



6th International
Conference on
**HIV TREATMENT
AND PREVENTION
ADHERENCE**

May 22-24, 2011 • Miami



jointly sponsored by



Postgraduate Institute
for Medicine



WELCOME

We are pleased to welcome you to the 6th 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 sixth 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), and the National Institute of Allergy and Infectious Diseases (NIAID) for their support. We equally appreciate commercial support provided by Bristol-Myers Squibb and Gilead Sciences. 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 21 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, PhD¹
Co-Chair



José M Zuniga, PhD, MPH²
Co-Chair

¹ Chief, Secondary HIV Prevention and Translational Research Branch, National Institute of Mental Health, Bethesda, MD, United States

² President/CEO, International Association of Physicians in AIDS Care, Washington, DC, United States



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CONFERENCE INFORMATION

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 6th 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

MEETING VENUE

The 6th 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 7:15 A.M. - 8:45 A.M., Monday, May 23, 2011, and Tuesday, May 24, 2011, in the Ocean Tower 1 Foyer/Ballroom. Neither lunch nor dinner will be provided by the conference. However, box lunches will be available for purchase in the Ocean Tower 1 Foyer. You may also visit the conference's Registration Desk for a list of 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 Steve Ketchum at sketchum@iapac.org or (312) 795-4934.

INTERNET ACCESS

The 6th 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, unlimited local phone calls, and unlimited long distance calls (within the country).

SLIDE PRESENTATIONS/ABSTRACTS

Slide presentations will be available at 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 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 10.5 *AMA PRA Category 1 Credit(s)*[™]. Physicians should claim only 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, Bristol-Myers Squibb, nor Gilead Sciences 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, Bristol-Myers Squibb, and Gilead Sciences. 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. On the navigation menu, click on "Find Post-Tests by Course" and search by Project ID 7891. Upon successfully completing the evaluation, a CME certificate will be made available to each participant.



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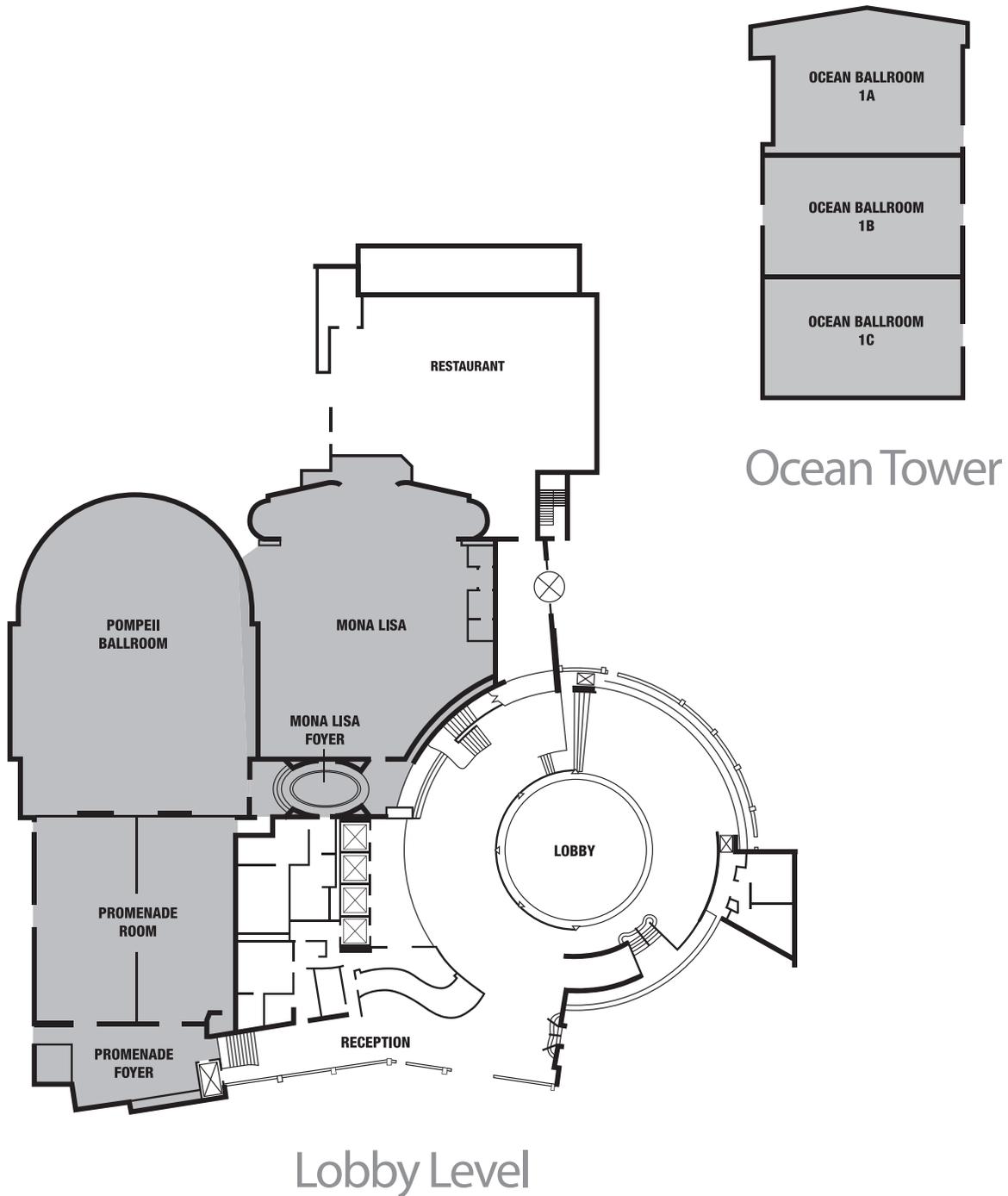
CONTINUING EDUCATION IN NURSING

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 10.5 CE Credits. A certificate of attendance will be available at the conference's Registration Desk.





EDEN ROC RENAISSANCE HOTEL



**Susannah Allison, PhD**

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New Haven, CT, USA

K Rivet Amico, PhD

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David R Bangsberg, MD, MPH

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Jeffrey Crowley, MPH

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Cindy Lyles, PhD

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SUNDAY, MAY 22, 2011

TIME	ACTIVITY	MONA LISA	PROMENADE A
1:30 P.M.–3:00 P.M.	Satellite Symposium	Prevention with People Living with HIV: Updating Recommendations from CDC and HRSA with a Focus on Linkage, Retention, and Adherence ¹ Peter H Kilmarx, MD; Cindy Lyles, PhD	Adherence Technologies in HIV and Drug Abuse Treatment ² Efrat Aharonovich, PhD; Robert Garofalo, MD, MPH; Deborah S Hasin, PhD; Karen Ingersoll, PhD; Shoshana Y Kahana, PhD (Moderator); David Moore, PhD
3:00 P.M.–4:30 P.M.	Satellite Symposium	Adherence 2.0 - Integrating HIV Treatment and Prevention Adherence Advances into Clinical Practice ³ Heidi M Crane, MD, MPH; Daniel B Klein, MD; Bruce Schackman, PhD; Jeffrey Weiss, PhD, MS (Moderator)	
4:30 P.M.–5:00 P.M.	Snack Break – Ocean Tower 1 Foyer		
TIME	ACTIVITY		
OPENING CEREMONY • POMPEII BALLROOM			
5:00 P.M.–5:10 P.M.	Welcome from Conference Co-Chairs José M Zuniga, PhD, MPH, IAPAC Christopher M Gordon, PhD, NIMH		
5:10 P.M.–5:20 P.M.	Welcome from the US Office of National AIDS Policy The Importance of Adherence within the Context of the US National HIV/AIDS Strategy Jeffrey Crowley, MPH		
5:20 P.M.–5:30 P.M.	Introduction to the “Gary S Reiter, MD, and Andrew Kaplan, MD, Memorial Lecture” David R Bangsberg, MD, MPH		
5:30 P.M.–6:00 P.M.	Memorial Lecture: The Promise of Testing and Linkage to Care Plus (TLC+) in US Domestic and Global Settings Wafaa El-Sadr, MD		
OPENING RECEPTION • OCEAN GARDEN (outdoors)			
6:00 P.M.–8:00 P.M.	¡Bienvenidos a Miami!		

