



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

June 3-5, 2012 • Miami

2012

jointly sponsored by



Postgraduate Institute  
for Medicine





## WELCOME

We are pleased to welcome you to the 7th International Conference on HIV Treatment and Prevention Adherence. As you will have noticed when registering for this year's conference, its focus has been expanded to explicitly address critical questions at the intersection of adherence and strategies for biomedical prevention of HIV. We have done so while keeping our program well-grounded in behavioral, clinical, and structural interventions to help promote, enhance, and maintain optimal adherence to HIV treatment.

In our seventh year, we continue to count on the support of some long-term partners, which the International Association of Physicians in AIDS Care (IAPAC) and National Institute of Mental Health (NIMH) wish to acknowledge. We are grateful to the Office of AIDS Research (OAR), the NIMH, the Office of Behavioral and Social Sciences Research (OBSSR), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute on Drug Abuse (NIDA) for their support. We equally appreciate commercial support provided by Abbott Laboratories, Boehringer Ingelheim, Gilead Sciences, and Merck & Co. And we thank the Postgraduate Institute for Medicine (PIM) and the Association of Nurses in AIDS Care (ANAC) for providing continuing education for our clinician-delegates.

Ultimately, though, a conference is in large measure successful because of its Program Committee and faculty, its delegates, and those individuals who submit their research for review and, if accepted, presentation via oral abstract or poster presentations. Our gratitude to the stellar faculty we have assembled for this year's conference, to the oral abstract and poster presenters who will share their exciting new data, and to delegates from 35 countries who are here with us for the next few days. Your research and clinical work has never been more important to HIV treatment and prevention.



Christopher M. Gordon, PhD<sup>1</sup>  
Co-Chair



José M. Zuniga, PhD, MPH<sup>2</sup>  
Co-Chair

<sup>1</sup> National Institute of Mental Health, Bethesda, MD, USA

<sup>2</sup> International Association of Physicians in AIDS Care, Washington, DC, USA



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## CONFERENCE INFORMATION

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### TARGET AUDIENCE

This activity has been designed to meet the educational needs of physicians, pharmacists, physician assistants, nurses, psychologists, social workers, and allied healthcare professionals working in the field of HIV medicine.

### STATEMENT OF NEED

Antiretroviral therapy can inhibit viral replication and reduce viral load to a point where viral particles are undetectable in the blood of infected individuals. Significant and sustained suppression of HIV replication is associated with improved clinical outcomes. However, these benefits are only tenable when adherence to precise dosing schedules is rigorous and other requirements are closely followed. Partial or poor adherence can lead to the resumption of rapid viral replication, poorer survival rates, and virus mutation to treatment-resistant strains of HIV. Similarly, adherence to antiretroviral-based prevention interventions will be critical to achieving the promise that pre-exposure prophylaxis (PrEP) and other biomedical interventions hold to dramatically curb HIV transmission rates among at-risk populations.

Behavioral and clinical interventions are integral to the success of any medication advance and its health outcomes. Therefore, understanding and enhancing HIV treatment and biomedical prevention adherence is a critical goal at individual, community, and public health levels, which requires multidisciplinary cooperation among patients, clinicians, researchers, and public health specialists.

### PROGRAM OVERVIEW

The 7th International Conference on HIV Treatment and Prevention Adherence will provide a forum where the state-of-the-science for HIV treatment and biomedical prevention adherence research will be presented, discussed, and translated into evidence-based approaches. The 2.5-day program will allow healthcare and human service professionals to examine scientifically sound and practical strategies to enhance adherence to HIV treatment and biomedical prevention interventions in a variety of domestic and international settings.

### EDUCATIONAL OBJECTIVES

After completing this activity, participants will be able to:

- Identify successes and challenges in HIV treatment adherence in various settings and populations worldwide
- Explain behavioral and clinical aspects of adherence that reflect a variety of HIV treatment team perspectives (e.g., patients, physicians, physician assistants, pharmacists, nurses, mental health professionals, adherence specialists)
- Describe current perspectives on biomedical HIV prevention interventions, including pre-exposure prophylaxis [PrEP] and antiretroviral-based microbicides
- Discuss the implications of HIV treatment and biomedical prevention adherence for individual, community, and public health
- Utilize adherence assessment tools and interventions that can be integrated into patient care and/or as components of prevention interventions

## GENERAL INFORMATION

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### MEETING VENUE

The 7th International Conference on HIV Treatment and Prevention Adherence is being held at the Eden Roc Renaissance Hotel. Plenary, Oral Abstract, Breakout Sessions, and the Poster Session will be held in various rooms off the hotel's Lobby (see the Conference Hotel Maps and the Conference Program on page 4 and pages 6-8, respectively).

### MEALS

Breakfast will be served from 7:30 A.M. - 8:30 A.M., Monday, June 4, 2012, and Tuesday, June 5, 2012, in the Ocean Tower 1 Foyer/Ballroom. Neither lunch nor dinner will be provided by the conference. Visit the conference's Registration Desk for a list of restaurants inside the hotel complex as well as local restaurants.

### QUESTIONS

If you have any questions during the conference, please locate an IAPAC staff member at the conference's Registration Desk. If you have any questions post-conference, please contact Alexis Weinstein at [aweinstein@contacthmc.com](mailto:aweinstein@contacthmc.com).

### INTERNET ACCESS

The 7th International Conference on HIV Treatment and Prevention Adherence does not provide Internet access to participants. In each sleeping room, guests have available: Wireless or Hard-Wired High Speed Internet for \$14.95 per 24 hours, with individual login. This fee includes High-Speed Internet access and unlimited local phone calls.

### SLIDE PRESENTATIONS/ABSTRACTS

Slide presentations will be available at [www.iapac.org](http://www.iapac.org) post-conference. The Program and Abstracts Book will be distributed at registration, and an electronic version will be available at [www.iapac.org](http://www.iapac.org) post-conference.



## CONTINUING EDUCATION

### CONTINUING MEDICAL EDUCATION

#### Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the International Association of Physicians in AIDS Care (IAPAC). The Postgraduate Institute for Medicine is accredited by the ACCME to provide continuing medical education for physicians.

#### Credit Designation

The Postgraduate Institute for Medicine designates this live activity for a maximum of 15.0 *AMA PRA Category 1 Credit(s)*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

#### Disclosure and Conflict of Interest

The Postgraduate Institute for Medicine assesses conflict of interest with its instructors, planners, managers, and other individuals who are in a position to control the content of CME activities. All relevant conflicts of interest that are identified are thoroughly vetted by PIM for fair balance, scientific objectivity of studies utilized in this activity, and patient care recommendations. PIM is committed to providing its learners with high quality CME activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

A Disclosure of Conflict of Interest handout is inserted in the Program and Abstracts Book. The handout reflects reports of financial relationships or relationships to products or devices faculty, planners, and managers, or their spouses/life partners, have with commercial interests related to the content of this CME activity. If you do not find this handout inserted in your Program and Abstract Book, please visit the conference's Registration Desk.

#### Disclosure of Unlabeled Use

This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the US Food and Drug Administration (FDA). Neither PIM, IAPAC, Abbott Laboratories, Boehringer Ingelheim, Gilead Sciences, nor Merck & Co. recommend the use of any agent outside of the labeled indications.

The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of PIM, IAPAC, Abbott Laboratories, Boehringer Ingelheim, Gilead Sciences, or Merck & Co. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

#### Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications on dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

#### Evaluation

Participants may complete an online evaluation at [www.cmeuniversity.com](http://www.cmeuniversity.com). On the navigation menu, click on "Find Post-Tests by Course" and search by Project ID 8404. Upon successfully completing the evaluation, a CME certificate will be made available to each participant.



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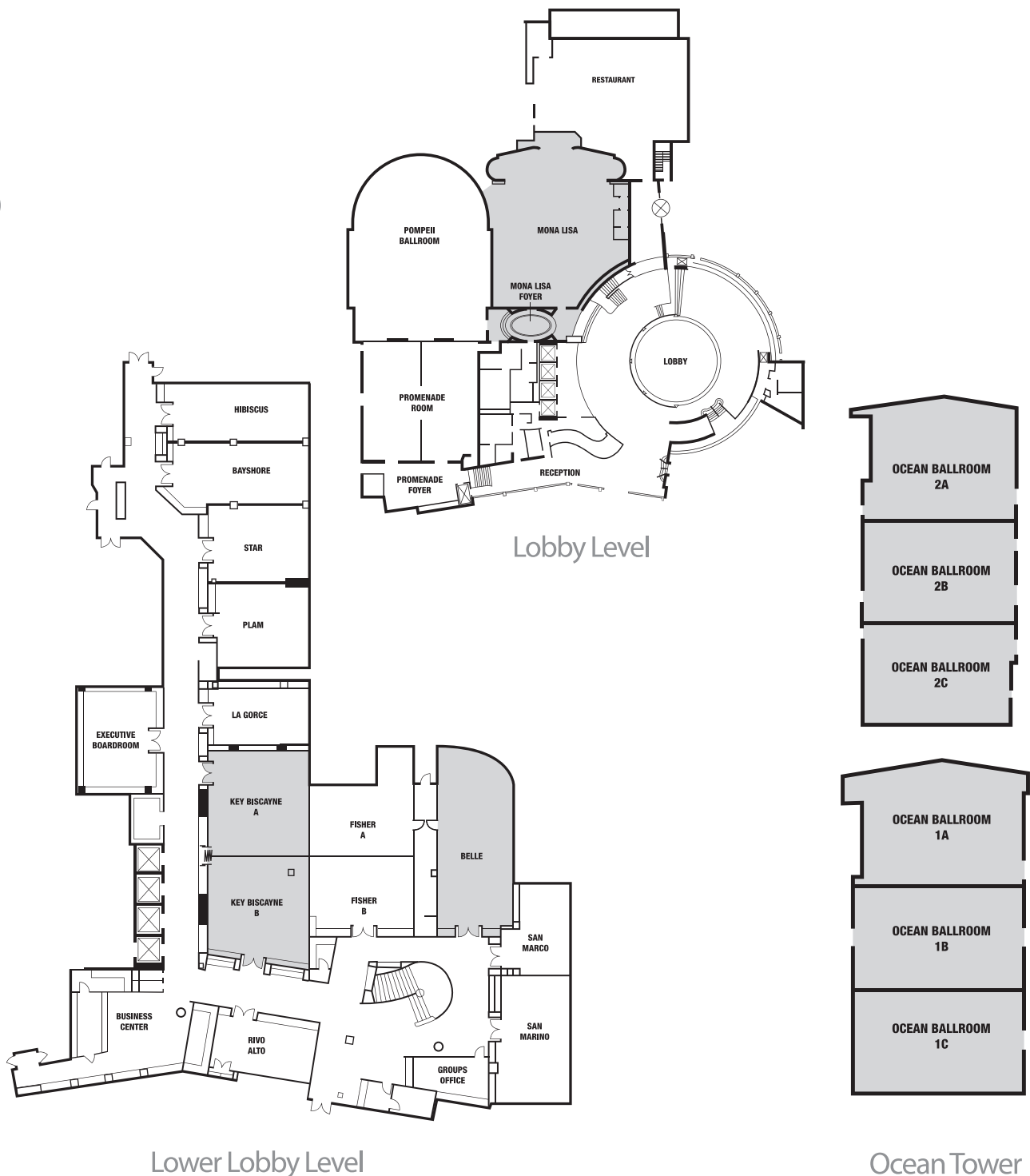
### CONTINUING EDUCATION IN NURSING

This conference is also jointly sponsored with the Association of Nurses in AIDS Care (ANAC), an approved provider of continuing education (CE) in nursing through the Virginia Nurses Association, which is accredited by the Commission on Accreditation of the American Nurses' Association. ANAC designates this educational activity for maximum 13.5 CE Credits. Certificates will be available at [www.cmeuniversity.com](http://www.cmeuniversity.com), Project ID number 8404.

**ANAC**  
ASSOCIATION OF  
NURSES IN AIDS CARE



## EDEN ROC RENAISSANCE HOTEL



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SUNDAY, JUNE 3, 2012

TIME	ACTIVITY	OCEAN TOWER 2 BALLROOM	MONA LISA
2:00 P.M.—3:30 P.M.	Satellite Symposia	Guidelines for Improving Entry into and Retention in Care and Antiretroviral Adherence for Persons with HIV Melanie Thompson, MD James D. Scott, PharmD, MEd Michael Mugavero, MD, MHSc K. Rivet Amico, PhD Michael J. Stirratt, PhD	Addressing the Achilles' Heel of HCV Clinical Management with Direct-Acting Antivirals Christopher O'Brien, MD Robert Gross, MD, MSCE Jeffrey J. Weiss, PhD
3:30 P.M.—4:00 P.M.	Break		
TIME	ACTIVITY	<b>OPENING SESSION • OCEAN TOWER 2 BALLROOM</b>	
4:00 P.M.—4:20 P.M.	Welcome from Conference Co-Chairs José M. Zuniga, PhD, MPH Christopher M. Gordon, PhD		
4:20 P.M.—4:25 P.M.	Introduction to the Gary S. Reiter, MD, and Andrew Kaplan, MD, Memorial Lecture David R. Bangsberg, MD, MPH		
4:25 P.M.—5:00 P.M.	Memorial Lecture: Antiretroviral Treatment is Prevention Myron Cohen, MD		
5:00 P.M.—6:00 P.M.	Treatment Adherence in Daily Life: Perspectives from People Living with HIV Moderator: Robert H. Remien, PhD Panelists: Moisés Agosto-Rosario; Sherwood Epps; Dab Garner; Quintara LadyQueen-Lane; Maria T. Mejia; Kathleen Reed-Cabrera; Jorge Luis Suarez-Suarez		
<b>OPENING RECEPTION • OCEAN GARDEN (outdoors)</b>			
6:00 P.M.—8:00 P.M.	¡Bienvenidos a Miami!		





# MONDAY, JUNE 4, 2012

TIME	ACTIVITY			
7:30 A.M.—8:30 A.M.	Breakfast Served in Ocean Tower 1 Foyer/Ballroom			
TIME	ACTIVITY	OCEAN TOWER 2 BALLROOM	BELLE	KEY BISCAYNE
8:00 A.M.—8:50 A.M.	Breakfast Discussion Groups	Moving HIV Adherence Research into Practice K. Rivet Amico, PhD	Clinical Pharmacists: A Clear Role in Promoting and Enhancing HIV Treatment Adherence James D. Scott, PharmD, MEd	Peer Navigators: Conscripting an Army of HIV-Positive Individuals to Supplement the Health Workforce Larry Chang, MD, MPH Kim Johnson, MD José M. Zuniga, PhD, MPH
8:50 A.M.—9:00 A.M.	Break			
TIME	ACTIVITY			
KEYNOTE ADDRESS • OCEAN TOWER 2 BALLROOM				
9:00 A.M.—9:45 A.M.	Antiretroviral-Based HIV Treatment and Prevention Strategies: Advancing Science to Practice Jared Baeten, MD, PhD			
PLENARY • OCEAN TOWER 2 BALLROOM				
9:45 A.M.—10:15 A.M.	Constructing Antiretroviral Regimens to Overcome Imperfect Adherence Amanda Corbett, PharmD			
10:15 A.M.—10:45 A.M.	Break			
TIME	ACTIVITY	OCEAN TOWER 2 BALLROOM	MONA LISA	OCEAN TOWER 1C
10:45 A.M.—Noon	Thematic Oral Abstract Sessions	Session 1: Assessing Biomedical Prevention Adherence	Session 2: Mental Health and ART Adherence	Session 3: Operations Research and Implementation Science
Noon—1:15 P.M.	Lunch/Networking			
1:15 P.M.—2:30 P.M.	Thematic Oral Abstract Sessions	Session 4: Linkage to and Retention in HIV Care	Session 5: Substance Use and ART Adherence	Session 6: Patient-Provider Perspectives, Communication, and Relationships
2:30 P.M.—3:30 P.M. POSTER SESSION • OCEAN TOWER 1 BALLROOM				
3:30 P.M.—4:00 P.M.	Break			
PLENARY • OCEAN TOWER 2 BALLROOM				
4:00 P.M.—5:00 P.M.	Three Top-Rated Oral Abstracts Moderator: Michael J. Stirratt, PhD			



TUESDAY, JUNE 5, 2012

TIME	ACTIVITY			
7:30 A.M.—8:30 A.M.	Breakfast Served in Ocean Tower 1 Foyer/Ballroom			
TIME	ACTIVITY	OCEAN TOWER 2 BALLROOM	BELLE	KEY BISCAYNE
8:00 A.M.—8:50 A.M.	Regional Discussions	Miami-Dade County Networking and Discussion Group Lisa Metsch, PhD Allan Rodriguez, MD	Sub-Saharan Africa Networking and Discussion Group Jean B. Nachega, MD, PhD	Latin America and the Carribean Region Networking and Discussion Group Rafael Mazín, MD, MPH
8:50 A.M.—9:00 A.M.	Break			
TIME	ACTIVITY			
	PLENARY • OCEAN TOWER 2 BALLROOM			
9:00 A.M.—9:30 A.M.	The Facilitating Roles of the National HIV/AIDS Strategy and the Affordable Care Act in Improving Care Engagement and Treatment Adherence in the United States Grant Colfax, MD			
9:30 A.M.—10:00 A.M.	Addressing Mental Health, Substance Use, and HIV Treatment Adherence Steven Safren, PhD			
10:00 A.M.—10:15 A.M.	Break			
TIME	ACTIVITY	OCEAN TOWER 2 BALLROOM	MONA LISA	OCEAN TOWER 1C
10:15 A.M.—11:30 A.M.	Thematic Oral Abstract Sessions	Session 7: Supporting PrEP Adherence	Session 8: ARV Regimens, Adherence, and Viral Suppression	Session 9: International Research in Priority Populations
11:30 A.M.—12:45 P.M.	Lunch/Networking			
12:45 P.M.—2:00 P.M.	Thematic Oral Abstract Sessions	Session 10: ART Adherence Monitoring and Measurement	Session 11: ART Adherence Interventions	Session 12: Child and Adolescent ART Adherence
2:00 P.M.—2:15 P.M.	Break			
2:15 P.M.—3:00 P.M.	Invited Speakers	Reducing Community Viral Load to Achieve Prevention Moupali Das, MD, MPH	Managing HCV Infection and Treatment Adherence in the Direct-Acting Antiviral Era: Learning from the HIV Experience Vincent Lo Re, MD, MSCE	CDC/HRSA Multisite Retention in Care (RiC) Study: Preliminary Results Lytt Gardner, PhD Gary Marks, PhD
3:00 P.M.—3:15 P.M.	Break			
	CLOSING PLENARY • OCEAN TOWER 2 BALLROOM			
3:15 P.M.—4:00 P.M.	When Paradigms Shift: Challenges of a World in Which Combination Prevention is Our Standard, Most Everyone is Eligible for Lifetime ART, and Treatment is Prevention  Moderators: Christopher M. Gordon, PhD; José M. Zuniga, PhD, MPH  Panelists: Moisés Agosto-Rosario; Carl Dieffenbach, PhD; Massimo Ghidinelli, MD			
4:00 P.M.	Adjourn			



## SATELLITE SYMPOSIA SCHEDULE

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### SUNDAY, JUNE 3, 2012

#### Satellite Symposium 1

2:00 P.M. - 3:30 P.M. / Ocean Tower 2 Ballroom

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##### **Guidelines for Improving Entry into and Retention in Care and Antiretroviral Adherence for Persons with HIV**

Recently published global guidelines<sup>1</sup> recommend evidence-based interventions to improve entry into and retention in HIV care, as well as anti-retroviral therapy (ART) adherence for HIV-positive individuals. This satellite symposium will feature an overview of 37 guidelines-recommended interventions across the following thematic areas: 1) entry into and retention in HIV care; 2) monitoring ART adherence; 3) ART strategies; 4) adherence tools; 5) education and counseling interventions; 6) health system and service delivery interventions; and 7) special populations (e.g., pregnant women, children/adolescents).

