these disparities. Telehealth (remote videoconferencing) shows promise as a potential approach. The goal of this study was to assess feasibility and acceptability of a telehealth medication counseling intervention.

Methods: HIV-positive Black youth (18-29 year-old), taking antiretrovirals for ≥30 days were enrolled in a 30-minute individual telehealth medication counseling session with an HIV clinical pharmacist followed immediately by a semi-structured qualitative interview by study staff. Interviews explored likes/dislikes of the telehealth format, modality, and content; potential impact on adherence; privacy issues; interaction quality; and whether participants would recommend telehealth to others.

Results: Fourteen participants, mean age=24 years, 86% male, mean CD4+=607 cells/mm3, 64% with undetectable viral load, and mean self-reported adherence in past week=87% were interviewed. All participants stated that they "liked" telehealth, would use it if offered in clinic or research settings, and would recommend it to others. Participants described telehealth as convenient, efficient, and comfortable to use, with positive impact on their HIV-related knowledge. Telehealth provided a modality to interact with providers that some participants described as less intimidating than in-person visits. Specifically, participants reported that telehealth made it easier to disclose barriers to adherence. Most participants indicated that their privacy was maintained.

Conclusions: Telehealth is a feasible and acceptable approach to delivering medication counseling to Black HIV-positive youth and may improve quality of communication and provider-patient dialogue. Use of telehealth for medication counseling may also lead to more disclosure of treatment difficulties, increased patient comfort, and improved health education.

High Prevalence of Syndemic Conditions Associated with Suboptimal ART Adherence in a Large Multinational Online Sample of HIV-Infected MSM

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Background: Suboptimal antiretroviral therapy (ART) adherence among HIV-infected who have sex with men (MSM) in the U.S. and other settings occurs in the context of intertwined mental health and substance use problems, or syndemics. This has not been examined in Spanish or Portuguese speaking settings.

Methods: Members (N=36,477) of a sexual networking site for gay, bisexual, and other MSM in Latin America, Spain, and Portugal completed an anonymous online survey. Seven potential syndemic factors—depression, hard drug use during sex, alcohol abuse/dependence, childhood sexual abuse, intimate partner violence, suicidal ideation, and sexual compulsivity—were assessed and their additive effect was examined in relation to suboptimal ART adherence (<100% of prescribed doses in the past month) using logistic regression.

Results: Self-reported HIV prevalence was 9.1% overall (Latin America 82%, Spain 6%, and Portugal 12%); 71.4% reported being on ART (2,049/2,851). Among those on ART, 66.5% reported taking 100% of prescribed doses in the past month. Among those on ART, distribution of syndemic factors was: zero=11.2%, one=28.8%, two=26.6%, three=15.3%, four=11.5%, five=4.8%, six=1.3%, and seven=0.4%. In a multivariable model adjusted for age, survey source (Latin America, Spain, or Portugal), sexual orientation, education, income, and urbanicity, the additive syndemic measure resulted in a lower odds of optimal ART adherence (referent group=zero) (all p-value<.05): one/two syndemic factors=(OR=0.64, 95%CI=0.44, 0.93); three/four=(OR=0.60, 95%CI=0.40, 0.90); and five or more=(OR=0.39, 95%CI=0.23, 0.65).

Conclusions: Adherence to ART among MSM in Latin America, Spain, and Portugal occurs in the context of intertwined mental health and substance use problems, or syndemics. The impact of these syndemics on adherence is additive. As has been suggested in the U.S. setting, adherence interventions for MSM need to address these problems as they may moderate the degree to which HIV-infected MSM would benefit from adherence skills building and counseling.
Perinatally Infected Adolescents: An Economic Empowerment Intervention Aimed at Increasing Adherence to ART

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Background: While the proliferation of first-line antiretroviral therapy (ART) in developing countries is a positive direction in slowing the spread of HIV, ART has a host of side effects that may contribute to sub-optimal adherence rates. One side-effect includes increased appetite, even intolerable hunger, which can present a barrier in adhering to treatment among HIV-positive populations in resource-constrained settings (Bangsberg, 2010). Economically disadvantaged populations in developing regions face compounding issues related to poverty and living with HIV. The resources needed for increased hunger pose additional financial burden on already economically constrained households, creating obstacles in adhering to HIV treatment. Other factors, including travel to clinics for follow-up appointments, also create economic-centered obstacles to adherence. The key question, therefore, is: would an economic empowerment program impact adherence to HIV medication among poor youth?

Methods: Our study, Suubi+Adherence: Evaluating a youth-focused economic empowerment approach to HIV treatment adherence, uses self-report as well as cellular technology to measure ART adherence among youth ages 11-16 years in southern Uganda. Two groups of participants will be compared in this longitudinal cluster randomized controlled trial. One group will receive an economic empowerment intervention with proven success among a comparable demographic in the same region (Ssewamala et al., 2009; 2010a; 2010b) as well as a package of bolstered standard of care for youth living with HIV, which includes counseling sessions on the importance of adhering to treatment. The other group will receive only the bolstered standard of care.

Results: We hypothesize that the group receiving the evidence-based economic empowerment intervention will show higher rates of adherence over a sustained period of time, as well as improved levels of psychosocial functioning, and decreased levels of sexual risk-taking intentions and behavior.

Conclusions: Economic empowerment interventions may have policy and practice implications for HIV treatment adherence among poor youth in sub-Saharan Africa.

Linking HIV+ Persons to Care: Building a Network Collaborative with a Shared Mission of Engaging the “Invisible”

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Introduction: In today’s economic climate collective efforts to improve HIV services and linkage-to-care networks are critical. The Bay Area Network for Positive Health (BANPH) had the goal of linking the most marginalized and hardest-to-reach HIV+ persons back into care through building HIV service and linkage infrastructure with an inter-agency collaboration that broke down service silos and actively shared resources.

Description: In order to address multiple HIV service gaps, an academic team pooled together agencies with complementary strengths, resources and abilities to create a collaborative linkage and service network comprising 12 agencies in San Francisco and Oakland in 2010. Service gaps were closed by assessing capacity of agencies and supporting them in: resource acquisition and provision; outreach training; technical assistance; system change efficacy; and ongoing meetings, communication and follow-up. In applying mixed methodologies BANPH demonstrated the efforts required to link the most disenfranchised persons into HIV care. HIV+ clients were located using street outreach, syringe exchange, jails, prisons, surveillance and clinic records. Clients completed a survey for barriers/needs assessment and then were linked to care and auxiliary services.

Lessons Learned: Nearly 400 PLWHA were linked to HIV care by BANPH. Individuals linked were out of care for an average of 10 years since diagnosis, and took nearly 2 months from first contact with BANPH to make their initial medical appointment. Partnerships at various levels can always improve service delivery and structural systems. Building such a linkage network requires buy-in from administrative and front-line staff and takes significant time.

Recommendations: Building collaborative networks for linking the most disenfranchised to HIV care may be a more effective strategy than working in silos or in competition. A linkage-to-care network model built with respect and a common mission has proven to be an effective approach to systems change with marginalized populations in hard economic times.
Biopsychosocial Distinctions Between HIV-Positive Youth with High Versus Lower Viral Loads

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Background: High viral load (VL; over 100,000 copies) in HIV is associated with significantly poorer prognosis for those patients as compared to others with lower VL. Understanding factors associated with elevated VL can provide insight into interventions for this very high risk population.

Methods: The current study included 58 youth, ages 11-23, living with HIV (Mage = 18.0±3.3; 91% African American; 52% male; 69% perinatally affected). Primary variables of interest were extracted through medical record review and included VL readings and concurrent Acuity Scale Ratings (ASRs). ASRs are completed by the patient’s medical case manager and rate the patient’s level of functioning and need for services in a number of social, medical, and psychological domains. The sample was divided into two groups: High VL (>100,000 copies; n=8) and Lower VL (<100,000 copies).

Results: One-way ANOVAs between the two groups showed High VL individuals to have significantly higher ASRs (indicative of poorer functioning and greater need for services) in the following areas: Basic Needs (e.g., access to food, clothing), Addiction (e.g., drugs, alcohol, sex), Knowledge of HIV (e.g., understanding of diagnosis, risks, medications), Nutrition (e.g., weight loss, eating problems), Family Functioning (e.g., family stability), and Support Systems (e.g., peers, social activities). These differences only were apparent when the High VL threshold was 100,000 copies or above; including even Moderate VL individuals (10,000-99,999 copies) showed no differences between groups.

Conclusions: Results indicate that High VL individuals show a distinct profile of difficulty and disadvantage in a number of areas, ranging from basic life needs to psychiatric illness, as compared to patients with lower VL. Such factors should be assessed and addressed as part of comprehensive medical care plans given that such factors can be formidable obstacles to effective adherence. This may be especially true for patients with high VL.

Psychosocial Needs and Viral Suppression in a Sample of Youth Living with HIV

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Background: For people living with HIV, Viral Load (VL) is an important marker of disease activity, medication adherence, and treatment success. Understanding correlates of VL can highlight critical points of intervention for these high-risk patients. Given that research with this sample previously has not identified associations between VL and more concrete “barriers to adherence” measures, the current investigation sought to examine whether broader psychosocial issues are salient factors associated with viral suppression among HIV positive youth.

Methods: Medical chart review was utilized to garner two primary variables of interest: VL and Acuity Scale ratings (ASRs). ASRs are completed by medical case managers to determine a patient’s level of functioning and need for services in a number of medical, social, and psychological areas. Based on the level of need, the scale outlines the frequency and intensity of engagement required. The current sample consisted of 58 youths ranging in age from 11 to 23 years of age (Mage = 18.0 ± 3.3; 48% female). Patients identified themselves as African American (91%), Caucasian (2%), Hispanic (5%), or Other (2%). 69% acquired HIV vertically, 28% were infected horizontally, and 3% had unknown mode of transmission.

Results: Bivariate correlations were used to examine relationships between VL and ASRs in 18 domains, with higher ASRs representing poorer functioning and greater need for services. Results indicated that higher ASRs on the Family Functioning scale were associated with high VL (r = .271, p = .040). Total Acuity Score also was positively correlated with VL (r = .299, p = .023).

Conclusions: Results indicate that, for HIV positive youth, family stability is a key factor associated with viral suppression and disease control. In general, environmental and psychosocial factors should be considered, in addition to more proximal, concrete barriers to treatment success, when working with complex and traditionally underserved patient populations.
Higher Levels of Psychosocial Syndemics Associated with Non-Adherence in HIV-Positive Individuals Screening for a Depression Treatment Trial

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Background: Depression, one of the most common comorbidities to HIV, is consistently associated with worse ART adherence. Depression in the context of HIV places one at risk for significant additional psychiatric and intertwined psychosocial or syndemic problems; which may have an additive negative effect on ART adherence.

Methods: Individuals with HIV (N=333) participated in an assessment for a depression treatment trial at three sites (2 in Boston, MA 1 in Providence, RI) that included a structured psychiatric diagnostic interview (inclusive of alcohol and other substance abuse/dependence), and a self-report assessment of childhood sexual abuse, childhood violence, and recent interpersonal violence. They then monitored their adherence to ART electronically for two weeks using MEMs, yielding a percent, on-time score, which was corrected for self-reported pocketed-doses. The syndemics variable was categorized as “none” (0), “some” (1 or 2), “a lot” (3 or 4) or “many” (5 or more). MEMs-based adherence, the outcome variable in a logistic regression analysis, was categorized as non-adherent (≤80%) or adherent (>80%).

Results: Distribution of the syndemics variable was none=33%, some=33%, a lot=40%, and many=24%. Per MEMs-based adherence, 66% of the sample was categorized as non-adherent. Syndemics was a significant negative predictor of adherence (p<0.01), with having “a lot” (OR=1.61, p<0.05) and having “many” (OR=2.138, p=0.01) differentiating from the referent group, “none”. A trend was observed for having “some” (OR=1.43, p=0.08).

Conclusions: In a sample of individuals with HIV opting to screen for a depression treatment trial, the majority had more than two co-occurring psychosocial problems (syndemics), indicating that depression, in the context of HIV, has a complex clinical presentation. The additive effect of co-occurring psychosocial syndemics was associated with significantly worse MEMs-based adherence. This underlies the importance of considering additional psychosocial syndemics when attempting to treat depression and improve treatment adherence in individuals with HIV.

Medication Adherence and Optimism-Pessimism in a Population of People Living with HIV/AIDS

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Background: Adequate adherence to antiretroviral therapy (ART) reduces morbidity and mortality, preserves immune function, and is a critical element of the "treatment as prevention" strategy for curbing transmission of HIV. A consensus on which factors, especially psychological ones, improve adherence has yet to be reached. We investigated the relationship between adherence and optimism in a population of people living with HIV/AIDS.

Methods: Using data from a randomized controlled trial conducted by the University of California San Francisco School of Nursing examining the efficacy of a symptom management manual, we performed a secondary analysis using two proxy measures of adherence, two expressions of optimism-pessimism, and several potential confounders. The first adherence measure was the self-reported frequency with which a person missed taking their medications for various reasons and the second inquired about confidence to take medications as prescribed by a healthcare provider. Optimism-pessimism was quantified as a single, bipolar metric and as two distinct, unipolar metrics. The first adherence measure was analyzed with robust Poisson regression and the second analyzed with ordinal regression.

Results: Our sample (n=353) was 62% male, 35% African American/Black, and mean age was 44 years (±9.2). While 25% of the sample reported perfect adherence, 50% reported total confidence. In age-stratified multivariable models, a one-unit increase in bipolar optimism-pessimism reduced non-adherence by 3.6% (p<0.001) and increased the odds of reporting higher confidence in taking medications by 7.0% (p<0.05) among patients <44 years. The unipolar measure of optimism also reduced non-adherence (4.8%, p<0.001) and increased confidence (12.2%, p<0.05) among the same subjects. Of the potential confounders, higher quality of life was most consistently associated with adherence (p<0.05 in all <44 models).

Conclusions: Adherence to ART is positively associated with optimism in HIV/AIDS patients <44 years old. Our findings indicate a differential relationship exists between adherence, optimism, and age.
Medication Persistence in Persons Treated for HIV

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Background: The difference between adherence (the proportion of prescribed doses of medication taken) and persistence (time over which the medication is taken) has been recognized as important. The permissible gap between doses varies but is likely to be at most several days for HIV treatment. These analyses evaluated the characteristics of persons who with medication impersistence.

Methods: As part of another study, 124 participants completed a battery of measures that included the Test of Functional Health Literacy in Adults (TOFHLA), the HIV Health Literacy scale (HIV-HL), and cognitive measures such as the Trail Making Test (Trails). Participants also completed the LifeWindows IMB scale. Medication adherence was monitored (Medication Event Monitoring Systems) for one month. Those with and without impersistence (medication free interval of 72 hours or more) constituted groups for comparison using chi-square and t tests.

Results: No relation between impersistence and gender, race, or age was found. Participants with impersistence had lower levels of health literacy (TOFHLA; t [df = 119] = 2.44, p = 0.02; HIV-HL t [df = 118] = 2.08, p = 0.04) and HIV-knowledge (LifeWindows scale; t [df = 113] = 2.14, p = 0.03). Impersistent participants had poorer executive function as assessed by the Trail Making Test (t [df = 1138] = -2.38, p = 0.02).

Conclusions: Results show that low levels of health literacy and cognitive function may be associated with medication impersistence in persons treated for HIV. Interventions to improve HIV knowledge and health literacy skills may be useful in addressing medication persistence.

A New Measure of Health Literacy Predicts Medication Adherence in Persons Treated for HIV

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Background: Health literacy is related to HIV knowledge and medication adherence in persons with HIV. Current measures of health literacy assess a limited range of skills. As part of a project to develop a new computer-administered measure of health literacy with improved characteristics, test items were administered to a group of 50 HIV+ persons who had previously participated in a study of HIV and health literacy.

Methods: Participants completed 208 new items assessing general health literacy (HL), numeracy (NUM), listening comprehension (LIS) and health-related knowledge (FACT). They had previously completed the LifeWindows IMB measure, a measure of HIV-related health literacy (HIV-HL) and their adherence had been electronically assessed. Correlations evaluated measures’ interrelations and a regression model evaluated the new measure’s relation to adherence.

Results: The numeracy scale of the new measure correlated significantly with the LifeWindows Information scale (r = 0.30, p = 0.04) and the HIV-HL (HL scale r = 0.51, p < 0.001; NUM r = 0.51, p < 0.001; FACT r = 0.46, p < 0.001; VID r = 0.39, p = 0.01). In a regression model that included demographic variables and the new measure’s scales, the HL scale was significantly related to participants’ medication adherence (chi-square = 4.75 [df=1], p = 0.03).

Conclusions: These results support the usefulness of the new measure of health literacy in understanding patients’ health-related knowledge and behaviors. The new measure’s scales predicted participants’ report of their own HIV-related information as well as their actual medication adherence. Development of the new measure is ongoing.
The Healthcare Attitudes Scale (HAS) in HIV

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Background: The Healthcare Attitudes Scale (HAS) is a ten-item self-report measure developed to assess patients’ general attitudes toward health. Items assess beliefs about the likelihood of positive outcomes from efforts to improve one’s health. We report here on the relation of the HAS to other measures in order to help establish its usefulness and validity.

Methods: As part of a study of an intervention to improve health literacy, participants completed a battery of cognitive and psychosocial measures. The battery included the Test of Functional Health Literacy (TOFHLA), and measures of self-efficacy (item A1 from the AIDS Clinical Trials Group adherence questionnaire, ACTG), HIV-related information, motivation, and behavioral skills (LifeWindows IMB scale), mood (Center for Epidemiological Studies Depression scale, CESD), stress (Perceived Stress Scale, PSS), and adherence (Medication Event Monitoring System, MEMS).

Results: One hundred twenty-four participants completed assessments. Cronbach’s alpha for the HAS was 0.77. It was correlated with health literacy (TOFHLA reading \( r = 0.35, p < 0.001 \)), self-efficacy (ACTG item \( r = 0.22, p = 0.02 \)), and elements of the IMB (Information \( r = 0.33, p < 0.001 \); Motivation \( r = 0.45, p < 0.001 \); Behavioral Skills \( r = 0.44, p < 0.001 \)). It was inversely related to depression (CESD \( r = -0.49, p < 0.001 \)) and stress (PSS \( r = -0.41, p < 0.001 \)). In a regression model that controlled for age, education, gender, and race, the HAS significantly predicted medication adherence (chi square \( [df = 1] = 7.01, p = 0.01 \)).

Conclusions: The HAS may be useful in understanding patients’ attitudes toward health maintenance and promotion and in predicting medication adherence.