¹ Sponsored by US Centers for Disease Control and Prevention (CDC); not CME-certified; see description on page 9

² Sponsored by National Institute on Drug Abuse (NIDA); not CME-certified; see description on page 9

³ Jointly sponsored by IAPAC and the National Association of Continuing Education (NACE) for 1.5 *AMA PRA Category 1 Credit(s)*[™]; see description on page 9 and announcement on inside back cover



MONDAY, MAY 23, 2011

TIME	ACTIVITY			
7:15 A.M.–8:45 A.M.	Breakfast Served in Ocean Tower 1 Foyer/Ballroom			
TIME	ACTIVITY	PROMENADE A	PROMENADE B	
8:00 A.M.–8:50 A.M.	Coffee Talks ¹	US CDC Identification of Evidence-Based Adherence Interventions: Results and Implementation Cindy Lyles, PhD	Medication Persistence: Implications for HIV Research, Care, and Patient Outcomes Frederick Altice, MD; Jason Bae, BA	
8:50 A.M.–9:00 A.M.	Break			
TIME	ACTIVITY			
KEYNOTE ADDRESS • POMPEII BALLROOM				
9:00 A.M.–9:45 A.M.	Adherence Powers Efficacy: Implications of CAPRISA 004 and iPrEx for Biomedical HIV Prevention Kenneth H Mayer, MD			
PANEL 1 • POMPEII BALLROOM				
9:45 A.M.–10:15 A.M.	Improving HIV Treatment Adherence and Outcomes in Specialized HIV and Primary Care Settings Michael J Mugavero, MD, MHS; Jean B Nachega, MD, PhD; Melanie Thompson, MD			
10:15 A.M.–10:45 A.M.	Snack Break			
TIME	ACTIVITY	POMPEII BALLROOM	PROMENADE A	MONA LISA
10:45 A.M.–Noon	Oral Abstract Sessions	Session 1 Biomedical Prevention Adherence	Session 2 Care Engagement and Outcomes	Session 3 Pediatric, Child, and Adolescent Antiretroviral Therapy Adherence
Noon–1:15 P.M.	Lunch (on your own)			
12:30 P.M.–1:15 P.M.	Satellite Symposium			The Portal: An Online Resource for HIV Service Providers ²
1:15 P.M.–2:30 P.M.	Oral Abstract Sessions	Session 4 Clinic and Provider Support for Antiretroviral Therapy Adherence	Session 5 Antiretroviral Therapy Initiation and Readiness	Session 6 Determinants of Care Engagement
POSTER SESSION • OCEAN TOWER 1 BALLROOM				
3:30 P.M.–4:00 P.M.	Snack Break – Ocean Tower 1 Foyer			
PLENARY 1 • POMPEII BALLROOM				
4:00 P.M.–5:00 P.M.	Three Top-Rated Oral Abstracts Michael J Stirratt, PhD (Moderator)			

¹ Not CME-certified

² Sponsored by Tibotec Therapeutics; not CME-certified; see description on page 9



TUESDAY, MAY 24, 2011

TIME	ACTIVITY			
7:15 A.M.–8:45 A.M.	Breakfast Served in Ocean Tower 1 Foyer/Ballroom			
TIME	ACTIVITY	PROMENADE A		
8:00 A.M.–8:50 A.M.	Coffee Talk ¹	Patient Panel: Meeting the Challenge of Adherence Robert H Remien, PhD (Moderator)		
8:50 A.M.–9:00 A.M.	Break			
TIME	ACTIVITY			
PLENARY 2 • POMPEII BALLROOM				
9:00 A.M.–9:30 A.M.	Addressing Disparities in HIV Disease, Care, and Outcomes Kimberly Y Smith, MD, MPH			
PLENARY 3 • POMPEII BALLROOM				
9:30 A.M.–10:00 A.M.	Sustained Viral Suppression Reduces Risk of Viral Rebound, Independent of Adherence David R Bangsberg, MD, MPH			
10:00 A.M.–10:15 A.M.	Break			
TIME	ACTIVITY	POMPEII BALLROOM	PROMENADE A	MONA LISA
10:15 A.M.–11:30 A.M.	Oral Abstract Sessions	Session 7 Improving Engagement in Care	Session 8 Substance Use, Mental Health, and Antiretroviral Adherence	Session 9 Antiretroviral Treatment Strategies, Adherence, and Outcomes
11:30 A.M.–1:00 P.M.	Lunch			
1:00 P.M.–2:15 P.M.	Oral Abstract Sessions	Session 10 Improving Antiretroviral Adherence	Session 11 Novel Determinants of Antiretroviral Adherence	Session 12 Antiretroviral Adherence Measurement
2:15 P.M.–2:30 P.M.	Snack Break – Ocean Tower 1 Foyer			
2:30 P.M.–3:45 P.M.	Invited Panels	Addressing Upstream Determinants of Treatment Access, Adherence, and Outcomes Michael A Horberg, MD; Homero Martinez, MD, PhD; Rafael Mazin, MD, MPH (Moderator); Laura Nyblade, PhD	Retention in Care in African Settings Thomas P Giordano, MD (Moderator); Denis Nash, PhD, MPH; Sydney Rosen, MPA; Norma C Ware, PhD	Strengthening Prevention Adherence in NIAID DAIDS Network Protocols K Rivet Amico, PhD; Vanessa Elharrar, MD (Moderator); Jonathan Fuchs, MD, MPH; Leila Mansoor, BPharm, PhD
3:45 P.M.–4:00 P.M.	Break			
CLOSING PLENARY • POMPEII BALLROOM				
4:00 P.M.–4:30 P.M.	Current Themes and Future Directions for HIV Adherence Research and Practice Moderators: Christopher M Gordon, PhD; José M Zuniga, PhD, MPH Panelists: K Rivet Amico, PhD; Michael J Mugavero MD, MHS; Jean B Nachega, MD, PhD; Ann Williams, EdD, RNC			

¹ Not CME-certified



SATELLITE SYMPOSIUM SCHEDULE

SUNDAY, MAY 22, 2011

Satellite Symposium 1

1:30 P.M. - 3:00 P.M. / Mona Lisa

Prevention with People Living with HIV: Updating Recommendations from CDC and HRSA with a Focus on Linkage, Retention, and Adherence

The US Centers for Disease Control and Prevention (CDC) and partner organizations are updating recommendations for prevention with persons living with HIV (PWP). This symposium will provide an update on new research and guidance on PWP, with a focus on linkage to and retention in care, use of antiretroviral medication for HIV prevention, and interventions to increase adherence to antiretroviral medication.

Presenters:

Peter H Kilmarx, MD, CDC, Atlanta, GA, USA
Cindy Lyles, PhD, CDC, Atlanta, GA, USA

Sponsored by CDC; not CME-certified

Satellite Symposium 2

1:30 P.M. - 3:00 P.M. / Promenade A

Adherence Technologies in HIV and Drug Abuse Treatment

This National Institute on Drug Abuse (NIDA) symposium will focus on technologies targeting HIV treatment adherence among substance-abusing populations. Recently funded grants highlighting NIDA's priorities around technologically delivered behavioral treatments will be featured.