##### **Presenters:**

**Melanie Thompson, MD**, AIDS Research Consortium of Atlanta, GA, USA

**Michael Mugavero, MD, MHSc**, University of Alabama at Birmingham, AL, USA

**James D. Scott, PharmD, MEd**, Western University, Pomona, CA, USA

**K. Rivet Amico, PhD**, University of Connecticut, Storrs, CT, USA

**Michael J. Stirratt, PhD**, National Institute of Mental Health, Bethesda, MD, USA

1. Thompson MA, Mugavero M, Amico KR, et al. Guidelines for Improving Entry into and Retention in Care and Antiretroviral Adherence for Persons with HIV. *Ann Intern Med*. 2012 (e-published March 5, 2012).

*Sponsored by IAPAC; CME-accredited by PIM.*

#### Satellite Symposium 2

2:00 P.M. - 3:30 P.M. / Mona Lisa

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##### **Addressing the Achilles' Heel of HCV Clinical Management with Direct-Acting Antivirals**

Infection with hepatitis C virus (HCV) is a global public health challenge that causes significant morbidity and mortality. There exist significant challenges to diagnosing and linking to treatment large numbers of HCV-infected patients who are unaware of their serostatus and thus are not on anti-HCV treatment, including the new standard of HCV treatment with direct-acting antivirals (DAAs). Additionally, bottlenecks preventing expanded access to HCV care must be addressed in light of shifting treatment paradigms, which requires an expanded number of clinicians from multiple disciplines to deliver HCV care.

This symposium will feature highlights from the 2nd International Conference on Viral Hepatitis, which the International Association of Physicians in AIDS Care (IAPAC) and Mount Sinai School of Medicine, New York, NY, USA, co-hosted March 26-27, 2012, in New York City, NY, USA.

##### **Presenters:**

**Christopher O'Brien, MD**, University of Miami, FL, USA

**Robert Gross, MD, MSCE**, University of Pennsylvania, Philadelphia, PA, USA

**Jeffrey J. Weiss, PhD**, Mount Sinai School of Medicine, New York, NY, USA

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MONDAY, JUNE 4, 2012

**Oral Abstract Session 1**  
**Assessing Biomedical**  
**Prevention Adherence**

10:45 A.M. - Noon / Ocean Tower 2 Ballroom  
Moderator: Kenneth Mayer, MD

- 79934** Performance of and Adherence to the Wisebag for Potential Monitoring of Gel Applicator Use in Durban, South Africa  
Ariane van de Straten (presenting)
- 80026** High Adherence among HIV-1 Serodiscordant Couples in the Partners PrEP Ancillary Adherence Study  
Jessica Haberer (presenting)
- 80028** A Pilot Study of Daily Short Message Service (SMS) Surveys of Sexual Behavior and PrEP Use among Kenyan HIV-1 Serodiscordant Couples  
Katie Curran (presenting)
- 80040** The Spectrum of Engagement in HIV Prevention: Proposal for a Pre-Exposure Prophylaxis (PrEP) Cascade  
Albert Liu (presenting)

**Oral Abstract Session 2**  
**Mental Health and ART**  
**Adherence**

10:45 A.M. - Noon / Mona Lisa  
Moderator: Cynthia Grossman, PhD

- 79988** Changes in HIV Providers' Management of Depression after Integration of Treatment Support into Clinical Care  
Brian Pence (presenting)
- 80001** Individualized Texting for Adherence Building (iTAB) Improves cART Adherence in HIV-Infected Persons with Co-Occurring Bipolar Disorder  
David Moore (presenting)
- 80064** A Culturally Adapted Intervention to Treat Depression and ART Non-Adherence on the US-Mexico Border: Final (Promising!) Results from a Pilot RCT  
Jane Simoni (presenting)
- 80459** Ziphamandla: The Feasibility and Usefulness of Implementing CBT-AD, a Cognitive Behavioral-Based Intervention for the Treatment of Adherence and Depression in a Primary ARV Clinic in Cape Town  
Lena Andersen (presenting)

**Oral Abstract Session 3**  
**Operations Research and**  
**Implementation Science**

10:45 A.M. - Noon / Ocean Tower 1C  
Moderator: Ann Williams, RNC, EdD

- 79426** Electronic Medical Records and Same Day Patient Tracing Improves Clinic Efficiency and Adherence to Appointments in a Community-Based HIV/AIDS Care Program in Uganda  
Stella Talisuna (presenting)
- 80016** Secondary HIV Transmission Prevention Counseling and Antiretroviral Adherence Messages in an African Setting: A Time-Motion Study  
Ann Kurth (presenting)
- 80135** Pre-ART Adherence Counselling is Not Associated with Improved MEMS Adherence in Rural Uganda  
David Bangsberg (presenting)
- 80466** Bridging Practice and Research: A Survey of Evidence-Based Practices Used in HIV Care for Linkage, Retention, and Adherence Support  
K. Rivet Amico (presenting)

**Oral Abstract Session 4**  
**Linkage to and Retention in**  
**HIV Care**

1:15 P.M. - 2:30 P.M. / Ocean Tower 2 Ballroom  
Moderator: Lytt Gardner, PhD

- 79940** Baseline Correlates of Retention in HIV Primary Care at Six HIV Clinics in the United States  
Jason Craw (presenting)
- 80002** Linkage and Engagement in Care as Predictors of Achieving and Maintaining Viral Suppression  
Amanda Castel (presenting)
- 80029** ART Ineligibility Confers High Risk of Poor Retention in the Pre-ART Period among Persons Newly Diagnosed with HIV Infection in Sierra Leone  
Dan Kelly (presenting)
- 80464** Early Adherence Patterns Predict Retention Rates in Large ART Cohort in Nigeria  
Seema Meloni (presenting)

**Oral Abstract Session 5**  
**Substance Use and ART**  
**Adherence**

1:15 P.M. - 2:30 P.M. / Mona Lisa  
Moderator: Shoshana Kahana, PhD

- 80047** Improvements in Medication Adherence and Healthcare Utilization as Evidenced from a Pilot Intervention Combining Contingency Management and Behavioral Activation to Reduce Stimulant Use among HIV-Infected Individuals  
Jennifer Mitty (presenting)
- 80081** Injection Drug Users' (IDUs) and their Caregivers' Social Network Factors Associated with IDUs' Viral Suppression  
Amy Knowlton (presenting)
- 80082** Factors Associated with Non-Adherence to Antiretroviral Therapy among Patients Attending HIV Care and Treatment Clinics in Kenya, Namibia, and Tanzania  
Harriet Nuwagaba-Biribonwoha (presenting)
- 80461** Intentional Non-Adherence to Antiretroviral Medications among Alcohol Drinkers: Prospective Study of Interactive Toxicity Beliefs  
Seth Kalichman (presenting)

**Oral Abstract Session 6**  
**Patient-Provider Perspectives,**  
**Communication, and Relationships**

1:15 P.M. - 2:30 P.M. / Ocean Tower 1C  
Moderator: Laura Cheever, MD, ScM

- 78354** African Americans' Perceptions of HIV Provider Cultural Competence that Promote Medical Self-Care and Antiretroviral Medication Adherence  
Gina Gaston (presenting)
- 79372** Barriers to Care among Patients with HIV in South Africa: Contrasts between Patient and Provider Perspectives  
Laura Bogart (presenting)
- 80000** The Quality of Patient-Provider Dialogue about Initiation of Antiretroviral Medications  
Mary Catherine Beach (presenting)
- 80080** Patient Satisfaction as an Innovative Method for Improving Adherence to HAART  
Bich Dang (presenting)





## MONDAY, JUNE 4, 2012 (CONTINUED)

### Three Top-Rated Abstracts

4:00 P.M. - 5:00 P.M. / Ocean Tower 2 Ballroom • Moderator: Michael J. Stirratt, PhD

**79956** Measuring Retention in HIV Care: The Elusive Gold Standard  
Michael Mugavero (presenting)

**80044** Psychosocial Predictors of Acceptability and Risk Compensation for Pre-Exposure Prophylaxis (PrEP): Results from Three Studies of Critical Populations  
Sarit Golub (presenting)

**80457** Data-Adaptive Super Learning to Predict Viral Rebound Based on Electronic Adherence Monitoring: An Analysis of the MACH-14 Cohort Consortium  
Maya Petersen (presenting)

## TUESDAY, JUNE 5, 2012

### Oral Abstract Session 7 Supporting PrEP Adherence

10:15 A.M. - 11:30 A.M. / Ocean Tower 2 Ballroom  
Moderator: Vanessa Elharrar, MD

**80031** Evaluation and Process Outcomes from an Adherence Intervention to Support HIV Pre-Exposure Prophylaxis (PrEP) Adherence in HIV-Serodiscordant Couples in Uganda  
Christina Psaros (presenting)

**80037** Enhancing Pre-Exposure Prophylaxis (PrEP) Adherence in Men who have Sex with Men: Determining Optimal Content for a PrEP Adherence Package  
Wade Taylor (presenting)

**80048** Preference for Daily versus Intermittent PrEP Dosing among Substance-Enhancing Pre-Exposure Prophylaxis in Men who have Sex with Men: Determining Optimal Content for a PrEP Adherence Package  
Matthew Mimiaga (presenting)

**80467** Integrated Next Step Counseling (iNSC): A Discussion-Based Sexual Health Promotion Conversation to Support Men who have Sex with Men (MSM) using Pre-Exposure Prophylaxis (PrEP) in the iPrEx Open Label Extension (iPrEx OLE)  
K. Rivet Amico (presenting)

### Oral Abstract Session 8 ARV Regimens, Adherence, and Viral Suppression

10:15 A.M. - 11:30 A.M. / Mona Lisa  
Moderator: Tia Morton, RN, MS

**79321** Real-World Adherence and Persistence to First-Line, Ritonavir-Boosted, Protease Inhibitor-Based Antiretroviral Regimens\*  
Timothy Juday (presenting)

*\* This presentation is not CME-certified*

**80042** MEMS-Defined Treatment Interruptions Independently Predict HIV RNA Controlling for Average Adherence in Rural Uganda  
Maya Petersen (presenting)

**80074** Differential Impact of Non-Adherence on Week 96 Outcomes in the Emtricitabine/Tenofovir DF (FTC/TDF) Subset of Pooled ECHO and THRIVE Studies Comparing RPV vs. EFV in Treatment-Naïve, HIV-1-Infected Adults  
Dushyantha Jayaweera (presenting)

**80453** Simultaneity and Adherence to Multiple Tablets Regimen among Subjects Starting Once-Daily Atazanavir/Ritonavir (ATV/RTV)-Based Therapy: The ANRS COPHAR 3 Study  
Jean-Jacques Parienti (presenting)

### Oral Session 9 International Research in Priority Populations

10:15 A.M. - 11:30 A.M. / Ocean Tower 1C  
Moderator: Rafael Mazin, MD, MPH

**79467** Intervening to Increase Adherence among HIV-Positive Patients in Northern India  
Deborah Jones (presenting)

**79946** Buddy System in Operationalizing Continuum of Care Intervention among Sex Workers in Mumbai, India  
Samita Bhardwaj (presenting)

**80057** Adherence in Mobile Populations: Qualitative Study of ART for Refugees in Sub-Saharan Africa  
Kelli O'Laughlin (presenting)

**80063** Women, ART, and Adherence: A Longitudinal Comparison of Antiretroviral Adherence by Gender  
Cathy Puskas (presenting)



TUESDAY, JUNE 5, 2012 (CONTINUED)

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**Oral Abstract Session 10  
ART Adherence Monitoring  
and Measurement**

12:45 P.M. - 2:00 P.M. / Ocean Tower 2 Ballroom  
Moderator: Robert Carroll, RN, ACRN

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- 79952** Lessons from Cognitive Testing of Self-Report Adherence Items  
Ira Wilson (presenting)
- 80027** Real-Time HIV Antiretroviral Therapy Adherence Monitoring among Adults and Children in Rural Uganda  
Maya Petersen (presenting)
- 80033** Is a Simple Self-Rating or Visual Analogue Scale (VAS) more Reliable than Prescription Refill (PR) Data as an Indicator of Non-Adherence in a Resource-Limited Setting in South Africa?  
Hannelie (JC) Meyer (presenting)
- 80066** Are Intervention (versus Control) Arm Participants in ART Adherence Promotion Interventions more Likely to Overestimate Adherence? Findings from the MACH14 Study  
Jane Simoni (presenting)

**Oral Abstract Session 11  
ART Adherence Interventions**

12:45 P.M. - 2:00 P.M. / Mona Lisa  
Moderator: Linda Koenig, PhD

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- 79967** Impact of Managed Problem Solving Antiretroviral Adherence Intervention on HIV Copy-Years  
Robert Gross (presenting)
- 79984** Results of an Online Social Support and Text Reminder ART Intervention  
Keith Horvath (presenting)
- 79993** Adherence and HIV Suppression after Behavioral Intervention in Patients with Elevated Viral Load  
Neil Schneiderman (presenting)
- 80038** A Computerized Tailored Information Intervention to Improve Health Literacy and Adherence in Persons with HIV Infection  
Raymond Ownby (presenting)

**Oral Abstract Session 12  
Child and Adolescent ART  
Adherence**

12:45 P.M. - 2:00 P.M. / Ocean Tower 1C  
Moderator: Susannah Allison, PhD

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- 79996** Qualitative Comparison of Disclosure among Perinatally and Behaviorally HIV-Infected Adolescents  
Idia Thurston (presenting)
- 80072** Evaluation of the Feasibility and Validity of Short Message System (SMS) Text Messaging for Assessment of Antiretroviral Therapy Adherence among Youth Living with HIV/AIDS (YLH)  
Nadia Dowshen (presenting)
- 80075** Qualitative Analysis of Factors Influencing Adherence of Pediatric Patients to ART in Rural Uganda  
Peter Olds (presenting)



## 78354 African Americans' Perceptions of HIV Provider Cultural Competence that Promote Medical Self-Care and Antiretroviral Medication Adherence

Gina Gaston<sup>1</sup> (presenting)

<sup>1</sup> University of Illinois at Chicago, Chicago, IL, USA

**Background:** Most studies examine health care provider definitions of cultural competence practice. However, this study explores the impact of African Americans' perception of HIV health care provider cultural competence on adherence to self-care and antiretroviral (ARV) medication.

**Methods:** The study was conducted at the CORE Center in Chicago, Illinois. The sample consisted of 202 African American adults with HIV/AIDS who were recruited from clinic waiting areas. Surveys were self-administered, and participants received a \$10 food gift card as an incentive. Cultural competence was measured using the Patient Assessments of Cultural Competency (PACC) survey developed by the Department of Health and Human Services Agency for Healthcare Research and Quality (AHRQ). Medical self-care was measured using 2 scales, and ARV medication adherence was measured using scales published by the Adult AIDS Clinical Trials Group. Data were analyzed using descriptive statistics, Pearson *r* correlation coefficients, and linear regression. Data were examined after controlling by covariates.

**Results:** There was a significant relationship between health care provider trust with communication ( $r = 0.41, p = .0001$ ) and adherence to health care provider advice ( $r = 0.40, p = .0001$ ). The less health care providers shared treatment decisions with patients, the less patients adhered to ARV medication ( $r = -0.45, p = .05$ ). Regression results revealed that the more adherent patients were to health care provider advice and instructions, the more culture was important,  $F(1, 138) = -0.029, p = .05$ . Participants with higher degrees,  $F(1, 138) = -0.136, p = .05$ , perceived that patient culture was less important in HIV care. The more patients trusted their providers, the more they engaged in medical self-care,  $F(1, 138) = 0.280, p = .01$ . Patients were less trustful of nurses,  $F(1, 138) = -5.559, p = .01$ .

**Conclusions:** Practice, research, and policy implications were discussed.

## 79321 Real-World Adherence and Persistence to First-Line, Ritonavir-Boosted, Protease Inhibitor-Based Antiretroviral Regimens

Timothy Juday<sup>1</sup> (presenting), Charu Taneja<sup>2</sup>, Larry Gertzog<sup>2</sup>, Jonathan Uy<sup>1</sup>, Tony Hebden<sup>1</sup>, Gerry Oster<sup>2</sup>

<sup>1</sup> Bristol-Myers Squibb, Plainsboro, NJ, USA

<sup>2</sup> Policy Analysis Inc., Brookline, MA, USA

**Background:** Successful HIV treatment requires high levels of adherence and long-term persistency with combination antiretroviral therapy (cART). Our study examines real-world adherence and persistency in HIV patients initiating first-line cART with a protease-inhibitor (PI)-based regimen.