Newly Diagnosed HIV Infections in Non-Urban Virginia: Portrait of a Population and Delayed Linkage to Care

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Background: The South is the new epicenter of the HIV/AIDS epidemic in the United States. In 2010, the South had the highest number of AIDS cases in both urban and non-urban settings as well as the largest number of people living with AIDS diagnoses outside of metropolitan areas. Compared to other regions, Southerners living with HIV start antiretroviral therapy later and have higher HIV-related morbidity. Because of these trends, we reviewed the data on all newly diagnosed HIV-infected patients in our clinic.

Methods: Data on all newly diagnosed HIV-infected patients from a semi-rural public HIV clinic were abstracted from the University of Virginia (UVA) Clinical Data Repository and clinic database (CareWARE) from 2008 through 2011. Analyses were performed using SPSS (IBM, version 20, 2011).

Results: One hundred and forty-nine people were newly diagnosed with HIV at the UVA HealthSystem from 2008 through 2011. Thirty-nine percent of people met criteria for AIDS at time of diagnosis. The average age was 42 years (range 4-69 years). Seventy-seven percent of the newly diagnosed were male, 38.9% of individuals were black/African-American, 5.4% were Hispanic, and 49% qualified as indigent. The mean absolute CD4+ count at first measure was 362 (range 1-1280) and the mean HIV viral load was 381897 copies/mL (range 0-7650000). Newly diagnosed patients missed an average of 22% of clinic visits (range 0-86%) after linkage to care. There was an average of 358 days (range 0-1679) between diagnosis and entry into care.

Conclusions: With the movement of the U.S. HIV epidemic outside of urban areas and specifically into the southeast, a more complete portrait of the newly diagnosed individuals is an important step towards creating targeted programs for testing, linkage to care, treatment, and prevention. Our cohort demonstrates that delayed linkage remains a problem which requires further attention.
Patient Navigation for Retention of HIV-Positive Patients in Washington, DC

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Description: A patient navigator (PN) identified 75 candidate patients by searching the electronic medical record (EMR) to find patients with a history of missed appointments. Reasons for missed appointments included lack of transportation, substance abuse, depression, feeling unwell and forgetting. After scheduling a future appointment with a provider, the PN worked closely with these patients creating individualized plans to ensure appointment attendance that included travel arrangements and assistance, flexible scheduling and appointment reminders. Once engaged in care, patients received continued support from the PN and nurse case managers to support appointment attendance, medication adherence and social services as needed.

Lessons Learned: After working with the PN, the patient cohort saw a 134.2% increase in kept appointments per patient per quarter. Among patients who had an appointment fifteen months before 4/1/2009 none were virally suppressed. Twenty-one months after 4/1/2009 when the PN began reengaging out-of-care patients, over half had viral loads less than 50 copies/ml. While implementation was not problematic, culling intervention data from the EMR presented several issues, namely due to a lack of standardized data entry. This resulted in fewer query results from the EMR. Additionally, comparing HIV biomarkers before and after working with the PN was difficult as many patients were previously out-of-care, eliminating the possibility of a baseline.

Recommendations: This intervention shows the marked, potential impact one PN can have. Future steps could broaden the scope of the intervention by hiring more PNs or training front desk staff to adopt the intervention’s practices. Ultimately, this intervention provides a potential strategy for addressing retention in care and viral suppression as part of the HIV-treatment cascade, while highlighting the importance of appointment attendance.

Feasibility, Safety, Acceptability, and Preliminary Efficacy of Measurement-Based Care Depression Treatment for HIV Patients in Bamenda, Cameroon

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Background: Depression affects 18-30% of HIV-infected patients in Africa and is associated with greater stigma, lower antiretroviral adherence, and faster disease progression. However, the region’s health system capacity to effectively treat depression is limited. Task-shifting models may help address this large mental health treatment gap.

Methods: We adapted a task-shifting model, Measurement-Based Care (MBC), for depressed HIV-infected patients in Cameroon and completed a pilot study to assess its feasibility, safety, acceptability, and preliminary efficacy. MBC trains a Depression Care Manager (DCM) to guide HIV providers in prescribing and managing antidepressant treatment. Key informant interviews guided the adaptation of medication and dosing recommendations and staffing. We then enrolled 55 HIV-infected patients with major depression who received acute management for 12 weeks and maintenance management for 9 months.

Results: A primary adaptation reflected the fact that amitriptyline was the only antidepressant on the government formulary. All participants started amitriptyline 25-50mg daily; by 12 weeks, most remained at 50mg (range 25-125mg daily). Median (interquartile range) PHQ-9 depressive severity scores declined from 13 (12-16) (baseline) to 2 (0-3) (week 12); 87% achieved depression remission (PHQ9<5) by 12 weeks. Intervention fidelity was high: HIV providers followed MBC recommendations at 96% of encounters. Most divergences reflected a failure to increase dose when indicated. No serious and few bothersome amitriptyline side effects were reported. The prevalence of suicidality decreased from 62% (baseline) to 8% (12 weeks); most suicidality was either passive or low-risk. Participant satisfaction was high (100%), and most participants (89%) indicated willingness to pay for medications if MBC were implemented in routine care.

Conclusions: The adapted MBC intervention demonstrated high feasibility, safety, acceptability, and preliminary efficacy in this controlled pilot study, even with only one available antidepressant. Further research should assess whether MBC could improve adherence and HIV outcomes in this setting.
Fidelity in Implementation of a Decision Support Intervention for Depression Management in HIV Clinics

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Background: Depression is highly prevalent in HIV-infected patients and negatively affects antiretroviral adherence and clinical outcomes, yet is largely undiagnosed, untreated, or under-treated, due to barriers to accessing specialty mental health services and lack of expertise in HIV clinics. Decision support models have the potential to improve HIV providers' recognition and quality of treatment of depression.

Methods: The SLAM DUNC Study is implementing Measurement-Based Care (MBC), a decision support depression treatment model, to test the effect of depression treatment on antiretroviral adherence and clinical outcomes. The MBC model generates a treatment recommendation (start antidepressant, increase dose, maintain dose) based on standardized patient assessments (measures of depressive severity and medication tolerability) that the provider may follow or not. Here, we examine the frequency with which MBC recommendations were followed and the reasons for divergence.

Results: Through November 2012, 115 participants had enrolled and been randomized to the MBC condition, encompassing 115 baseline and 377 follow-up encounters. MBC recommendations were not followed at 49 encounters (10.0%), with divergence more frequent at baseline (18.3%) than follow-up (7.4%). Most baseline divergences were patient-driven and involved not starting an antidepressant when indicated (e.g., ambivalence about antidepressants or viewing symptoms as situational). Most follow-up divergences were also patient-driven and involved not increasing the antidepressant dose when recommended. Provider-driven divergences at baseline and follow-up usually related to deciding to treat other presenting comorbidities before starting antidepressants, viewing symptoms as situational, or concern about side effects.

Conclusions: Overall, fidelity to MBC treatment recommendations was high. Divergence most commonly tended toward inertia (failure to increase doses when recommended). These data suggest high acceptability of MBC to HIV providers and patients, supporting its likely real-world effectiveness and potential to positively impact HIV adherence and clinical outcomes.

The Pill Count Effect: Do Unannounced Pill Counts to Measure Adherence Change Pill-Taking Behavior?

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Introduction: Adherence to antiretroviral (ARV) medications improves the health of people living with HIV and AIDS (PLWHA) and decreases the risk of transmission. Among methods to measure adherence, the unannounced pill count (UPC) is increasingly used in research studies. However, UPCs themselves may influence adherence. We assessed patients’ perspectives regarding the effect of UPCs on adherence.

Methods: As part of the SLAM DUNC randomized controlled trial testing the effect of depression treatment on ARV adherence, participants’ adherence is measured by phone-based UPCs monthly for 12 months. At study completion, a set of study acceptability questions assesses participants’ perception of whether and how UPCs affected their pill-taking habits.

Results: Of the 69 participants who have completed these questions to date, two-thirds are male, 70% are African American, and ages range from 22-64 years. Forty-one percent of participants reported some change in pill-taking behavior as a result of the UPCs. Twenty-nine percent reported that the monthly UPCs changed the way they took their ARVs, 29% reported that the UPCs changed the way they organized their ARVs, and 17% reported that the UPCs changed the way they took their antidepressants. In open-ended questions, participants described most changes as positive (e.g., improved organization). Self-reported behavior change was positively associated with study engagement: 50% of participants who completed 11-13 (of 13 possible) UPCs reported behavior change, compared to 33% of participants who completed 7-10 counts, and 25% of those who completed 0-6 counts.

Conclusions: Medication adherence among PLWHA is important for maintaining health and preventing drug resistance, and accurate measurement of adherence is central to many research studies. These preliminary data indicate that phone-based UPCs, intended as a data-collection method, may actually affect pill-taking behavior, potentially by providing an opportunity for self-monitoring. Further research is necessary to more fully understand the effect.
**138 Patient-Tailored HIV Prevention Strategies**

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**Background:** More information is needed to understand how the newer HIV prevention methods should be positioned and which mix of prevention methods should be offered and promoted within the at-risk populations. This study sought to obtain data about the preferences for effective biomedical interventions by individuals from the diverse ethnic and racial backgrounds that comprise the STD clinic populations in Miami.

**Methods:** A cross-sectional survey was used to assess knowledge and preference of traditional (condoms) and new biomedical methods to prevent HIV (Circumcision -C-, Pre-exposure prophylaxis -PrEP and microbicides -M) in STD clinic patients. After an initial assessment, the study coordinator provided basic simple descriptions of three new methods of HIV prevention by pamphlets and/or recorded video. The relative preference for each of all the prevention strategies was re-assessed information was provided.

**Results:** Thirty-five participants are reported in this interim analysis; 55% were female; 58% were African American; 25% were Hispanic and 12% were Haitians. Most of the participants were not aware of the efficacy of C (68%), PrEP (77%) or M (79%) in decreasing the risk of acquiring HIV infection. At baseline, participants described as their preferred method to prevent HIV the use of male condoms (77%) and had marginal preference for the newer methods C (3%), M (6%) and PrEP (3%). After the information about the new methods was provided, most of the participants reported to be aware of these methods (80%) and although male condoms was still the first choice for most of the participants (46%) a higher percentage of participants preferred M (20%) and PrEP (14%).

**Conclusions:** STD clinic patients who participated in this study had very limited knowledge about the new biomedical strategies to prevent HIV infection. A brief informational session can increase their willingness to use the newer HIV preventive strategies.

**139 Gender-Specific Awareness and Acceptability of Pre-Exposure Prophylaxis to Prevent HIV Infection among Youth in Western Kenya: Implications for Implementation**

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**Background:** Youth ages 15-24 in sub-Saharan Africa are more impacted by HIV/AIDS than any other age group in any other region globally. In Kenya, young females are 4 times more likely to be positive than males. Gender-specific HIV prevention combining behavioral, structural, and biomedical modalities is necessary to impact the epidemic. Trials of pre-exposure prophylaxis (PrEP) showed efficacy in reducing HIV risk when adherence ≥85%. Risk-perceptions and knowledge affect adherence and ultimately intervention efficacy. The study examined youth knowledge, acceptability, facilitators, and barriers to PrEP adherence.

**Methods:** Twelve focus groups were conducted in Nyanza, Kenya composed of youth ages 15-24, parents and teachers of youth, and community, district, and religious leaders. Youth focus groups were gender and age (15-17 and 18-24 years old) specific.

**Results:** Forty-six females and 66 males participated (n=112). A content analysis identified themes and sub-themes related to PrEP. Four major themes emerged: (1) limited knowledge of PrEP as an HIV prevention method; (2) PrEP advantages; (3) concern about side effects; (4) belief that it could result in risk compensation. Sub-themes highlighted a desire for sensitization campaigns, the idea of PrEP as life saving, and potential adherence challenges.

**Conclusions:** Findings indicate a need for increased PrEP awareness. Youth expressed willingness to use PrEP when coupled with pre-counseling and acceptance support. Potential adherence to the PrEP regimen is linked to knowledge, widespread use, and acceptability. Adherence remains a challenge with variability in access to medicines, risk perceptions, and concerns about side effects. Some participants believed HIV risk reduction outweighed potential side effects. Overall, participants indicated PrEP could be an effective tool in HIV prevention.

Considering the efficacy of recent PrEP trials, combination HIV prevention studies should explore incorporating PrEP. Interventions need to provide gender-specific options to reduce PrEP misconceptions, reduce risk compensation, and support adherence.
140 Crofelemer for HIV-Associated Diarrhea: Sustained Efficacy, Safety, and Adherence During a 6-Month Randomized, Placebo-Controlled Trial

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**Background:** Diarrhea remains a significant burden in HIV-positive individuals taking antiretroviral therapy (ART), and negatively impacts adherence and quality of life. Crofelemer (CRO), a botanically-derived, minimally absorbed, first-in-class anti-diarrheal agent was recently approved for symptomatic treatment of non-infectious diarrhea in adults with HIV/AIDS on ART. A 6-month study assessed the efficacy, safety, and adherence profile of CRO 125mg bid.

**Methods:** This randomized, double-blind, placebo (PBO)-controlled, adaptive design trial in HIV-positive adults on stable antiretroviral therapy (ART) incorporated dose selection (Stage I) and dose assessment stages (Stage II). Each stage included a 4-week, PBO-controlled phase and a 20-week, PBO-free phase. Primary efficacy endpoint was proportion of clinical responders, defined as ≥2 watery stools/week for ≥2 of 4 weeks during the PBO-controlled phase. Secondary efficacy assessments included daily watery stools, daily stool consistency, daily abdominal pain/discomfort, and days/week of fecal incontinence. Adverse events were recorded. Adherence was measured by pill counts.

**Results:** Demographic and baseline characteristics were similar between CRO (n=136) and PBO (n=138) groups. Overall, subjects (mean age: 45; race: 58-61% non-White) experienced 18.9-21.0 watery stools/week, and 75% attributed diarrhea to ART (RTV-containing: 34-36%; EFV/TDF/FTC: 15-22%; NFV: 0%). During the PBO-controlled phase, the proportion of clinical responders was significantly higher for CRO vs. PBO (p=0.0096), with greater efficacy associated with more severe baseline diarrhea (p=0.026), longer history of diarrhea (p=0.03), or history of unsuccessful anti-diarrheal medication use (p=0.025). Daily watery bowel movements, stool consistency, abdominal pain/discomfort, and days/week of fecal incontinence improved over the PBO-free phase. Interestingly, PBO-controlled phase adherence rates of 96.5% improved to 100% in PBO-free phase. The safety of CRO was comparable to PBO and no changes in ART effectiveness were discernible.

**Conclusions:** The addition of crofelemer 125mg to stable ART regimens in HIV-positive individuals is well-tolerated and results in sustained decreases in diarrhea and associated symptoms.

141 Combination HIV Prevention for Youth in High Burden Settings (MP3 Youth): A Pilot Study

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**Introduction:** Young females and males (15-24 years old) in sub-Saharan Africa have disproportionately high risk of HIV infection compared to adults. High coverage of HIV testing and counseling (HTC) is essential for early linkage to care and prompt initiation of ART by positive youth, and for facilitating delivery of evidence-based gender-specific primary prevention interventions. Our research team explored the most effective combination HIV prevention intervention package for female and male youth in Kenya.

**Description:** A systematic review of the literature and expert panel were used to select HIV prevention interventions effective for youth in sub-Saharan Africa. The combination package includes offering HTC and ART at ≥350 cells/mm³ for all youth; voluntary medical male circumcision (VMMC) and condoms for males; and pre-exposure prophylaxis (PrEP), conditional cash transfer, and contraceptives for females.

We estimated the potential impact of providing the combination package, including female- and male-specific interventions, by using an age-sex-risk stratified mathematical model representing HIV heterosexual transmission in Nyanza, Kenya. The package will be delivered using mobile health teams. A longitudinal cohort will be followed using cell phone SMS surveys to prospectively assess uptake, adherence, and risk compensation behaviors.

**Lessons Learned:** The mathematical model predicts halving HIV incidence in ten years among youth if the full package of interventions is implemented and continued at specific coverage levels. The decision to include PrEP, which requires ongoing clinical contact, in a mobile delivery intervention, was a challenge. We are conducting intensive field visits to explore clinical capacity for PrEP inclusion.

**Recommendations:** The literature indicates behavioral, biomedical, and structural interventions can significantly reduce HIV risk. Mathematical modeling shows interventions tailored to young males and females could have substantial impact when combined. However, to be effective in the overall population, interventions need to be implemented at relatively high coverage levels.
142 Unmet Need among Hospitalized HIV Patients who are Out of Care

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Background: Unmet needs among persons hospitalized with HIV who are out of care may delay or prevent engagement in HIV care following discharge. Unmet needs among hospitalized HIV patients have not been well documented. Using data from a hospitalized cohort of HIV patients who were out of care, we examined unmet needs and their association with CD4 and VL.

Methods: Baseline data from a cohort of hospitalized HIV-infected patients at a large publically-funded hospital who were out of care and enrolled into a randomized intervention trial between July 2010 and June 2012 was used. The baseline survey included 19-items on personal and medical needs in the 6 months before hospitalization and whether these needs were met. Level of unmet need was determined by the count of unmet needs. Baseline CD4 and VL were collected. Univariate analyses were conducted to examine associations between unmet need and CD4 and VL.

Results: 274 HIV-infected patients were enrolled. 93% reported having at least one need in the past 6 months. The most frequently reported needs were dental (66%), financial (55%), food (46%), transportation (44%), and housing (42%). Patients age<30 years (p=0.05) and black race/ethnicity (p=0.03) had significantly higher levels of need compared to other age and race groups. 88% of patients with needs reported having ≥1 need that was not met. The average number of unmet needs was 3.59 (s.d. = 2.8). Only 19% of dental, 27% of financial, 49% of food, 40% of transportation, and 23% of housing needs were met. Blacks had a greater number of unmet needs than other race/ethnicities (p<0.01). Unmet need was not associated with baseline CD4 or VL.

Conclusions: The vast majority of hospitalized out-of-care persons with HIV report unmet needs. Efforts to address unmet needs in hospitalized HIV patients may improve linkage and retention in care.

143 Barriers to Medication Adherence Remain in the Era of Potent HIV Therapy

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Background: Optimal antiretroviral therapy (ART) adherence is essential to personal and public health. Barriers to ART adherence have been well described but much of this work pre-dates the availability of more potent and convenient ART regimens. We examined perceptions regarding ART and adherence among persons living with HIV (PLWH) receiving ART.