Moderator:

Shoshana Y Kahana, PhD, NIDA, Bethesda, MD, USA

Presenters:

Personalized Text Messaging Enhanced with Ecological Momentary Assessment: A New Tool for Assessment and Just-in-time Intervention for Rural HIV-Positive Drug Users

Karen Ingersoll, PhD, School of Medicine, University of Virginia, Charlottesville, VA, USA

Using Text Messaging to Improve Adherence among HIV-Positive Adolescents and Young Adults

Robert Garofalo, MD, MPH, Children's Memorial Hospital and Northwestern University Feinberg School of Medicine, Chicago, IL, USA

Development of Individualized Texting for Adherence Building (iTAB): An Intervention for HIV-Positive Methamphetamine Users

David J Moore, PhD, University of California, San Diego, CA, USA

HealthCall: Brief IVR-Based Interventions to Reduce Alcohol and Drug Abuse in HIV Primary Care

Deborah Hasin, PhD, Columbia University College of Physicians & Surgeons and New York State Psychiatric Institute, New York, NY, USA
Efrat Aharonovich, PhD, Columbia University College of Physicians & Surgeons and New York State Psychiatric Institute, New York, NY, USA

Sponsored by NIDA; not CME-certified

Satellite Symposium 3

3:00 P.M. - 4:30 P.M. / Mona Lisa

Adherence 2.0 - Integrating HIV Treatment and Prevention Advances into Clinical Practice

The International Association of Physicians in AIDS Care (IAPAC) and partner organizations are engaged in efforts to translate and integrate HIV treatment and biomedical prevention adherence advances into clinical practice to achieve individual, community, and public health goals. Implementation science and a review of treatment and prevention intervention adaptations made pre- and post-implementation will be reviewed during this symposium from academic medicine and managed care perspectives.

Moderator:

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

Presenters:

Where is the Science in Implementation Science?

Bruce R Schackman, PhD, Weill Cornell Medical College, New York, NY, USA

Integrating HIV Treatment Adherence Self-Report into Routine Practice

Heidi M Crane, MD, MPH, University of Washington, Seattle, WA

Implementing HIV Guidance in a Managed Care Setting: Implications for PrEP

Daniel B Klein, MD, Kaiser Hospital, Hayward, CA

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MONDAY, MAY 23, 2011

Satellite Symposium 4

12:30 P.M. - 1:15 P.M. / Mona Lisa

The Portal: An Online Resource for HIV Service Providers

Tibotec Therapeutics has launched a free, innovative online resource to help HIV service providers meet their client education and professional needs. This symposium will include instruction on features of this website: An expansive library of easy-to-read fact sheets on topics concerning HIV disease, treatment, adherence, prevention and healthy living, a brochure builder with customizable client content, a search function to locate and share information with other service providers across the United States, and links to more than 200 national, state, and local HIV/AIDS organizations and resources.

Presenters:

Donna Sabatino, Tibotec Therapeutics, Miami, FL, USA
Joseph Leahy, Tibotec Therapeutics, Los Angeles, CA, USA

Sponsored by Tibotec Therapeutics; not CME-certified



MONDAY, MAY 23, 2011

**Oral Session 1
Biomedical Prevention
Adherence**10:45 A.M. - Noon / Pompeii Ballroom
Moderator: Kenneth H Mayer, MD

- 69949** A Novel Breath-Based Technology to Assess Use of Vaginally Applied Products: A Pilot Study
van der Straten A presenting
- 70095** Barriers and Facilitators to Pill-Use among MSM at Risk for HIV: Lessons for Pre-Exposure Prophylaxis (PrEP) Programs in the United States
Liu AY presenting
- 70014** What's Love Got to Do With It? - A Relationship Framework for Research on Adherence to Antiretroviral Therapy (ART) as Pre-Exposure Prophylaxis
Ware NC presenting
- 70065** An Adherence Intervention to Support HIV Pre-Exposure Prophylaxis (PrEP) Adherence in Serodiscordant Couples in Uganda
Psaros C presenting

**Oral Session 2
Care Engagement and
Outcomes**10:45 A.M. - Noon / Promenade A
Moderator: Laura Cheever, MD, ScM

- 70353** Epidemiology and Subsequent Engagement in Care for a Cohort of Known HIV-Infected Individuals who Undergo Repeat HIV Testing
Astiz M presenting
- 70063** Feasibility of a Test and Treat Approach in Routine HIV Care
Giordano TP presenting
- 70022** Gaps in HIV Care: An Evaluation of the Association of Gap Length with Virologic and Immunologic Outcomes
Melendez AG presenting
- 70076** Appointment Keeping, Medication Adherence, and Clinical Outcomes in Patients with HIV
Erlen JA presenting

**Oral Session 3
Pediatric, Child, and Adolescent
Antiretroviral Therapy Adherence**10:45 A.M. - Noon / Mona Lisa
Moderator: Susannah Allison, PhD

- 69336** Adherence to Syrup and Tablet Antiretroviral Therapy in Children Attending an Urban HIV Clinic
Bagenda A presenting
- 70094** Psychosocial Distress and Treatment Failure in HIV-Positive African Youth
Lowenthal ED presenting
- 70129** Association between Disclosure of Children's HIV Infection Status and Adherence
Enejoh VA presenting
- 69948** Qualitative Comparison of Barriers to Antiretroviral Medication Adherence among Perinatally and Behaviorally HIV-Infected Youth
Thurston IB presenting

**Oral Session 4
Clinic and Provider Support for
Antiretroviral Therapy Adherence**1:15 P.M. - 2:30 P.M. / Pompeii Ballroom
Moderator: Linda Koenig, PhD

- 70488** HIV Treatment Adherence Levels, Patient Literacy, and Health Care Provider-Patient Communication: A Global Survey of 2,035 Adults
Nachega JB presenting
- 70029** HIV Provider's Confidence and Expertise in Treating Depression as a Means of Addressing Antiretroviral Adherence
Bess K presenting
- 70494** Impact of Routine Clinical Care Assessment of Patient-Reported Outcomes (PROs) with Same-Day Pre-Visit Provider Reports
Crane HM presenting
- 69194** Determination of Optimized Multidisciplinary Care Teams (MDCT) for Maximal Combination Antiretroviral Therapy (ART) Adherence
Horberg MA presenting

**Oral Session 5
Antiretroviral Therapy Initiation
and Readiness**1:15 P.M. - 2:30 P.M. / Promenade A
Moderator: James Scott, PharmD

- 69222** A Measure of Treatment Expectancies and Readiness to Predict Uptake of Antiretroviral Therapy
Johnson MO presenting
- 69940** HIV Conspiracy Beliefs Predict Subsequent Readiness to Initiate Antiretroviral Therapy
Wald RL presenting
- 70058** Predicting the Emergence of Antiretroviral Therapy (ART) Side Effects: The Role of Psychological Variables
Horne R presenting
- 69968** Medication Adherence: A Consensus on Taxonomy
Vrijens B presenting

**Oral Session 6
Determinants of Care
Engagement**1:15 P.M. - 2:30 P.M. / Mona Lisa
Moderator: Susanna Allison, PhD

- 70077** Factors Affecting Enrollment of Newly Diagnosed HIV-Positive Persons into ART Services in India: An Observational Cohort Study
Sebastian M presenting
- 69936** Why Patients Taking ART in Jos, Nigeria Miss Clinic Visits: A Qualitative Analysis
Awoloye G presenting
- 69906** Why Do I Forget My Appointments? Neurocognitive Predictors of Adherence to Outpatient HIV Medical Appointments
Waldrop-Valverde D presenting
- 69951** Intimate Partner Violence, Childhood Sexual Abuse, and Implications for Engagement in Care
Schafer KR presenting



MONDAY, MAY 23, 2011 (CONTINUED)

Three Top-Rated Abstracts Session

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

- 70075** Defining and Predicting Detection Rates of Intracellular Emtricitabine-Triphosphate (FTC-TP) and Tenofovir-Diphosphate (TDF-DP) in the iPrEx HIV Pre-Exposure Prophylaxis (PrEP) Trial
Amico KR presenting
- 69938** Impact of Early Retention in Care on Viral Load Suppression among Patients Newly Initiating Outpatient HIV Care
Mugavero MJ presenting
- 70087** Patterns of Non-Adherence and Impact on Viral Load among HIV-Positive Patients from the MACH-14 Study
Genberg BL presenting