**Methods:** Retrospective cohort study using data from a large US commercial health insurance claims database spanning the period 01/01/2003 to 09/30/2009. Subjects included all persons aged 18 years and older with at least 1 inpatient or 2 outpatient claims with an HIV diagnosis code who initiated a first-line, ritonavir-boosted, PI-based cART regimen during this period. Analysis included only those regimens initiated by at least 100 patients. Adherence was defined as proportion of days covered (PDC) for all components of the index regimen; non-persistency was defined based on evidence of discontinuation, switching, or augmentation of any component of this regimen. Generalized linear model (GLM) regression analysis was used to assess differences in non-adherence (1-PDC) between treatments over 12 months after adjusting for potential confounders (i.e., differences in patient characteristics at cART initiation). Differences in non-persistency were examined using Cox multivariate proportional hazards regression analysis.

**Results:** The study sample consisted of 1118 patients who initiated ritonavir-boosted atazanavir (ATV/r,  $n = 559$ ) or lopinavir (LPV/r,  $n = 559$ ). The 2 groups were similar in terms of age, sex, region, and comorbidities. In multivariate analyses, patients receiving LPV/r were found to have a greater number of uncovered days over 12 months than those receiving ATV/r (rate ratio = 1.25;  $p = 0.05$ ). Patients receiving LPV/r also were more likely to be non-persistent than those receiving ATV/r over 12 months (hazard ratio = 1.55,  $p < 0.01$ ).

**Conclusions:** Adherence and persistency are critical in optimizing the likelihood of long-term HIV treatment success. Further analyses should be undertaken to understand the reasons why adherence and persistency differ between ritonavir-boosted PI-based regimens.

\* Not CME-certified



## 79372 Barriers to Care among Patients with HIV in South Africa: Contrasts between Patient and Provider Perspectives

Laura Bogart<sup>1</sup> (presenting), Senica Chetty<sup>2</sup>, Janet Giddy<sup>2</sup>, Laurel Sticklor<sup>3</sup>, Alexis Sypek<sup>4</sup>, Rochelle Walensky<sup>5</sup>, Elena Losina<sup>6</sup>, Jeffrey Katz<sup>6</sup>, Ingrid Bassett<sup>7</sup>

- <sup>1</sup> Harvard Medical School/Children's Hospital Boston, Boston, MA, USA
- <sup>2</sup> McCord Hospital, Durban, South Africa
- <sup>3</sup> Children's Hospital Boston, Boston, MA, USA
- <sup>4</sup> Massachusetts General Hospital, Boston, MA, USA
- <sup>5</sup> Harvard Medical School/Massachusetts General Hospital/Brigham & Women's Hospital, Boston, MA, USA
- <sup>6</sup> Harvard Medical School/Brigham & Women's Hospital, Boston, MA, USA
- <sup>7</sup> Harvard Medical School/Massachusetts General Hospital, Boston, MA, USA

**Background:** Half of people with HIV in South Africa fail to initiate care shortly after diagnosis, yet there are few reports of challenges associated with linkage to care.

**Methods:** We collected qualitative data (semi-structured interviews with 11 health care providers and 10 patients; 8 focus groups with 41 patients) to explore barriers to linkage to care. Patients were not yet taking antiretroviral treatment. Two raters used a structured coding scheme that emerged from the narratives. Average Kappa across themes (0.82) indicated excellent inter-rater consistency.

**Results:** Patients (mean age 38 years [SD = 11.1], 51% female) reported that they were diagnosed an average of 1.9 years (SD = 2.9) prior. While both patients and providers identified HIV stigma (discrimination, fear of prejudice) as one of the most significant barriers facing newly diagnosed patients, they differed on beliefs about patients' responsibility for overcoming barriers. Providers believed that patients should take responsibility for overcoming internalized stigma, disclosing their serostatus, and finding social support. Patients felt that stigma-related issues were largely beyond their control, fearing discrimination if they disclosed to employers or if they were seen visiting clinics in their communities. Patients had considerable concerns about inconvenient clinic hours, long queues, difficulty in scheduling appointments, and disrespect from staff. Providers did not believe that cost or waiting times were major issues and did not recognize the extent of patient dissatisfaction. Both patients and providers felt that more education and open discussion about HIV were needed in communities to overcome stigma and increase support. Patients emphasized the need for reduced clinic fees, additional clinic staff, and convenient clinic hours.

**Conclusions:** Stigma remains a critical barrier among people with HIV in South Africa, although health care system barriers are also significant for patients. Better communication and understanding between patients and providers about challenges faced is needed to facilitate greater patient satisfaction and retention.

## 79426 Electronic Medical Records and Same-Day Patient Tracing Improves Clinic Efficiency and Adherence to Appointments in a Community-Based HIV/AIDS Care Program in Uganda

Stella Talisuna<sup>1</sup> (presenting)

- <sup>1</sup> Reach Out Mbuya HIV/AIDS Initiatives, Kampala, Uganda

**Background:** Patients who miss clinic appointments make unscheduled visits that compromise the ability to plan for and deliver quality care. We implemented Electronic Medical Records (EMRs) and same-day patient tracing to minimize missed appointments in a community-based HIV clinic in Kampala, Uganda.

**Methods:** Missed, early, on-schedule appointments, and waiting times were evaluated before (pre-EMR) and 6 months after implementation of EMR and patient tracing (post-EMR). Reasons for missed appointments were documented pre- and post-EMR.

**Results:** The mean daily number of missed appointments significantly declined from 21 pre-EMRs to 8 post-EMRs. The main reason for missed appointments was forgetting (37%) but declined significantly by 30% post-EMR. Loss to follow-up (LTFU) also significantly decreased from 10.9% to 4.8%. The total median waiting time to see providers significantly decreased from 291 minutes to 94 minutes.

**Conclusions:** Our findings suggest that EMR and same-day patient tracing can significantly reduce missed appointments and LTFU and improve clinic efficiency.





## 79467 Intervening to Increase Adherence among HIV-Positive Patients in Northern India

Deborah Jones<sup>1</sup> (presenting), Aman Sharma<sup>2</sup>, Ryan Cook<sup>1</sup>, Szonja Vamos<sup>1</sup>, Drenna Waldrop-Valverde<sup>3</sup>, Stephen Weiss<sup>1</sup>, Mahendra Kumar<sup>1</sup>, Ritu Nehra<sup>2</sup>

<sup>1</sup> University of Miami Miller School of Medicine, Miami, FL, USA

<sup>2</sup> Postgraduate Institute of Medical Education and Research, Chandigarh, India

<sup>3</sup> Emory University, Atlanta, GA, USA

**Background:** Adherence to HIV antiretroviral (ARV) medication is a function of treatment engagement, essential to both controlling HIV and limiting transmission. This study examined the psychosocial correlates of adherence among HIV-positive patients in Northern India.

**Methods:** Participants (n = 80) were recruited from a hospital clinic and randomly assigned to a 3-month group intervention to enhance ARV adherence or the individual standard of care and assessed monthly for 6 months.

**Results:** Participants were primarily male (70%), aged 19-56 years extremely low income, with 4-9 years of education. Half (49%) had an HIV-positive spouse, of whom 18% were on ARVs. Adherence measures included: prescription refill, pill count, and short- and long-term self report. At baseline, short-term self-reported adherence was not associated with long-term self-report or pill count. Missing doses was negatively correlated with self-efficacy ( $p = .02$ ,  $r = -.26$ ), and positive beliefs about medication ( $p = .03$ ,  $r = -.25$ ) and its necessity ( $p = .03$ ,  $r = -.24$ ). Cognitive functioning was related to infrequent missed doses ( $p = .01$ ,  $r = .28$ ), however, adherence was not associated with physical health or health care utilization. At follow-up, pill count adherence baseline to 6 months post-intervention ( $F = 5.49$ ,  $p = .02$ ) among experimental condition participants improved in comparison with control participants. Among experimental participants, patient-provider communication was associated with fewer missed doses ( $p = .04$ ,  $r = .36$ ), while among control participants, patient-provider communication was negatively associated with pill count ( $p = .02$ ,  $r = .35$ ).

**Conclusions:** Results support the implementation of interventions enhancing patient-provider communication, and more importantly, accurate assessment of adherence. A strategy for rapid pill count may be a useful adjunct for accurate adherence appraisal in the clinical setting. Future studies should explore the impact of peer support on adherence and treatment engagement.

## 79934 Performance of and Adherence to the Wisebag for Potential Monitoring of Gel Applicator Use in Durban, South Africa

Ariane van der Straten<sup>1</sup> (presenting), Elizabeth Montgomery<sup>1</sup>, Anushka Naidoo<sup>2</sup>, Helen Cheng<sup>1</sup>, Diantha Pillay<sup>2</sup>, Jeanna Piper<sup>3</sup>, Gonasagie Nair<sup>2</sup>

<sup>1</sup> RTI International, San Francisco, CA, USA

<sup>2</sup> CAPRISA, Durban, South Africa

<sup>3</sup> NIAID/NIH, Bethesda, MD, USA

**Background:** Options to objectively measure microbicide use are limited. Wisebag (WB), an electronic events-monitoring system, provides an indirect measure of gel use. We assessed the technical performance of 3 different WB and device functionalities and participants' adherence to daily opening of the WB over 2 weeks.

**Methods:** A 3-arm, double-blinded pilot study of WB was conducted in HIV-negative women screened out of the VOICE trial in Durban, South Africa. Participants were randomized in a 2:2:1 ratio to receive WB with online (events transmitted via cellular signal in real-time; n = 20), offline (events stored in device memory; n = 20), or inactive "dummy" (n = 10) devices. To simulate daily gel use, participants were instructed to open the WB daily and retrieve a sticker from the bag. At exit, participants were asked about WB use.

**Results:** Fifty women, aged 19 to 42 years, enrolled and completed the study. There were 13 days of non-observed WB openings, with a median of 11 days (range 1-13) with one opening event only. Per electronically recorded events, 26% of women were perfectly adherent to the 1x/day opening instructions compared with 48% by self-report at exit ( $p < .001$ ). Of those reportedly non-adherent, 92% did not open WB mostly due to forgetting or travelling, while 22% opened WB >1x/day, mostly to show it to a friend/relative. No differences in opening events or self-reports were noted between women who received the online or offline devices. At study exit, 94% of women did not know the type of device they received. When asked to identify the 3 types of WB functionalities, only 26% guessed correctly.

**Conclusions:** Device blinding was successful, and use of offline or dummy WB can be considered to lower cost in larger studies. Perfect adherence by WB events was significantly lower than by self-report, highlighting the importance of including objective measures of adherence in clinical trials.



## 79940 Baseline Correlates of Retention in HIV Primary Care at 6 HIV Clinics in the United States

Jason Crow<sup>1</sup> (presenting), Tracey Wilson<sup>2</sup>, Thomas Giordano<sup>3</sup>, Michael Mugavero<sup>4</sup>, Jeanne Keruly<sup>5</sup>, Mari-Lynn Drainoni<sup>6</sup>, Allan Rodriguez<sup>7</sup>, Robert Mills<sup>8</sup>, Lytt Gardner<sup>9</sup>

- <sup>1</sup> ICF International, Atlanta, GA, USA
- <sup>2</sup> SUNY Downstate Medical Center, School of Public Health, New York, NY, USA
- <sup>3</sup> Baylor College of Medicine, Houston, TX, USA
- <sup>4</sup> University of Alabama at Birmingham, Birmingham, AL, USA
- <sup>5</sup> Johns Hopkins University, Baltimore, MD, USA
- <sup>6</sup> Boston University School of Public Health, Boston University School of Medicine, Boston, MA, USA
- <sup>7</sup> University of Miami Miller School of Medicine, Miami, FL, USA
- <sup>8</sup> Health Resources and Services Administration, Merrifield, VA, USA
- <sup>9</sup> US Centers for Disease Control and Prevention, Atlanta, GA, USA

**Background:** Retaining patients in HIV primary care promotes viral suppression, which reduces risk of HIV transmission. Evaluation of demographic and behavioral variables, barriers to care, and patient unmet needs may enhance understanding of retention and help target interventions to improve outcomes.

**Methods:** We assessed retention in primary care among patients at 6 HIV academic clinics during a 12-month period prior to enrolling in a retention trial. Retention in care was examined using electronic visit records archived at the clinics and was defined as having  $\geq 1$  kept primary care visit in each of 3 consecutive 4-month intervals (visit constancy). Enrollees completed a baseline computer survey. New patients were excluded from analyses due to limited pre-enrollment visit history.

**Results:** The analytic sample ( $n = 1307$ ) was 70% black, 37% female, mean age 46 years, and 75% had  $\geq 1$  undetectable viral load (VL) test ( $<400$  copies/mL) reported in medical records in the past 12 months. Overall, 65% met visit constancy criteria by having  $\geq 1$  kept visit in all three 4-month intervals. In bivariate analyses, the following were significantly associated with achieving visit constancy: female gender, black race (vs white), age  $\geq 50$  years (vs 18-39 years), stable housing, having insurance, currently on antiretroviral medication, no recent incarceration or drug use, no unmet needs,  $\geq 1$  undetectable VL test, and clinic site. In multivariate analyses adjusting for number of scheduled (non-cancelled) primary care appointments the following had significantly higher odds of achieving visit constancy: older age [OR = 1.87, (1.32, 2.64)], having no unmet needs [OR = 1.58 (1.19, 2.10)], and having  $\geq 1$  undetectable VL in the past 12 months [OR = 1.80 (1.31, 2.48)].

**Conclusions:** Older patients, those with no unmet needs, and patients with  $\geq 1$  undetectable VL test in the past 12 months had better retention in care prior to enrolling in a retention trial. Addressing and reducing unmet needs may help improve retention in care among all patients.

## 79946 Buddy System in Operationalizing a Continuum of Care Intervention among Sex Workers in Mumbai, India

Samita Bhardwaj<sup>1</sup> (presenting), Sudipto Roy<sup>1</sup>, Virupax Ranebennur<sup>1</sup>, Sanjeev Singh Gaikwad<sup>1</sup>

- <sup>1</sup> FHI 360, Mumbai, India

**Introduction:** Limited access to antiretroviral therapy (ART) services and inadequate family support for people living with HIV (PLHIV)-sex workers (SWs) make operationalization of Continuum of Care (CoC) challenging in HIV prevention programs.

**Description:** CoC, established by FHI 360 under the Aastha project on STI/HIV prevention for SWs in Mumbai, India, encompasses referral and service provisions including a "buddy" or "Aastha Sangini" as an intervention for ensuring improved and regular uptake of government ART services. The buddy is chosen by the HIV-positive SW from within the community, to whom she voluntarily discloses her status and who accompanies her for CD4 cell count testing and ART initiation. The buddy helps build linkages with other care and support services, including nutrition, legal, and economic services. As most SWs live without their families, buddies play a critical role in monitoring ART adherence. A total of 601 PLHIV (October 2011) currently avail project services and have disclosed their status to at least one project staff, of which 200 PLHIV (33.2%) have disclosed their status to buddies. Among the 200 PLHIV with buddies, 130 (65%) have been linked to care and treatment services, which is significantly higher compared with 214 (53.4%) among 401 PLHIV without a buddy (OR 1.62 [95% CI 1.14-2.30]). Within typologies, only brothel-based SWs showed significant difference, with 51 (64.6%) of 79 SWs with buddies linked to CoC services compared with 107 (35.4%) of 302 SWs without buddies (OR 3.319 [95% CI 1.978-5.571]).

**Lessons Learned:** A focused approach integrating a buddy system in a CoC framework enables PLHIV-SWs to access care and treatment services. Buddies help PLHIV understand the significance of care and treatment services and strengthen follow-up of referrals for different services, thereby reducing loss to follow-up.

**Recommendations:** Introduction of a buddy system in CoC programs for PLHIV-SWs can increase linkages to care and treatment services. Encouraging beneficial disclosure among buddies is critical for improved CoC services.



## 79952 Lessons from Cognitive Testing of Self-Report Adherence Items

Ira Wilson<sup>1</sup> (presenting), Floyd Fowler<sup>2</sup>, Carol Cosenza<sup>2</sup>, William Rogers<sup>3</sup>, Joanne Michaud<sup>1</sup>, Judith Bentkover<sup>1</sup>, Laura Kogelman<sup>3</sup>, Aadia Rana<sup>4</sup>

<sup>1</sup> Brown University, Providence, Rhode Island, USA

<sup>2</sup> UMASS Boston, Boston, MA, USA

<sup>3</sup> Tufts Medical Center, Boston, MA, USA

<sup>4</sup> Miriam Hospital, Providence, RI, USA

**Introduction:** Self-report consistently overestimates HIV antiretroviral therapy (ART) adherence. To improve the quality of self-report items, we conducted cognitive testing on a wide variety of items with 66 patients at 2 institutions.

**Methods:** Existing self-report items were comprehensively reviewed. Popular items and items whose validity had good empiric support, as well as new items, were selected for testing. Cognitive testing experts conducted 1- to 2-hour patient interviews using standard techniques to determine how questions were understood and answered. Four rounds of testing were done testing new and revised versions of questions. All selected patients were taking ART, and most were also taking other medications.

**Results:** Of the 66 participants, 30% were female, 71% had a high school education or less, and 59% were nonwhite. Patients were consistently unable to generate a medication list. Reference periods, such as the "last week" and the "last month," were often misunderstood; the "last 7 days" and the "last 30 days" worked better. Respondents recalled 7 days better than 30 days, but specific recall for both was limited. Items that ask for calculations or reports of percentages consistently caused problems, with participants making many types of errors. The phrase "exactly as your doctor prescribed" was troublesome, with patients having multiple interpretations. The phrase "the way you are supposed to take" a medication was more consistently understood. Unless patients were very adherent, they rarely recalled specific episodes of missed doses. Instead, patients estimated. Response tasks that use adjectives or adverbs, rather than numbers, are better suited to the level of information that most patients have to report.

**Conclusions:** Common approaches to adherence self-report items often fail basic cognitive testing. We used the results of this comprehensive cognitive testing to develop a short set of items to be tested for psychometric characteristics and validity.