Methods: Focus groups were conducted with 36 PLWH in NC (11 female, 25 male; 29 African-American, 5 White; 12 on initial ART). Focus groups were audio-recorded, and transcripts were reviewed to identify salient themes.

Results: Participants viewed ART as being important to well-being, but described struggling to adhere to these medications. Many who started earlier ART regimens reported having to overcome side effects and pill burden of these older therapies. For some, adverse effects, especially nausea, continue to challenge adherence. Among the major adherence obstacles participants currently experience was HIV stigma and a fear that taking ART risks disclosure of serostatus. One participant stated, “I was living with someone and I didn’t want them to know that I was taking meds so I just stopped at one point for about, whew, maybe three or four months…” In addition, some endorsed developing medication fatigue after years of treatment. “I’m telling you it’s very depressing, you got to take it every day, every day, every day … and sometimes you want to say, Lord, I want to take a break. I’m tired of taking pills.” Despite these challenges, most reported being able to maintain adherence.

Conclusions: PLWH continue to experience obstacles to ART adherence, including adverse effects that impact quality of life, and fears that medication can lead to unwanted HIV status disclosure. Despite advances in HIV treatment, barriers to adherence remain a significant challenge. A validated measure for identifying these barriers among PLWH may help tailor discussions for optimizing adherence.
Findings from the current study highlight preferences and coping mechanisms critical for culturally appropriate depression treatment among HIV-infected women living in rural areas of the Southeastern U.S. Because of the close relationship between depression, ART non-adherence and retention in care, interventions that address barriers to mental health care are sorely needed to improve health outcomes among HIV-positive women residing in rural areas.

Conclusions: For highly sexually active GBM, willingness to take PrEP is associated with loss of behavioral control. Further, our findings suggest a contrast to risk compensation for some highly sexualized people who seem to demonstrate an inability to control sexual thoughts and behaviors – PrEP as both behavioral and biomedical risk reduction. Men already engaging in lower risk behavior indicated they would use condoms more with PrEP and would therefore have added protection. Men already engaging in HIV risk behavior indicated they would continue to engage in risk, or increase their levels of risk, while taking PrEP.
**147 HIV+ MSM in China Recommend Strategies for Care Engagement, Retention, and Adherence**

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**Background:** Free HIV treatment has been available in China since 2006, but acute stigma and lack of awareness limit the extent to which Chinese men who have sex with men (MSM) get tested for HIV, engage in care, and then remain in care with high levels of antiretroviral ARV adherence.

**Methods:** Four focus groups with HIV+ MSM were conducted in Beijing, China in 2011. Eligible participants were Mandarin speaking, self-reported MSM, and at least 18 years of age. They were recruited through peer networks of a local CBO.

**Results:** Group sessions were audio-recorded, transcribed, and then translated. Content analysis conducted by 3 coders (2 fluent in Mandarin and 1 English only) identified multiple strategies to promote engagement and retention in care at the structural and individual levels, many of which focused on the psychological impact of the diagnosis and ongoing psycho-social support. Recommended approaches included involving members of the individual’s support network and training peer advocates to disseminate accurate, high-quality information; foster motivation through enhancing beliefs about positive outcomes of engaging in HIV care; and develop skills to navigate HIV care, advocate for one’s self, and adhere to ARV.

**Conclusions:** China’s current resources for treating HIV will need to evolve to be able to provide the suggested structural changes and to adopt creative strategies to address mental health-related concerns.

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**148 Determinants of Adherence to cART in HIV-Infected Children and Adolescents: Preliminary Results of a Long-Term Cohort Study, 2004-2012**

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**Background:** The complexity of cART – multiple medications, formulations, and dosing intervals – makes adherence challenging for children and adolescents. The objective of this study is to compare adherence in a cohort from children in two distinct moments in 2004 and 2012.

**Methods:** This study is being carried out at the UFMG AIDS Pediatric Immunology Clinic. Of the 103 children evaluated in 2004, 86 (83%) are still in follow-up in 2012, 4 (4%) died, 7 (7%) were lost to follow-up and 6 (6%) were transferred to adult clinic. Subjects or caregiver responded to the same adherence questionnaire that was used in the first time. The questionnaire was adapted from the PENTA network. Good cART adherence was defined as no missed doses in the last 3 days.

**Results:** From the initial group in 2004, 39 (47%) children were reassessed from Jul 2012 to Dec 2012. Current ARV regimens were: 2 NRT + 1 NNRTI - 41%; 2 NRTI + 1 PI- 41%; MDRT (Multi-drug rescue therapy) - 18%. Only 8 (20.5%) were in their initial cART. Approximately half (22/39 = 56.4%) of participants reported that taking ARV did not interfere in their daily routine, 33 (84.6%) reported at least one reason for not taking the dose. Good adherence rates were similar in both periods: 73.7% and 64.1%, for 2004 and 2012, respectively (p=0.5). In subjects evaluated in 2012, adherence was influenced by monthly income (p=0.027) and viral load (p=0.037). Gender, age, hospitalization or caregiver education did not affect adherence. This study is ongoing and evaluation of the remaining subjects is anticipated to be completed by May/13.

**Conclusions:** Adherence rates did not change substantially over time in this cohort of children and adolescents, suggesting that more interventions to improve adherence should be implemented.
152 Is Pre-ART Interval Associated with Immunologic Outcomes among HIV Seropositive Patients on HAART?

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Background: Patients’ treatment preparedness is accepted as a crucial Pre-ART requirement because it’s been shown to improve retention. However, little is known of the effect of the pre-ART duration on treatment outcome. We determined the association between pre-ART interval and immunologic stability among HIV-infected patients on ART in Nigeria.

Methods: In March 2011, we collected retrospective clinical and laboratory information for 5320 randomly-selected HIV-positive adults receiving care at 37 facilities. Eligible patients were enrolled ≥15 months prior to the evaluation. We excluded 2381 patients who were pre-ART, transferred, discontinued care, died or were lost-to-follow-up. Outcome was “Absence of CD4 count <350 cells/ml in 1 year period”. Association between Pre-ART interval and immunologic outcomes was determined by logistic regression.

Results: Of 2939 patients who received ART, 2561 (87.1%) had ≥1 CD4 test done in the review period, 1667 (56.1%) females; 887 (34.6%) Males; Median age: 35.8 years. In univariate analyses, significant correlates of high CD4 counts were: Pre-ART interval (<2 weeks OR=1.33, p=0.001) vs >2 weeks; Gender (Male OR=0.52, p=0.001) vs Females; Baseline CD4 count >350 Cells/ml (OR=2.93, p=0.001) vs ≤350 Cells/ml; Baseline weight (OR=1.01, p=0.001 per kg increase); Baseline WHO Stage 2 (OR=1.82, p=0.06); Stage 3 OR=0.88, p=0.001; Stage 4 OR=0.51, p=0.003) vs Stage 1; Level of facility (Secondary OR=0.50, p=0.02) vs Primary Care Centers; Urban location of facility (OR=1.32, p=0.003 vs Rural); However, in our multivariate model, pre-ART interval did not predict high immunologic outcomes. Baseline weight and CD4 counts, gender and time on ART were the only significant predictors of our outcome.

Conclusions: Patients undergo treatment preparation during the PreART phase and this has been shown to improve retention. However, Pre-ART time did not predict immunologic outcomes in our study. Time on ART was the most significant predictor of high CD4 counts. These results support the test-and-treat strategy especially in PMTCT where delays in treatment initiation may be risky. The decision on the treatment preparation interval should be flexible and depend on whether retention or timely outcomes is the major focus.

153 Predictors of Adherence to HAART Using Doctor’s Appointment Attendance Measure of Adherence

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Background: The gain in the provision of antiretroviral therapy in resource limited settings has put pressure on the available infrastructure including the care providers. High patient load has lead to weak monitoring of the patients on HAART. The aim of this study was to determine patients’ adherence to Doctor’s appointment attendance over time and to predict factors affecting adherence in patients assessing care in a treatment centre in Lagos, Nigeria.

Methods: The study was longitudinal in design, carried out between December, 2006 to December, 2010 using validated questionnaires and monitoring of patients’ clinical progress. Doctor’s appointment attendance was calculated as Total # of appointment scheduled - # of doctor’s appointment missed/ Total # of appointment scheduled *100. Patients with 95% or more were considered adherent. An intervention reducing patients’ doctors’ appointment to quarterly and tying it to drug refill was done in 2010. SPSS version 15.0 was used to analyze the data collected from 248 patients. Predictors of adherence were determined using Logistic regression model.

Results: Social and clinical demographic data analysis showed that 134 (54.0%) were married, 148 (59.7%) females, 106 (42.7%) had secondary school education and 208 (66.4%) employed. Mean age was 40.4±8.8 years, mean baseline CD4 cells of 143.5±92.7 cells/microlitre. Trend in adherence rate was 51.3% in 2007 (N=119), 35.9% in 2008 (N=248), 14.9% in 2009 and 93.1% in 2010. Average rate of patients’ adherence was 48.8%.

None of the socio-demographic variable was a predictor of adherence. Statistically significant predictors of adherence were: in 2007, patients’ knowledge of management; 2008 knowledge of adherence; and in 2010, patients’ smoking and alcohol consumption habit.

Conclusions: Average adherence rate was 48.8%. Intervention statistically improved patients’ adherence to doctor’s appointment. Patients’ knowledge of management, adherence, and some social habit were identified as predictors of adherence.
154 Challenges in Testing for CD4 Upon Receipt of HIV-Positive Diagnosis: Experience at Three Public Sector Clinics in Durban, South Africa

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Background: CD4+ count is a key determinant of whether a newly-diagnosed HIV+ individual is eligible for ART. South African treatment guidelines recommend that blood for CD4+ count be obtained at the initial HIV diagnosis. We examined whether blood was drawn on the day of diagnosis and reasons why it was not among 327 newly-diagnosed women and men who subsequently enrolled in a prospective cohort study.

Methods: Participants were recruited from three public sector clinics in Durban. They were interviewed prior to HIV testing, immediately after, and up to one month later by trained interviewers in isiZulu or English.

Results: Most participants were women (70%), mean age was 30 years (range=18-57), and 72% were currently unemployed. Only 23% reported a blood draw on the same day they tested HIV+, although an additional 19% reported having blood drawn prior to the additional interview within one month. Of those without blood drawn by this interview (N=186), reasons included no time to stay (24%), need to return home to care for family or others (6%), clinic was closing (12%), too shocked to take further steps (5%), fear of learning CD4+ results (3%), and desire to go elsewhere for CD4+ testing (2%); 26% reported a pending appointment, but 7% indicated they were unaware or weren’t informed that a blood draw for CD4+ was needed.

Conclusions: Only one quarter of this sample of newly-diagnosed individuals had blood drawn for CD4+ count on the day of diagnosis. Reasons for delay were largely due to individuals’ need to return home, clinic-related factors, and emotional distress. Given the importance of CD4+ count results for staging HIV+ individuals, strategies to ensure prompt blood draws and reduce barriers to returning to the clinic warrant investigation.

155 Investigating Cognitive, Behavioral, and Environmental Barriers to HIV/AIDS’ Patients Adherence in Nigeria

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Background: Much of health care today involves helping patients manage conditions whose outcomes can be greatly influenced by lifestyle or behavior change. HIV/AIDS is an imminent life-threatening disease. HIV/AIDS patients’ adherence to health behaviors is related to their perceptions of the severity of a potential illness or the consequences of not preventing or treating the illness. Nonadherence involves patients taking medications incorrectly or not at all, forgetting or refusing to make essential behavioral changes for their care, and persisting in behaviors including high-risk sexual activity that jeopardize their health. Adoption of technology is slow in behavioral healthcare. This paper investigates the inherent individual and environmental barriers to HIV/AIDS’ patient adherence in an ongoing research on Women’s Health in Nigeria.

Methods: A mix of both qualitative and quantitative indicators are used to develop case studies of the inherent individual and environmental barriers to patient adherence. Focus groups discussions and semi-structured interviews. The study currently covers a clinic and a university teaching hospital each in case selected across rural and urban Ekiti, Lagos, Ogun, Ondo, and Oyo States of Nigeria.

Results: The primary causes of nonadherence are poor provider-patient communication, lack of understanding of the treatment and its importance, lack of trust and mutual caring in the therapeutic relationship, and provider behavior that is controlling and paternalistic. Depressed patients with HIV have decreased adherence to antiretroviral therapy. Increased patient adherence to diagnostic and therapeutic plans leads to greater clinical efficiency and effectiveness.

Conclusions: The main drivers fuelling Nigeria’s HIV/AIDS epidemic include low risk perception, multiple concurrent sexual partners, informal transactional and intergenerational sex, lack of STI services, gender inequalities, stigma and discrimination, and inadequate health services. HIV/AIDS’ patients are required to take 95% or more of antiretroviral medications to control the disease.
Longitudinal Predictors of Adherence to ARV Treatment (ART) as Prevention (TasP) in HPTN 052, A Large-Scale, Multi-Site, International Trial of Early ART to Prevent HIV Transmission in Sero-Discordant Couples

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Background: HPTN052, a treatment as prevention (TasP) trial, demonstrated early ART prevented the sexual transmission of HIV in 1750 sero-discordant couples in 9 countries. Because ART adherence maximizes the chances of suppressing HIV RNA, and therefore decreasing HIV transmissibility, studying adherence in HPTN052 participants can inform global TasP scale-up.

Methods: Outcomes: adherence via pill count (PC=did not miss any pills), ACTG self-report adherence questions (SR=derived via principal-components analysis). Predictors: quality of life (QOL), substance use, binge drinking, social support, sexual behaviors, and demographics. Life-Steps adherence counseling was adapted and provided at study visits. Analyses: Logistic and linear regression models 1 month after ART initiation and GEE model accounting for within-subject correlations for longitudinal (two years) analyses; reported results are p\(\leq0.05\). A checklist of reasons for non-adherence was also used.

Results: Adherence was generally high: forgetting, traveling, and side-effects being the most frequently reported reasons for non-adherence at initiation. At initiation, psychosocial and demographic variables were not predictive of adherence. Longitudinal multivariable models, however, are as follows: For PC, significant predictors were QOL-mental health (OR=1.04), social support to help remember pills (perceiving highest level (OR=1.19), moderate level (OR=1.28), or n/a, did not ask (OR=.83) compared to “none”)), and Asia (OR=2.07; North/South America=referent group). For SR, significant predictors were age (b=.01), QOL-mental health (b=.014), satisfaction with social support (b=.16 for somewhat dissatisfied versus very dissatisfied), social support to help remember pills (perceiving somewhat (b=.14), n/a did not ask (b=-.15) compared to none), being a woman (b=.06), and not from Asia (b=.19).

Conclusions: In the context of a TasP trial for globally diverse sero-discordant couples, adherence counseling, and generally high adherence, psychosocial variables such as mental-health and social support remain important longitudinal predictors. Including behavioral science interventions to address these mental-health factors are important in supporting global TasP efforts.
Lessons-in-Progress: Case Study of a Partnership Between a Pharmacy School and Community Pharmacy to Pilot Test a Pharmacy-Based ART Adherence Intervention

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Introduction: Pharmacy-based programs can be effective in improving antiretroviral (ART) adherence in HIV-positive persons. A partnership between a community pharmacy and a School of Pharmacy provides an ideal opportunity for both groups to design, methodically implement, and rigorously test brief, patient-centered pharmacy adherence interventions.

Description: Initial discussions between the University of California San Francisco School of Pharmacy (UCSF-SOP) and a community pharmacy began in June 2010, to include two of the pharmacies as sites for an NIH-funded pilot study. The block-randomized controlled study (n=20) would test feasibility of conducting a telephone intervention based in motivational interviewing for patients late picking up ART refills. First participants were enrolled in January 2013; recruitment is ongoing.

Lessons Learned: When conducting research in community pharmacies, various unpredictable elements can come into play that the team must adapt to. Identifying proper institutional review board (IRB) procedures can be confusing when dealing with two institutions. Most pharmacies do not conduct research regularly, may not have a Federalwide Assurance Number, and may not be allowed to defer to the University IRB. Obtaining a concise pharmacy data report in a usable research format may require persistent communication with information technology (IT) staff. Unexpected events such as board inspections and setting up new pharmacy locations may cause delays in research. Having dedicated pharmacy staff involved in the research is invaluable to identifying key contact personnel when problems arise and to serve as a familiar bridge to the research subjects.

Recommendations: University partnerships with community pharmacies combine the expertise of persons from both groups to study interventions to improve ART adherence. Early questions prior to engaging in a research study should center on IRB processes and IT support. Having a flexible timeline and identifying one or more pharmacist champions can ensure the success of the research.

HIV Counselors’ Beliefs About ART and Childbearing among HIV+ Women and Men in Durban, South Africa

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Background: Healthcare providers’ opinions may influence the care they provide.

Methods: We conducted qualitative interviews with five HIV counselors at one public-sector clinic in Durban, South Africa, to develop a structured questionnaire, which was then administered to 20 counselors at three other public-sector clinics. We assessed beliefs and counseling practices around ART initiation, care and treatment, and HIV and childbearing.

Results: In qualitative interviews, some counselors believed that smokers and drinkers should not initiate ART because of increased risk for liver and lung problems and the potential to develop resistance due to poor adherence. Among those assessed quantitatively, a sizeable minority agreed that HIV+ people who were unwilling to take ARVs for life (N=8), would not stop drinking and smoking (N=7), and would have difficulty adhering (N=4) should be discouraged from initiating ART. These views were not associated with whether the counselor reported always discussing ART at post-test counseling.

Regarding childbearing, in qualitative interviews counselors indicated they believed HIV+ individuals had the right to have biological children, but some were concerned about the risks to the child’s health, risk of transmitting HIV to an uninfected partner, and care for the child should the HIV+ parent(s) become sick or die. In the quantitative interviews, the majority (n=13) agreed that although an HIV+ person has the right to have a child, this should be discouraged. Those who held this belief were more likely to always discuss where the child should the HIV+ parent(s) become sick or die.

Conclusions: HIV counselors’ opinions on childbearing were associated with whether they prioritized counseling around family planning services, but their opinions on contraindications for ART were not associated with counseling practices. Because of our small sample size these findings merit further investigation.
160 Preliminary Support for Transgender-Specific Predictors of Uptake and Adherence to ART and Viral Load among HIV+ Transgender Women

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Background: Transgender women have disproportionately high HIV rates, and those living with HIV have a three-fold higher viral load than other groups and are less likely to be taking antiretroviral therapy (ART). Among those who initiate ART, transgender women report lower rates of ART adherence and more difficulty integrating treatment into their lives than non-transgender adults. These findings strongly suggest that transgender women face culturally unique challenges to uptake and adherence to ART.