TUESDAY, MAY 24, 2011

Oral Session 7

Improving Engagement in Care

10:15 A.M. - 11:30 A.M. / Pompeii Ballroom
Moderator: Jeanette M Hosseini, PhD

- 69965** Improving Retention in HIV Care through Patient Tracking in Sub-Saharan Africa
Dadem N presenting
- 69841** Linkage of Preliminary Reactive Diagnosed Clients to Care and Treatment Services: An Intensive Approach to Initiating and Ensuring Linkage to Care for Preliminary Reactive Diagnosed High Risk Heterosexual African-American Clients in Wards 7 and 8 of DC
Young AT presenting
- 69986** Evaluating the Implementation of a Comprehensive Care Coordination Program in New York City (NYC)
Grant YT presenting

Oral Session 8

Substance Use, Mental Health, and Antiretroviral Adherence

10:15 A.M. - 11:30 A.M. / Promenade A
Moderator: Shoshana Kahana, PhD

- 70490** Alcohol Abuse, Depression and Adherence to Antiretroviral Therapy in HIV-Infected Adults in Africa: A Systematic Review and Meta-Analysis
Nachega JB presenting

- 70064** Depression - Evidence of its Key Role for ART Adherence in Sub-Saharan Africa
Linnemayer S presenting

- 69366** Impact of Executive Function on the Day Level Association of Methamphetamine and Missed Medication
Kowalczyk WJ presenting

- 70096** Medication Adherence Outcomes are Mediated by Treatment-Related Changes in Depression among People with HIV in Treatment for Opiate Dependence
O'Cleirigh C presenting

Oral Session 9

Antiretroviral Treatment Strategies, Adherence, and Outcomes

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

- 70365** Pooled Week 48 Safety, Efficacy, and Adherence Results from ECHO and THRIVE Phase 3 Trials Comparing TMC278 vs EFV in Treatment-Naïve HIV-1-Infected Patients Receiving FTC/TDF
Elion R presenting
- 70492** Adherence Patterns to Raltegravir (RAL)-Based Regimens and Their Influence on Virologic Outcome: A Prospective Cohort Study (RALTECAPS Study)
Parianti JJ presenting

- 70002** Adherence is the Major Factor Associated with Virologic Outcomes on a Dual-Class, Dual-Drug Regimen of Raltegravir with a Protease Inhibitor
Gardner EM presenting

- 69969** Improving the Estimation of HIV Treatment Efficacy by Combining Structural Nested Mean Models with Pharmacokinetic Models of Antiretroviral Drug Exposure*
Vrijens B presenting

** This presentation is not CME-certified*

Oral Session 10

Improving Antiretroviral Adherence

1:00 P.M. - 2:15 P.M. / Pompeii Ballroom
Moderator: Linda Koenig, PhD

- 69967** Identification and Assessment of Adherence-Enhancing Interventions: Results of a Literature Review
Vrijens B presenting
- 70366** Antiretroviral Adherence Interventions from Randomized Trials using Electronic Monitors of Adherence
Golin CE presenting
- 69963** How Treatment Partners Help: Social Analysis of an African Adherence Support Intervention
O'Laughlin KN presenting
- 70115** A Culturally Adapted Intervention to Treat Depression and ART Nonadherence on the US-Mexico Border: Feasibility and Initial Results from a Pilot RCT
Simoni JM presenting



TUESDAY, MAY 24, 2011 (CONTINUED)

Oral Session 11
Novel Determinants of
Antiretroviral Adherence

1:00 P.M. - 2:15 P.M. / Promenade A
Moderator: Jeanette M Hosseini, PhD

70101 Relation of Chronic Disease
Treatment Adherence to
Antiretroviral (ART) Adherence
Catz SL presenting

69219 What's Love Got to Do With It?
Relationship Factors and HIV
Treatment Adherence
Johnson MO presenting

69952 Medical Mistrust May Mediate
the Relationship of Perceived
Discrimination to Treatment Non-
Adherence among Latino Men
Living with HIV
Bogart L presenting

69220 Health Care Empowerment and HIV
Treatment Adherence
Johnson MO presenting

Oral Session 12
Antiretroviral Adherence
Measurement

1:00 P.M. - 2:15 P.M. / Mona Lisa
Moderator: Wendy Nilsen, PhD

70078 Definitive Medication Adherence
Monitoring is Unaffected by
Potential Food Interferents*
Melker RJ presenting

** This presentation is not CME-certified*

70356 Using Prescription Refills May
Overstate Actual Adherence
Because Patients Fail to Pick Up the
Prescriptions That Have Been Filled
Grimes DE presenting

70489 Pharmacy Refill Data Combined with
Self-Report Adherence Questions
Improves Prediction of Boosted
Protease Inhibitor Regimen Failure
Nguyen H presenting

70018 Closing the Gap between Practice
and Research: Collecting Quality
Adherence Data in the Real World
Behforouz HL presenting



69194 Determination of Optimized Multidisciplinary Care Teams (MDCT) for Maximal Combination Antiretroviral Therapy (ART) Adherence

Michael A Horberg¹ (presenting), Leo B Hurley², William J Towner, MD³, Michael Allerton⁴, Beth Tang⁵, Sheryl Catz⁶, Michael J Silverberg², Charles P Quesenberry²

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- ⁴ The Permanente Medical Group, Inc., Oakland, CA, USA
- ⁵ Kaiser Permanente Southern California, Pasadena, CA, USA
- ⁶ Group Health Research Institute, Seattle, WA, USA

Background: Little data exist as to the optimal composition of HIV MDCT for many HIV-related outcomes. We seek to determine optimized MDCT composition for ART adherence.

Methods: We analyzed all new regimen starts (n = 10,801) among HIV-positive patients in Kaiser Permanente California from 1997-2006. 5106 had no prior antiretroviral use. We measured 12-month adherence to ART (pharmacy records), and assessed medical center-specific patient exposure to HIV/ID specialist (specialist), clinical pharmacist (pharmacist), nurse case manager (nurse), non-nurse care coordinator (coordinator), dietician, social worker/benefits coordinator (social work), and mental health (mental health). We used a classification and regression tree approach (recursive partitioning) to ascertain potential MDCT compositions that had maximal mean ART adherence. We then employed mixed linear regression with clustering by provider and medical center (adjusting for ART experience, age, gender, race/ethnicity, HIV risk, HCV-positive, ART regimen class and temporal trend) to test which potential MDCT identified by recursive partitioning had maximal association with ART adherence. Adherence statistics reported from linear regression.

Results: Reference group was specialist only (mean adherence 74.4% unadjusted). In the recursive partitioning analysis, the presence of a clinical pharmacist consistently was ranked first in terms of variable importance (+3.3% difference; 95%CI: +0.8-+5.8%). We found maximal increase in adherence was with pharmacist + coordinator (+8.1%; +2.7-+13.5%). Other MDCT teams with significant (p <0.05) improved adherence compared to specialist only were: nurse + social work (+7.5%; +5.4-+9.7%); specialist + mental health (+6.5%; +2.6-+10.4%); pharmacist + social work (+5.7%; +4.1-+7.4%). There were no significant differences in mean adherence between these MDCTs (Wald test, p = 0.29). Some recursive partitioning analyses showed higher adherence despite lack of team components, such as mental health, suggesting indication bias. The significant benefit of a pharmacist persisted in analyses stratified by ART experience, while the relative benefit of other MDCT components varied.

Conclusions: Our analytical approach can be used to determine optimized MDCT for maximal ART adherence. Various MDCTs were associated with improved adherence, but the clinical pharmacist was the most consistent beneficial component. These findings have potential application to HIV care team design.

69219 What's Love Got to Do with It? Relationship Factors and HIV Treatment Adherence

Mallory O Johnson (presenting), Samantha E Dilworth, Megan Comfort, Lynae Darbes, Jonelle Taylor, Torsten B Neilands

University of California at San Francisco, San Francisco, CA, USA

Background: Primary partners' roles in fostering or derailing optimal HIV treatment adherence may provide insights and opportunities for HIV treatment adherence interventions. The purpose of this presentation is to present dyadic findings from couples to begin to explain the effects that partners may have on adherence.