## 79956 Measuring Retention in HIV Care: The Elusive Gold Standard

Michael Mugavero<sup>1</sup> (presenting), Andrew Westfall<sup>1</sup>, Anne Zinski<sup>1</sup>, Jessica Davila<sup>2</sup>, Mari-Lynn Drainoni<sup>3</sup>, Jeanne Keruly<sup>4</sup>, Faye Malitz<sup>5</sup>, Gary Marks<sup>6</sup>, Lisa Metsch<sup>7</sup>, Tracey Wilson<sup>8</sup>, Thomas Giordano<sup>2</sup>

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<sup>6</sup> US Centers for Disease Control and Prevention, Atlanta, GA, USA

<sup>7</sup> University of Miami, Miami, FL, USA

<sup>8</sup> SUNY Downstate, New York, NY USA

**Background:** Measuring retention in care is complex as it includes multiple visits scheduled at varying intervals over time. Several retention measures have been significantly associated with HIV outcomes. We compare 5 commonly used retention measures to one another and to viral load (VL) outcomes.

**Methods:** Clinic-wide patient-level data from 6 academic HIV clinics were used for 12-months preceding implementation of the US Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Retention in Care intervention. Five retention measures were calculated for each patient based upon scheduled primary HIV medical provider visits during the 12-month observation period: missed visits: dichotomous "no show" visit measure; visit adherence: proportion of kept/scheduled visits; gap: >6-month interval between kept visits; visit constancy: number of 4-month intervals with a kept visit; HRSA HIV/AIDS Bureau (HAB) measure: 2 kept visits separated by >90 days. Spearman correlation coefficients and separate logistic regression models were used to compare retention measures to one another and with 12-month VL suppression, respectively. The discriminatory capacity of each retention measure was assessed with the c-statistic.

**Results:** Among 10,053 patients (mean age 46, 35% female, 64% black, 49% heterosexual), 8235 (82%) had 12-month VL measures, with 6,304 (77%) achieving suppression (VL <400 copies/mL). Measures incorporating "no show" visits (missed visit and visit adherence) were highly correlated (Spearman coefficient = 0.83), as were measures based solely upon kept visits (gap, visit constancy, HRSA HAB; Spearman coefficient range = 0.72-0.77). Correlation coefficients were lower across these 2 groups of measures (range = 0.22-0.57). All 5 retention measures were significantly ( $p < .0001$ ) associated with 12-month VL suppression (OR; 95%CI, c-statistic): missed visit (3.2;2.8-3.6, 0.62), visit adherence (3.9;3.5-4.3, 0.69), gap (3.0;2.6-3.3, 0.61), visit constancy (2.8;2.5-3.0, 0.63), and HRSA HAB (3.8;3.3-4.4, 0.59).

**Conclusions:** Five retention measures displayed a wide range of correlation with one another (Spearman coefficient = 0.22-0.83), yet each measure had significant association ( $p < .0001$ ) and modest discrimination (c-statistic = 0.59-0.69) for VL suppression. These data suggest there is no clear gold standard to measure retention in HIV care.



## 79967 Impact of Managed Problem Solving Antiretroviral Adherence Intervention on HIV Copy-Years

**Robert Gross<sup>1</sup> (presenting)**, Scarlett Bellamy<sup>1</sup>, Jennifer Chapman<sup>1</sup>, Xiaoyan Han<sup>1</sup>, Jacqueline O'Duor<sup>1</sup>, Steven Palmer<sup>1</sup>, Peter Houts<sup>2</sup>, James Coyne<sup>1</sup>, Brian Strom<sup>1</sup>

<sup>1</sup> University of Pennsylvania Perelman School of Medicine, Philadelphia, PA, USA

<sup>2</sup> Pennsylvania State University College of Medicine, Hershey, PA, USA

**Background:** Managed problem solving (MAPS) is a 5-step behavioral adherence intervention delivered by trained staff through 4 face-to-face and 9 telephone contacts over 3 months followed by monthly telephone "booster sessions." It has already been shown to improve adherence, but the impact on the biological outcomes of HIV copy-years is unknown.

**Methods:** We conducted a secondary analysis of this randomized single-blind trial comparing MAPS with usual care (UC). Patients were: older than 18 years, newly starting antiretroviral therapy (ART), or starting a new regimen after failing current ART with HIV RNA >1000 copies/mL. All regimens included >3 drugs, at least 2 fully active. HIV viral load (VL) was assessed quarterly (<75 copies/mL assigned as 0). The biological outcome was HIV copy-years calculated as average log<sub>10</sub> VL over each quarter x 3 months, and summed over the year. HIV copy-years were compared between groups using rank sum tests. Missing VLs were analyzed as: 1) intention to treat (ITT) with baseline VL replacing missing; and 2) as treated (AT) with last observation carried forward.

**Results:** Ninety-one were randomized to MAPS and 89 to UC. Median age was 42 years, with 61% male, 85% black, median baseline VL of 2000 copies/mL, and median CD4 cell count of 250 cells/mm<sup>3</sup>. Characteristics were balanced between groups. Thirty-three MAPS and 23 UC patients were lost to follow-up. In both ITT and AT analyses, HIV copy-years were lower for the MAPS than UC group (ITT-MAPS: 1.54 log copy-years vs UC: 2.02 log copy-years,  $p = 0.046$ ; AT-MAPS: 1.36 log copy-years vs UC: 1.87 log copy-years,  $p = .027$ ).

**Conclusions:** MAPS improves HIV copy-years outcome and, therefore, should be implemented where the resources are available. Further consideration should be given to adapting and evaluating MAPS for addressing retention in care, since the intervention's effects were attenuated by losses to follow-up.

## 79984 Results of an Online Social Support and Text Reminder ART Intervention

**Keith Horvath<sup>1</sup> (presenting)**, B.R. Simon Rosser<sup>1</sup>, J. Michael Oakes<sup>1</sup>, Joe Konstan<sup>1</sup>, Gene Danilenko<sup>2</sup>, Heather Vezina<sup>1</sup>, K. Rivet Amico<sup>3</sup>, Jane Simoni<sup>4</sup>, Mark Williams<sup>5</sup>

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**Background:** Online social media and mobile technology intervention may enhance antiretroviral therapy (ART) adherence. However, the feasibility, acceptability, and efficacy of this approach among people living with HIV (PLWH) have not been fully examined, which was the purpose of this study.

**Methods:** Gay or bisexually-identified men self-reporting less than 100% ART adherence in the past 30 days were recruited online and randomized to the control ( $n = 57$ ) or 8-week intervention ( $n = 67$ ) arm, and evaluated at baseline, post-intervention, and 1-month follow-up (1MFU). The intervention, grounded in the Information-Motivation-Behavioral Skills model, contained 3 main components: 1) an online interface for participants to interact with each other by posting messages; 2) articles and videos addressing topics related to ART adherence and living with HIV; and 3) an online medication adherence self-monitoring system with the option for text-message dose reminders. We calculated difference scores between baseline and 1MFU for self-reported 30-day percent (0%-100%) overall ART adherence, medication taken within 2 hours of scheduled dosing, and ART taken correctly with food; differences were examined using t-tests.

**Results:** Participants resided in 32 US states and had lived with HIV an average of 12.8 years. Most were non-Hispanic white (59%) and had attended some college ( $M = 15.2$  years schooling). 1MFU assessment completion rates for the intervention (85%) and control (91%) arm were satisfactory. On a 7-point Likert scale (7 = more favorable), participants rated the intervention high in information (mean item score range = 5.7-6.2) and system (mean item score range = 5.6-6.1) quality and were satisfied with the intervention (mean = 5.8). Intervention group participants were significantly more likely to take ART correctly with food (difference = 11.9,  $p < .05$ ) and somewhat more likely to take medication within 2 hours of scheduled dosing (difference = 9.6,  $p < .10$ ); however, they were not significantly more likely to report higher overall ART adherence (difference = 3.8, ns).

**Conclusions:** This online social support and text message ART intervention proved to be feasible, appears to be highly acceptable to users, and may have assisted some PLWH to refine their adherence behaviors. Recommendations for future research include using larger sample sizes, increasing the intensity and duration of intervention, and enrolling samples of PLWH with worse baseline ART adherence.





## 79988 Changes in HIV Providers' Management of Depression after Integration of Treatment Support into Clinical Care

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**Background:** Depression, a common co-morbidity in HIV patients, worsens antiretroviral (ARV) medication adherence and HIV clinical outcomes. Although evidence-based approaches for treating depression are well-established, adherence to these guidelines by non-psychiatric providers is low. One-time trainings in best-practices principles usually have short-lived effects on provider behavior. We sought to assess whether onsite depression management decision support for a minority of HIV providers' patients improved providers' overall knowledge and use of best-practices principles for depression management after one year.

**Methods:** The SLAM DUNC (Strategies to Link Antidepressant and Antiretroviral Management at Duke and UNC) Study deploys Depression Care Managers (DCM) at HIV clinics to test whether the application of evidence-based antidepressant decision support improves HIV outcomes, including ARV adherence. Each provider may be working with the DCM for a small number of his or her patients (range: 0-5; mean: 1.3). Providers were interviewed before study launch and after one year of study implementation about depression management knowledge and practices.

**Results:** Forty-one providers completed pre-study and one-year follow-up interviews. Relative to baseline, after one year a higher proportion of providers reported adjusting antidepressant doses to account for ARV interactions (53% vs 37%,  $p = .15$ ), evaluating antidepressant efficacy by measuring symptoms (24% vs 12%,  $p = .15$ ), and using the full FDA-approved dosing range for antidepressants (63% vs 41%,  $p = .06$ ). Fewer providers reported following up within 2 weeks with patients newly starting antidepressants (3% vs 20%,  $p = .02$ ), considering efficacy and tolerability when deciding to change antidepressant doses (15% vs 44%,  $p < .01$ ), or maintaining antidepressant treatment at least 6 months (51% vs 73%,  $p = .04$ ). A summary best-practices score combining 12 metrics was virtually unchanged (5.9 vs 5.7 on a 0-10 scale,  $p = .67$ ).

**Conclusions:** Providers' self-reported behaviors in considering antidepressant-ARV interactions, using higher antidepressant doses, and measuring effectiveness increased, but follow-up and maintenance practices decreased after one year.

## 79993 Adherence and HIV Suppression after Behavioral Intervention in Patients with Elevated Viral Load

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**Background:** Not all HIV-positive patients receiving highly active antiretroviral therapy (HAART) show adequate viral suppression. This may partially reflect suboptimal adherence. The present analysis examined whether behavioral interventions in the Multi-site Adherence Collaboration in HIV (MACH14) cohort decreased HIV viral load (VL) and whether changes in VL were associated with adherence measured by a Medication Event Monitoring System (MEMS).

**Methods:** Subjects were included from 10 MACH14 randomized controlled trials in which contact occurred between an interventionist and subjects. We studied 435 participants who had: a VL  $\geq 400$  copies/mL when assessed within 3 months before the pre-intervention baseline visit (date closest to the baseline visit); a VL assessment 3-6 months after baseline (date closest to 3 months); and one week of adherence data available at 3-6 months post-baseline (dates closest to 3 months).

**Results:** At baseline, log VL was 4.35 in both the control and behavioral intervention conditions ( $p > .05$ ). Post-intervention log VL was 2.65 in the control and 2.41 in the behavioral intervention condition. A repeated measures analysis of variance confirmed that VL decreased significantly between Visit 1 and Visit 2 ( $p < .0001$ ). However the visit by treatment condition interaction was not significant ( $p > .021$ ), indicating that the behavioral intervention per se did not reliably decrease VL. Statistical analysis (t-test) also indicated that the post-intervention period difference in measured adherence between the control (60%) and behavioral intervention (58%) conditions was not significant ( $p > .05$ ).

**Conclusions:** Among patients enrolled in MACH14 intervention trials who initially had VL  $\geq 400$  copies/mL, medication initiation or change alone may explain the significant decrease in VL. The behavioral adherence interventions as a group, however, did not lead to significantly higher adherence measured by MEMS or to differentially lower VL when compared with a control condition.



## 79996 Qualitative Comparison of Disclosure among Perinatally and Behaviorally HIV-Infected Adolescents

**Idia Thurston<sup>1</sup> (presenting)**, Laura Bogart<sup>1</sup>, Errol Fields<sup>1</sup>, Caroline Hu<sup>1</sup>, Margie Skeer<sup>2</sup>, Elizabeth Closson<sup>3</sup>, Steven Safren<sup>4</sup>, Matthew Mimiaga<sup>3</sup>

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**Background:** Although disclosure can be beneficial for HIV treatment adherence, disclosure potentially can lead to negative consequences, including discrimination. However, little is known regarding how mode of transmission may affect disclosure. We used qualitative methods to explore how disclosure patterns differed among perinatally versus behaviorally infected adolescents.

**Methods:** From August 2010 to June 2011, we conducted semi-structured qualitative interviews with 30 HIV-infected adolescents aged 14-24 years (M = 20.2, SD = 2.6). Participants were asked questions relevant to adherence, including their disclosure patterns, interpersonal relationships, and barriers/facilitators to adherence. Interviews were recorded, transcribed, and examined using thematic analysis.

**Results:** Sixty percent (n = 18) were perinatally infected. Forty percent were female and 7% transgender. Forty-three percent identified as gay, bisexual, or other. Thirty-seven percent were Latino, 50% black, and 20% white. Although most adolescents struggled with disclosure decisions, differences emerged between perinatally and behaviorally infected adolescents. Perinatally infected adolescents tended to disclose less often and to fewer people (with family primarily being aware of their serostatus), have their status disclosed without their consent, and have disclosure occur much earlier in their lives. Behaviorally infected adolescents tended to share their status with friends and partners more often than with family, were more open about their serostatus even when they had prior negative experiences with disclosure, and continued to maintain close relationships with people to whom they had disclosed. Both perinatally and behaviorally infected adolescents were concerned about privacy. Lack of disclosure in perinatally infected adolescents was related to missed doses while away from home, persistent fear of being found out, and stress coping with the emotional aspects of nondisclosure. Because behaviorally infected adolescents were more open about their HIV status, they reported fewer disclosure-related barriers.

**Conclusions:** Findings suggest the presence of unique disclosure patterns among perinatally vs behaviorally infected adolescents. Given the relationship between disclosure and adherence, route of transmission and disclosure should be taken into account when designing adherence interventions.

## 80000 The Quality of Patient-Provider Dialogue about Initiation of Antiretroviral Medications

**Mary Catherine Beach<sup>1</sup> (presenting)**, P. Todd Korthuis<sup>2</sup>, Ira Wilson<sup>3</sup>, M. Barton Laws<sup>3</sup>, Richard Moore<sup>1</sup>, Somnath Saha<sup>4</sup>

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**Objectives:** We sought to evaluate clinicians' adherence to guidelines for initiating antiretroviral therapy (ART) in HIV-infected adults, which recommend that, prior to writing the first prescriptions, clinicians should assess: 1) patients' readiness to take medication; 2) factors limiting adherence; 3) patient understanding of the disease/ regimen; 4) social support; 5) work/home situation; and 6) daily schedule.

**Methods:** As part of the Enhancing Communication and HIV Outcomes (ECHO) Study, routine follow-up visits between 426 HIV-infected patients and 45 clinicians were audio-recorded, transcribed, and coded for the presence of recommended behaviors in ART-initiation dialogue. Additional qualitative analysis was conducted to identify overarching themes related to ART initiation.

**Results:** ART-initiation dialogue occurred in 24/426 encounters (6%). Within these conversations, providers made 3.74 times more utterances than patients did. Patient readiness to initiate treatment was discussed most often (n = 12); patients either spontaneously offered their readiness ("How about I wait 2 or 3 months?") or providers specifically asked briefly in either a closed ("Is this something you are ready to do?") or open ("What do you think about this?") manner. Factors limiting adherence were seldom (n = 3) assessed, and each instance exclusively focused on the logistics of pill-taking ("Do you have trouble swallowing pills?"). Patient work/home situation ("Are you moving soon?") and daily schedule ("So I don't know whether that's mornings for you? Dinnertime?") were each briefly assessed once. Patient understanding and social support were never assessed. Additional qualitative analysis revealed physicians' providing highly complex or disorganized information without checking patient understanding, but also examples of collaborative patient-physician dialogue in promoting readiness to initiate ART.

**Conclusions:** Providers often do not discuss recommended topics prior to prescribing ART and may not use effective strategies when they do. Improving the quality of patient-provider communication about ART initiation may improve patient adherence and reduce HIV/AIDS morbidity and mortality.



## 80001 Individualized Texting for Adherence Building (iTAB) Improves cART Adherence in HIV-Infected Persons with Co-Occurring Bipolar Disorder

David Moore<sup>1</sup> (presenting), Amelia Poquette<sup>1</sup>, Carolina Posada<sup>1</sup>, Kaitlin Blackstone<sup>1</sup>, Ben Gouaux<sup>1</sup>, Jayraan Badiee<sup>1</sup>, Igor Grant<sup>1</sup>, J. Hampton Atkinson<sup>1</sup>

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**Background:** HIV-infected individuals with co-occurring bipolar disorder (BD) have significant difficulties with adherence to combination antiretroviral therapy (cART). Intensive and individualized interventions might prove useful to improve cART adherence in this population; therefore, the present study aimed to develop and evaluate the efficacy of a text message intervention (i.e., individualized texting for adherence building [iTAB]) to improve cART adherence.

**Methods:** Participants included 28 HIV-infected, bipolar (HIV+/BD+) individuals who were randomized into 2 groups, iTAB (n = 14) and an active comparison intervention (CTRL) (n = 14). Both groups received a psycho-education (about 30 min) on the importance of cART adherence and a daily text message to evaluate mood. The iTAB group additionally received medication reminder texts at the prescribed dose time for their selected antiretroviral (ARV) and psychotropic (PSY) medications. We tracked the ARV and PSY using an electronic monitoring system for 30-days, and classified participants as "adherent" or "non-adherent" based on  $\geq 90\%$  adherence to prescribed doses.

**Results:** iTAB participants were significantly more ARV adherent (92.9%) compared with CTRL (57.1%) ( $p = .02$ ). The same effect did not hold for PSY adherence ( $p > .05$ ); 64.3% of both iTAB and CTRL participants were classified as PSY adherent. On a post-intervention questionnaire, iTAB participants perceived the intervention to be more helpful than CTRL participants ( $p = .007$ ), and there was a trend toward iTAB participants having higher post-intervention self-perceived ability to adhere to ARVs compared with CTRL participants ( $p = .05$ ).