Methods: We administered quantitative surveys to 137 transgender women; 63 were HIV+ (46%) and were part of the current analyses. The majority were African-American (N=46, 71%). We assessed transgender and HIV-specific psychosocial influences on uptake and adherence to ART guided by two novel models: the Model of Gender Affirmation and the Model of Health Care Empowerment (HCE).

Results: Overall, 100% reported having ever been seen by a health care provider, 86% reported having ever been on ART, 83% reported currently being on ART, and 67% reported having an undetectable viral load. We found that access to gender affirmation was positively associated with self-reported ART adherence (r=0.433, p<.01), need for gender affirmation was positively associated with having a detectable viral load (t=1.97, p<.05), body appreciation was associated with current ART use (t=2.28, p<.05), and stress appraisal of transphobic experiences was associated with self-reported viral load (t=3.03, p<.01). Both HCE scales (informed, collaborative, committed, engaged and tolerance for uncertainty) were associated with self-reported adherence (r=0.40, p<.01; r=0.43, p<.01).

Conclusions: These results provide preliminary support for two models that may help elucidate health care disparities observed among transgender women living with HIV. These models may be useful in guiding interventions that aim to improve health outcomes among this disproportionately impacted group by addressing transgender and HIV-specific factors associated with engagement in and adherence to HIV treatment.

161 A Qualitative Investigation of Barriers to Treatment Initiation and Engagement among Transgender Women Living with HIV

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Background: Transgender women are among the most highly impacted groups in the HIV epidemic, and yet are under-researched and underserved. This examination of culturally unique barriers to engagement and retention of transgender women in HIV care will provide insight and guidance to those wishing to better engage and serve this population, and contribute to efforts to understand and mitigate the forces that result in disproportionately poor health outcomes for transgender women.

Methods: This qualitative study explored HIV+ transgender women’s experiences, perspectives, and life contexts of engagement and retention in HIV treatment through 5 focus groups and 20 individual interviews (total N=58). Data was coded and analyzed using the Behavioral Model of Health Services Use and the Model of Health Care Empowerment as theoretical frameworks.

Results: Transgender women living with HIV face unique challenges in initiating and adhering to HIV care, such as limited access to and avoidance of healthcare due to stigma and past negative experiences, prioritization of gender-related healthcare, and concerns about adverse interactions between ART and hormone therapy. Once engaged in care, the cultural competency of the provider and environment of the clinic is extremely important to retention. Facilitators to retention include the provider’s ability to provide both hormones and HIV care, knowledge of trans-related medical issues, and ability to treat the patient with dignity and respect.

Conclusions: Primary themes that emerged from the data included delays in diagnosis, difficulties with adjustment to diagnosis, prioritization of transition-related care, substance use, and low provider cultural and clinical competency in the provision of care for transgender patients. Interventions must fully attend to the social, economic, and psychological context of transgender women’s lives and address the multiple barriers to health care engagement, treatment adherence, and empowerment that serve to create, maintain, and deepen HIV-related health disparities among transgender women.
Measurement of the HIV Cascade of Care Using Surveillance Data in Cuyahoga County

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Introduction: Despite the development of effective combination antiretroviral therapy (ART), many patients do not access HIV clinical care for a variety of reasons. Early linkage after a new diagnosis has been associated with favorable clinical outcomes. Integrating public health surveillance data and programs with local clinical services may increase rates of linkage to care.

Description: An evaluation of HIV care linkage and retention in Cuyahoga County was performed using surveillance data of new HIV cases reported in 2009 and 2010 from the Ohio Department of Health. Medical records were examined at local HIV clinics to determine if patients were linked to care within 3 months, retained in care for 12 months, prescribed ART, and achieved viral suppression in the 12 month period after diagnosis.

Lessons Learned: The lack of integration of public health and clinical services resulted in redundancy of efforts. Nearly 10% of the patients reported to the health department were previously diagnosed, but may not have been reported. More than half the patients that were unable to be located by the health department had accessed clinical services in the year following diagnosis. The cascade of care in Cuyahoga County is similar to previously reported national estimates with less than half of the patients retained in care and only one quarter with a suppressed viral load 12 months after diagnosis.

Recommendations: Increased collaboration between health department partner services and HIV clinicians could improve HIV linkage and streamline the workflow of both organizations within the context of a complex and fragmented healthcare system. Strengthening the partnership between public health and clinical care will result in more accurate and robust data for both parties in order to provide more comprehensive care to people living with HIV.

Barriers to Treatment and Adherence among Vulnerable Women and Sex Workers in South Africa

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Introduction: South Africa has the most people living with HIV and although PEPFAR and South African government programs proclaim success in linking HIV positive people to care, many with reduced CD4 count, like sex workers face barriers. Those who are receiving ARVs face structural and economic barriers for adherence.

Description: A NIDA-funded (R01 DA032061) study is currently reaching vulnerable drug-using women using a prospective, geographically clustered, randomized design to compare the impact of HIV testing with a woman-focused HIV prevention intervention on treatment linkage and ARV adherence. This on-going study uses community outreach to find and test vulnerable women in Pretoria, South Africa. With HIV among 57% (105/184) of all women tested and 67% among sex workers, only 16% (17/105) are currently on ARVs. A majority of these women face barriers that prevent them from initiating treatment. Those who do initiate treatment face barriers that lead to low rates of retention and adherence. These barriers include; lack of follow through with pre-ARV counseling, lack of referral linkages between clinics, fear about ARVs, and stigma toward sex workers. Structural issues of food insecurity, lack of ARVs in nearby clinics, having ARVs stolen, mandatory ID requirements for ARV initiation, and concomitant substance abuse with lack of affordable drug rehabilitation programs are major challenges.

Lessons Learned: Because many clinic barriers are related to shifts in PEPFAR funding priorities, our community advisory board has helped with their access and linkages. Study participants have been escorted for clinical staging and ARV initiation, getting help acquiring IDs and in demystifying ARVs. Regular contact to ensure ARV adherence and storing ARVs has become essential.

Recommendations: Strategic planning across groups responsible for reaching vulnerable women to problem solve the gaps in service delivery, reduce structural barriers and implement this in combination with behavioral interventions is essential.
Providing Drug-Level Feedback to US Men who have Sex with Men (MSM) Using Pre-Exposure Prophylaxis (PrEP) in the iPrEx Open Label Extension (OLE): A Qualitative Evaluation of Participant Perspectives

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Background: There is emerging interest in providing PrEP study participants with pharmacokinetic results from drug-level testing to improve accuracy of self-reported adherence and guide counseling. In iPrEx OLE, plasma samples collected in the first 12 weeks of study participation were tested for tenofovir/emtricitabine. Study clinicians shared results (detectable/undetectable) with participants at their 24-week visit. We evaluated participant perspectives on receiving these results at US study sites.

Methods: OLE participants (MSM and transwomen) enrolled in San Francisco, Boston, and Chicago were purposefully sampled to include those with detectable and undetectable levels. In-depth interviews (IDIs) explored experiences with drug-level feedback, including perceived usefulness and recommendations. IDIs were transcribed, coded, and analyzed for themes.

Results: From April-September 2012, we conducted 49 IDIs (17 had undetectable drug-levels). Chicago participants were younger and more likely African-American or Latino. Generally, participants had positive attitudes towards receiving drug-levels, citing curiosity and a desire to “know” if enough drug was present to provide protection. Participants with detectable drug felt affirmed, safer/more protected, and experienced a sense of accomplishment. Participants reported a desire for greater specificity, particularly quantitative drug levels needed for protection. Several participants noted they would leverage other prevention strategies during periods of low drug detection. In a few cases, undetectable results led to increased efforts to take PrEP consistently. Overall, participants were inclined to provide accurate self-reported adherence because of drug-level monitoring.

Conclusions: Drug-level feedback was acceptable and possibly supportive of enhancing accuracy of self-report in iPrEx OLE. Strategies to increase the salience of drug-level results should be explored, including using feedback to target counseling, and expediting testing to ensure feedback reflects recent PrEP-use. Future studies should evaluate the feasibility of providing quantitative drug-levels using biomarkers of longer-term PrEP exposure (hair/dried blood spots) and the impact of sharing these results on drug detection and self-report accuracy.
Adherence and HIV “Transmissibility” in High-Risk HIV-Infected Individuals from Diverse Geographic Settings: Baseline Data from HPTN063

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Background: With global expansion of ART-treatment, and subsequent reduced transmissibility, data are needed to inform treatment-as-prevention (TasP) approaches. HPTN063 is an observational study in Rio de Janeiro, Brazil, Chiang Mai, Thailand, and Lusaka, Zambia, of high-risk HIV-infected heterosexual men (HM), heterosexual women (HW), and MSM (Brazil and Thailand only).

Methods: Assessments: adherence, depression, alcohol-use, substance-use (yes/no), quality of life, social support, HIV-disclosure, and transmission risk behavior (TRB with HIV-negative/unknown-status partners via ACASI) (N=750, approximately 100 per risk-group, per site), HIV-RNA (extracted from charts, Brazil/Thailand only), and STIs (via testing).

Logistic regression (OR for continuous predictors=per 1 unit increase on scale) modeled two outcomes: non-adherence (6 categories, ordinal), and “infectious/risky” (bivariate: engaged in TRB with detectable viral load or STI).

Results: 86% of the sample reported taking ART. In bivariate analyses, adherence was significantly worse with increased depression (OR=1.01) and alcohol use (OR=1.05). However adherence was better with better QOL-general health (OR=.99) and QOL-social (OR=.96); and in Brazil (OR = 0.53) and Zambia (OR = 0.48) compared to Thailand. In the multivariable model, increased alcohol (OR=1.04) was associated with worse adherence, and better QOL-general health (OR=.99) and being from Brazil (OR=.41) or Zambia (OR=.58) compared to Thailand with better adherence.

Infectious/risky: 29% of 448 (Brazil/Thailand only) met criteria for infectiousness/TRB. Bivariate analyses: High transmission risk was associated with Brazil (OR=2.84) compared to Thailand, with HW (OR=1.79) and MSM (OR=3.49) compared to HM, and with higher HIV disclosure (OR=1.87). Multivariable: HW (OR=1.58) and MSM (OR=3.05) and patients from Brazil (OR=2.43) compared to Thailand were more likely to meet criteria.

Conclusions: TasP approaches require interventions to maximize adherence, with health perceptions and alcohol use being of potentially high importance. Providing more intensive behavioral interventions to the subset of individuals at higher biological risk for transmissibility, may amplify the effectiveness of TasP.
Feasibility and Acceptability of a Real-Time Adherence Monitoring Device among HIV-Positive Patients in China

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Background: We collected preliminary data on feasibility and acceptability in China of a real-time web-linked adherence monitoring container which uses wireless technology to track on-time medication dosing. “Wisepill” transmits a signal by general packet radio service to a central server each time it is opened. Wisepill has been used to monitor adherence in various studies, but its potential as an adherence support tool is unknown.

Methods: The study was conducted at the Guangxi Center for Disease Control HIV clinic in Nanning, China. Ten patients on antiretroviral therapy (ART) used Wisepill for one of their ART medications for one month. We monitored device use and ART adherence, and collected data on acceptability of the device among patients, and feasibility of monitoring adherence wirelessly in China.

Results: Subjects were current and former injection drug users (90%); 70% had a history of depression. Mean adherence levels were 76% (SD 27%) using Wisepill data, but 95.5% by self-report (visual analogue scale). Half of the subjects reported a positive or very positive overall experience with Wisepill (the other five reported “somewhat negative”); seven were willing or very willing to participate in a larger effectiveness study. Eight found the device very easy to use. However, seven said that it was inconvenient or very inconvenient, supported by comments that it was large and conspicuous. Five were somewhat or very worried about disclosure of their HIV status due to the device; no disclosures were reported. Minor technical difficulties were encountered and addressed.

Conclusions: Use of a real-time, SMS-enabled web-linked ART adherence monitoring system among predominantly IDU HIV patients in China is feasible; further analysis of acceptability is warranted. Concerns about disclosure and stigma should be explored. The device shows potential for adherence interventions that deliver rapid adherence-support behavioral feedback directly to patients, as well as in clinical settings.

STaR Study: Single Tablet Regimen Rilpivirine/Emtricitabine/Tenofovir DF Is Non-Inferior to Efavirenz/Emtricitabine/Tenofovir DF in ART-Naïve Adults Regardless of Adherence

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Background: HIV medication adherence can be improved with regimen simplification and better tolerability. In previous studies efficacy of regimens has correlated with optimal adherence rates. Rilpivirine/Emtricitabine/Tenofovir DF (RPV/FTC/TDF) and Efavirenz/Emtricitabine/Tenofovir DF (EFV/FTC/TDF) are once-daily, single tablet regimen (STR) HIV treatment options.

Methods: STaR is an ongoing, open-label, international, 96-week study evaluating the safety and efficacy of the STR RPV/FTC/TDF compared to the STR EFV/FTC/TDF in treatment-naïve HIV-1 infected subjects. Subjects were randomized 1:1 to RPV/FTC/TDF or EFV/FTC/TDF. The primary endpoint was the proportion of subjects with HIV-1 RNA <50 c/mL at Week 48 as determined by FDA snapshot algorithm (12% pre-specified non-inferiority margin). Outcomes stratified by <95% and ≥95% adherence according to pill count were also analyzed.

Results: A total of 786 subjects were randomized and received at least one dose of study drug (394 RPV/FTC/TDF; 392 EFV/FTC/TDF). RPV/FTC/TDF was non-inferior to EFV/FTC/TDF (86% vs 82%) at Week 48 for HIV RNA <50 c/mL (difference 4.1%, 95% CI [-1.1%, 9.2%]). Non-inferiority was demonstrated for HIV-1 RNA >100,000 c/mL (n=276), 80% RPV/FTC/TDF vs 82% EFV/FTC/TDF (difference -1.8%, 95% CI [-11.1%, 7.5%]) and a statistically significant difference was seen for baseline HIV-1 RNA ≤100,000 c/mL (n=510), 89% RPV/FTC/TDF vs 82% EFV/FTC/TDF (difference 7.2%, 95% CI [1.1%, 13.4%]). In the RPV/FTC/TDF arm, 76.3% of subjects had optimal adherence of ≥95% vs 71.1% in the EFV/FTC/TDF arm.

Conclusions: The STR RPV/FTC/TDF demonstrated overall non-inferior efficacy compared to STR EFV/FTC/TDF in treatment-naïve HIV-1 infected subjects. Most subjects were highly adherent to their STR; adherence was correlated with efficacy.
174 Time Preferences Predict Adherence to Antiretroviral Therapy and Mortality among HIV-Infected Adults in Kenya

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Background: Antiretroviral therapy (ART) adherence may be thought of as an inter-temporal choice of whether to incur immediate costs that yield delayed health benefits. Costs include inconvenience of taking medications daily and side effects, while health benefits include viral suppression and reduced morbidity. Economic theory suggests that such choices are partially influenced by individuals’ time preferences, which describe the extent to which they prefer immediate vs. delayed rewards. While previous research has identified various barriers and facilitators to adherence, few studies have measured patients’ time preferences and examined their association with adherence and mortality.

Methods: 671 HIV-infected adults in Kenya who initiated ART participated in a randomized trial of text message reminders and were followed for 18 months. All participants were administered a baseline questionnaire in which they were asked to choose between hypothetical monetary payments offered immediately or in the future. We classified responses as demonstrating patient or impatient time preferences. The main outcomes were 12-month Medication Event Monitoring System (MEMS) adherence >0.90 and 12-month mortality. Regression analyses examined the association between time preferences and outcomes.

Results: When presented with the hypothetical choice of receiving money today versus a larger amount of money in one year, 39% chose money today (impatient preferences). 50% had 12-month MEMS adherence >0.90 and 5% were deceased at 12 months. In regression analysis that controlled for demographic characteristics, wealth, and alcohol use, having impatient preferences was associated with a 6.9% decrease in the likelihood of adherence >0.90 (p<0.05) and a 3% increase in likelihood of mortality (p<0.05).

Conclusions: Simple measures of the time preferences of patients initiating ART can predict adherence and mortality. Time preference measurement could be utilized more widely in HIV care and treatment programs. The improved understanding of adherence behavior can pave the way for better targeting of adherence interventions.

176 Promoting Access and Adherence to HIV Prevention, Care, and Treatment among Public Sector Workers in Uganda

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Background: The Government of Uganda (GoU) is at the forefront of integrating HIV/AIDS interventions into workplace to increase employee access to services for the last two decades. The Supporting Public sector workplaces to Expand Action and Responses against HIV/AIDS project (SPEAR) implements workplace-based HIV/AIDS prevention, care and treatment interventions for public sector workers (PSW) in Uganda since 2008.

Methods: Assessing Drivers of HIV Infection (ADHI) was a cross-sectional descriptive study to evaluate overall knowledge, behaviors and risk factors and perceptions for HIV transmission and the factors that impact adherence to HIV/AIDS prevention, care and treatment services among PSW in three ministries in Uganda: Ministry of Education and Sports (MoES), Ministry of Internal Affairs (MoIA), and Ministry of Local Government (MoLG). Data was collected and entered using Epilinfo version 3.5.1 and analyzed using Stata version 9.2. This abstract documents the role on Behavior Change Agents (BCAs) in promoting and maintaining adherence among PSW in the SPEAR Project.

Results: Over 3,000 trained BCAs served as SPEAR project-trained conduits for information and access to HIV services between the three ministries and PSWs, reaching over 40,000 individuals with HIV counseling and testing services and over 58,000 individuals with behavior change communication (BCC). Availability of BCAs increased by 41% in the ministries, with higher representation at MoES (57%), and UPS (50%). BCAs contributed to reduction of HIV-related stigma by 24%, with 91% reporting HIV testing, service uptake range from 32%-75%, 70% being aware of workplace HIV policies, 62% receiving BCC, and 94% reported family approval of services.

Conclusions: BCAs are effective agents to improve access to information, utilization HIV services and increase adherence to HIV prevention, care and treatment services among PSW. The use of BCAs should form an integral part of all HIV services among PSW and their families.
Missed Opportunities for Promoting ARV Use among Established Patients in Care

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Background: National guidelines recommend antiretroviral therapy (ARVs) for all HIV-infected individuals to reduce the risk of disease progression and transmission. Poor continuity of care and lack of access are frequently cited as root causes of non-treatment. To look beyond these factors, this study sought to identify determinants of ARV coverage among established patients visiting their usual source of care. The relationship between ARV coverage, healthcare utilization, and visit disposition was also examined.