Methods: 91 serodiscordant and 119 seroconcordant HIV male couples (N = 420 men) were surveyed simultaneously and separately using computer assisted interviewing and blood was drawn for viral load. Multivariate actor/partner dyadic analyses identified individual variables (e.g., depression, beliefs about treatment) and relationship variables (e.g., satisfaction, commitment, intimacy and communication) from both partners associated with well-validated key adherence outcomes (e.g., self-efficacy, self-reported adherence, and viral load). An actor effect indicates an association between partner A's variables and his own outcomes. A partner effect reports an association between partner B's variables and partner A's outcomes.

Results: Controlling for key covariates, higher adherence self-efficacy was related to the actor's positive beliefs about medications, his reports of higher autonomy and intimacy in his relationship, and lower depression; whereas the partner's lower depression and higher relationship satisfaction were linked to the actor's higher adherence self-efficacy. Actor adherence was related to his positive appraisal of communication in his relationship; whereas his better adherence was associated with his partner's beliefs of treatment efficacy. In both partners, higher general medication concerns were associated with lower adherence in the actor. The only variable associated with the actor's lower viral load was the partner's higher commitment to his relationship with the actor.

Conclusions: Both actor and partner depression, treatment beliefs, and relationship quality are associated with adherence-related indicators. Future goals are to explore these effects in a broader range of couples, to determine specific mechanisms for these effects, and to identify opportunities to harness beneficial relationship dynamics while mitigating relationship-related barriers to optimal adherence.



69220 Health Care Empowerment and HIV Treatment Adherence

Mallory O Johnson (presenting), Samantha E Dilworth, Jonelle Taylor, Torsten B Neilands

University of California at San Francisco, San Francisco, CA, USA

Background: With a growing number of people living with HIV and requiring lifelong treatment, there is a need to better understand and optimize long-term engagement in medical care. One critical component of engagement in HIV medical care is adherence to antiretroviral therapy (ART). The purpose of the current analysis is to evaluate an innovative measure of the multidimensional construct of Health Care Empowerment (HCE) for its associations with ART adherence related constructs. The measure of HCE includes five subscales of collaboration, commitment, information, engagement, and tolerance of uncertainty.

Methods: 127 HIV-positive men on ART were interviewed as part of an ongoing study of ART adherence. Measures included HCE, ART adherence self efficacy, and two validated measures of self-reported adherence (30-day visual analog scale and AACTG 3-day adherence).

Results: The sample was 17% Latino, 14% African American, had a mean age of 46, and the average CD4 count was 568 cells/mm³ (range 41-1430). All subscales of HCE had adequate internal reliability ($\alpha = .80-.90$) and were associated with ART adherence self-efficacy (r 's = .18-.41, $p < .05$). Higher 30-day VAS adherence was associated with higher scores of HCE commitment ($p < .05$) and HCE tolerance of uncertainty ($p < .01$). Higher 3-day adherence was associated with higher HCE commitment ($p < .001$), HCE information ($p < .05$), HCE engagement ($p < .05$), and HCE tolerance of uncertainty ($p < .005$).

Conclusions: The broad construct of HCE is related to adherence self-efficacy and self-reported ART adherence in directions consistent with the model of HCE. Next steps are to determine whether the model of HCE can predict or explain other indicators of HIV treatment engagement, including uptake of ART, appointment-keeping, shared decision-making, and retention in care. The current conceptualization of HCE may shed light on the broader challenge of engagement in HIV clinical care beyond the narrow issue of medication adherence.

69222 A Measure of Treatment Expectancies and Readiness to Predict Uptake of Antiretroviral Therapy

Mallory O Johnson (presenting), Eunice Stephens, Samantha E Dilworth, Torsten B Neilands

University of California at San Francisco, San Francisco, CA, USA

Background: Timely initiation and adherence to antiretroviral therapy (ART) are critical to optimizing treatment outcomes among people living with HIV. As growing clinical evidence supports early initiation of ART, a greater understanding of the barriers and facilitators to uptake are needed. The purpose of the current study is to demonstrate whether an expectancy-based measure of treatment readiness, treatment ease, treatment efficacy, and social/stigma related concerns can predict uptake of ART among an urban poor sample of adults who meet guidelines for but are not taking ART.

Methods: Non-intervention enrollees in an ongoing study, with CD4 counts < 500 cells/mm³ and not on ART, were surveyed at baseline and followed monthly for 6 months minimum. A measure of treatment expectancies that includes subscales of treatment readiness, treatment ease, treatment efficacy, and stigma/social ART concerns was administered. Baseline scores on each scale were evaluated for their ability to predict who would subsequently start ART.

Results: The sample ($N = 73$) was 88% male, 48% African American, 11% Hispanic; 70% completed high school or less and the mean age was 43. Average CD4 at baseline was 236 cells/mm³ and 95% had detectable viral load. To date, 42 (57%) reported initiation of ART during follow up. Those who initiated had higher baseline scores on readiness to start ART (OR = 1.20 [1.08, 1.35]; $p < .01$); anticipated ease of taking ART (OR = 1.20 [1.07, 1.35], $p < .01$); and beliefs in ART efficacy (OR = 1.23 [1.05, 1.47]; $p < .05$). Expectancies related to stigma/social concerns did not predict ART uptake.

Conclusions: A simple to administer self-report measure of treatment expectancies and readiness can differentiate between those who subsequently initiate ART from those who do not. Social/stigma related concerns, as currently constructed, did not appear to be a driver of the decision to initiate. Interventions that target these dimensions of treatment expectancies/readiness may facilitate the timely initiation of ART.



69336 Adherence to Syrup and Tablet Antiretroviral Therapy in Children Attending an Urban HIV Clinic

Anne Bagenda (presenting), Linda Barlow-Mosha, Rebecca Sakwa, Philippa Musoke

Makerere University School of Public Health/MU-JHU Research Collaboration, Kampala, Uganda

Background: Major challenges remain in paediatric HIV management including challenges with adherence to syrup formulations and lifelong therapy in the face of non-disclosure. To determine adherence levels at 12, 24, 36 and 48 weeks using three measures, compare adherence on syrups and then on tablets and caregivers' attitudes towards medication formulations.

Methods: Retrospective cohort review of medical charts for 129 HIV-positive Ugandan children aged 6 months-12 years. Adherence measured using pharmacy refill data, caregiver self reports and unannounced home visit pill counts. Key informant interviews (KI) with caregivers for their experiences when using syrups and tablet antiretroviral therapy (ART).

Results: Using pharmacy refill data 89.9%, 95.4%, 93.8% and 93.8% achieved >95% adherence at 12, 24, 36, and 48 weeks respectively. Caregiver self-report proportions were 9.2%, 100%, 100%, 99.2% and for unannounced home visits 89.8%, 92.4%, 88.9% and 86.2%. Median adherence to syrups (97%, IQR93-98) was significantly lower than tablets (100%, IQR97-100) [$p = 0.012$, $n = 28$]. Children who started on syrups, then tablets were more likely to have <95% adherence score after 48 weeks (R.R. = 1.6; 95%CI: 1.2-2.3, $p = 0.001$) compared to children who took tablets throughout. Drug formulation did not significantly affect viral load suppression ($p = 0.4$). KI revealed preference for administering tablets to children vs syrups; lack of support from immediate family due to non-disclosure as barrier to paediatric adherence.

Conclusions: In these children, adherence to tablets was better than on syrups.

69366 Impact of Executive Function on the Day Level Association of Methamphetamine and Missed Medication

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Background: The management of HIV infection requires individuals to exhibit behavioral control to maintain almost-perfect medication adherence. Numerous studies have documented executive dysfunction (ED) in HIV participants and impairment in this very same domain has been associated with poor adherence. Complicating the behavioral control in HIV-positive individuals is substance use, particularly methamphetamine (MA) use. The present study examines the effect of MA use and ED on missed med days.