**Conclusions:** Personalized text messaging interventions, such as iTAB, appear effective for increasing cART adherence in HIV+/BD+ persons. The intervention was well tolerated and perceived to be helpful. Further studies will evaluate iTAB in other difficult-to-treat HIV-infected samples and evaluate the efficacy of the intervention over longer periods of time.

## 80002 Linkage and Engagement in Care as Predictors of Achieving and Maintaining Viral Suppression

Amanda Castel<sup>1</sup> (presenting), Sarah Willis<sup>2</sup>, Angelique Griffin<sup>3</sup>, Tiffany West<sup>3</sup>, Gregory Pappas<sup>4</sup>

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**Background:** In the District of Columbia (DC), a city with a 3.2% HIV prevalence rate, the DC Department of Health (DOH) is actively engaged in test-and-treat activities. For this strategy to succeed, HIV-infected persons need to be linked to and remain in care to subsequently achieve and maintain viral suppression (VS) and reduce ongoing transmission. This analysis sought to characterize rates of VS and identify factors associated with achievement and maintenance of VS among newly diagnosed HIV-infected persons.

**Methods:** HIV-infected adults and adolescents diagnosed from 2006-2007 were identified in the DC DOH HIV/AIDS surveillance database. Cases with an initial detectable viral load (VL) followed by at least one additional VL test reported to DC DOH prior to 12/31/10 were included in the analysis. Among those persons who achieved VS (VL  $< 400$  copies/mL) the time to VS, the number of visits, and the number of days from diagnosis to VS were calculated. Linkage to care and continuity of care (2 visits within a 12-month period at least 3 months apart) among those achieving VS were compared to those who did not. Lastly, maintenance of VS was measured over the 12-month period after achieving it and predictors of maintenance were examined.

**Results:** Among 988 newly diagnosed cases, 65.6% achieved VS prior to 12/31/2010. The median number of laboratory visits from the initial visit to VS was 3 visits (range 1-22), while the median number of days between diagnosis and VS was 674 (1.8 years; range 25-1,726). A slightly greater proportion of VS cases were linked to care within 3 months (71.0% vs 67.1%,  $p = .20$ ) and significantly more were in continuous care (31.9% vs 22.4%,  $p = .0015$ ). As of 2010, VS was maintained for 62.9% of cases. Persons who maintained VS were more likely to be white than black (AOR 2.49, 95% CI 1.32, 4.70). Slightly more cases that maintained VS remained in continuous care in the year following VS compared with those that did not maintain VS (45.9% vs 40.5%,  $p = .26$ ).

**Conclusions:** Rapid linkage to care and retention in continuous care were observed among those HIV-infected persons who were able to achieve VS. These findings further support the test-and-treat approach and the importance of individual-level VS to reduce HIV incidence.



## 80016 Secondary HIV Transmission Prevention Counseling and Antiretroviral Adherence Messages in an African Setting: A Time-Motion Study

**Ann Kurth<sup>1</sup> (presenting)**, Martin Were<sup>2</sup>, Changyu Shen<sup>2</sup>, John Sidle<sup>2</sup>, Kara Wools-Kaloustian<sup>2</sup>, Stephen Macharia<sup>3</sup>, Abraham Siika<sup>4</sup>

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**Background:** Sub-Saharan Africa has 67% of global HIV and 3% of health providers. Interventions to support positive prevention and antiretroviral therapy (ART) adherence must be scalable at low cost and staff-use.

**Methods:** We conducted a time-motion study (n = 190 return-visit adult patients on ART) in one urban/one rural USAID-Academic Model Providing Access to Healthcare Partnership clinic in western Kenya. The goals were to: assess frequency, length, types of staff-delivered ART adherence, and positive prevention messages; identify unmet counseling needs; and determine times during visits when non-staff-dependent forms of counseling could be delivered. Patients were contacted by trained research assistants (RAs) as soon as they entered clinic; only patients who consented were included. We collected demographic data, including age, gender, languages spoken, monthly income, and travel time to clinic. RAs used PDAs (HandBase<sup>®</sup> software) to record activities, including all counseling and adherence messages received during visits, and the duration of these messages. Unit of analysis was clinic visit, recorded from patient registration to the time he or she left clinic.

**Results:** Observations for 96 rural-clinic patients and 94 urban-clinic patients totaled 194 hours. Mean visit length at rural was 44.5 (SD = 27.9) minutes and at urban 78.2 (SD = 42.1) minutes. Wait times averaged 29.1 (rural) and 61.3 (urban) minutes. 174 (92%) patients were asked about pill-taking behaviors and 57 (30%) about risky behavior during their visit. Patient counseling: ART adherence (n = 188, 99%), positive prevention messages (n = 129, 68%), disclosure (n = 121, 64%), contraception/pregnancy (n = 95, 50%), and alcohol and drug use (n = 62, 33%). Staff-delivered positive-prevention messages averaged 17 and 39 seconds at respective clinics. A randomized controlled trial of a computerized counseling tool is now underway in these 2 clinics.

**Conclusions:** In these sampled clinics there were relatively high rates of counseling, but limited amounts of time spent by providers on counseling. We identified significant amounts of wait time that could be used for self-administered patient education and counseling.

## 80026 High Adherence among HIV-1 Serodiscordant Couples in the Partners PrEP Ancillary Adherence Study

**Jessica Haberer<sup>1</sup> (presenting)**, Jared Baeten<sup>2</sup>, Connie Celum<sup>2</sup>, Elly Katabira<sup>3</sup>, Allan Ronald<sup>4</sup>, Elioda Tumwesigye<sup>5</sup>, Kathleen Thomas<sup>2</sup>, Deborah Donnell<sup>6</sup>, David Bangsberg<sup>1</sup>

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**Background:** Recent trials of pre-exposure prophylaxis (PrEP) against HIV infection have generated conflicting efficacy data. Objective measures of adherence are critical for interpreting trial data and may help explain the variability in efficacy results across trials.

**Methods:** The Partners PrEP Study ("the parent trial") is a placebo-controlled trial of oral tenofovir and emtricitabine/tenofovir PrEP among 4758 HIV-1 serodiscordant couples in East Africa. Adherence was measured through clinic-based pill counts and self-report on a monthly basis. An ancillary adherence study (AAS) also measured adherence with unannounced home-based pill counts (UPC; conducted every month for the first 6 months and quarterly thereafter) and the Medication Event Monitoring System (MEMS; ongoing recordings of bottle openings) at 3 sites in Uganda. Sociodemographic data were collected at enrollment.

**Results:** A total of 1147 HIV-uninfected partners were enrolled in the AAS at the time parent trial efficacy data were released (July 2011): 47% were female, median age was 34 years (IQR 30-40), median years of education were 6 (IQR 3-7), 98% were living with their HIV-infected partner, the median duration of partnerships was 8.5 years (IQR 3.7-15.3), and 29% reported having unprotected sex within the month prior to enrollment in the parent trial. Enrollment in AAS and the parent trial occurred concurrently in 25% of couples; the remainder started the AAS 1-21 months after randomization in the parent trial. Median AAS follow-up was 11 months (IQR 7-15). Median adherence among AAS participants was 98.8% (IQR 96.0-99.8) by clinic-based pill counts, 99.4% (IQR 98.0-100.0) by self-report, 99.1% (IQR 96.9-100.0) by UPC, and 92.1% (IQR 85.9-94.2) by MEMS.

**Conclusions:** Adherence in this subset of participants in the Partners PrEP Study was high by multiple measures, thus providing confidence in the efficacy data from the trial. The lower adherence levels seen by MEMS likely reflect device non-use.





## 80027 Real-Time HIV Antiretroviral Therapy Adherence Monitoring among Adults and Children in Rural Uganda

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**Background:** Current antiretroviral therapy (ART) adherence assessments typically detect missed doses long after HIV viral suppression is lost, and often after drug resistance develops. Real-time, wireless monitoring strategies may enable prevention of treatment failure, thus sustaining the effectiveness of inexpensive and available first-line regimens.

**Methods:** Adherence was measured prospectively in 49 adults and 46 children (aged 2-11 years) by a wireless pill container (Wisepill™) that transmits a cellular signal when opened, and weekly self-report of adults and caregivers of children via interactive voice response (IVR) and Short Message Service (SMS) surveys. HIV RNA was determined every 3 months and during ongoing Wisepill interruptions. Data reflect the first 2261 person-weeks (median 27.5 weeks per participant).

**Results:** Median Wisepill adherence was 91.9% among adults and 96.8% among children. There were 45 and 19 interruptions of 48+ hours among adults and children, respectively. The causes were 6 forgot doses, 2 intentional non-dosing, 4 pocket doses, 2 hospitalizations, 1 unexpected travel, and 2 temporary changes in caregiver; 42 interruptions had no clear cause, possibly reflecting undetected technical problems and/or unreported adherence lapses. All but 2 participants (97%) reported Wisepill was "easy/very easy" to use; all stated they "liked/really liked" being monitored. Mean Wisepill adherence correlated with HIV RNA ( $r = -0.44$ ,  $p = .01$ ). Of 26 ongoing Wisepill interruptions, 4 (15.4%) indicated new viral rebound. Responses were successfully transmitted for 55% of IVR and 82% of SMS surveys. Adherence was reported as 100% in 39% of IVR and 59% of SMS surveys. Median adherence for imperfect adherence was 93.7% by IVR and 96.1% by SMS.

**Conclusions:** Real-time wireless adherence monitoring is feasible and acceptable in a rural, resource-limited setting and correlates with HIV RNA, although data collection needs refinement. Further study should ensure technical function and scalability, as well as explore patterns of viral rebound and real-time intervention development.

\* To be presented by Maya Petersen

## 80028 A Pilot Study of Daily Short Message Service (SMS) Surveys of Sexual Behavior and PrEP Use among Kenyan HIV-1 Serodiscordant Couples

Katie Curran<sup>1</sup> (presenting), Nelly Mugo<sup>2</sup>, Ann Kurth<sup>3</sup>, Kenneth Ngure<sup>4</sup>, Renee Heffron<sup>1</sup>, Connie Celum<sup>1</sup>, Jared Baeten<sup>1</sup>

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**Background:** Mobile phone text messaging represents an emerging low-technology and low-cost option for data collection in Africa. Pre-exposure prophylaxis (PrEP) is a novel HIV prevention strategy. Adherence to PrEP is key for effective HIV prevention, and understanding patterns of adherence related to sexual behavior may be especially important for PrEP efficacy. We are conducting a study of daily Short Message Service (SMS) data collection among HIV-uninfected members of HIV serodiscordant couples to measure sexual behavior and PrEP use.

**Methods:** Participants were recruited from an ongoing PrEP clinical trial in Thika, Kenya (Partners PrEP Study). Eligible participants were literate, owned a mobile phone, knew how to send and receive SMS, and had a high response rate ( $\geq 5$  daily surveys completed) during the first week of the study. Short surveys were automatically sent through SMS to participants on a daily basis for up to 2 months. Participants received a password question, followed by 3-4 yes/no questions on sexual activity, condom use, sexual intentions for the next day, and PrEP use in the last day. Participants were compensated with delivery of "airtime" to their mobile phone twice a week.

**Results:** Since December 2011, 64 participants have enrolled. A total of 1713/1839 (93.1%) daily surveys have been completed. Among complete surveys, sex was reported on 32.0% of days, and 25.0% of participants reported sex without a condom at least once. Participants reported taking PrEP on 92.2% of days, and 47 participants (73.4%) took PrEP on  $\geq 90\%$  of days surveyed. Non-responses were explained by lack of airtime, mobile phone network outage, and temporary phone problems.

**Conclusions:** Daily SMS data collection on sexual behavior and PrEP use is acceptable and feasible in this study of HIV-uninfected persons taking PrEP. Automated reimbursement and improved mobile phone network capacity may increase response rates.



## 80029 ART Ineligibility Confers High Risk of Poor Retention in the Pre-ART Period among Persons Newly Diagnosed with HIV Infection in Sierra Leone

Dan Kelly<sup>1</sup> (presenting), Franck Lamontagne<sup>2</sup>, Sulaiman Conteh<sup>3</sup>, Lily Chattopadhyay<sup>4</sup>, Gregoire Lurton<sup>2</sup>, Cora Nally<sup>5</sup>, Mohamed Barrie<sup>5</sup>, Brima Kargbo<sup>3</sup>, Thomas Giordano<sup>1</sup>

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**Introduction:** Loss to follow-up occurs at every clinical step in HIV care, yet retention rates and risk factors for the pre-antiretroviral therapy (pre-ART) period are not well understood. Few studies in sub-Saharan Africa have followed a cohort of patients from HIV testing through ART initiation.

**Methods:** We followed a prospective cohort of 155 persons newly diagnosed with HIV infection in Freetown, Sierra Leone. At baseline, participants completed a survey, including Duke-UNC functional social support scale, household food insecurity and access scale, and Medical Outcomes Survey HIV. HIV testing, ART eligibility and initiation, and appointments were measured. There were up to 3 observation periods, depending on clinical relevance: 90 days after diagnosis, 90 days after first clinical visit, and 90 days after ART initiation. During the observation period, persons were expected to attend monthly appointments. If persons attended no subsequent visits, they were considered "out-of-care." Participants were dichotomized as "in-care" and "out-of-care."

**Results:** Among 155 participants newly diagnosed with HIV infection, 123 people (81%) were staged for ART. Of the 101 ART-eligible and 22 ineligible people, 19 (19%) and 17 (77%) were "out-of-care," respectively. Of the 82 ART-eligible, in-care persons, 5 did not initiate ART. Of the 77 persons who initiated ART, 21 (27%) were "out-of-care." In total, 89 of 155 persons (57%) were "out-of-care," and 68 of them (76%) were lost during the pre-ART period. The risk for being "out-of-care" was not significantly predicted by overall scores for social support, HFIAS, MOS-HIV, distance from clinic, educational level, and income. In a logistic regression, persons "out-of-care" were more often male (OR 4.5 [1.4-14.5],  $p = .01$ ), younger (OR 1.1 [1.0-1.2],  $p = .01$ ), and ART ineligible (OR 5.2 [1.3-19.7],  $p = .02$ ).

**Conclusions:** Most participants went "out-of-care" during the pre-ART period, especially before staging or after being staged as ART ineligible. More attention should be given to retaining the pre-ART population in care.

## 80031 Evaluation and Process Outcomes from an Adherence Intervention to Support HIV Pre-Exposure Prophylaxis (PrEP) Adherence in HIV-Serodiscordant Couples in Uganda

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**Background:** Daily pre-exposure prophylaxis (PrEP) can be an effective HIV prevention strategy, but high levels of adherence are required for maximum benefit. We describe characteristics of a PrEP adherence intervention delivered in the context of the Partners PrEP Study, and preliminary data on its impact on adherence.

**Methods:** The Partners PrEP Study is a placebo-controlled trial of oral tenofovir and emtricitabine/tenofovir PrEP among uninfected members of HIV-serodiscordant couples, which includes an ancillary adherence study (AAS) at 3 of 9 study sites (Kabwohe, Kampala, and Tororo, Uganda). Participants with <80% adherence (measured by unannounced pill count [UPC] conducted at home monthly for 6 months, then quarterly thereafter) received standardized adherence counseling using principles of cognitive-behavioral theory, motivational interviewing, and problem-solving. The intervention was developed using an iterative process, and is based on an evidence-based HIV treatment adherence intervention. Data are through July 10, 2011, when the Partners PrEP Study reported its primary efficacy results.

**Results:** A total of 1147 HIV-seronegative participants were enrolled in the AAS: 53% were male and the median age was 34 years. One-hundred twenty-four participants (10.8%) ever had <80% UPC adherence, 101 (81%) received at least one intervention session. Average length of intervention sessions was 30.2 minutes, and participants attended an average of 6.8 sessions (range 1-16). Among those with identified adherence barriers, travel (focus of 19% of sessions) and forgetting (focus of 18% of sessions) were most common. Among those with at least 2 UPC post-intervention, adherence improved to >80% in 61 of 66 (92%); 54 (82%) remained at >80% UPC adherence for the remainder of follow-up.

**Conclusions:** A PrEP adherence intervention was feasible in a clinical trial of PrEP in Uganda and improved short-term PrEP adherence. Future research must identify PrEP users with low adherence for intervention and determine optimal duration of intervention to maximize PrEP effectiveness.



## 80033 Is a Simple Self-Rating or Visual Analogue Scale (VAS) More Reliable than Prescription Refill (PR) Data as an Indicator of Non-Adherence in a Resource-Limited Setting in South Africa?

Hannelie (JC) Meyer<sup>1</sup> (presenting), Beverley Summers<sup>1</sup>, Pearl Lentsoane<sup>1</sup>, Vincent Mokoka<sup>1</sup>, Jacob Nyingwa<sup>1</sup>, Shirley Teffu<sup>1</sup>

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**Background:** Valid, inexpensive, rapid assessment of adherence is essential to monitor antiretroviral treatment (ART) in resource-limited settings. Previous studies identified (electronic) PR data as a strong predictor of sub-optimal adherence. Functional computer systems are not always available in resource-limited settings to facilitate reliable and easily-traceable PR data.

**Methods:** Data were collected for 253 patients (32% male; 68% female) who were on ART at least 6 months. Self-reported adherence measures included a 6-level rating scale and VAS (11 medicine containers from empty to full, to assess tablets left). PR adherence (days in possession of ART, relative to days of ART prescribed) was calculated for 7 months prior to the interview. Viral load (VL) (n = 184) and CD4 cell count (n = 164) for the prior 8 months, were collected. Agreement among adherence measures and association with clinical markers were assessed (Spearman's rank correlation). Sensitivity and specificity of adherence measures were calculated for different adherence cut-points.

**Results:** Mean (median) adherence was 86.5% (90%) for the VAS, 84.3% (80%) for the rating scale and 93.6% (95.6%) for PR. The rating scale and VAS showed best agreement among the 3 adherence measures ( $\rho = 0.632$ ;  $p < .0001$ ). All measures showed an association with VL; but rating scale was the strongest ( $\rho = 0.333$ ;  $p < .0001$ ). Change in CD4 cell count was associated with the rating scale ( $\rho = 0.247$ ;  $p = .0028$ ) and VAS ( $\rho = 0.231$ ;  $p = .0052$ ). The rating scale performed best to detect possible treatment failure with sensitivity/specificity of 96%/25% for immunologic failure and 90%/30% for virological failure when non-adherence was defined as <95% or "less than excellent."