Methods: HIV-related visits for adult patients (age >18) were identified from the 2009-2010 National Hospital Ambulatory Medical Care Survey using primary ICD-9-CM codes for HIV (042, V08, 079.53). Only established patients receiving services from their usual source of care were included. Healthcare utilization was calculated as the number of clinic visits within the last year. Visit disposition was coded as either: return to the clinic, refer to other physician, or refer to the emergency department (ED) or hospital for admission. Bivariable analyses were conducted for comparisons on the basis of treatment status (ARV-treated vs. non ARV-treated).

Results: Approximately 2.5 million HIV-related clinic visits were analyzed. Overall, 69% of visits were for patients with ARV coverage. Lack of ARV coverage was more prevalent among women, African-Americans, Medicaid recipients, and patients living in impoverished neighborhoods (p<0.001). Healthcare utilization did not differ by treatment status. Compared to ARV-treated patients, non-treated patients were less likely to be instructed to return to the clinic (p<0.001) and were more likely to be referred to the ED or hospital for admission (p<0.001).

Conclusions: Many patients lack ARV coverage despite having a usual source of healthcare. Established non-ARV treated patients utilize care at similar rates as ARV-treated patients, yet their visits are more likely to result in ED or hospital admission. Routine clinic visits may be missed opportunities to promote ARV use for these vulnerable patients.

Barriers to HIV Care enrollment, Retention, and Timely ART Initiation: Provider Perspectives at Four Ethiopian HIV Clinics

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Background: Despite increased access to HIV testing, and care and treatment services in Ethiopia, initiation of antiretroviral therapy (ART) late in disease remains common. Health care providers can provide insight into barriers to prompt linkage, sustained engagement in HIV care, and timely ART initiation.

Methods: Trained interviewers conducted in-depth interviews with 12 providers (4 VCT counselors, 4 doctors, and 4 nurses) and 4 HIV-positive peer educators at clinics with varying levels of late ART initiation in Oromia, Ethiopia. Interviews were translated, transcribed, and content-coded.

Results: Patient-level barriers to timely linkage and retention in care cited by providers and peers included patients’ difficulty accepting their HIV diagnosis, fear of stigma, prioritization of non-allopathic treatments (such as holy water), living far from the clinic, lack of understanding regarding the need for services early in disease, and a general reluctance to start ART resulting from concerns about potential side effects and fear of being seen taking medication. Additionally, some providers indicated that patients diagnosed as part of provider-initiated testing were unprepared for their diagnosis and received insufficient post-test counseling following diagnosis, placing them at risk for delayed linkage to care. Structural barriers cited included long wait times for pharmacy and laboratory services and staff who were not supportive or empathetic. Conversely, HIV-positive peers believed that the experiential-based support they provided was especially helpful to HIV-positive individuals.

Conclusions: Providers recognize that prompt linkage to HIV care, sustained engagement in HIV care and timely ART initiation require attention to patients’ social context and treatment literacy, as well as proper interactions with providers and a clinic environment conducive to efficient patient care. Providers and peer educators may be useful allies in developing interventions to improve linkage and retention in HIV care.
**POSTER ABSTRACTS**

**179 Association Between Self-Efficacy and Adherence to Antiretroviral Therapy In Brazilian Children and Adolescents**

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**Background:** Brazilian public health provides free access to HAART, but patient adherence remains challenging. Evaluation of self-efficacy, characterized by the individual self-evaluation of his/her ability to perform specific behaviors, has been proposed for adherence assessment. We aimed to evaluate the association between self-efficacy and adherence to HAART in pediatrics.

**Methods:** A population comprising 108 HIV-infected patients on HAART (80 boys), from 8 to 19 years-old, was assessed cross-sectionally. Self-efficacy was measured by a validated scale, scoring 0 to 100. Adherence was evaluated in patient-caregiver dyads by standardized questionnaires and pharmacy refill data (PRD). Patients who received less than 95% of prescribed doses in 24 hours or 7 days before the interview, or who had an interval >37 days between refills, were considered nonadherent. The association between adherence outcomes and independent variables related to demographical, medical and psychosocial conditions was estimated. Statistical analysis was performed by multivariate Odds Ratios, Mann-Whitney test, and Spearman Correlation Coefficient. Results were statistically significant if p ≤ 0.05. The study was approved by the Internal Review Board of the State University of Campinas Medical School.

**Results:** Nonadherence prevalence varied from 11.1% (nonadherent in 3 instruments), 15.8% (24-hour self-report), 27.8% (7-day self-report), 45.4% (PRD) to 56.3% (at least one of the outcomes). Self-efficacy scores were lower in non-adherent patients according to 24h and 7-day self-report, and PRD. After multivariate analysis, independent variables associated with lower self-efficacy were: difficulty of ministration by caregiver, lack of virological control, lower CD4/CD8 ratio, HAART ministration by patient, missed consultations in the former 6 months, lack of religious practice by patient and lower per capita income.

**Conclusions:** A high prevalence of HAART nonadherence was observed in the study population, being PRD the most sensitive measurement. Additionally, an association was observed between adherence outcomes and self-efficacy scores.

**180 Understanding How Risk Perception Frames HIV-Positive Adults’ Decision to Refuse Antiretroviral Treatment at an HIV Testing Center in Soweto, South Africa**

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**Background:** South Africa has the largest antiretroviral treatment (ART) program in the world. Despite this, many treatment-eligible individuals are choosing not to initiate care. To date, few studies have addressed why HIV-positive adults are not starting treatment. We identified one likely cause of delayed ART initiation: 20% of ART-eligible individuals presenting for Voluntary Counseling and Testing (VCT) in Soweto declined ART upon learning their CD4 count. We inductively identified and characterized reasons for ART-refusal in this population, to develop an explanatory framework for understanding why HIV-positive adults choose not to engage in care.

**Methods:** Using a qualitative approach, we purposively-sampled 50 ART-eligible adults presenting for VCT across a spectrum of decision making and their care providers, and performed in-person, semi-structured interviews from 3/2012-2/2013. The goal of this strategy was to perform in-depth investigation by tapping multiple perspectives, to gain a detailed understanding of factors driving ART-refusal. An inductive approach to category construction, based upon grounded theory methodology, was used to analyze these data.

**Results:** Our data indicate that ART-refusal may be driven by a weighing of the perceived risks of taking ART. Individuals may decide taking ART ultimately does more harm than good, despite widespread recognition of its efficacy. Refusers reported that ART was efficacious and life-saving, however, they expressed a higher concern for risks associated with starting ART, including an inability to adhere, stigma resulting from taking ART or being seen at the clinic, and medication side-effects. Ultimately, the costs of being on treatment outweighed the benefit for those who refused to initiate.

**Conclusions:** Optimizing engagement and long-term retention of HIV-positive individuals in care will require understanding their motivation for treatment refusal. Our explanatory framework using a risk perception model provides a basis for further research and interventions designed to engage HIV-positive individuals in care.
184 Validation of the Massachusetts General Hospital Virologic Failure Prediction Rule

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Background: A rule predicting virologic failure (VF) in virologically suppressed HIV-infected patients was developed at Massachusetts General Hospital (MGH) and validated at Brigham and Women’s Hospital, an affiliated hospital. Whether the 1-year VF prediction rule could be generalized to other settings has not been tested.

Methods: Data from a community-based HIV clinic, the AIDS Resource Center of Wisconsin (ARCW), was used to further validate the prediction rule. Study period was 4/1/2006 to 4/1/2008. Inclusion criteria: HIV+ and ≥2 clinic visits. Study entry: first clinic visit with RNA ≤400 while on combination antiretroviral. The MGH 1-year VF prediction rule uses the “risk score,” the sum of seven risk factors: suboptimal adherence (<85%); CD4 <100 cells/µL; highly ART experienced; drug/alcohol use; missed ≥1 appointment; prior VF; and suppressed <12 months. VF was defined as at least 2 consecutive HIV RNA measurements >400 copies/mL documented in the electronic health record within the first year of follow-up or 1 HIV RNA measurement >400 copies/mL and no confirmatory test in the subsequent 3 months. VF rates and univariate/multivariate associations were calculated. Chi-square and c statistics were used to test the calibration and discrimination of the risk scores and Kaplan-Meier curves and Log-Rank were used to compare risk categories (score 0-1, 2-3, >4).

Results: 356 patients with two-years of follow-up data were included in the analysis. Sixty-eight (19.1%) and 99 (27.8%) experienced VF at year 1 and year 2, respectively. The 1-year VF model showed reasonable discrimination ($c$ statistic, 0.72) and calibration ($\chi^2 = 5.7; p=0.57$). Stratifying patients into low (0-1), medium (2-3), and high (≥4) risk categories resulted in 1-year VF rates of 7.5%, 15.6%, and 36.8%, respectively.

Conclusions: The MGH 1-year VF prediction rule has reasonable discrimination using community-based HIV clinic data and could be used to identify patients for adherence interventions.

185 Patterns and Motivation for HIV Testing and Time from HIV Diagnosis to Antiretroviral Treatment (ART) Initiation at Six Clinics in Ethiopia

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Background: HIV testing plays an important role in the timeliness of diagnosis and ART initiation, with the potential to reduce morbidity and onward HIV transmission. We examined HIV testing history among persons initiating ART at six clinics in Oromia State, Ethiopia.

Methods: Using a structured questionnaire, adults (n=563) initiating ART at six clinics during 2012 were interviewed at the time of HIV treatment initiation about HIV testing history and circumstances, including timing, reasons for testing, and location of HIV-positive tests.

Results: Common reasons reported for testing among those initiating ART included feeling sick (54%); death, sickness or HIV diagnosis of a spouse or partner (17%); and a provider recommendation (14%). 55% reported receiving their HIV diagnosis via a provider-initiated test. In addition to the positive test that resulted in enrollment into HIV care, 223 (40%) reported an additional prior HIV test (57% reported a prior positive test and 42% a prior negative test). One-third of all participants reported doubt about their HIV-positive status after diagnosis, and this was more common among individuals with multiple HIV-positive tests (OR 6.1, 95% CI 4.0-9.4, p<0.0001). Among 168 patients who delayed care enrollment by >1 month after diagnosis or reported >1 HIV-positive test, reasons included feeling healthy (19%), disbelief about HIV positive status (19%), concern about being seen at the clinic (14%), work or family responsibilities (10%), and reluctance to start ART (8%). The median time between diagnosis and ART initiation among patients with only one HIV-positive test was 2.0 months (IQR 1.0-11.9) and 21.2 months among those who had ≥1 HIV-positive test (IQR 7.6-51, p<0.0001).

Conclusions: We observed high levels of provider-initiated testing, combined with missed opportunities for prevention and timely care initiation among those with prior HIV tests, underscoring the important role of post-test counseling.
**187 Healthcare-Related and Other Major Determinants of Recent HIV Testing among New York City (NYC) Adults, 2010**

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**Background:** HIV testing guidelines increasingly call for systematic screening for HIV infection in clinical settings. We examine healthcare-related and other major correlates of recent HIV testing in a population-based sample of NYC adults.

**Methods:** The 2010 NYC Community Health Survey (CHS) is a stratified random sample of 8,665 non-institutionalized adults aged >18 years. The association of recent HIV testing (last 12 months) with receipt of other medical screening tests was investigated using multivariate logistic regression, accounting for other factors related to HIV testing (age, gender, race/ethnicity, socioeconomic status, sexual activity/behaviors, health insurance, and marital status). Subgroup analysis by gender and sexual activity was performed. Estimates were weighted and age-adjusted to the 2010 US standard population.

**Results:** Among all participants, sexual activity in the last 12 months (adjusted odds ratio [AOR]: 2.8; 95%CI: 2.2-3.6), Black and Hispanic (vs. White) race/ethnicity (AOR: 3.5; 95%CI: 2.7-4.5 and 2.6; 95%CI: 2.0-3.5, respectively) were the strongest predictors of recent HIV testing. Among all sexually active participants, number of sex partners, history of anal sex, and condom use at last sex were not significantly associated with recent HIV testing. Among women<65 years old, Pap smear was significantly associated with recent HIV testing (AOR: 4.3; 95%CI: 2.8-6.8) while mammography (among women >40 years) showed a weaker association (AOR: 1.5; 95%CI: 1.0-2.3). Among older sexually active adults, while condom use was associated with recent HIV testing among those eligible for mammography (AOR: 1.7; 95%CI 1.0-2.7) and colonoscopy (AOR: 2.7; 95%CI 1.7-4.3), actual receipt of these screening tests was not.

**Conclusions:** Receipt of medical screening may be an important determinant of HIV screening. However, there may be missed opportunities among sexually active adults at high risk for HIV infection. Availability and accessibility of HIV testing outside of clinical settings remains important for those at risk for HIV who may not routinely access medical care.

**188 Identification of Intentional Non-Adherence to HAART in Routine Care**

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**Background:** To assess the extent to which HIV care providers successfully identify intentional non-adherence to HAART.

**Methods:** A routinely-collected assessment of patient-reported outcomes (PROs) was administered to patients immediately prior to their clinic visit over a ~2 year period from March 2011 to Feb 2013. Patients who indicated missing 2 or more doses in the past 30 days were asked whether or not they had missed any doses during this time period “on purpose”. Medical records were reviewed from the same day of the assessment. Provider notes pertaining to adherence were extracted and coded for 1) whether adherence was discussed; 2) whether the discussion included patient mention or admission of non-adherence; and 3) whether reasons for non-adherence were identified. Notes were also coded for thematic content indicating rationale for missed doses and/or HAART interruption.

**Results:** 435 PRO assessments indicated missing 2 or more doses in the past 30 days. Of these, 68 sessions indicated missing doses “on purpose”, representing 61 unique patients. In 12 (18%) of visits, providers documented 100% adherence to HAART. Two-thirds of these patients were non-Caucasian. 10 (15%) of visits lacked provider documentation regarding adherence. Non-adherence was documented in 46 (68%) of provider notes. Of these, 4 (10%) did not document a reason for non-adherence; of the 42 that did (91%), 85% documented a reason for intentional non-adherence, and 15% documented a single non-intentional reason (i.e., forgetting). Nearly all visits in which non-adherence was documented described a single reason; most commonly avoidance of side effects (20%), and reasons related to substance use (15%).

**Conclusions:** PROs are known to catalyze discussions of adherence. However, there is room for improvement. Provider training and identification of feedback delivery needs may enhance utilization of patient-reported adherence measures.
Understanding Patient and Provider Priorities for Measuring Patient-Reported Outcomes Such as Adherence in Routine Clinical Care Settings

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Background: As part of the NIH-based Patient Reported Outcome Management Information System (PROMIS) initiative we sought to understand how HIV-infected patients and their providers prioritize patient-reported domains for inclusion in clinical care.

Methods: Patients living with HIV participated in focus groups and completed ranking exercises with lists of PRO domains. We conducted individual interviews with ~20-25% of patients surveyed to assess rationale for rank order choices. Using modified Delphi techniques, HIV providers from 8 clinical CFAR Network of Integrated Clinical Systems (CNICS) sites across the US ranked PRO domains for clinical care and research. List 1 included anger, anxiety, depression, fatigue, physical function, pain, and sleep disturbance. List 2 included alcohol abuse, cognitive function, HIV stigma, HIV and treatment symptoms, medication adherence, positive effect, sexual risk behavior, sexual function, social roles, spirituality/meaning of life, and substance abuse. Interviews were transcribed and coded for domain-specific and thematic content.

Results: 74 providers and 66 patients participated; 15 of the 66 patients were interviewed. In list 1, concordance was high between patients and providers; both patients and providers ranked depression as most important to address in clinical care. In list 2, both ranked adherence highly (#1 for providers, #2 for patients). However, patients ranked substance abuse and alcohol abuse considerably lower than providers as important to address in care (#7 and #8 vs. #3 and #4, respectively). Substance use, but not alcohol, ranked even lower among Black patients (#10). HIV-related stigma ranked third most important to patients, and seventh for providers. Among women, Latinos, and those diagnosed with HIV <5 years, stigma ranked first.

Conclusions: Both patients and providers ranked adherence and depression as key PRO priorities for clinical care. In contrast, providers considered some of the key adherence barriers such as alcohol and substance use as much higher priorities for clinical care than patients.

Qualitative Exploration of Experiences with Receipt of HIV Diagnosis and Engagement in HIV Care among MSM Living with HIV in Beijing, China

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Background: Despite the availability of HIV care at minimal or no cost in Beijing, timely linkage into and subsequent retention in HIV care remains problematic for a number of HIV positive men with have sex with men (HIV+MSM). However, the extent to which stigma, structural barriers and affective struggles factor into personal narratives about one’s experience with being diagnosed positive and linking to care is not well understood. We sought the insights of HIV+MSM to address this gap.

Methods: Three focus groups with HIV+MSM in Beijing. Guides included questions about experiences of testing positive and with HIV-care. Groups were recorded, transcribed, and translated into English, and reviewed by 3 coders (2 fluent in Mandarin and 1 English only). Themes were identified using framework analysis focused on extracting guidance for the study team in developing a linkage intervention for this community.

Results: Focus group participants (n=40) ranged in experiences of diagnosis receipt, from highly stigmatizing to supportive. Examples of interactions with providers included being called “a carrier” or lectured on HIV resulting from their ‘careless’ or ‘incorrect’ behaviors. Stigma was noted as a major barrier across most stages of the HIV continuum of care, both emanating apparently from testing and care sites and from the community. Recommendations included normalizing testing and treatment, mobilizing existing social support structures specifically for MSM, addressing crisis, and improving negative attitudes encountered in medical care. Structural improvements desired included extending hours of care clinics, decreasing wait times at clinic and increasing clarity in treatment plan.

Conclusions: Experiences with discrimination and stigma were reflected in focus group discourse. HIV diagnosis was reflected on as a time of crisis for most participants, exacerbated by the isolation of stigma. Concrete recommendations provided by the groups will be utilized in creating a peer based intervention to support HIV+MSM in Beijing.
Measuring Antiretroviral Therapy Adherence in a Clinical Care Setting in the Recent IDU-Driven HIV Epidemic in Estonia

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Background: Poor health outcomes (e.g. virologic failure) of patients on antiretroviral therapy (ART) and recent rapid increase in HIV drug-resistance in Estonia have been suggested to stem predominantly from poor adherence. A reliable adherence measure is vital for monitoring adherence and delineating adherence related barriers and facilitators. Thus two indirect methods for measuring adherence (patient self-report, pharmacy refill) were compared in a clinical care setting.

Methods: We report data from a prospective study comparing patient self-reported (3-day recall) and pharmacy refill based adherence measures to viral load from 125 patients receiving outpatient HIV care (a convenience sample).

High adherence rate for the self-reported measure was defined as 90% of pills taken as prescribed, and for pharmacy refill as 90% of days covered with medication during past 1 month.