Methods: Men who have sex with men ($n = 112$) were recruited from an ongoing behavioral intervention targeting MA use and HIV med adherence. ED predictors included the Iowa Gambling Task and variant (IGT; decision-making), the D-KEFS trails (cognitive flexibility), and the Counting Span (CS; working memory). A 14-day Time Line Follow Back interview was used to collect MA use and missed meds for each day. Generalized estimating equations were used to examine the day level association between MA use and missed meds, as well as the impact of ED on both missed meds and the strength of relationship between MA use and missed medications.

Results: Analyses indicated that missing meds was nearly three times as likely on a MA-day compared to a non-MA day ($p \leq .001$, $\text{Exp}(B) = 2.9$). Controlling for MA use and entering one ED variable at a time, impairment on the IGT ($p \leq .01$, $\text{Exp}(B) = 1.5$), the IGT variant ($p \leq .05$, $\text{Exp}(B) = 1.9$), the CS ($p \leq .05$, $\text{Exp}(B) = .7$) and the D-KEFS trails ($p \leq .05$, $\text{Exp}(B) = 1.3$) were associated with an increased likelihood of missing meds. In these same analyses, the interaction of ED and MA revealed that impairment on the CS ($p \leq .05$, $\text{Exp}(B) = 1.5$) reduced the strength of association between MA use and missing medications, and impairment on the IGT variant produced a similar trend. In a model including all four ED predictors, MA use continued to predict missed medications ($p \leq .001$, $\text{Exp}(B) = 5.7$), while impairment on the IGT variant reduced the strength of that association ($p \leq .05$, $\text{Exp}(B) = .36$).

Conclusions: This study provides further evidence of the negative impact of ED on adherence. MA use also increased the likelihood of missed meds. However, that relationship was lessened by impairment, and strengthened by intact function. These data may suggest that intact participants only miss meds in the presence of MA. But it is also possible that, similar to effects seen with ADHD patients, MA may enhance functioning among those with deficits, lessening the negative impact of MA use on adherence.



69841 Linkage of Preliminary Reactive Diagnosed Clients to Care and Treatment Services: An Intensive Approach to Initiating and Ensuring Linkage to Care for Preliminary Reactive Diagnosed High Risk Heterosexual African-American Clients in Wards 7 and 8 of DC

A Toni Young (presenting)

Community Education Group, Washington, DC, USA

Background: Throughout 2008 and 2009 Community Education Group (CEG) counseling, testing, and referral (CTR), referral and linkage, and management staff identified a problem with linking clients diagnosed preliminary reactive through rapid HIV testing to partner care and treatment providers using the traditional method of offering preliminary reactive diagnosed clients referrals to care and treatment services. Our overall linkage to care rate for individuals diagnosed preliminary reactive through rapid HIV testing was under 5%. In October 2009, CEG staff developed and implemented an intensive linkage strategy in order to ensure that clients being diagnosed as preliminary reactive through rapid HIV testing were being linked to HIV-specialty providers to receive care and treatment services.

Methods: In October 2009, Community Education Group (CEG) staff developed and implemented an intensive linkage to care strategy in order to ensure that clients being diagnosed as preliminary positive through rapid HIV testing were being linked to HIV care and treatment services. CEG utilizes incentives, in the form of a grocery store gift card, strong connections and agreements with medical facilities and intense follow-up methods to ensure successful linkages. CEG employs the following methods to ensure successful linkages:

- Incentives (in the form of a grocery store gift card)
- Frequent follow-up phone calls
- Appointment reminder calls
- Obtaining comprehensive releases of information
- Providing staff escort (transportation) to medical visits
- Staff support during medical visits

Results: As a result of this aggressive strategy and existing relationships with care and treatment providers, CEG has conducted 6,487 HIV rapid tests with 153 individuals being diagnosed as preliminary positive. 146 of the 153 preliminary positive diagnosed clients were newly linked (64) or re-linked (89) to care and treatment services using the intensive linkage to care model implemented on October 1, 2009.

Conclusions: Using a more intensive strategy for linking clients to care and treatment services has shown to be far more effective than simply "referring" clients to care. The benefit in a more intensive linkage to care and treatment strategy is shown in the number of clients that CEG has been able to link and provide assistance to remain in care, thereby decreasing their viral load and increasing their quality of life while living with HIV.

69906 Why Do I Forget my Appointments? Neurocognitive Predictors of Adherence to Outpatient HIV Medical Appointments

Drenna Waldrop-Valverde¹ (presenting), Raymond L Ownby², Deborah Jones¹

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² Nova Southeastern University, Fort Lauderdale, FL, USA

Background: Engagement in HIV care is essential to optimize treatment yet missed medical appointments remain a common problem. Moreover, HIV-associated neurocognitive deficits are estimated to occur in nearly 50% of those infected and have been linked to suboptimal medication adherence. However, whether neurocognitive dysfunction may impact medical appointment adherence is not known. We therefore prospectively tested the ability of neurocognitive functioning to predict adherence to outpatient medical appointments among HIV-positive patients receiving care at a public HIV clinic.

Methods: HIV-positive men and women (N = 125) completed a standardized neuropsychological test battery at baseline and medical records were abstracted to document missed medical appointments over the following 7-months. The neuropsychological test scores were converted into NPZ scores according to standard methodology in four domains of function: executive, verbal memory, psychomotor speed, and sustained attention.

Results: The sample was mostly African American (83%) with an average age of 47 (SD = 7.4); just over half were women. Sixty-two percent of participants had undetectable viral loads (<50 copies/mL) according to their medical records and 50% reported using alcohol or drugs over the past 7 months. Participants attended 75% of appointments on average. Hierarchical multiple regression analysis with percentage of scheduled medical appointments attended as the dependent variable showed that no use of alcohol or drugs in the last 7 months, a detectable viral load, and sustained attention were significantly associated greater appointment adherence. Age, executive skills, verbal memory, and psychomotor speed were unrelated to appointment adherence [R² = .187, p = .001].

Conclusions: To our knowledge, this is the first study to show the relationship between the ability to sustain attention and HIV medical appointment attendance, thereby identifying a potentially modifiable target for cognitive rehabilitation. Future studies should examine the impact of cognitive rehabilitation as an avenue to improve appointment adherence.



69936 Why Patients Taking ART in Jos, Nigeria, Miss Clinic Visits: A Qualitative Analysis

Grace Awoleye¹ (presenting), Nancin Dadem¹, Monique Wyatt², Pat Agaba¹, Oche Agbaji¹, Norma Ware²

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² Harvard Medical School, Boston, MA, USA

Background: Understanding why patients taking antiretroviral therapy (ART) miss clinic visits is critical, particularly in Africa, where loss-to-follow-up is high. Missed visits mean prescriptions are not refilled, and alternative drug regimens are not widely available.

Methods: This qualitative interview study examines reasons for missed clinic visits among patients in Jos, Nigeria who have been absent from care and located by the clinic's tracking team. Interviews with 30 such patients investigated reasons for missed visits. Data were analyzed inductively to derive descriptive categories from interview transcripts. The categories define and illustrate reasons for missing that appeared repeatedly in the data.

Results: Forty-eight (N = 48) reasons were given by the 30 interviewees. Analysis revealed four major reasons for missing visits: (1) Errors: Patients missed visits because of errors stemming from lack of information or inaccurate information about some aspect of treatment, services, or expectations; (2) Violence: Encounters with violence, including but not limited to conflict in the region during data collection, disrupted care for some study participants; (3) Family Obligations: Family obligations are high priorities, such that traveling to provide help for a family member may take precedence over keeping clinic appointments; and (4) Decisions: Some interviewees reported having made a decision to abandon treatment due to fear of stigma, negative clinic experiences, or preference for another form of care.