**Conclusions:** A simple rating scale and VAS detected non-adherence and can identify patients in need of treatment support and/or at risk of treatment failure. These tools are ideally suited for a resource-limited setting where sufficient human resources to perform time-consuming adherence assessments and computer systems to calculate PR adherence are not available.

## 80037 Enhancing Pre-Exposure Prophylaxis Adherence in Men who have Sex with Men: Determining Optimal Content for a PrEP Adherence Package

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**Background:** Pre-exposure prophylaxis (PrEP) is a promising biomedical approach to primary HIV prevention for men who have sex with men (MSM). Recent clinical trials showed that effectiveness was closely tied to medication adherence. The purpose of the current study was to determine the optimal content for a comprehensive PrEP package that can maximize adherence and minimize risk compensation.

**Methods:** In order to understand barriers and facilitators of PrEP adherence, we conducted 2 focus groups (N = 18) with HIV-uninfected MSM who participated in the iPrEx or CDC PrEP studies at Fenway Health Institute, Boston, MA, and who were currently taking PrEP. Participants were asked questions about their experiences taking PrEP, perceived barriers and facilitators affecting PrEP adherence, and their suggestions for interventions that could improve PrEP adherence. Focus groups were recorded, transcribed, and examined using thematic analysis.

**Results:** Participants' mean age was 44 (SD = 7.4). Fourteen MSM identified as white, 4 as African American/black, and one as Hispanic/Latino. Participants expressed a high level of motivation to participate in PrEP adherence interventions that could enhance PrEP efficacy. Several descriptive themes to enhance PrEP adherence emerged: (1) providing a better understanding of PrEP effectiveness; (2) addressing substance use and mental health barriers; (3) using novel facilitators (text message reminders, alarm clock/phone); (4) educating about the problems of inconsistent use (drug resistance if acutely infected) and/or long-term use (bone-density loss); (5) addressing potential HIV stigma from friends and partners; and (6) training providers of PrEP in rapport building.

**Conclusions:** These themes were used to inform the development of a PrEP curriculum adherence package, which consists of PrEP psycho-education, solving adherence barriers, promoting individualized facilitators, and managing possible stigma associated with taking PrEP. The next step is to conduct a pilot of this intervention to assess feasibility and enhance participant acceptability.



## 80038 A Computerized Tailored Information Intervention to Improve Health Literacy and Adherence in Persons with HIV Infection

Raymond Ownby<sup>1</sup> (presenting), Drenna Waldrop-Valverde<sup>2</sup>, Joshua Caballero<sup>1</sup>, Robin Jacobs<sup>1</sup>, Amarilis Acevedo<sup>1</sup>

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**Background:** Among persons treated for HIV infection, lower levels of health literacy have been related to less knowledge about HIV and its treatment and lower levels of medication adherence. The purpose of this study was to develop a computer-delivered intervention to improve health literacy in this group using the Information-Motivation-Behavioral Skills (IMB) model as a content framework and to evaluate whether improvements in health literacy resulted in better medication adherence.

**Methods:** We enrolled 124 persons with HIV infection in the study, which comprised 3 sessions at 1-month intervals: (1) baseline, during which self-reported knowledge about HIV and its treatment was assessed and participants were oriented to the use of an electronic pill bottle to monitor their adherence (Medication Event Monitoring System or MEMS); (2) intervention, at which 1-month adherence was recorded and participants completed the study intervention, and (3) follow-up, during which post-intervention adherence was recorded and HIV-related knowledge was again assessed. Mood and health-related self-efficacy were also assessed at baseline and follow-up. Outcomes were analyzed in repeated measures ANCOVA models correcting for age, education, gender, race, and cognitive status.

**Results:** Analyses showed that participants reported significant increases in Information and Behavioral Skills after participating in the intervention and that these gains were retained after 1 month. Among those participants with less than 95% adherence at baseline ( $n = 51$ ), MEMS adherence increased ( $F [1,42] = 4.72, p = .04$ ), and among those with less than 80% adherence ( $n=18$ ) increased even more (baseline mean = 55%; follow-up mean = 73%; ns). Participants showed significant decreases in depression and corresponding but non-significant increases in self-efficacy.

**Conclusions:** A computer-delivered and individually tailored intervention can improve the health literacy of individuals treated for HIV infection. Changes in health literacy may be related to improved HIV knowledge, medication adherence, self-efficacy, and mood.

## 80040 The Spectrum of Engagement in HIV Prevention: Proposal for a Pre-Exposure Prophylaxis (PrEP) Cascade

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**Introduction:** Pre-exposure prophylaxis (PrEP) is a rapidly emerging HIV prevention strategy. Following release of iPrEx results, several demonstration projects are being planned to evaluate PrEP delivery in real-world settings. While steps in the spectrum of engagement in HIV care have been defined and used to identify gaps and build interventions to improve health on the individual and population level, a similar framework has not been developed for daily PrEP in HIV-uninfected populations. We propose a cascade of PrEP delivery as a model to define metrics of success in PrEP implementation programs.

**Description:** Adapting models of engagement in HIV care, we define 6 key steps in the cascade of PrEP delivery: 1) identification of potential PrEP candidates (including confirmed HIV-negative individuals who meet behavioral eligibility criteria); 2) individual decision to adopt PrEP as a prevention strategy; 3) successful referral and linkage of individuals from the testing site to the PrEP program; 4) initiation of PrEP among those assessed to be medically and behaviorally eligible; 5) retention in the PrEP program over time; and 6) maintaining adherence and persistence to PrEP medication to achieve a detectable drug level associated with protection. Clinic-based metrics (steps 4-6) can be obtained through data collected at the PrEP delivery site, while measures on identification, interest, and referrals (steps 1-3) may require use of existing and novel outreach and surveillance strategies (eg, use of electronic health records).

**Lessons Learned:** The PrEP cascade provides a framework for understanding individual and structural factors which may determine the overall public health impact of PrEP programs. These metrics can evaluate the relative magnitude of gaps at each stage of PrEP delivery and whether gaps vary by key populations (e.g., men of color, young men who have sex with men); findings may signify the need for targeted interventions to achieve equity in PrEP outcomes across diverse populations.

**Recommendations:** We suggest use of a cascade of PrEP delivery to plan data collection in upcoming PrEP demonstration projects and to evaluate their success. Use of common metrics will also allow for meaningful comparisons across different PrEP programs. Once populated with actual data from these projects, modeling can be conducted to evaluate the impact of potential interventions targeting various stages of the PrEP cascade with the goal of maximizing public health impact.



## 80042 MEMS-Defined Treatment Interruptions Independently Predict HIV RNA Controlling for Average Adherence in Rural Uganda

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**Background:** HIV adherence is most often characterized as the number of pills taken as a proportion of the number of pills prescribed. Structural and economic barriers to care can lead to HIV antiretroviral treatment interruptions in resource-limited setting with otherwise good adherence. We compared the contribution of Medication Event Monitoring System (MEMS)-defined extended treatment interruptions of greater than 10 days with average adherence in a cohort of HIV-positive people starting antiretroviral therapy (ART) in Mbarara, Uganda.

**Methods:** The Uganda AIDS Rural Treatment Outcomes (UARTO) cohort includes treatment-naïve people living with HIV/AIDS (PLWHA) initiating ART in Mbarara, Uganda, followed quarterly with MEMS caps, structured interviews, and HIV RNA determinations. The outcome of interest was viral failure (>400 copies/mL). The primary exposures of interest were average adherence over the previous 90 days (per 10% increment, specified as a continuous variable) and whether or not the participant had experienced any extended treatment interruptions lasting 10 days or more in the prior 90 days (specified as a binary variable). We estimated logistic regression models with cluster-correlated robust estimates of variance to account for dependence of observations within participants over time. All estimates were adjusted for duration of treatment, socio-demographic variables, alcohol use, CD4+ T-lymphocyte count, and Hopkins Symptom Checklist depression score.

**Results:** A total of 466 persons were included. Across all time periods, average 90-day adherence was 85%. Among the participants, 38 (8.2%) had 101 treatment interruptions. Average adherence was 74.7% among those with extended treatment interruptions and 85.5% among those without extended treatment interruptions. In 2 separate multivariable logistic regression models, viral failure was associated with both average adherence over the previous 90 days (AOR = 0.84; 95% CI, 0.78-0.92) and any 10-day treatment interruption in the previous 90 days (AOR = 5.84; 95% CI, 2.28-15.0). When both average adherence and treatment interruptions were added simultaneously to the regression model, both retained statistically significant associations with viral failure: average adherence (AOR = 0.88; 95% CI, 0.81-0.96) and treatment interruptions (AOR = 3.32; 95% CI, 1.27-8.66).

**Conclusions:** Treatment interruptions, even in the context of high average adherence, have substantive adverse effects on virologic outcomes among PLWHA.

\* To be presented by Maya Petersen

## 80044 Psychosocial Predictors of Acceptability and Risk Compensation for Pre-Exposure Prophylaxis (PrEP): Results from 3 Studies of Critical Populations

Sarit Golub<sup>1</sup> (presenting), Corina Lelutiu-Weinberger<sup>1</sup>, Kristi Gamarel<sup>1</sup>, Jonathan Rendina<sup>1</sup>, José Nanin<sup>2</sup>, Jeffrey Parsons<sup>1</sup>

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**Background:** Pre-exposure prophylaxis (PrEP) has the potential to become a powerful HIV prevention tool; however, many questions remain about its acceptability and impact on behavior among men who have sex with men (MSM). Brief surveys have been conducted to assess willingness to take PrEP, but almost no studies have examined psychosocial predictors of both PrEP acceptability and its potential influence on sexual risk-taking.

**Methods:** Data were collected from 3 populations critical to the success of PrEP as a prevention strategy: a) lesbian, gay, bisexual, and transgender (LGBT) youth (aged 16-24 years) in the Ballroom scene in NYC (n = 85); b) black-identified MSM never tested for HIV (n = 45); and c) highly sexually active MSM (median of 20 partners in the past 90 days; n = 80). Participants completed self-report surveys about PrEP knowledge, acceptability, and risk compensation. All data were collected between March and December 2011 (i.e., after the release of the iPREx results.)

**Results:** Among youth, the most important predictor of PrEP acceptability was a desire to escape constant worry about HIV infection. On the other hand, youth expressed concern about the association of daily antiretroviral (ARV) medication use with "being sick." Among Black MSM, HIV conspiracy beliefs - especially negative beliefs about HIV medications - were the strongest predictor of resistance to PrEP. Among highly sexually active MSM, 34% reported that taking PrEP would increase their risk behavior. Risk compensation was strongest among MSM who: a) make decisions about condom use based on situational risk perception (p < .001); and b) prefer unprotected sex because they consider it transgressive (p < .001).

**Conclusions:** Findings from all 3 studies underscore the importance of social-behavioral data in the development of PrEP policies and interventions. The creation of effective PrEP messaging must acknowledge an existing sociopolitical context around HIV prevention for many MSM, which may influence the way messages are interpreted and internalized. Behavioral interventions to support PrEP use are critical, and must recognize the role of risk perception and affect in sexual decision-making.





## 80047 Improvements in Medication Adherence and Healthcare Utilization as Evidenced from a Pilot Intervention Combining Contingency Management and Behavioral Activation to Reduce Stimulant Use among HIV-Infected Individuals

Jennifer Mitty<sup>1</sup> (presenting), Elizabeth Closson<sup>2</sup>, David Pantalone<sup>3</sup>, Michael Garber<sup>2</sup>, Wade Taylor<sup>2</sup>, Steven Safren<sup>4</sup>, Matthew Mimiaga<sup>4</sup>

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**Background:** Among HIV-infected individuals, stimulant use, including crack/cocaine and methamphetamines, is a prevalent and treatment-refractory problem. Across studies, stimulant use is strongly associated with suboptimal antiretroviral therapy (ART) adherence and decreased utilization of medical care. Evidence-based treatments for stimulant use are not widely available; however, the effects of such interventions may positively impact HIV self-care outcomes.

**Methods:** We piloted a novel intervention combining a 12-week voucher-based contingency management (CM) program for stimulant use, with behavioral activation, an evidence-based treatment for depression, with 11 HIV-infected stimulant users. Assessments were conducted at baseline, 3-, and 6- months and included validated ART adherence measures.

**Results:** Participant's mean age was 45 years (SD = 7.8) and 35% were ethnic/racial minorities. Of the 7 completers, at baseline, all were prescribed ART, met DSM-IV criteria for stimulant dependence, and had a mean depressive symptoms score of 26 (CES-D), which was reduced to 17 at the 6-month assessment. As previously reported, reductions in stimulant use over the course of the intervention were achieved suggesting a high effect size estimate. At baseline, self-reported mean adherence (past 30 days) scores were 90% and improved to 96% at month 6 (mean % change = 6.5%; Cohen's  $d = 0.89$ ). On average, participants reported missing 10% doses in the past 7 days at baseline, and this improved to 2% at 6 months (mean % change = 80%; Cohen's  $d = 0.85$ ). At baseline, 71% felt substance use affected their ability to follow-up with HIV care and this improved to 14% at the 6-month assessment.

**Conclusions:** This pilot intervention to decrease stimulant use among HIV-infected individuals improved participants' adherence and decreased the role of substance use as a barrier to HIV care. This combined, novel intervention should be further investigated through efficacy testing, and if successful, adopted into HIV clinical care settings.

## 80048 Preference for Daily versus Intermittent PrEP Dosing among Substance-Dependent High-Risk MSM

Jennifer Mitty<sup>1</sup>, Elizabeth Closson<sup>2</sup>, Blake Rowley<sup>2</sup>, Kenneth Mayer<sup>2</sup>, Matthew Mimiaga<sup>3</sup> (presenting)

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**Background:** Pre-exposure prophylaxis (PrEP) has been shown to decrease HIV transmission in high-risk men who have sex with men (MSM), but to be effective, adherence must be optimized. MSM who use drugs (e.g., crystal meth/GHB/cocaine/ecstasy/poppers) to enhance sexual activity are at increased risk for HIV acquisition and may be a particularly important group to consider when designing PrEP intervention and uptake protocols.

**Methods:** We are collecting 40 semi-structured qualitative interviews with HIV-uninfected MSM who meet DSM-IV criteria for substance abuse/dependence and report unprotected anal sex with a casual or serodiscordant male partner while using drugs in the past 3 months. The interview guide addresses: substance use, sexual-risk, social-support, healthcare, employment/housing, knowledge of PrEP, and logistical considerations for PrEP utilization. Interviews were recorded, transcribed, and examined using thematic-analysis.

**Results:** Twenty participants have completed the interviews thus far. The mean age was 36 years (SD = 12.0), 33% were black and Latino, and their mean number of partners in the last 3 months was 7 (SD = 5.8). Seventy-two percent had heard of PrEP, and 86% were "likely" to use it. The most salient theme regarding perceived PrEP adherence was the preference for daily PrEP rather than PrEP before sex. Although benefits of intermittent use (e.g., mitigating side effects, cost) were discussed, subthemes to contextualize preferences for daily use included: 1) ease of integrating PrEP with other medications/into daily routines; 2) concerns about missing doses of intermittent PrEP due to drug/alcohol use; 3) ambivalence of using PrEP around casual partners due to privacy concerns; 4) reluctance to carry pills away from their residence; and 5) inability to plan ahead about sex.

**Conclusions:** Among substance using, high-risk MSM, daily dosing of PrEP may enhance acceptability/adherence to this HIV prevention strategy. Further data elucidating facilitators and barriers to PrEP will inform intervention development to improve access and utilization of biomedical prevention among this population.



## 80057 Adherence in Mobile Populations: Qualitative Study of ART for Refugees in Sub-Saharan Africa

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**Background:** Efforts to scale-up distribution of antiretroviral therapy (ART) among refugee populations in sub-Saharan Africa have increased access and utilization of therapy. Yet we know little of the experience of refugees taking ART or of the adherence obstacles they face. This qualitative study addresses that gap.

**Methods:** Open-ended interviews were conducted with HIV-positive refugees living in Nakivale Refugee Settlement in southwest Uganda. Interviews focused on: (1) accessibility of HIV/AIDS-related testing and care; (2) experiences of ART adherence; and (3) perspectives on how to improve access to testing and care, adherence, and retention. Data were collected at the Nakivale HIV/AIDS Clinic from March to July 2011 and included patient (n = 73) and staff (n = 4) interviews, and observations of clinical activities. Category construction methods were used to analyze the data.

**Results:** Despite the pull to focus energy on immediate survival needs, Nakivale refugees living with HIV/AIDS prescribed ART prioritized adherence to therapy. Yet they experienced interruptions in treatment. Circumstances leading to treatment interruptions included: food shortages, insecurity in the settlement, delays in returning home when moving without medications, inability to access ART during extended stays outside Nakivale, and delays in accessing ART during repatriation. Key adherence strategies employed included: carrying medications when traveling, using medication reminders, traveling to clinic immediately upon feeling unwell, having a plan for refilling ART and accessing care when acute issues arise, and avoiding travel outside Nakivale to remain close to the HIV clinic.

**Conclusions:** Refugees face similar but more extreme adherence challenges compared with other sub-Saharan African populations. Despite considerable barriers to adherence, they take significant steps to ensure treatment success. To facilitate adherence during travel away from Nakivale, interventions should seek to: (1) improve continuity of care during travel; and (2) implement procedures for transfer of care for refugees transitioning permanently out of the settlement.

## 80063 Women, ART, and Adherence: A Longitudinal Comparison of Antiretroviral Adherence by Gender

Cathy Puskas<sup>1</sup> (presenting), Kate Salters<sup>2</sup>, Wendy Zhang<sup>2</sup>, Cari Miller<sup>1</sup>, Julio Montaner<sup>3</sup>, Robert Hogg<sup>2</sup>

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**Background:** Women living with HIV in high- and very high- human development index countries are often considered to be more vulnerable to antiretroviral therapy (ART) non-adherence than men. In order to identify the impact of gender on non-adherence in British Columbia, Canada, where ART is available free of charge, we compared adherence between men and women by length of time on treatment and calendar year.