Results: Participants were 54% male, mean age 34 years, infected with HIV for average 5.4 years (62% of through intravenous drug use), and on ART for an average 1.8 years.

Majority (97%) of respondents reported high adherence based on self-report and less than half (46%) were highly adherent according to pharmacy refill data (p<0.001).

At the end of the reporting period, viral load was undetectable for 61% (95% CI 51…70%) among those highly adherent by self-report and for 67% (95% CI 53…79%) highly adherent by pharmacy refill data. Neither the self-reported nor the pharmacy refill based adherence was associated with detectable viral load (Fisher’s exact test p-values 0.507 and 0.569, respectively). Receiver operator characteristics analysis indicated that both the adherence measures had similar predictive values for indicating detectability of viral load (areas under the curve 0.507 and 0.569, respectively, p=0.231).

Conclusions: Measuring ART adherence remains complex. Rigorous but user-friendly measures of adherence fitting into busy clinic routine are needed. Reasons for non-adherence warrant further research, and enhanced adherence support is vital.

Text Messaging Improves Antiretroviral Adherence among Depressed Individuals: Using Ecological Momentary Assessment to Inform Interventions

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Background: Antiretroviral (ARV) medication regimens have been greatly simplified; yet, subgroups, such as HIV+ persons with co-occurring bipolar disorder (HIV+/BD+), still evidence poor ARV adherence. Recent evidence suggests that texting interventions improve ARV adherence. Depression has been long-linked to poor adherence, and ability to assess mood and adherence via ecological momentary assessment (EMA) may provide critical information for adherence interventions.

Methods: 50 HIV+/BD+ persons were randomized to either “individualized Texting for Adherence Building” (iTAB; n=25), which provides personalized text adherence reminders at participant-selected times, or an active comparison intervention (CTRL; n=25). Both groups received daily text message evaluating mood. A sentinel ARV was tracked daily using an electronic monitoring system for approximately 30 days. Participants who took at least one dose per day were classified as “adherent” for the day. We used mixed effects regression models to assess the influence of time, mood, and intervention on daily medication adherence. Time effect was measured by odds ratio per 5-day increase.

Results: ARV adherence decreased over time in both the iTAB and CTRL groups (OR=0.9, p=0.01). Overall responsiveness to the mood messages dropped significantly over time among those classified as “Depressed” (i.e., reporting depressed mood on greater than half of the days followed; n=6, OR=0.71, p=0.002), while the overall response rates of those who reported no mood problems on most days (n=41) were stable (OR=1.03, p=0.46). Interestingly, a significant 3-way interaction emerged suggesting that “Depressed” participants assigned to iTAB were less likely to show time-related ARV adherence declines compared to CTRL (iTAB: OR=1.03, p=0.05; CTRL: OR=0.50, p=0.006).

Conclusions: Personalized daily text messaging reminders may reduce ARV nonadherence among depressed individuals. As medication adherence interventions for HIV-infected persons evolve, real-time interventions using text messaging and EMA should be considered to possibly enhance and improve long-term adherence outcomes in persons at risk for nonadherence.
196 Impact of Integrating HIV Services with Other Development Programs in Agriculture, Nutrition and Saving Scheme to Promote Adherence for Orphans and PLWHA in Rwanda: Lessons from Ibyiringiro Project

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Introduction: USAID/Ibyiringiro Project is funded through the United States President’s Emergency Plan for AIDS Relief (PEPFAR), to improve access to high quality, sustainable and comprehensive services, through integrated HIV services with livelihood security and resiliency for orphans and households affected and afflicted by HIV and AIDS.

Description: Ibyiringiro Project was implemented by World Vision in partnership with ARDA and FHI in six out of 30 districts in Rwanda. The project integrated HIV prevention care and treatment services with nutrition education, counseling, assessment and monitoring of body mass index (BMI); promoting vegetables and fruits gardens, Framers Field Schools through the use of energy saving Bio-Intensive Agricultural Techniques (BIAT), household budgeting, financial management and access to low interest savings and lending scheme (SILC), and created linkages to complementary package to clinical services for PLWHA.

Lessons Learned: Among the 6972 total beneficiaries, 78% (3655 females, and 1765 males) were living with HIV/AIDS; 85% of the children had normal BMI, 5% were moderately malnourished while only 1% was severely malnourished. The average a total of 5832 (4093 females and 1739 males) beneficiaries monthly participated in HIV/AIDS awareness programs, positive living, hygiene and sanitation, adherence to ARTs and PMTCT.

A total of 6640 farmers received vegetable and fortified seeds with training in BIAT. The BIAT technique beneficiaries reported a 3-5 times increased production of vegetables with increased household access to vegetables and food security, improved household income generation and resiliency of HIV/AIDS affected families and empowered beneficiaries economically.

Recommendations: Integrating HIV and AIDS comprehensive services with other development programs in agriculture, nutrition and economic empowerment interventions improved health outcomes for orphans and PLWHA and should form the basis of minimum package for effective HIV interventions for vulnerable populations.

197 Examining Relationships between Neuro-Cognitive Impairment and Antiretroviral Treatment Adherence among HIV-Positive Adults who Abuse Alcohol

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Background: As a neurotropic virus, HIV may cause a range of neuro-cognitive impairment (NCI), which is frequently hypothesized to adversely affect disease management, specifically, adherence to antiretroviral treatment (ART). Because adherence has been shown to reduce viral load to levels where health outcomes improve and risk of transmission is greatly reduced, it is important to understand the determining role of NCI, particularly in more compromised alcohol-abusing patients.

Methods: Measures of NCI included Color Trails Test 2 (CTT2); Short Category Test (SCT); and the Rey Auditory Verbal Learning Test (AVLT). Alcohol use severity was measured using the Alcohol use Disorders Identification Test (AUDIT) and adherence was a self-reported percentage over a seven day period. Data was gathered from 171 HIV-positive adults in Miami, FL who reported recent alcohol use-the majority were male (61%) and of minority race/ethnicity (85%); mean age was 45.9; 72.5% reported 100% adherence; and 45.6% did not complete high school. NCI data was normed for this sample on age, gender, and education. Significant (p<0.1) factors from bivariate linear regression were included in a multivariate linear regression.

Results: In this sample a mean AUDIT score of 15.7 indicated hazardous drinking. Means of raw SCT (40.1), AVLT (9.2), and CTT2 (58.2) exceeded norms and indicated possible impairment. In bivariate regression, greater age (p=.003) and lower education level (p=0.49) significantly predicted ART adherence. In the multivariate model, both factors remained significant predictors: greater age (p=.003 and lower education level (p=0.49) significantly predicted ART adherence. In the multivariate model, both factors remained significant predictors: greater age (p=.002; CI=.23, -048, ß=-0.64) and lower years of education (p=.038; CI=-5.4, -0.16; ß=-2.8). Neither bivariate nor multivariate analyses indicated a relationship between NCI and ART adherence.

Conclusions: While NCI may seriously impact HIV-positive adults who use alcohol, other factors such as age and education may play a greater role. Additional research investigating factors that may affect ART adherence in this population is recommended.
Fluctuations in Depressed Affect among Men who have Sex with Men on Antiretroviral Therapy

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Background: Depressed affect has been identified as a risk factor for suboptimal treatment adherence but is usually studied as a relatively stable variable. The current study examined fluctuations in depressed affect over the course of seven weeks in men who have sex with men (MSM) taking antiretroviral medication.

Methods: Participants comprised a convenience sample of 116 HIV-positive MSM living in New York City taking antiretroviral medication. Men completed a weekly structured survey and reported their level of depressed affect in the past week in Week 1, 3, 5, and 7. To describe sources of variance and reliability in depressed affect, we decomposed the available variance, following Cronbach’s generalizability theory approach, as described by Shrout and colleagues (Shrout & Lane, 2011; Cranford, Shrout, Iida, Rafaeli, Yip, & Bolger, 2006).

Results: Individual differences between persons accounted for a quarter of the total variance in depressed affect over the seven weeks of the study (depressed affect: 23%). Reliability for these individual differences was high ($R_{IF} = 0.98$). In addition, we found that another substantial part of variance came from fluctuations in depressed affect from week to week (11%). Reliability for these within-person fluctuations was high as well ($R_{C} = 0.85$).

Conclusions: In line with current approaches to studying distress, depressed affect showed some stability over seven weeks in MSM taking antiretroviral medication. In addition, we found considerable fluctuations around the person mean across time, and these can be reliably measured. Fine-grained longitudinal studies that capture these fluctuations can help to gain a better understanding of the link between negative affect and adherence.

Informal Caregiver Reports of Care Recipients’ ART Adherence: Implications for Dyadic Intervention

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Background: Informal HIV care receipt has been found to be predictive of virologic outcomes of antiretroviral therapy (ART) in a population vulnerable to treatment failure. We examined associations between caregivers’ reports of recipients’ ART adherence and recipients’ viral load, and identified individual and relationship factors associated with agreement in these data. The findings will further an understanding of caregivers’ involvement in a vulnerable population’s ART adherence, with implications for adherence intervention.

Methods: Participants were former or current injection drug using (IDU) persons on ART and their main caregivers (n=256 dyads). Analysis included multivariate logistic regression.

Results: Care recipients reported a median of 10 years on ART, 23% impaired physical functioning, 85% African American race/ethnicity; 70% were found to be virally suppressed. Of caregivers, 46% were recipients’ partners, 29% kin, and 26% friends; 59% reported someone close had died of AIDS, 74% reported recipient expressed considerable affection and gratitude, and 36% reported fear of HIV (re)infection from HIV care giving. Results indicated 73.4% of caregivers’ adherence reports agreed with recipients’ viral suppression status. Adjusting for cohabitation and recipient drug use, agreement was positively associated with recipient expressing affection or gratitude, caregiver having had someone close die of AIDS, and fearing care giving related HIV (re)infection. Agreement was not associated with role relation.

Conclusions: Our findings provide further evidence of caregivers’ role in this population’s ART adherence. The results suggest strategies for promoting caregivers’ attentiveness to recipients’ ART adherence and drug users’ HIV health outcomes.
Reasons for Missing Doses and Optimal Adherence to HIV Medication: A Prospective Study among a Sample of People Living with HIV in Atlanta

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Background: Curbing HIV sexual transmission by virtue of undetectable viral loads requires sustained high levels of adherence to antiretroviral therapy (ART) among people living with HIV/AIDS (PLWHA). This study aims to facilitate design of adherence intervention by exploring reasons for missing doses and their relationships with ART adherence.

Methods: 300 PLWHA who self-reported to have missed HIV medication during past month were followed for five weeks with a baseline assessment at week one and two follow-ups taken two weeks apart. We evaluated the frequency at which each of the 15 listed reasons was selected and their stabilities over time by gender, chart-abstracted viral-load, and involvement in unprotected discordant sex in the past four months. Generalized equation modeling was used to assess relationships between reasons and ART adherence, measured by unannounced pill counts.

Results: The top four reasons with 20%-40% of endorsement were “I was too busy doing other things”, “something unexpected came up”, “I slept through dose time” and “I did not have the right pill with me at the time”. These reasons also had higher stabilities with 66%-73% of participants who chose the reason to have always chosen the same reason. The pattern of selected reasons differed slightly by gender and involvement in unprotected discordant sex, but not viral-load status. Reasons that predicted optimal adherence (pill counts/285) over the next two-week period were: “I was too busy doing other things”, “I got confused about what I should take”, “I was too drunk or high at the time”, “I could not afford my medication”, and “I have been drinking so I did not take my medication”.

Conclusions: Adherence interventions may work to improve time management skills, and reduce alcohol use among PLWHA. Efforts are also needed to reduce pill burden and costs, and identify chronic difficulties of adherence.

Predictors of Antiretroviral Adherence among HIV-Positive Alcohol Abusing Adults: A Bayesian Network Model

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Background: Nearly perfect treatment adherence is essential for yielding positive health outcomes and reducing HIV transmission. Bayesian network modeling is much underused in examining probabilities of varying antiretroviral treatment (ART) adherence levels for important variables such as neurocognitive impairment (NCI), alcohol abuse, and social contextual factors.

Methods: Data was gathered from 171 HIV-positive adults in Miami, FL who report recent alcohol use—the majority were male (61%) and of minority race/ethnicity (85%); mean age was 45.8; 73% reported 100% adherence; mean years living with HIV was 16.4; and 45.6% did not complete high school. Adherence was a self-reported percentage over a 7-day period. Stress was measured using Life Experiences Survey and social support was measured using the Medical Outcomes Test. Measures of NCI included Color Trails Test 2 (CTT2); Short Category Test (SCT); and the Rey Auditory Verbal Learning Test (AVLT). Alcohol use severity was measured using the Alcohol use Disorders Identification Test (AUDIT). Means were imputed into GeNie software to yield discretized values using a hierarchical method for the Bayesian analysis in order to examine potential impact upon mean adherence.

Results: Several factors were identified as significant in this model: increased stress, greater HIV/STD knowledge, female gender, lower CTT2, and lower AVLT were associated with greater mean adherence and entered into the analysis. The model allows for examination of probabilities: e.g.—if 100% of the sample indicated high stress scores, 68% of the total would be expected to report perfect treatment adherence. If 100% of the sample had higher CTT scores, ART adherence drops to 61%.

Conclusions: Bayesian modeling is a useful, dynamic form of analysis allowing us to consider what changes in a health outcome or behavior like ART adherence might be expected with changes risk factors such as NCI and stress.
Medication Assistance from Family or Friends is Protective of Effects of Current Substance Use on Virologic Control: Implications for Intervention

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Background: Informal care giving relationships have robust effects on physical and mental health outcomes of persons with serious chronic conditions. Few studies have examined caregiver effects on care recipients’ medical adherence as a potential pathway to the health benefits of care giving relationships. Understanding effects of caregiver assistance on antiretroviral (ART) adherence among drug using populations at risk for failed ART will inform interventions to improve their HIV health outcomes.

Methods: Participants were urban current or former injection drug using (IDU) persons on ART (n=383). Measures included self-reported assistance with medications, and various types of medication-related assistance, in the prior year; and depressive symptoms, assessed by the CES-D. Analysis included multivariate logistic regression of independent variables on viral suppression.

Results: Participants reported a median of 10 years on ART, 58% reported current drug use or alcohol misuse (including 50% current heroin or cocaine use), 85% African American race/ethnicity, 23% reported impaired physical functioning and 37% any assistance with medications in the prior year, and various ways their main caregiver assisted them with medication taking. 70% were found to be virally suppressed. In analysis adjusting for depressive symptoms and other confounders, a significant interactive effect was found in regard to associations of medication assistance and current substance use on viral suppression. For those who reported no assistance with medications, current substance use was strongly negatively associated with viral suppression; for those who received medication assistance, current substance use was not significantly associated with viral suppression.

Conclusions: The findings contribute to growing evidence of the role of informal HIV caregivers on medical adherence among vulnerable substance abusing populations. The study results suggest that promoting informal care giving and caregivers’ resources and skills for sustained care may be viable approaches to optimizing health outcomes and addressing HIV health disparities among this vulnerable population.

Suicidal Ideation in Patients with HIV Enrolling in Clinical Trial of Measurement-Based Depression Care

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Background: Depression is a barrier to antiretroviral adherence for people living with HIV (PLWH). Measurement-Based Care (MBC) is an effective approach to expand availability, accessibility, and effectiveness of antidepressant therapy in primary care settings. As part of a clinical trial to evaluate the use of MBC for PLWH, suicidal ideation (SI) was assessed. We hypothesized that a greater burden of physical illness would be associated with SI in this population.

Methods: Depression screening was performed with PHQ-9, which includes questions on emotional (5), and physical (3) symptoms and SI (1). Depression was confirmed with the Mini-International Neuropsychiatric Interview (MINI). Descriptive statistics and prevalence ratios were used to assess baseline characteristics, frequencies and predictors of SI.

Results: Depression screening was completed for 1286 patients and 72 (6%) reported SI (38% with PHQ9\(_{\geq10}\); 1% with PHQ9<10). The 245 enrolled study subjects were 44 years old (average), male (70%), infected with HIV for >3 years (85%), had HIV suppression (65%) and a cd4 count >500 c/mm\(^3\) (56%). All study subjects had PHQ-9 score >8; 71% reported no SI; 17% reported passive SI and 12% reported active SI and a prior history of a suicide attempt was present in 30%. Presence of any SI was not associated with age, gender, time since HIV diagnosis, emotional or physical symptoms, depressive severity, HIV RNA, CD4 count; active (vs. passive) SI declined with age (PR per 10 years=0.60, 95%CI=0.42-0.86). Prevalence risk of active SI for those with a diagnosis for HIV <3 years was 2.18-fold compared to those with HIV >3 years but did not reach statistical significance (p=0.09).

Conclusions: SI is a common symptom and plans for depression screening must include management strategies for providers and clinic staff who may not have experience evaluating patients with SI.
Initiation of a Retention in Care (RiC) Program in a Semi-Rural Clinic in the Southeastern United States

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Introduction: People living with HIV (PLWH) who do not regularly see an HIV provider risk worse personal health outcomes. This abstract describes initiation of a clinic-level retention in care (RiC) program that strives to better assess and address barriers to retention in care in a semi-rural clinic.

Description: The target population was defined as all living, non-relocated patients ever seen at the clinic who had not attended a visit for >6 months. In the first three months, 105 patients were identified. Clients were added on a rolling basis. 40 (38%) were reached by telephone. 65 (62%) clients have not been located. 25/40 (63%) contacted clients returned to care. 18/65 (28%) not located returned to care. Patients reached by telephone were invited to participate in a survey that queried them about perceived barriers to HIV care. 20/40 participated.

Lessons Learned: Clients reached by the RiC coordinator were more likely to return to care. However, only a minority of the clients have been located. Of the survey participants, gender was a predictor of return to care (RTC). 8/9 (89%) female participants returned; 4/11 (45%) male participants returned. Those who cited scheduling conflicts as a significant barrier were more likely to RTC (46% vs 14%). Other survey questions assessing demographics and perceived barriers did not identify additional significant predictors of RTC in the current sample.

Recommendations: Establishment of a RiC program with review of all clients ever served is feasible in a medium-sized semi-rural clinic and results in increased RTC, even by patients with multi-year absences. Attention to maintenance of accurate client contact information is critical to RiC. Health system navigation assistance by a RiC coordinator may be particularly helpful to clients who perceive that scheduling appointments is a problem. More qualitative information on barriers to RiC for semi-rural PLWH is needed.