Conclusion: Overall, missed visits were not intentional in this patient sample. Results indicate patients missed clinic visits not because they decided to discontinue care, but because they encountered unanticipated obstacles outside their control.

69938 The Impact of Early Retention in Care on Viral Load Suppression among Patients Newly Initiating Outpatient HIV Care

Michael J Mugavero¹ (presenting), K Rivet Amico², Andrew O Westfall¹, Heidi M Crane³, Anne Zinski¹, James H Willig¹, Julie Dombrowski³, Wynne E Norton¹, James L Raper¹, Mari M Kitahata³, Michael S Saag¹

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³ University of Washington, Seattle, WA, USA

Background: Following HIV diagnosis and initial linkage to care, achieving and sustaining viral load (VL) suppression has implications for patient outcomes and secondary HIV prevention. We evaluated factors associated with achieving VL suppression and cumulative VL burden among patients establishing outpatient HIV care.

Methods: Patients newly initiating HIV care from January 2007-October 2010 at 2 academic HIV clinics were included. Multivariable Cox PH and linear regression models were used to evaluate factors associated with time to VL suppression (<50 copies/mL) and cumulative VL burden, respectively. Viremia copy-years (VCY), an area under the longitudinal VL curve measure, was used to estimate 2-year cumulative VL burden from clinic enrollment.

Results: Among 676 patients (mean age 36 years, 82% male, 43% white, 36% uninsured, 33% CD4 <200 cells/mm³, 25% >2 "no show" visits), 63% (n = 425) achieved VL <50 copies/mL in a median of 308 days (Kaplan-Meier estimate) from initial visit. In multivariable Cox PH analysis, patients with more time-varying "no show" visits experienced delayed VL suppression (HR = 0.83 per "no show" visit, 95%CI = 0.76,0.91, P <0.01). Among 258 patients with >2-years potential follow-up from clinic enrollment, 2-year cumulative VL burden (mean±SD log₁₀VCY) was 4.3±0.8 log₁₀ copy-years, and visit adherence (proportion of completed/scheduled visits) was 0.84±0.16. The following visit adherence categories each included roughly one-third of the study sample: 100% (n = 80), 80-99% (n = 95) and 0-79% (n = 83). Greater 2-year cumulative VL burden was observed with decreasing visit adherence (mean±SD log₁₀VCY); 4.1±0.7 (100% visit adherence), 4.3±0.7 (80-99% visit adherence) and 4.6±0.8 (0-79% visit adherence) log₁₀ copy-years, respectively (P <0.01). In multivariable linear regression, visit non-adherence was independently associated with greater cumulative VL burden (log₁₀VCY) during the first 2-years in HIV care (Beta coefficient = 0.08 per 10% visit non-adherence, 95%CI = 0.03-0.13, P <0.01).

Conclusions: Early retention in care is independently associated with both achieving VL suppression and 2-year cumulative VL burden among patients newly initiating outpatient HIV care. These findings have important implications for individual health outcomes and secondary HIV prevention.



69940 HIV Conspiracy Beliefs Predict Subsequent Readiness to Initiate Antiretroviral Therapy

Rebecca L Wald (presenting)

University of Maryland School of Medicine, Baltimore, MD, USA

Background: Recent studies have found high rates of conspiracy beliefs among HIV-positive African Americans, but there have been mixed reports of how conspiracy beliefs affect ART use. This prospective study examined whether conspiracy beliefs predict subsequent readiness to initiate antiretroviral therapy (ART) among treatment-eligible patients.

Methods: Participants were 98 African Americans (53% male, mean age 45) enrolled in an inner city HIV clinic. Mean CD4 count was 182 cells/mm³; all had CD4+ <400 cells/mm³. None were on ART at baseline. At baseline and at 9-month follow-up, participants completed a structured interview about ART use and intentions and a battery of questionnaires, including a measure of conspiracy beliefs created for this study.

Results: A significant minority endorsed HIV conspiracy beliefs: "the government caused HIV" (40%); "a cure is not sincerely sought" (40%); "a secret cure exists" (38%); "HIV doctors unfairly experiment on minorities" (21%); "HIV was designed as a genocidal agent" (19%); and "HIV has not been proven to cause AIDS" (16%). Conspiracy beliefs at baseline were correlated with lower readiness to initiate ART at follow-up, $r = -.35$, $p = .03$. Readiness for ART initiation at follow-up was also correlated with measures of mistrust ($r = -.30$, $p = .05$) and irrational health beliefs ($r = -.31$, $p = .04$) at baseline and with daily alcohol use ($r = -.32$, $p = .04$), but not with locus of control, perceived barriers, HIV knowledge, patient-provider communication, or symptoms of mental illness. When these variables were entered into a stepwise multiple regression analysis, only baseline conspiracy beliefs emerged as a significant predictor of readiness to initiate ART nine months later $B = -.35$, $t = -2.308$, $p = .03$.

Conclusions: Conspiracy beliefs appear to have a significant and stable negative influence on readiness to initiate ART among HIV-positive African Americans. Treatment programs must address belief barriers to ART use.

69948 Qualitative Comparison of Barriers to Antiretroviral Medication Adherence among Perinatally and Behaviorally HIV-Infected Youth

Idia B Thurston^{1,2} (presenting), Laura M Bogart^{1,2}, Errol L Fields^{1,2}, Margie R Skeer³, Laurel Sticklor^{1,2}, Elizabeth F Closson⁴, Steven A Safren^{2,5}, Matthew J Mimiaga^{2,5}

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³ Brown University, Providence, RI, USA

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Background: Of the 25,036 13- to 24-year-olds living with HIV as of 2008, ~77% were behaviorally infected and 23% infected via perinatal or other exposures. Medication adherence among HIV-positive youth ranges from 28-69% of doses prescribed, well below the >90% thought necessary for viral suppression. We examined adherence barriers by mode of transmission among perinatally versus behaviorally infected youth.

Methods: We conducted semi-structured qualitative interviews with 30 HIV-infected youth aged 13- to 24-years-old (40% behaviorally infected, 60% perinatally infected). Half were male, 41% female, and 9% transgender. 52% identified as gay, bisexual, or other. 59% were Latino, 36% Black, and 18% White. Youth were asked questions relevant to adherence, including their interpersonal relationships, relationships with medical providers, experience taking medications, and barriers and facilitators to adherence. Interviews were recorded, transcribed, and examined using thematic analysis.

Results: Some barriers to adherence emerged consistently across perinatally and behaviorally infected youth, including lack of social support, irregularity of daily schedules, lack of disclosure, HIV stigma, poor comprehension of long term consequences of non-adherence, depressed and anxious mood, substance use, and side effects. Several barriers seemed unique to perinatally infected youth: fatigue from chronicity of HIV; reactance (i.e., unwillingness to listen to instructions of others, especially authority figures); regimen complication and frequent medication changes due to development of drug-resistant HIV; transition to independent HIV care management from parental/guardian management; and complicated disclosure patterns due to parental HIV status and secrecy in the family. Among behaviorally infected youth, distinct barriers included: self-blame (i.e., internalized stigma) for infection; greater control over starting medications; and stigma associated with risk behaviors. Behaviorally infected youth typically were taking medications for a shorter duration and often showed greater disclosure to peers.

Conclusions: Findings suggest the presence of unique barriers among perinatally versus behaviorally infected youth. Interventions and clinical management strategies are needed that address distinct emotional and logistical barriers to HIV treatment and medication adherence by mode of transmission.



69949 A Novel Breath-Based Technology to Assess Use of Vaginally Applied Products: A Pilot Study

Ariane van der Straten¹ (presenting), Scott Wasdo², Katharine Rivett¹, Matthew Booth², Helen Cheng¹, Elizabeth T Montgomery¹, Karen Smith-McCune³, Judith Wishin², Tim Morey², Donn Dennis⁴

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⁴ Xhale, Inc. Gainseville, FL, USA

Background: No practical validated methods are currently available to measure definitive adherence to vaginal product use (e.g., microbicide gel or condoms). We assessed the feasibility of using a novel breath-based system to detect women's use of vaginal products tagged with Generally Recognized As Safe (GRAS) flavorants in a clinical setting.