**Methods:** Using the HAART Observational Medical Evaluation and Research (HOMER) cohort, a longitudinal cohort following all HIV-positive individuals in British Columbia receiving ART from 1996 to present, we compared the proportion of men and women adherent to ART by calendar year as well as time on therapy. We evaluated 4162 individuals, 3375 (81%) males and 787 (19%) females. The sample was stratified by injection drug use (IDU) status, and self-reported Aboriginal ethnicity. Adherence was defined as whether or not  $\geq 95\%$  adherence to ART was reached during 6-month periods, based on pharmacy refill adherence. Chi-squared test was used to assess significance between the proportion of men and women reaching  $\geq 95\%$  adherence.

**Results:** Women had a significantly lower level of adherence than men in all categories, with a difference of approximately 20% in the proportion meeting the cutoff of 95%. From 1999 onward, women showed significantly lower adherence than men, although levels of adherence improved at a similar rate in men and women. When examined by length of time on treatment, women were significantly less adherent than men up to 9.5 years on therapy. This pattern was observed among IDU and non-IDU, Aboriginals and Non-Aboriginals; however, the proportion of individuals attaining  $\geq 95\%$  adherence was considerably lower among IDUs and those of Aboriginal ethnicity.

**Conclusions:** HIV-positive women in British Columbia are significantly less adherent to ART than their male counterparts, in the study sample as a whole, as well as within each individual group.



## 80064 A Culturally Adapted Intervention to Treat Depression and ART Non-Adherence on the US-Mexico Border: Final (Promising!) Results from a Pilot RCT

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**Background:** Although antiretroviral therapy (ART) is increasingly available and accessible on the US-Mexico border, preliminary studies indicate that poor adherence (ADH) and depressive symptomatology detract from its potential success.

**Methods:** We culturally adapted Safren's cognitive-behavioral therapy program for treatment of poor adherence and depression (CBT-AD). Participants were 40 clients of Mexican descent at a community-based HIV primary care clinic in El Paso, Texas, who reported depressive symptomatology and less than optimal ADH. Intervention participants received at least 12 sessions of CBT-AD in English or Spanish over 6 months as well as electronic reminders (via MedSignals®); control participants received the clinic's usual care. Assessments were conducted at baseline, post-intervention, and 9-month follow-up and included ADH according to a 7-day visual analog scale (VAS) and 2-week electronic data monitoring (EDM); depressive symptomatology according to the self-report Beck Depression Inventory (BDI) and the clinician-administered Montgomery-Asberg Depression Rating Scale (MADRS); and the biomarkers of HIV-1 RNA viral load (VL) and CD4 cell count. Analyses were not powered for statistical tests of efficacy; therefore, the focus was on ascertaining the magnitude and valence of the intervention effects with p values provided for reference.

**Results:** Longitudinal intention-to-treat analyses with generalized estimating equations indicated improvement in the intervention over control arm from baseline to post-intervention, which was maintained at follow-up for both self-reported ADH (odds ratio [OR] post-intervention = 3.43,  $p = .001$  / OR follow-up = 2.11,  $p = .08$ ) and EDM ADH (OR = 3.92,  $p = .03$  / 3.23,  $p = .22$ ) as well as BDI-rated (estimate [Est] = -3.64,  $p = .05$  / -4.80,  $p = .01$ ) and MADRS-rated (est = -5.14,  $p = .14$  / -1.41,  $p = .68$ ) depression. Although there was improvement in CD4 cell count at post-intervention (est = 69.45 cells/mm<sup>3</sup>,  $p = .07$ ), the effect did not remain significant at follow-up (est = 25.71 cells/mm<sup>3</sup>,  $p = .89$ ), and there were negligible effects on VL (possibly due to ceiling effects).

**Conclusions:** The culturally adapted CBT-AD merits further evaluation as a tool to treat depression and non-adherence among Latinos on the US-Mexico border.

## 80066 Are Intervention (versus Control) Arm Participants in ART Adherence Promotion Interventions More Likely to Overestimate Adherence? Findings from the MACH14 Study

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**Background:** Typically, intervention-arm participants in antiretroviral therapy (ART) adherence-promotion trials are exhorted to adhere to their prescribed ART regimens, possibly creating demand characteristics that would lead to overestimates of adherence. Subsequently, self-reports of adherence are often considered unacceptable, or not rigorous, in determining intervention efficacy. For example, in evaluating adherence interventions for possible dissemination, the US Centers for Disease Control and Prevention relegated outcomes based on self-reported adherence to the category of "good" but not "best" evidence of efficacy, which was reserved for purportedly more objective assessment methods.

**Methods:** The Multi-site Adherence Collaboration in HIV (MACH14) is a collaboration across 16 studies (14 sites) in the US that assessed ART adherence with electronic drug monitoring (i.e., Medication Event Monitoring System [MEMS]). Individual-level data were pooled. Of the 16 studies, 9 (N = 1711) had non-missing data on the relevant variables for intervention- (n = 1055) and control- (n = 656) arm participants. The final sample was mainly male (70%); African American, (49%), white (30%), Latino (12%); and gay (42%). Self-reported adherence was assessed at immediate post-intervention for the previous 3 days, averaged across medication. The MEMS adherence estimate for the exact corresponding interval was calculated for each participant. Viral load (VL) data matching closest to the self-reported adherence date were used. Main effects for arm, self-reported adherence, and the interaction term adhXarm were entered in 2 models: one with the outcome of VL and the other with the outcome of MEMS. Models were adjusted for age, sex, race/ethnicity, education, and sexual orientation.

**Results:** The interaction term for VL was non-significant, but the MEMS model was significant, indicating that participants in the control condition (not, as expected, the intervention arm) were more likely to overestimate their adherence compared with MEMS data.

**Conclusions:** Findings suggest self-reported adherence in ART adherence promotion intervention trials is not susceptible to demand characteristics and may constitute a valid outcome for the purposes of intervention efficacy evaluations.



## 80072 Evaluation of the Feasibility and Validity of Short Message System (SMS) Text Messaging for Assessment of Antiretroviral Therapy Adherence among Youth Living with HIV/AIDS (YLH)

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**Background:** For youth living with HIV/AIDS (YLH), non-adherence to antiretroviral therapy (ART) can lead to poor health outcomes and decreased life expectancy. Reliable real-time methods to assess adherence are needed to facilitate early intervention and promote viral suppression. The purpose of this study was to assess feasibility and validity of short message system (SMS) text messaging for assessment of adherence among YLH.

**Methods:** This pilot study was conducted from 2009 to 2010. Eligibility criteria included HIV-positive serostatus, aged 12-29 years, use of personal cell phone, English-speaking, and on ART with poor adherence. During the 24-week study period participants received personalized daily SMS reminders with a follow-up message one hour later asking whether they took medication and directing a response via return text message. To determine whether or not responsiveness to text messages would be a feasible, valid measure of adherence, we calculated the overall percentage of text back responses and compared positive responses to a reliable, valid measure of self-reported adherence, the Visual Analogue Scale (VAS).

**Results:** Participants (n = 25) were mean age = 23 years, largely male (92%), black (60%) and behaviorally infected (84%). In response to text messages from the research team, the text-back function was used only 48% of the time to indicate whether medication had been taken or not. In addition, while average adherence during the follow-up period was approximately 91% as measured by the VAS, participants texted back that they had taken medication only 40% of the time; the 2 measures were positively, but weakly and non-significantly correlated (r = .33, p > .05).

**Conclusions:** This pilot study showed low adherence with the text-back function and the level of adherence indicated was not well correlated with a reliable adherence measure (VAS). However, the text-back function may provide important real-time information that may help providers to address adherence issues and its role should be further explored.

## 80074 Differential Impact of Non-Adherence on Week 96 Outcomes in the Emtricitabine/Tenofovir DF (FTC/TDF) Subset of Pooled ECHO and THRIVE Studies Comparing RPV vs EFV in Treatment-Naive, HIV-1-Infected Adults

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**Background:** In the ECHO and THRIVE studies, rilpivirine (RPV) demonstrated noninferior efficacy to efavirenz (EFV) at Week (W) 48 with a favorable tolerability/safety profile. In multivariate analyses, adherence was prognostic of W48 virologic response for both arms. Impact of adherence in ECHO/THRIVE participants receiving FTC/TDF is important due to availability of single tablet regimens (STRs) of FTC/RPV/TDF and EFV/FTC/TDF.

**Methods:** ECHO/THRIVE subjects receiving FTC/TDF with RPV or EFV were included. Adherent subjects defined as >95% using Modified-Medication Adherence Self-Report Inventory (M-MASRI). Baseline viral load (BLVL) classified as low ( $\leq 100,000$  copies/mL) or high ( $> 100,000$  copies/mL). Fisher's Exact test was used for comparisons. Multivariate analysis of W96 virologic response (HIV-1 RNA VL  $< 50$  copies/mL; ITT-TLOVR) included age, race, gender, weight, adherence, BLVL, and baseline CD4 cell count.

**Results:** Of 1096 evaluated participants, 94% had M-MASRI data; of those, 87% (RPV+FTC/TDF) and 85% (EFV+FTC/TDF) were classified as adherent. Baseline characteristics were similar across study arms for adherent and non-adherent subjects: median age (34-37 years), BLVL ( $5.0-5.1 \log_{10}$  copies/mL), baseline CD4 cell count (231-285 cells/mm<sup>3</sup>), female (19%-26%), and Hispanic ethnicity (24%-26%). The non-adherent group had more black subjects vs the adherent group: 46% vs 20% (RPV+FTC/TDF) and 37% vs 20% (EFV+FTC/TDF) [both p < .01]. Overall W96 virologic responses for RPV+FTC/TDF and EFV+FTC/TDF were identical at 77%. Responses were 16%-25% higher in adherent vs non-adherent: 81% vs 56% (RPV+FTC/TDF) and 83% vs 67% (EFV+FTC/TDF). For RPV+FTC/TDF this adherence-based difference was present for both BLVL strata. For low BLVL, Wk 96 responses for RPV+FTC/TDF and EFV+FTC/TDF were 87% in the adherent group and 62%-63% in the non-adherent group. At high BLVL, response to EFV+FTC/TDF was less impacted by adherence (80% adherent vs 70% non-adherent) compared with RPV+FTC/TDF (74% vs 50%). Detailed results of the multivariate analysis will be presented.

**Conclusions:** These data suggest that for high BLVL, adherence impacted outcomes more with RPV+FTC/TDF compared with EFV+FTC/TDF. Further research assessing efficacy and adherence of existing STRs by BLVL is needed.



## 80075 Qualitative Analysis of Factors Influencing Adherence of Pediatric Patients to ART in Rural Uganda

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**Background:** High antiretroviral therapy (ART) adherence is critical for successful HIV treatment. Little is known about the factors that support high adherence and good clinical outcomes among caregiver-child dyads in developing settings.

**Methods:** The Pediatric Real-time Adherence Monitoring Study (PedRAMS) involved prospective adherence monitoring among 46 ART-experienced children for 6 months in rural Uganda, using a wireless medication container (Wisepill™) that transmits real-time adherence data over cellular networks. We conducted in-depth interviews of 35 caregivers who participated in this study to understand motivating factors for adherence. We used open-ended questions eliciting information on social support, adherence experiences, and barriers to care. An inductive approach in which explanation was derived from review, reduction and interpretation of interview transcripts was used to analyze study data.

**Results:** Salient themes that arose during interviews that were related to patient experiences of adherence included: "Structural and economic obstacles to health care," "Child who takes responsibility," "Adherence-motivating event," "Coordination among caregivers," "Caregiver feels deep responsibility and/or sacrifice," "Reciprocated support," "Non-reciprocated support," "People to talk to about the child's health," and "High expectations of the child."

**Conclusions:** Pediatric adherence typically involves individuals other than the patient. "Coordination among caregivers," "Child who takes responsibility," and "High expectations of the child" help define the relationship among the caregiver, patient, and others in the household, which may support consistent medication adherence. Sources of social support varied among participants and were critical for caregivers in managing difficulties related to the patient's treatment and adherence (e.g., procuring food, childcare, transportation to clinic). The findings are limited by a potential Hawthorne effect given the participants' participation in an ART adherence study. Further research is needed to better understand how the caregiver's social networks and relationship with the child and others in the household relate to ART adherence.

## 80080 Patient Satisfaction as an Innovative Method for Improving Adherence to HAART

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**Background:** Although many organizations use patient-satisfaction scores to complement other indicators of clinical performance, little is known about the role of patient satisfaction on medication adherence. The objective of this study was to determine the association between satisfaction ratings with HIV clinic care received and adherence to highly active antiretroviral therapy (HAART).

**Methods:** We conducted a cross-sectional study of 489 patients aged 18 years and older receiving outpatient HIV primary care at Thomas Street Health Center (TSHC) and the Veterans Affairs Medical Center (VAMC) in Houston, Texas, from January 13 to April 21, 2011. The patient satisfaction score was based on validated survey questions that measure patients' evaluation of their clinic experience over the most recent 12-month time frame. The medication adherence item was based on a validated self-reported single item measure with a 30-day recall period. We performed multivariable linear regression analysis to determine the strength of association between overall satisfaction ratings and adherence to HAART.

**Results:** A total of 489 patients were included in the analyses, 101 from VAMC and 388 from TSHC. The participation rate among eligible patients was 94% (489/521). The majority were men (71%), non-Hispanic black (61%), had a household income of less than or equal to \$10,000 (54%), and reported unprotected heterosexual contact as an HIV risk factor (50%). Patients' overall satisfaction with care received in clinic correlated with adherence to HAART (standardized  $\beta = 0.147$ ,  $p = .001$ ). Analyses were controlled for age, health status, self-efficacy, Spanish language preference, and illicit drug and alcohol use.

**Conclusions:** Patients' satisfaction with their overall HIV clinic care was significantly associated with adherence to HAART. Our study suggests that focusing on improving patients' overall satisfaction could serve as an innovative method for improving adherence to HAART.





## 80081 Injection Drug Users' (IDUs') and Their Caregivers' Social Network Factors Associated with IDUs' Viral Suppression

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**Background:** Injection drug users (IDUs) experience disparities in highly active antiretroviral therapy (HAART) adherence, which contribute to IDUs' disparities in HIV morbidity and mortality and to US racial disparities in HIV outcomes as African Americans comprise the vast majority of US IDUs with HIV/AIDS. We have found in our prior research that most US IDUs with HIV have support networks and informal care-giving relationships, and have identified aspects of their networks and care-giving relationships associated with IDUs' access and adherence to HAART. In this study we sought to identify aspects of IDUs' own support networks and their informal caregivers' networks associated with IDUs' viral suppression.

**Methods:** Data are from the Beacon study, which assessed former or current IDUs on HAART (n = 383) and their main informal caregivers (n = 384) in an urban US epicenter. Personal networks were assessed based on Barrera, et al (1981). Multivariate logistic regression was used to adjust for depressive symptoms (CES-D), substance use, and other potential confounders.

**Results:** Among IDUs, median years since initiated HAART was 10 years; 50% reported current drug use and 70% had an undetectable viral load. IDUs' network factors independently associated with viral suppression included having a greater number of support network members, greater frequency of contact with them, and having fewer children younger than 18 years. In separate analysis, caregivers' network factors independently associated with IDUs' viral suppression included having a greater number of non-kin in their network, fewer drug users in their network, and fewer children with legal justice involvement.

**Conclusions:** The findings extend prior research on the importance of social environmental factors in successful HIV treatment among IDUs by identifying aspects of both IDUs' own social network and their caregivers' network associated with successful treatment. The findings are consistent with and extend prior findings on network drug use and parental role conflict interfering with, and peer ties promoting, optimal HIV medical adherence. Support network and dyad focused intervention is needed to promote IDUs' sustained HAART adherence. Interventions are also needed to provide parenting support. As participants were recruited mostly from an academic HIV clinic, further research is needed to determine the extent to which findings may generalize to other IDUs on HAART.

## 80082 Factors Associated with Non-Adherence to Antiretroviral Therapy among Patients Attending HIV Care and Treatment Clinics in Kenya, Namibia, and Tanzania

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**Background:** Adherence to antiretroviral therapy (ART) is important to protect the health of the HIV-positive individual and to prevent HIV transmission to uninfected sex partner(s) and children. We describe factors associated with nonadherence to ART among HIV-positive patients receiving HIV clinical care in PEPFAR supported clinics in Kenya, Namibia, and Tanzania.

**Methods:** As part of a larger study, approximately 200 HIV-positive patients from each of 18 HIV care and treatment clinics (6 per country) were randomly selected, enrolled, and administered a structured questionnaire to collect data that included socio-demographics, patient behavior, HIV care, and ART adherence. Patients were classified as adherent (self-reported no missed doses of antiretroviral medications in the previous 30 days) or non-adherent. Logistic multivariate regression was used to identify factors associated with non-adherence to ART.

**Results:** A total of 3537 patients were enrolled in the study, of whom 2137 (60%) were on ART (based on self-report and medical chart review of prescribed antiretroviral medications). Of the patients on ART, 47% were male, the median age was 37 years (IQR 33-43 years), and the median time on ART was 21 months (IQR 9-34 months). Non-adherence was reported by 303 (14%) patients. In multivariate analysis, non-adherence was associated with alcohol use (using WHO's Alcohol Use Disorders Identification Test). Compared to nondrinkers, patients who reported non-problem drinking (OR = 2.15; 95% CI: 1.50, 3.06), harmful drinking (OR = 4.27; 95% CI: 2.30, 7.93), or dependent drinking (OR = 3.90; 95% CI: 1.76, 8.63) were more likely to report ART non-adherence. There was also a small, but significant association with self-reported depressive symptoms (OR = 1.02; 95% CI = 1.01-1.04). Adherence was not associated with gender, health status, or transportation costs to clinic, among other factors.

**Conclusions:** These findings suggest that health care providers should screen and target patients who report alcohol use for additional adherence counseling and support. Providing alcohol reduction counseling as part of routine patient care may also help improve ART adherence and patient health, as well as reduce transmission risk. Referrals to alcohol reduction programs, such as Alcoholics Anonymous, should be provided where available.



## 80135 Pre-ART Adherence Counseling is not Associated with Improved MEMS Adherence in Rural Uganda

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**Background:** Many countries in sub-Saharan Africa mandate adherence counseling prior to initiation of HIV antiretroviral (ARV) medications, however the additional benefit of pre-ARV counseling is not known. Given the frequency of patient attrition in the pre-treatment period, we sought to measure an association between pre-therapy adherence counseling and ARV adherence.