Impact of ART Adherence Counseling and Access to Comprehensive Prevention with Positive (PwP) Services for PLHWA: Experience from STEPS OVC Project in Zambia

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Introduction: USAID funded Sustainability Through Economic Strengthening, Prevention and Support for Orphans and Vulnerable Children (STEPS OVC) is a World Vision-led project with overall goal to strengthen capacity of Zambian communities to provide sustainable HIV prevention, care and support services. Assessing the impact of adherence counseling on access to full PwP services for PLWHA is presented in this abstract.

Description: Adherence counseling and assessment were critical components of STEPS OVC intervention. Adherence counseling were assessed in six areas (assessment of ART adherence, sexual activity, sexually transmitted diseases (STIs), HIV status of household members, family planning (FP) needs and community support needs) and clients were linked to PwP services. ART adherence also assessed emerging ART drug resistance, body mass index (BMI), mid-upper arm circumference (MUAC), self-report of missing doses and spot check of ART at home. Observations were monitored and documented over the life of the project.

Lessons Learned: STEPS OVC registered 390,995 OVC in partnership with 388 local CBOs/FBOs of which 80% of the beneficiaries received at least one care service in FY 2012. Over same period a total of 93,020 PLHIV on ART (37,866 males; 54,154 females) received adherence counseling and 34% (31,407) of these were children under 18 years. All beneficiaries were assessed for sexual activity and HIV status of household members; 76% were assessed for STIs, 65% for FP needs and only 4% received all six PwP package. Identified gaps in access to full PwP services included training resources focusing on basic care package, incomplete documentation of all services by caregivers and mentorship for caregivers as they apply their new PwP skills.

Recommendations: ART Adherence counseling is an essential link to PwP services, and appropriate training resources, adequate documentation and mentorship of community caregivers are necessary in improving access to full PwP package for beneficiaries.
Development and Feasibility Testing of a Bidirectional Text Messaging Tool to Promote HIV Treatment Adherence among Non-Urban Substance Users

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Background: Adherence interventions among HIV+ substance users show moderate, temporary effects and come too late to prevent viral rebound. Bidirectional text messaging could reach non-urban patients to assess HIV nonadherence and respond in real time to improve adherence.

Methods: We have developed a combined HIV adherence assessment and intervention text messaging tool for non-urban drug users with a modified ecological momentary assessment methodology. The tool has a web interface for study staff to manage participants, generates a message log of all communications, and sends automated text messages to participants. Participants respond to queries about medication adherence, mood, and substance use. The substance use query is coded for privacy. The study will compare the 12-week text messaging intervention to usual adherence care at 3M and 6M on objective primary outcomes of Missed Visit Percentage, Pharmacy Refill Adherence, and Unannounced pill counts by telephone.

Results: Among the first 9 patients randomized to the text messaging condition, the system recorded 2941 sent & 1153 received messages. Participants responded to 76% of adherence, 63% of substance use, and 58% of mood queries. Medication queries resulted in responses that were 59.6% positive and 8.5% negative, with nonresponse to 32%. Mood responses were 57% positive and 43% negative. Participants reported no drinking/drug use in the past 24 hours to 40.3% of queries, and reported substance use to 36% of queries.

Conclusions: Non-adherent people living with HIV in non-urban settings responded to medication, mood, and substance use queries, but initiated few messages. Participants responded to over half of all queries. Patients will report poor mood and substance use, but just-in-time reporting of nonadherence is uncommon. Nonresponse may indicate nonadherence or episodes of drug use.

Self-Perceived vs. Calculated HIV Risk as Indicators of Willingness to Use Pre-Exposure Prophylaxis

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Background: Washington, DC has a generalized HIV epidemic with a 2.7% prevalence rate and all major risk groups affected by HIV. With the availability of pre-exposure prophylaxis (PrEP), significant reductions in HIV incidence may be possible; however, uptake of PrEP by at-risk individuals will require awareness of one’s HIV risk profile and interest in using PrEP as an HIV prevention method. The objective of this analysis was to compare self-perceived to actual HIV risk behaviors and to determine how HIV risk might impact PrEP uptake.

Methods: We surveyed clinic-attending populations at three DC locations and assessed participants’ demographics, behaviors, self-perceived HIV risk, and willingness to use PrEP. Using DC HIV/AIDS case and behavioral surveillance data for known HIV risk factors, an objective measure of participant risk was calculated. The median score was used to dichotomize calculated risk: no-low risk (NLR) versus moderate-high risk (MHR) categories. Distribution of calculated risk (CR) was compared to self-perceived risk (SP) and potential differences between the two measures were assessed in relation to potential PrEP use.

Results: 278 participants reported their SP HIV risk; 69.1% reported NLR and 30.9% reported MHR. On a scale of 7.5-54.2, the median CR was 30.9 (range: 9.80-49.05). After stratification, 52.4% of participants were at NLR for HIV and 47.6% were at MHR. There were no statistically significant differences in CR versus SP risk with regard to potential PrEP use however there was marginally higher perception that PrEP would be highly effective among those with a higher CR (30.4% vs. 44.6%, p=0.0536).

Conclusions: When asked to assess their own risk for HIV, in comparison to local epidemics, persons may underestimate their actual risk for HIV. However, despite this difference in self-perceived versus known risks for HIV, willingness to use PrEP does not vary by risk category as hypothesized.
216 Remotely-Delivered Cognitive Behavior Therapy and Contingent Reinforcement of Real-Time Monitored Adherence for Substance Using People with HIV

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Background: Substance using HIV patients are at risk for non-adherence, and most interventions have had modest effects. Contingency Management (CM) is a promising intervention but requires face-to-face visits and its effects have not been maintained after discontinuation. We hypothesized the improvement in adherence from remotely-delivered CM could be maintained if it was combined with Cognitive Behavior Therapy (CBT), a substance abuse treatment that has been associated with a sustained and post-treatment benefit.

Methods: The Centralized Off-site Adherence Enhancement (CARE) program involved real time transmission of bottle opening data from a WisePill device to a website system which generated instant text messages to patients’ phones indicating the amount of cash-reinforcement earned if medication was taken within a specified time with monetary reinforcement wired to patients’ debit card. Real time reinforcement of medication-taking was coupled with twelve sessions of CBT by phone.

Results: Eight were recruited to pre-pilot the system. Patients were predominately male (75%) and Latino (62.5%), with median age 44.5 years. The intervention was well-received with good participation and retention (2/8 completed the pre-pilot with 97.6% and 91.6% persistence) along with targeted care management using a stepped-care approach with problem solving therapy (PST) for those with persistent issues. Care management is provided by clinic case managers enhancing generalizability to other HIV clinical sites.

Conclusions: The adherence pattern of the substance user population improved not only on taking the dose every day but reduce the dose timing error. CARE appears to be engaging and feasible. It is important to define therapist, patient, and site clinician roles prior to implementation as some logistic issues cannot be negotiated by phone with this patient population.

217 A Randomized Controlled Trial Protocol to Evaluate the Effectiveness of an Integrated Care Management Approach to Improve Adherence among HIV-Infected Patients in Routine Clinical Care

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Introduction: Many adherence intervention trials exclude psychologically complicated patients including those with substance use or depression and therefore do not consider many of the patients with inadequate adherence encountered in clinical settings. Additionally, many interventions are time-intensive and not feasible for routine care. Here we describe the design of an on-going randomized controlled trial (RCT) and the rationale for key methodologic decisions.

Description: We are conducting an RCT to determine the effectiveness of an integrated care management adherence intervention as part of HIV care. This study is based on routine integration of patient-reported outcomes (PROs) and an adaptation for clinical care of a previously tested care management approach. The intervention includes healthcare delivery team notification of PRO results (including measures of adherence and adherence barriers such as depression) along with targeted care management using a stepped-care approach with problem solving therapy (PST) for those with persistent issues. Care management is provided by clinic case managers enhancing generalizability to other HIV clinical sites.

Lessons Learned: We implemented PROs including adherence measures as part of routine clinical care which facilitated conducting this trial in a clinical setting. We use a stepped-care approach allowing interventions tailored to patient needs. PST and more intensive interventions are costly and time-consuming. The stepped-care approach allows us to target these interventions to those with the greatest needs, thereby enabling the incorporation of these tools into a busy clinical practice.

Recommendations: There is little data to guide implementation of adherence interventions into clinical care settings. Focusing on interventions that are both effective and feasible will help bridge the gap between research and clinical care, develop practice-informed science, and improve care.
**HIV Elimination Potential via TasP Is Determined by R0 More Than Early Transmission Fraction**

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**Background:** The debate on potential TasP effects often assumes there is a direct relationship between the number of transmissions that can be prevented per individual receiving prevention services and the total effects in the population. That is not the case, however, when two realistic aspects of HIV transmission systems are added to models. The two model aspects are dynamic partnerships and individual changes in casual sex risk behavior across time.

**Methods:** A model is presented to illustrate how and why these aspects of reality change what TasP can do.

**Results:** In systems where most transmissions occur within partnerships formed between infected and uninfected individuals, as low as 4% of transmissions might occur in early infection. That is because new partners are usually beyond acute infection and they cannot transmit back to the partner that infected them. But at these low early infection transmission fractions, other aspects of the system can make it TasP sensitive or resistant. When most transmissions occur during episodes of high risk casual sex behavior, as many as 77% of transmissions can occur during early infection. That is because high risk behavior and early infection coincide and because high risk settings get an influx of high risk susceptible individuals. Again, however, systems with these high rates of early infection can be TasP sensitive or resistant. A new way of formulating R0 and the relationship between endemic levels of infection and R0 explain TasP sensitivity. These relationships demonstrate how TasP population level effects can be high given low fractions of transmission prevented in individuals and vice versa.

**Conclusions:** Various implications of this for organizing HIV prevention services will be discussed. A major implication is that surveillance using genetic sequences and partner services data is needed to focus control efforts effectively.

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**Measurement of Self-Reported Adherence Behaviors Across Multiple Chronic Diseases**

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**Introduction:** Detection of inadequate medication adherence prior to the development of poor outcomes remains one of the most important and elusive goals in the treatment of patients across many chronic diseases. We need valid, accurate, and effective measures to collect self-reported adherence information for use both in clinical research and clinical care. Lack of a practical, systematic and cross-disease approach to self-reported adherence assessment is a critical gap in our healthcare delivery system.

**Description:** To develop a medication adherence behavior item pool for patient populations across multiple chronic diseases, we reviewed and assembled adherence instruments and items across multiple chronic disease conditions (e.g. HIV, diabetes, hypertension, dyslipidemia, transplant, epilepsy, etc.) with a particular focus on format, recall period, and self-rating items.

**Lessons Learned:** In assembling adherence behavior items used across disease conditions to develop an item pool, we found that a surprisingly large number and complex array of adherence behavior dimensions were being asked of patients such as frequency, missing partial doses, stopping therapy, avoiding medications, taking only if feeling sick/well, dose adjustments, etc. This increasing complexity was noted across several chronic diseases in contrast to the increasing simplicity of some measures used in HIV. There was a lack of consistency regarding which dimensions were measured across different diseases as well as varying time-frames and response task variability. Within specific dimensions, there was little or no consistency regarding how items were asked even within specific diseases.

**Recommendations:** We need valid, accurate, and effective measures to collect self-reported adherence for use both in clinical research and clinical care. Facilitating better communication regarding adherence measurement across diseases will facilitate advances made in one chronic condition leading to improvements in care across other diseases. Ideally, adherence measurement will be considered more broadly across chronic diseases, with less isolated development.
223 Cultural, Ethnic, and Socioeconomic Issues in Treatment Initiation and Adherence

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Background: Adherence to ART is a key issue in reduction of ART failure despite of free supply. The present study focusing on cultural, ethnic, and socioeconomic issues to measure the adherence rates in PLWHA on ART treatment and regimen

Methods: 484 PLWHA aged 15 to 49 years on ART excluding seriously ill cases, were studied after their consent in this longitudinal study from December 2008 to November 2012. The patients were followed for 6 months for adherence, & factors affecting adherence. The data was tabulated & analyzed using Microsoft excel & SPSS 14 version.

Statistical analysis: Chi square test, Fischer’s exact test, Logistic regression

Results: Among the 484 study population, Females (55%) preponderance, illiterates from rural areas (62%), unskilled by occupation (64%) & being from poor socioeconomic status (85.9%) were common. 31.6% were consistent adherers, & 81.4% had 95% adherence after 6 months of ART. Common reasons for missing doses were forgetfulness (44.9%), depression (22.5%), fear of disclosure (21.5%), adverse effects (17.1%), Loss of interest, loss of hours of job, myths & misconceptions about ART etc. Patients belonging to BPL families {Adjusted Odds Ratio (AOR) 3.763}, feeling burden to travel to ART centre (AOR 5.383), & CD4 counts at initiation (AOR 1.007) were negatively associated with adherence, while CD4 count increase after treatment (AOR 1.007), weight increase after treatment (AOR 1.277), being an earning member (AOR 2.865) were positively associated with adherence.

Conclusions: Suboptimal Adherence was noted in 81.4 % of PLWHA. Economic factors affect non adherence more than psychological & other health factors. There needs to be focus on female literacy, decentralizing ART services, economic incentives to PLWHA throughout treatment period, adopting DOT strategy as in Tuberculosis & on increasing the adherence levels of the patients to achieve lesser ART failures.

227 Accessing and Adhering to Medical Care after Prison Release: The Individuals Motivating to Participate in Adherence, Care, and Treatment (imPACT) Trial

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Background: Health benefits of effective HIV care provided in prison are often lost after release due to poor utilization of medical care. To address these issues, programs to help HIV-infected released prisoners access, utilize, and adhere to medical care are needed.

Methods: We used formative studies and theory to develop imPACT, a program to help released prisoners access, use, and adhere to HIV care after prison release. Four main components include: 1) Videos to prepare for release; 2) Motivational Interviewing (two in-prison in-person and six post-release phone sessions); 3) Link coordination to schedule medical appointments within 5 days of release; and 4) medication text reminders. Virally suppressed prisoners on antiretrovirals from two states were randomized into a controlled trial of imPACT. Unannounced phone pill counts are used to measure antiretroviral adherence.

Results: As of February 17, 2013, 118 participants had enrolled. Mean age was 42 years; 47% had not graduated high school; 74% were African American, 8% Latino, 21% women. Of the 63 in both arms who had completed 2 weeks post-release follow-up, 6 (10%) were working and 26 (41%) seeking work, 12 (19%) had stable housing; 48 (76%) had attended a medical visit, and 19 (30%) self-reported missing a dose of antiretrovirals. Of the 26 who had reached 6 weeks post-release, 42% had stable housing, 15% were working and 35% seeking work. 85% had attended at least one medical visit but 54% reported missing antiretroviral doses in the previous 2 weeks; 35% reported missing 4 or more doses.

Conclusions: Program components to help HIV-infected prisoners transition and adhere to care outside of prison are being implemented successfully in this trial. Longer term follow-up with the full sample comparing intervention and control groups will illuminate the intervention features associated with positive health outcomes, including viral load.
228 Adherence and Hypertension Control in Patients with HIV Infection

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Background: Hypertension is a common condition in patients with HIV infection that is often not adequately controlled. The role of medication adherence has not been studied.

Methods: Adult patients on medication for HIV infection and hypertension were recruited from outpatient HIV practices at a NYC academic medical center. Electronic monitoring (MEMS) was used to measure medication adherence for one ARV medication and one anti-hypertensive over ten weeks.

Results: We recruited 115 patients (59% male) with a mean age of 53.5 (s.d.=8.5); 57% of patients were black, 32% Hispanic, 10% white. The mean CD4+ cell count is 603 cells/mL (s.d.=286) and 94% have well controlled HIV infection (<400 copies/mL). Rates of medication adherence are high for both ARVs and anti-hypertensives [mean HIV =91.8% (s.d.=14.3); mean anti-hypertensive =89.2 (s.d.=18.5)] and highly correlated (r=0.78; p<0.01). Of those with well-controlled HIV infection, 38% have poorly controlled hypertension (systolic > 139 or diastolic > 89 mmHg). Subjects self-reported their illness perceptions and medication beliefs for HIV/ARVs and hypertension/anti-hypertensives. Subjects reported greater perceived need for ARVs (4.0 vs. 3.5, p<0.01) compared to anti-hypertensives and greater concern about taking ARVs (2.4 vs. 2.2, p<0.01). Of those with well-controlled HIV infection, 38% have poorly controlled hypertension (systolic > 139 or diastolic > 89 mmHg). Subjects self-reported their illness perceptions and medication beliefs for HIV/ARVs and hypertension/anti-hypertensives. Subjects reported greater perceived need for ARVs (4.0 vs. 3.5, p<0.01) compared to anti-hypertensives and greater concern about taking ARVs (2.4 vs. 2.2, p<0.01). Illness perceptions differed on multiple dimensions (p < 0.01) with HIV being viewed as less controllable by medication (3.7 vs. 3.9), more understood (4.0 vs. 3.7), more chronic (3.2 vs. 2.7), eliciting more emotions (2.8 vs. 2.3), and having more consequences (3.3 vs. 2.8) than hypertension. There was no difference between degree of personal control over HIV and hypertension (4.0 vs. 4.0; p=0.99).

Conclusions: Rates of adherence to ARVs and anti-hypertensives are high in this urban sample and highly correlated. Despite this, hypertension is not as well controlled as HIV. Patients view HIV as a more significant concern than hypertension. Efforts to improve hypertension control are needed as it is a risk factor for cardiovascular disease.

231 Mobile Phone Ownership and Appointment Attendance among HIV Care Clients in Swaziland Prior to an SMS Appointment Reminder Pilot - A Baseline

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Background: To improve appointment attendance among ART and pre-ART patients in Swaziland, the Automated Patient Appointment (AP) Reminder pilot was launched in five health facilities and 35 affiliated primary healthcare clinics (PHC). The AP Reminder automatically sends SMS messages to clients two days before their appointments, with prior consent. An analysis was conducted to investigate mobile phone ownership and appointment attendance before the pilot - “setting the baseline”.

Methods: Datasets from the existing HIV patient electronic medical records system were extracted from pilot facilities. Using Excel, Access and STATA, an analysis was carried out for the 12-month period preceding the pilot (April 2011-March 2012).

Results: Of the 21,810 HIV patients, females comprised 65%. Among ART patients, mean time since ART initiation was 33 months. Of the documented 131,473 client visits, mean number of visits/patient/year was 6. Mobile phone ownership was 66%, reaching 75% including treatment supporters when a client’s number was unavailable. Phone ownership varied by age (lowest among 2-14 years) and health facility type (lower in PHCs than secondary/tertiary). Total proportion of patients lost to follow-up (>90 days late, not returned into care) was 9%, reaching 14% among patients initiated 6 months prior, and 19% for patients initiated 1 year prior. Among scheduled appointments kept (n=112,730), 77% attended on exact date, while 88% were considered on-time (7 days early - 2 days late). Appointment timeliness was similar across gender and mobile phone ownership. For the 12% attending late, mean number of days late was 25.0, and was greater in PHCs (35.6 days) than secondary/tertiary facilities (18.7 days).

Conclusions: The combination of loss to follow-up, missed appointments, and mobile phone ownership provides opportunity for the AP Reminder to be impactful on appointment attendance, and possibly adherence to care and treatment. This finding provides an important pre-intervention baseline for the SMS appointment reminder intervention.
Women and Suboptimal ART Adherence in High-Income Countries

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Background: Women have been observed to be more vulnerable to suboptimal adherence than men in high-income countries. In British Columbia (BC), we explored whether this was because women were disproportionately from sub-populations where barriers to adherence are higher irrespective of gender.

Methods: Analysis was limited to HIV-positive, antiretroviral naïve adults 19 years and older in BC who initiated therapy from 1996 on. Optimal adherence was defined as taking ≥95% of prescribed antiretrovirals in each 6-month period. Viral suppression was defined as <500 copies. A longitudinal regression confounder model was constructed to determine whether gender was a significant predictor of suboptimal adherence after adjusting for Aboriginal identity, injection drug use (IDU), and year of first HAART use. An additional confounder model explored the relationship between viral suppression and suboptimal adherence after adjusting for gender, IDU, Aboriginal identity and year of first HAART use.

Results: A total of 2,443 individuals who initiated antiretroviral therapy between July 1996 and September 2010 were included in the adherence model. Of these, 486 (20%) were women, 1,241 (50.8%) were injection drug users, and 581 (23.8%) were of Aboriginal descent. Mean proportion adherent was 60.0% among men and 40.0% among women. Viral load suppression was significantly correlated with optimal adherence after adjusting for confounders. Women were less likely to adhere after adjusting for IDU, Aboriginal identity, and calendar year (OR: 0.63; CI: 0.52 to 0.75; p-value<0.001). When sub-populations were compared, we observed that women were less likely to adhere across all sub-groups, however, only among non-IDU Aboriginal women was it not significant. This was likely due to small numbers, as the OR remained less than one.

Conclusions: In BC, like other high-income settings, women are less likely to adhere to therapy than men. This relationship appears to be independent of IDU, Aboriginal identity, and calendar year.

Impact of a Continued Active Intervention Strategy on Adherence to Antiretroviral Therapy in Children Living with HIV

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Background: Since antiretroviral therapy (ART) has been successfully introduced, the infection has become a chronic manageable disease. Adherence is critical to achieve the benefits of the treatment. Multiple aspects, including social and psychological issues, as well as pediatrics formulations, affect adherence. There is limited evidence of strategies to improve children’s adherence. The aim of this study is to evaluate the effects of a strategy, active intervention (AI), to improve ART adherence in pediatrics.

Methods: A prospective study is being conducted in an HIV clinic. Patients having ART with suboptimal adherence (SOA) were identified. AI strategy consists in individual psychological interviews with patients and their caregivers, monthly workshops (WS) and telephone calls, during a 2 year period. To assess AI effect, viral loads were measured prior to initiation AI and after 6 months period. The results of this ongoing study are presented in this preliminary analysis.

Results: Thirteen of 38 patients on ART were identified SOA. Mean age was 9.38±4.56 years (range 4-16); 10 (76%) were female. Baseline viral load was >1000 copies/ml in all, 69% were class A of CDC HIV classification. Five of 8 patients older than 6 years knew their diagnosis. Prior to the AI strategy the mean number of clinical visits per year was 5±3.59. Mean time to access to clinic was 1.40 hours (range: 0.5-2.5). Twelve were cared by their parents. After 6 months of AI, mean psychological interviews was 4.53±2.43, mean participation at WS was 1.53, and a mean of 2.7 telephone calls/patient were done. After 6 months, viral load was <1000 c/ml in 7 patients.

Conclusions: An individual active intervention on children and their caregivers to improve adherence could positively impact viral load improving the course of the disease. Longer follow up time is needed to evaluate the effects of this intervention.
What are the Barriers to Antiretroviral Adherence in People from UK Black-African and Black-Caribbean Communities? A Qualitative Study

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Background: In the UK nearly one third of those initiating antiretroviral therapy (ART) report suboptimal adherence within 6 months. Substantial numbers of people of black African (UKBA) and black Caribbean (UKBC) heritage access HIV care, and identifying barriers to their adherence is a priority.

Methods: A cross-sectional, qualitative interview study explored barriers to adherence in 50 people living with HIV (PLWH) (43 UKBA, 7 UKBC) with a history of incomplete ART adherence. Purposive sampling ensured representation in terms of gender and symptomatic status. Interviews were subjected to thematic analysis.

Results: From the poorly adherent patient’s perspective, ART acts as a barrier to achieving/maintaining a good quality of life in its various domains. Physical wellbeing. PLWH associated ART, rather than HIV, with poorer physical health including the experience of side effects and pain. Psychological wellbeing. ART was a constant reminder of HIV which had negative connotations on how PLWH viewed themselves and how they perceived others saw them. Feelings of shame associated with ART added to difficulty in committing to treatment. Social relationships. The meaning of being on ART and its consequences, including stigma, ostracism, and homelessness, impacted on adherence over and above the consideration of the specific benefits (e.g. lower viral load) and costs (e.g. side effects). Independence. ART was associated with the loss of autonomy, forcing PLWH to rely on medication and doctors. Spirituality. For some PLWH dependence on ART attested to not being sufficiently deserving of miraculous healing.

Conclusions: Along with some culturally unique issues, some of the factors common to other populations with HIV can act in complex ways within these cultural settings. Representations of ART, which from a clinical perspective appeared to be misplaced, had a common-sense rationale. Interventions to improve ART uptake/adherence are likely to be more effective if they take into account these representations.

Cell Phones to Augment Study Visit Retention for HIV+ Individuals Recently Released from Prison Participating in the imPACT Study

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Background: HIV+ individuals released from prison are a challenging population to study longitudinally, with relatively high rates of loss to follow-up expected as participants navigate community re-entry. Cell phones are a useful method for communication with study participants through voice and text messaging. The imPACT Study is an RCT of an intervention based on motivational interviewing (MI), linkage to care, and cell phone text medication reminders, designed to maintain HIV suppression among HIV+ prison releasees in NC and TX. Within 48 hours of release, cell phones are provided to both the intervention (for phone-based MI, text medication reminders, unannounced pill counts, and study visit reminders) and control arms (for unannounced pill counts and study visit reminders).

Methods: We examined retention and study visit adherence among imPACT participants in NC. Adherence to study visits (number attending visit/number eligible for that visit) at weeks 2, 6, 14 and 24 post-release was assessed, as was loss to follow-up.

Results: Of the 60 participants enrolled to date, 45 (23 in intervention arm) have been released. Most are men (73%) and African-American (84%); median age is 45 years. Study visit adherence is listed below.

<table>
<thead>
<tr>
<th>Study Visit Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 2</td>
</tr>
<tr>
<td>34/38 (89.5%)</td>
</tr>
<tr>
<td>Week 6</td>
</tr>
<tr>
<td>27/29 (93.1%)</td>
</tr>
<tr>
<td>Week 14</td>
</tr>
<tr>
<td>18/20 (90%)</td>
</tr>
<tr>
<td>Week 24</td>
</tr>
<tr>
<td>8/8 (75%)</td>
</tr>
</tbody>
</table>

Two participants have been lost to follow-up including one who did not receive a cell phone. Two others have been missing since release, neither received a phone. One participant’s phone was reported as stolen, and he has been missing since. Research staff report cell phones have been critical to retention in both study arms.

Conclusions: Providing cell phones to HIV+ former prison inmates is feasible. Cell phones facilitate contact with participants, and may be associated with retention in both the intervention and control arms of this study.
The Impact of Behavioral and Clinical Factors on Associations Between Age and Medication Adherence: Age Moderates the Substance Use-Adherence Association

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Background: Prior research, limited by smaller studies and lack of psychosocial variables, has often demonstrated higher levels of antiretroviral therapy (ART) adherence among older patients. This study examines differences in rates and predictors of adherence focusing on older and younger patients in clinical care in the era of an aging HIV-infected patient population.

Methods: Patients complete a touch-screen-based assessment including ART adherence (self-rating scale), drug/alcohol/tobacco use, depression, anxiety, health-related quality-of-life (HRQL) and sexual risk behavior measures as part of care. Data from 5 CNICS sites (Seattle, Boston, Birmingham, San Diego, San Francisco) were included. We used separate generalized estimating equations by age category with robust standard errors adjusting for demographic and clinical characteristics including all illicit substances, at-risk alcohol use, and binge drinking. Our primary outcome was ART adherence.

Results: 8,879 assessments were completed by 3,831 patients <40 and ≥50 years of age receiving ART. Similar associations were found with adherence for many clinical characteristics among patients <40 and ≥50 years of age in adjusted analyses including clinical characteristics, depression, and HRQL (p values <0.001-0.015). Although rates of binge alcohol use differed by age category, when present a similar negative association was found with mean adherence in both age groups (p values 0.02-0.04). In contrast, the associations of current and past substance use with adherence differed by age. For example, current amphetamine use was associated with poorer adherence in both age groups (p values <0.001), but among older patients, current cocaine/crack use was associated with even lower adherence than amphetamine use. Current marijuana use was associated with poorer adherence only among younger patients (p values 0.02 vs. 0.4).

Conclusions: The impact of substance use and other risk factors that influence adherence differ across age groups. Understanding these differences will facilitate directed interventions as HIV-infected patient populations continue to age.

WelTel Retain Preliminary Qualitative Investigation of Healthcare Provider and Patient Perceptions

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Background: As access to antiretroviral therapy (ART) continues to expand throughout sub-Saharan Africa, levels of patient retention in care have become widely recognized as critical to the success of HIV care and treatment programs. Widespread cell phone use presents new opportunities to develop strategies to engage patients in care. As part of a study testing the effectiveness of the WelTel text messaging intervention to promote pre-ART patient retention in care, we conducted a qualitative study involving patients and healthcare providers to inform implementation of the text message intervention.

Methods: Semi-structured interviews were conducted with five healthcare providers and fifteen patients. Healthcare providers were eligible if they were employed at the Kibera Community Health Centre (KCHC), Nairobi, Kenya. Patients were eligible if they were a KCHC client, ≥18 years, and HIV positive. Interviews were conducted in English, with a translator fluent in Kiswahili and English present to assist. The interviews were recorded, translated into English, and transcribed verbatim. Two researchers read the transcripts and coded for important concepts, events, and experiences using NVivo software. Interview data was analyzed using thematic analysis.

Results: Patients discussed the importance of being treated with respect and dignity by healthcare providers when they attended a clinic, and recalled a number of instances when poor service led them to seek care elsewhere. Patients and healthcare providers were excited at the prospect of communicating through text messaging. Healthcare providers anticipate having a better understanding of patients’ individual concerns if in contact on a more regular basis, and patients appreciate the potential of having questions answered without having to travel to the clinic.

Conclusions: Establishing open and regular communication via text messaging was thought by both groups to be a viable and positive approach to increasing and maintaining patient engagement in care in a pre-ART setting.
Does Literacy Level Moderate the Effects of Behavioral Interventions on MEMS-Measured Antiretroviral Adherence: Combined Results from Two MACH14 Trials

Carol Golin (presenting), Judith Erlen, Yan Wang, Lisa Tamres, Robert Remien, Nancy Reynolds, Marc Rosen, Jane M. Simoni, Honghu Liu

Background: Low health literacy level has been linked to poor health outcomes in several settings. Interventions that mitigate literacy have shown mixed results in their effect on health outcomes. We sought to understand the extent to which health literacy may moderate the effects on adherence of antiretroviral interventions that are not specifically designed to mitigate low literacy.

Methods: Data were pooled from the two randomized, controlled clinical trials of adherence-focused behavioral interventions that also measured health literacy in the Multi-site Adherence Collaboration on HIV (MACH14) study. The primary outcome was the dichotomous variable “achieving at least 95% electronically-monitored mean ART adherence” (defined as percent of prescribed doses taken) at twelve weeks following baseline from 429 patients. In both studies, health literacy was assessed using the Test of Functional Health Literacy Assessment short form (TOFHLA-S). We conducted multivariate regression analysis including an interaction term for intervention group arm and TOFHLA score (possible range 0-36), and control covariates of age, gender, education, ethnicity, income, and employment status.

Results: Adherence was similar across groups (70% intervention, 72% controls > 95%). Average TOFHLA scores varied widely within the total sample (Mean 32.8, SD 4.81, range = 2-36), but were similar across the intervention (Mean 33, range 12-36) and control (M = 32.4; range 2-36) groups. After controlling for potential covariates and intervention status, logistic regression revealed that literacy was a significant predictor of >95% adherence (OR = 0.926; 95% CI = 0.880, 0.974), but the interaction between intervention status and TOFHLA was not.

Conclusions: Literacy was a significant independent predictor of medication adherence, but literacy level did not moderate the relationship between intervention status and adherence. Even high quality adherence interventions are unable to overcome literacy’s impact on adherence. Better strategies to overcome literacy’s deleterious impact are needed.

Private Facebook Groups: Leveraging Technology to Increase Social Connectivity and Maximize Retention in HIV Care

Jen McMillen Smith (presenting), Ann Avery

Introduction: Social networks can positively impact health. People who are socially integrated live longer (Cohen and Janicki-Deverts, 2009) and have better prognoses for chronic illnesses, conversely, those who are the most isolated are the most likely to have poorer health (House, Landis & Umberson, 1988). People living with HIV/AIDS (PLWHA) are vulnerable to isolation, thus arguably, poorer health, in part because of the stigma our society still places on HIV.

Description: In 2012, MetroHealth collaborated with Blue Star Design, who specializes in graphic, web and social media design, to develop a Facebook group exclusively for PLWHAs. Using a private Facebook (FB) group allows us to accomplish 3 aims: 1) connect with our patients in the way they connect with each other, 2) provide wellness messaging with a focus on retention in care, and 3) market social-service programs for PLWHA in order to strengthen their social networks with a group of peers who will be supportive.

Daily posts are utilized for: reminding participants about support and education groups, linking to interesting HIV-related articles and/or websites, providing wellness messaging, and encouraging members. Members can post and comment, and often use the group to garner support for HIV-related issues, for example; relationships and disclosure, starting and/or adhering to HIV meds, and sharing happy news or struggles.

Lessons Learned:
- Utilize FB privacy settings so the group isn’t searchable.
- Use a “pass-through” friend to identify people to invite into the group.
- Organizations (including ASOs) are not accepted.
- Develop policies for what participants can post and participation guidelines.
- Use a content schedule to plan posts in advance.

Recommendations: The next step is to evaluate participant satisfaction and impact on self-assessment of health.
Implementation of Routine Collection of Patient-Reported Data and Outcomes (PROs) in Clinical Care: Findings from CNICS (CFAR Network of Integrated Clinical Sciences) and CHAR (Community Health Applied Research Network)

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Introduction: PROs including adherence enhance patient-provider communication, improve care, and facilitate research. However, there are barriers to collecting PROs in clinic settings. We previously described PRO implementation in HIV clinics. Here we provide an update on PRO collection, describe the impact on clinical care for HIV-infected patients, and describe methods and challenges of expanding routine self-reported PRO collection to several community health clinics.

Description: Patients presenting for routine care use touch-screen tablet PCs to complete a survey including adherence, depression, drug/alcohol/tobacco use, and HIV risk behavior. Providers receive feedback immediately prior to the patient's visit. We use an open-source, non-proprietary web-based survey software application. The system tracks patient eligibility and time since last assessment. Emphasis is placed on not disrupting clinic workflow. We have plotted the reporting of PRO data into an electronic health record.

Lessons Learned: We demonstrated the feasibility of collecting PROs in busy, multi-provider HIV clinics across the US and have recently expanded to several non-specialty community health clinics. Over 21,000 PRO assessments have been completed to date providing a tremendous resource of data for clinical care and research. We found a high prevalence of poor medication adherence, moderate-to-severe depression, substance abuse, and high symptom burden. Features such as real-time, automated pager notification when patients indicate suicidality are especially valuable. Among patients with HIV, PRO feedback improved provider awareness and/or actions for adherence, depression, alcohol, and substance use but not for sexual risk behavior. Tailored implementation approaches were required for community health clinics vs. HIV specialty clinics.

Recommendations: We have demonstrated the feasibility and value of incorporating routine PRO collection. Ongoing efforts focus on qualitative studies of provider feedback format, direct communication with multiple clinic’s electronic health records to both read patient scheduling data and report PRO data, and system-level interventions on clinical care.

A MACH14 Cross Protocol Comparison of Self-Reported and eElectronic Antiretroviral (ARV) Adherence: It's Not Only the Type of Measure used that Influences Adherence Estimates

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Background: Studies comparing measures of ARV adherence have shown inconsistent results. This could be attributable to differences in designs that have not been consistently controlled in prior studies.

Methods: In the multi-site MACH14 study, we evaluated the concordance and predictive value of two measures of ARV adherence [(self-report 3-day recall (SR); electronic (EDM)], controlling for factors that could influence the relationships. A series of analyses were conducted using pooled, individual level longitudinal data from the 11 eligible MACH14 studies with viral load and matching SR and EDM adherence data collected up to 48 weeks. Each measurement event at 12, 24, and 48 weeks with matching 3-day SR and EDM data for a specific ARV were included in the analyses and mean percentage adherence was analyzed as a continuous variable.

Results: The study sample (n=1325) was 67.5% male, mean age of 41.6 (range 18-70), 44.9% AA and 75.7% > HS education. Matched SR and EDM data were significantly (p<0.05) associated (r=0.37, 0.37, 0.24 at 12, 24, and 48 weeks, respectively), but concordance of the SR and EDM data varied by ARV and time interval (mean difference across matched SR/EDM estimates = 0.19, range 0.10-0.27). In multi-level models of repeated measures that adjusted for age, gender, ethnicity, education level, and prior ARV experience, SR and EDM adherence were consistently associated with viral outcome (p<0.001), with mean 3-day SR and EDM having greater predictive value than single day summary measures.

Conclusions: The findings support the validity and predictive value of these widely used SR and EDM adherence measures, but highlight how comparative analyses may be influenced by study design. The science of ARV adherence would likely be advanced more readily if common sources of heterogeneity were routinely taken into account in the design and reports of ARV adherence studies.
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