**Methods:** We performed a secondary analysis of data from a prospective cohort, augmented with primary data collection from medical records at the Immune Suppression Syndrome Clinic at Mbarara Regional Referral Hospital in Uganda. Subjects older than 17 years were enrolled in a prospective cohort at the time of initiation of ARVs. Our primary exposure of interest was ARV adherence counseling prior to initiating therapy. Our outcomes of interest were: 1) average adherence >90% in first 3 months of therapy; 2) any treatment interruptions >72 hours in first 3 months of therapy; 3) number of treatment interruptions >72 hours in first 3 months of therapy; and 4) viral load >400 copies/mL at the 3-month visit. We fit both univariable and multivariable regression models, adjusted for known predictors of ARV adherence, to estimate the association between completion of pre-therapy counseling and our outcomes

**Results:** Three hundred participants had records of adherence counseling, of whom 231 (77%) received counseling prior to the initiation of ARVs. Median was 33 years, 71% were female, and median CD4 cell count was 133 cells/mm<sup>3</sup>. Average adherence in the cohort was approximately 97%. There were no significant differences between those who received pre-treatment counseling and those who did not in terms of demographic or clinical characteristics. Participants who completed pre-therapy counseling had significantly longer delays from ARV eligibility to initiation (median 49 vs 14 days,  $p < .01$ ). In multivariable analyses, completing pre-therapy adherence counseling was not associated with average adherence >90% (AOR 0.9, 95% CI 0.5-1.8), absence of treatment gaps (AOR 0.6, 95% CI 0.2-1.9), or number of treatment gaps (AIRR 1.81, 95% CI 0.5-6.2), or HIV viremia (AOR 0.9, 95% CI 0.3-2.6).

**Conclusions:** Because mortality and loss-to-follow-up remain high in the pre-ARV period, policy makers should reconsider the benefit of requiring added counseling visits prior to ARV initiation.

## 80453 Simultaneity and Adherence to Multiple Tablets Regimen among Subjects Starting Once-Daily Atazanavir/Ritonavir (ATV/RTV)-Based Therapy: The ANRS COPHAR 3 Study

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**Background:** High adherence levels and simultaneous drug intake are particularly important for subjects starting ritonavir-boosted protease inhibitors. We aimed to assess those patterns among naive HIV-1-infected patients who initiated antiretroviral therapy (ART) in the once-a-day, low-pill-burden era.

**Methods:** We conducted a 24-week prospective multicenter trial with individuals starting tenofovir + emtricitabine (TVD, 1 pill), atazanavir (ATV) (300 mg, 1 pill) and ritonavir (RTV) (100 mg, 1 pill). Patients were monitored for adherence, tolerance, CD4 cell count and HIV-RNA, safety and pharmacologic parameters. Average adherence (%; pills taken/prescribed) and persistence (time on therapy) to RTV, ATV and TVD were measured by 3 Medication Event Monitoring System (MEMS) caps that record time openings.

**Results:** 35 subjects were included, median age: 38 years [range, 24 to 66]; 83% male. At enrolment 9% had AIDS; median CD4 cell count was 280 cells/mm<sup>3</sup> [111 to 461] and HIV-RNA, 4.4 log copies/mL [2.0 to 5.6]. Overall, 5526 days were monitored. One subject did not persist due to hyperbilirubinemia at Week 8. Five (14%) had overall average adherence <95%. Average adherence for each drug was: ATV, 95.9%; RTV, 95.7%; and TVD, 95.8%. Seventy days (1.3%) recorded only 1 or 2 MEMS openings per day, while 204 days (3.7%) recorded no opening. Among the 5252 remaining days with 3 MEMS openings, 5225 (99.5%) days had the 3 openings performed within 30 minutes. HIV-RNA was >50 copies/mL at Week 24 in 3 patients and was associated with high baseline HIV-RNA level ( $p < .03$ ) but not with average adherence >95% ( $p = 1.0$ ).

**Conclusions:** The ATV/RTV/TVD combination was associated with high adherence, persistence, and efficacy during the first 24 weeks, possibly because the regimen was simple and well tolerated. Suboptimal adherence was rare and seems to have minimal effect on efficacy. Selective non-adherence and doses staggering were uncommon with those 3 pills taken once-a-day. A Hawthorn effect cannot be excluded.



## 80457 Data-Adaptive Super Learning to Predict Viral Rebound Based on Electronic Adherence Monitoring: An Analysis of the MACH14 Cohort Consortium

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**Background:** Electronic adherence monitoring has the potential to improve outcomes by triaging viral load tests and adherence interventions. Machine learning (automated algorithms for signal detection from complex data) may improve the accuracy with which viral failure can be identified.

**Methods:** We applied an ensemble machine-learning algorithm ("Super Learner") to predict viral failure (rebound >400 copies/mL after suppression to ≤400 copies/mL) using pooled data from the MACH14 consortium and compared the cross-validated accuracy of the resulting predictor to that achieved by traditional approaches. Medication Event Monitoring System (MEMS) data were analyzed to predict viral rebound using: 1) average adherence; 2) a logistic regression model including average adherence and interruptions of at least 3 days; 3) Super Learner applied to 142 a priori selected candidate predictor variables, including basic clinical data and 134 adherence summaries (averages, nadirs of moving averages, variances, and frequencies and durations of interruptions). Super Learner employed internal cross-validation to data adaptively select from among a user-specified library of algorithms, including random forests, generalized additive models, Bayesian and Lasso regularized generalized linear models, and neural networks. Cross-validated area under the receiver operating characteristic curves [AUC] were calculated based on data not used in model fitting.

**Results:** 1137 patients with complete data for each predictor variable contributed 3149 HIV RNA tests. 138 of 771 patients (18%) had at least one failure observed subsequent to 1810 suppressed HIV RNA tests. The AUCs for simple average adherence and average adherence + 3 day interruption were 0.64 (95% CI, 0.59-0.68) and 0.64 (95% CI, 0.59-0.70), respectively. The cross-validated AUC for the Super Learner predictor was 0.72 (95% CI, 0.68-0.76).

**Conclusions:** Super Learner analysis of electronic adherence data predicted viral failure with reasonable accuracy in a highly heterogeneous population of HIV-infected individuals and could potentially be combined with real-time monitoring to triage viral-load testing and/or target patients for adherence interventions.

## 80459 Ziphamandla: The Feasibility and Usefulness of Implementing CBT-AD, a Cognitive-Behavioral-Based Intervention for the Treatment of Adherence and Depression in a Primary ARV Clinic in Cape Town

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**Introduction:** Depression in people living with HIV/AIDS (PLWHA) in South Africa is highly prevalent and exerts a significant effect on medication adherence, retention in care and mortality. There is currently an urgent need for the systematic integration of an empirically-validated psychological intervention for depression into primary antiretroviral (ARV) care; however, information on the feasibility and usefulness of implementing short-term psychotherapeutic interventions into primary ARV care in South Africa is sorely lacking. The purpose of this study was to determine the feasibility and usefulness of implementing a short-term intervention known as cognitive-behavioral therapy for adherence and depression (CBT-AD) in a primary ARV clinic in Cape Town.

**Method:** Twenty HIV-positive adult patients attending Infectious Disease Clinics (IDCs) for ARV treatment at 2 primary health care centers in the Cape Town area, who met criteria for major depressive disorder, received 6-8 sessions of a cognitive-behavioral intervention consisting of psycho-education, activity scheduling, problem-solving training, relaxation training, and a Life Steps adherence intervention. Patients were assessed pre- and post-treatment for depressive symptom severity, level of functioning, global distress and impairment, and co-morbid psychiatric diagnoses. Depressive symptoms were assessed at each weekly session and ART adherence was monitored in real-time using Wisepill™ technology. To evaluate the feasibility of implementing the intervention process, indicators and qualitative data were collected.

**Results:** Preliminary recruitment and completion rates suggest participants were able and willing to attend therapy over a 6-8 week period. So far participants have reported a reduction in their depressive symptoms, global distress, and level of impairment upon completion of treatment. Adherence rates have varied among participants.

**Conclusion:** Implementing a brief cognitive-behavioral therapy intervention for depression in primary IDC clinics in Cape Town is not only feasible, but beneficial to the health and well-being of HIV-positive patients.



## 80461 Intentional Non-Adherence to Antiretroviral Medications among Alcohol Drinkers: Prospective Study of Interactive Toxicity Beliefs

Seth Kalichman<sup>1</sup> (presenting), Christina Amaral<sup>1</sup>, Tamar Grebler<sup>1</sup>, Moira Kalichman<sup>1</sup>

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**Background:** Antiretroviral therapy (ART) adherence is key to successful treatment and alcohol is a known barrier to adherence. In addition to cognitive impairments and intoxication, ART adherence is impacted by beliefs that mixing alcohol and medications is toxic. Cross-sectional studies show that beliefs about the hazards of mixing ART with alcohol (interactive toxicity beliefs) are held by as many as half of people receiving ART. In this study we examined the prospective relationships among factors contributing to intentional medication non-adherence when drinking.

**Methods:** People who both receive ART and drink alcohol (N = 178) enrolled in a 12-month prospective cohort study that monitored interactive toxicity beliefs, alcohol consumption using electronic daily cell-phone diaries, ART adherence assessed by both unannounced pill counts and self-report, and chart abstracted HIV viral load.

**Results:** Participants who reported skipping or stopping their ART when they are drinking (n = 90, 51%) demonstrated significantly poorer ART adherence, were less likely to be viral suppressed, and more likely to have CD4 cell counts under 200 cells/mm<sup>3</sup>. Controlling for global frequency and quantity of alcohol use, individuals who stated that they skip or stop medications when drinking had significantly poorer adherence over the entire year of unannounced pill counts. Participants who stated that they skip or stop their medications when drinking also had poorer adherence assessed by recall. Confirming our main hypothesis, prospective analyses found that individuals who stated at baseline that they skip or stop their ART had significantly more days with concurrent alcohol use and missed medications at the daily level.

**Conclusions:** Confirming earlier cross-sectional studies, the current prospective findings show that half of HIV positive drinkers receiving ART intentionally skip or stop their medications when drinking. Interventions are needed to correct alcohol-related interactive toxicity misinformation and promote alcohol reduction as well as medication adherence among drinkers.

## 80464 Early Adherence Patterns Predict Retention Rates in Large ART Cohort in Nigeria

Seema Meloni<sup>1</sup> (presenting), Charlotte Chang<sup>1</sup>, Holly Rawizza<sup>2</sup>, Toyin Jolayemi<sup>3</sup>, Bolanle Banigbe<sup>3</sup>, Prosper Okonkwo<sup>3</sup>, Phyllis Kanki<sup>1</sup>

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**Background:** High levels of adherence to antiretroviral therapy (ART) and program retention are required for successful long-term virologic suppression. While adherence patterns have been shown to be associated with long-term retention rates, no studies have done detailed evaluations of the impact of early adherence patterns on retention rates in a large cohort from a resource-limited setting. Our aim was to examine if early adherence patterns could be used as a low-cost and simple method to identify patients requiring more focused adherence counseling to reduce risk of loss to follow-up (LTFU).

**Methods:** Since 2004, Harvard/AIDS Prevention Initiative in Nigeria (APIN) has received PEPFAR funds to develop a sustainable HIV prevention, care and treatment program across multiple hospitals and medical centers in Nigeria. All patient ART data have been collected and stored electronically. Pharmacy refill data were used to calculate adherence rates and LTFU was defined  $\geq 60$  days since last scheduled refill date. Parametric univariate statistical methods were used to examine the relationship between adherence patterns and rates of subsequent LTFU. Predictors found significant in univariate testing were selected as candidates for logistic regression modeling.

**Results:** Between 2004-2010, we collected data on 76,293 ART patients at 36 sites in the Harvard/APIN program. Overall retention at Month 6 was 82% and at Month 12 was 77%. Of the patients with at least 6 months on treatment, 64% had average adherence of  $\geq 95\%$ . The rate of loss was higher in patients with  $< 80\%$  regimen adherence as compared with those with  $\geq 95\%$  adherence (9.5% vs 6.5%, respectively;  $p < .001$ ). There were no significant differences in adherence patterns by sex, but women were less likely than men to be LTFU ( $p < .001$ ). When comparing those lost during Month 6-12 with those retained past Month 12, there was a statistically significant difference in baseline (142 cells/mm<sup>3</sup> vs 170 cells/mm<sup>3</sup>;  $p < .001$ ) and Month 6 CD4 cell counts (234 cells/mm<sup>3</sup> vs 297 cells/mm<sup>3</sup>;  $p < .001$ ). In logistic regression modeling, early adherence patterns, when controlling for baseline CD4 cell count and sex, was a significant predictor of LTFU.

**Conclusions:** This study found that early adherence, during the first 3 months of ART, was predictive of risk of LTFU. For programs seeing large numbers of patients, where LTFU is a major barrier for successful treatment, assessment of early adherence data may be an easy and effective method for selecting patients for targeted counseling services and result in better overall program outcomes.





## 80466 Bridging Practice and Research: A Survey of Evidence-Based Practices Used in HIV Care for Linkage, Retention, and Adherence Support

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<sup>2</sup> International Association of Physicians in AIDS Care, Washington, DC, USA

**Background:** Newly published evidence-based international guidelines advise HIV care providers to adopt strategies to monitor and support linkage, retention, and antiretroviral therapy (ART) adherence in HIV care. However, little is currently known about standards of care or commonly used methods for monitoring or providing support for these critical behaviors. To gather this information, we conducted an Internet-based survey of HIV care providers.

**Methods:** HIV care providers were invited via email to complete an Internet-based English-language questionnaire. Items inquired about use of various evidenced-based and promising strategies to monitor and support linkage, retention, and ART adherence, overall satisfaction, and suggestions for improvements.

**Results:** A total of 395 surveys were partially ( $n = 65$ ) or entirely ( $n = 330$ ) completed. Respondents were from 58 countries, 50% from the United States, most (70%) serving medium to large ( $>200$  to  $>1000$ ) clinic populations offering care to mixed urban-rural patients (45%), and most patients on ART (77%). Forty percent reported monitoring visits for all patients for retention. The most common adherence monitoring strategy for all or most patients was verbal self-report (94%) with systematic methods being less common. Multiple adherence support strategies were reported; most common offered to most/all patients included 1:1 education, messaging on expectation/importance of perfect adherence, and 1:1 counseling, with peers and group education used more frequently outside the United States. More than 75% felt that the strategies in place for supporting retention or adherence needed improvement, and facilitators for how to do this included funding resources, improved information exchange (technical assistance), and performance measures. Differences by region and clinic size also emerged.

**Conclusions:** Many clinics are actively implementing monitoring and support strategies for linkage, retention, and ART adherence. Some differences in specific strategies were identified by region and by clinic size. However, respondents across these groups reported a general sense of needing improvement and offered suggestions for how to achieve improvement.

## 80467 Integrated Next Step Counseling (iNSC): A Discussion-Based Sexual Health Promotion Conversation to Support Men who have Sex with Men (MSM) Using Pre-Exposure Prophylaxis (PrEP) in the iPrEx Open Label Extension (iPrEx OLE)

K. Rivet Amico<sup>1</sup> (presenting), Vanessa McMahan<sup>2</sup>, Julia Marcus<sup>2</sup>, Pedro Goicochea<sup>2</sup>, Lorena Vargas<sup>3</sup>, Robert Grant<sup>2</sup>, Albert Liu<sup>3</sup>

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**Introduction:** iPrEx OLE is an open-label study of daily oral PrEP in MSM and the first PrEP demonstration project to launch globally. Counseling strategies to support PrEP adherence and reduce risk are critical components of the PrEP package, yet need to be streamlined to ensure uptake and deliverability in the real world. We developed an integrated approach to facilitate PrEP use and other prevention strategies in iPrEx OLE and future implementation programs.

**Description:** iNSC is the “next generation” of Next Step Counseling (NSC), a client-centered approach to support pill use previously used in iPrEx. This semi-structured discussion based on a situated Information-Motivation-Behavioral Skills (IMB) model proved feasible and acceptable. iNSC combines risk-reduction and PrEP-use counseling into a tailored streamlined conversation that promotes exploration of context, identification of needs (factors promoting ease of adoption of a behavior), strategizing around identified needs, and selecting strategies to meet those needs. The conversation first focuses on behavioral prevention strategies, then focuses on strategies to facilitate PrEP use, and concludes with an integrated sexual health plan. iNSC is a strengths-based approach that strives to achieve “prevention synergies” with PrEP use.

**Lessons Learned:** All iPrEx OLE sites were trained on iNSC through on-site trainings, including observed role plays and supplemental training materials. Approximately 1981 iNSC sessions have been conducted by sites in 5 countries since launch in June 2011. Counselor feedback suggests feasibility. Important implementation issues have included careful attention to ensure iNSC addresses local HIV counseling guidelines and to provide additional training on the range of harm-reduction strategies available for sexual health promotion discussions.

**Recommendations:** Counseling approaches to support adherence and reduce risk compensation will be important to maximize the public health impact of PrEP. Additional studies are needed to evaluate the impact of iNSC and other approaches on adherence and sexual practices in upcoming demonstration projects.





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NOTES



# NOTES





June 3-5, 2012

To Whom It May Concern:

This letter is a confirmation that \_\_\_\_\_ attended the 7th International Conference on HIV Treatment and Prevention Adherence, held June 3-5, 2012, at the Eden Roc Renaissance Hotel in Miami, FL, United States. This 2.5-day conference was jointly sponsored by the International Association of Physicians in AIDS Care (IAPAC); the National Institute of Mental Health (NIMH); and the Postgraduate Institute for Medicine (PIM).

Sincerely,

José M. Zuniga, PhD, MPH  
Conference Co-Chair







## IN MEMORIAM



1949 – 2012

The International Association of Physicians in AIDS Care (IAPAC) dedicates the 7th International Conference on HIV Treatment and Prevention Adherence to the memory of our colleague Stephen Ketchum, MPH, IAPAC Director of Programs, who passed away in March 2012. He is sorely missed...



The 7th International Conference on HIV Treatment and Prevention Adherence is co-hosted by the **International Association of Physicians in AIDS Care (IAPAC)** and the **National Institute of Mental Health (NIMH)**, who wish to express their gratitude to the government sponsors as well as the institutional and commercial supporters whose generosity have made this conference possible.

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