Methods: Thirteen healthy non-pregnant women were enrolled in a double-blind randomized study in San Francisco, USA, randomized to tagged or untagged products (5:1 ratio), and inserted in a clinical setting under direct observation: 4ml of a vaginal gel (10 tagged with 15 mg 2-pentyl acetate; 3 untagged) at visit 1, and a dildo with a lubricated condom (11 tagged with 15 mg 2-butyl acetate; 2 untagged) at visit 2. Using a mini-gas chromatograph (mGC), the presence/absence of taggants was determined in breath specimens collected prior to, and at timed intervals following product exposure (up to 75 minutes). Demographic, clinical and product use experience data were collected by structured interview.

Results: The 13 participants (median age 26, range 21-48), completed all 26 visits and correctly inserted their assigned products. Breath data was not usable for 1 visit (mGC sample port damaged). In the 25 visits with usable data, the mGC result was 100% accurate in identifying placement of tagged (or untagged) vaginal products, confirmed by the presence (or absence) of taggants in breath above baseline concentrations for at least two successive time points. Four mild and 2 moderate product-related AEs were reported (irritation, heating or cooling sensation, discharge, itching, burning) among 6 participants receiving tagged products. All were transient and resolved spontaneously. Two participants reported discomfort caused by vaginal gel insertion.

Conclusions: The tagged vaginal products were well tolerated by the study participants. This breath-based system has the potential to accurately monitor definitive adherence of vaginal products.

69951 Intimate Partner Violence, Childhood Sexual Abuse, and Implications for Engagement in Care

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Background: For HIV-positive patients, high rates of lifetime trauma exposures are associated with AIDS-related and all-cause mortality, increased opportunistic infections, progression to AIDS, and decreased adherence to therapy. Intimate partner violence (IPV) and childhood sexual abuse (CSA) are violent traumas whose impact on adherence and HIV outcomes is unknown.

Methods: HIV-positive men and women, recruited from a semi-rural public HIV clinic with a large African-American population participated in this ambidirectional cohort study (n = 213). Participants completed an interview that evaluated IPV, CSA exposure, and covariates using validated screening tools. Health information was abstracted from the medical record. In a planned interim analysis, we used univariate measures to test associations between IPV, CSA exposure, and engagement in care ("no show rate" [NSR]). Multivariate regression analysis was then performed and covariates were included in the model if $p < 0.3$ in the univariate phase.

Results: Seventy-three percent of the participants are male, 54.5% are Caucasian, and 49.8% self-identify as men who have sex with men (MSM). IPV prevalence is 33.3% with no significant difference by gender or sexual orientation. CSA prevalence is 31.1% for molestation and 23.4% for penetrative sexual abuse, with significant differences between men (both molestation and penetrative sexual abuse) based on sexual orientation ($p = 0.02$). In univariate analysis, poorer engagement in care for men is predicted by both IPV ($p = 0.007$) and CSA ($p < 0.0001$). In multivariate regression analysis, CSA ($p = 0.001$) and IPV ($p = 0.022$) were independent predictors of NSR regardless of age, race, education, drug abuse, smoking, and socioeconomic status.

Conclusions: Preliminary results suggest that IPV and CSA independently impact engagement in HIV care. We anticipate a more complete model of these relationships when enrollment is complete (n = 400) which could lead to development of targeted interventions to mitigate the impact of IPV and CSA on HIV-positive individuals.



69952 Medical Mistrust May Mediate the Relationship of Perceived Discrimination to Treatment Nonadherence among Latino Men Living with HIV

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Background: HIV-infected Latino men who have sex with men (MSM) are at the nexus of multiple stigmatized identities related to race/ethnicity, HIV serostatus, and sexual orientation. Prior work indicates that perceived discrimination is associated with poor health behaviors, including nonadherence. However, research has not sufficiently examined mechanisms by which discrimination can lead to nonadherence, or fully assessed socio-cultural determinants of nonadherence among Latinos. In a sample of Latino men, we examined the relationship of discrimination to nonadherence, and whether medical mistrust can help to explain this association. We hypothesized that chronic discrimination may engender mistrust of societal institutions, including healthcare, which in turn may lead to suspicion of medical treatments and reluctance to adhere to provider recommendations.

Methods: A total of 137 Latino men on antiretroviral treatment completed interviews measuring adherence, medical mistrust, and discrimination due to HIV serostatus, race/ethnicity, and sexual orientation.

Results: Nearly a quarter (23%) reported missing a medication dose the day before the interview. In separate models, greater medical mistrust [OR = 0.37, $p < .01$] and perceived discrimination due to HIV-serostatus [OR = 0.78, $p < .01$], race/ethnicity [OR = 0.82, $p < .05$], and sexual orientation [OR = 0.82, $p < .05$] were significantly associated with nonadherence; racial ($r = .24$, $p < .01$) and HIV serostatus discrimination ($r = .18$, $p < .05$) were significantly correlated with medical mistrust. Bootstrapping tests of indirect effects indicated that medical mistrust significantly mediated the associations between both racial/ethnic discrimination [95%-confidence interval (CI) = $-.16, -.02$] and HIV serostatus discrimination [95%CI = $-.15, -.01$], and nonadherence: when medical mistrust was added to models predicting adherence with racial/ethnic and HIV serostatus discrimination, the effects for discrimination were reduced to nonsignificance.

Conclusions: Chronic experiences with discrimination can contribute to mistrust of healthcare, and in turn, worsen treatment adherence among Latino men living with HIV. Culturally-tailored interventions to promote adherence should acknowledge medical mistrust and improve coping skills for discrimination-related stress, especially from racism and HIV stigma.

69963 How Treatment Partners Help: Social Analysis of an African Adherence Support Intervention

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Background: Treatment partners help persons taking antiretroviral therapy for HIV/AIDS to adhere to dosing requirements. Treatment partnering is an intervention developed in sub-Saharan Africa to improve HIV treatment outcomes. We describe the social functions treatment partners also serve and show how these functions contribute to social health and survival for patients with HIV/AIDS.

Methods: Functions of treatment partners were examined using qualitative research methods. Twenty pairs of adult HIV/AIDS patients and treatment partners treated at a public HIV-care setting in Tanzania were interviewed. Multiple "minimally structured" interviews were conducted with each patient ($N = 20$) and treatment partner ($N = 20$). Ninety-eight interviews with these 40 individuals comprised the data set. Category construction methods were used to analyze the data.

Results: Analysis revealed four social functions of treatment partners: (1) encouraging disclosure; (2) combating stigma; (3) restoring hope; and (4) reducing social difference. These functions restore social connections and reverse the isolating effects of HIV/AIDS. Restoration of social connection ensures access to "community safety nets" necessary for survival in settings of resource scarcity.

Conclusions: In addition to encouraging antiretroviral adherence, treatment partners play a critical social role in the lives of the patients they support. Treatment partnering is a behavioral intervention that also contributes to "social health" for patients. Social health as well as HIV treatment success is essential to survival for persons living with HIV/AIDS in sub-Saharan Africa.



69965 Improving Retention in HIV Care through Patient Tracking in Sub-Saharan Africa

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Background: Retention is a major barrier to the success of long-term antiretroviral therapy (ART) in sub-Saharan Africa. Patient tracking, an approach developed by Africans, for Africans, is a potentially effective retention intervention. Trackers are trained health workers who travel outside clinical sites to locate patients in the community.

Methods: We present data and theory examining tracking as a retention intervention at a large HIV treatment clinic in Jos, Nigeria. Patients who had missed routine clinic visits for three months or more and lived within 50 km of the city center were followed up by the clinic's tracking team. Patients who were located and gave permission participated in qualitative interviews about their tracking experiences (N = 30). Researchers also carried out multiple interviews with each clinic tracker and shadowed each tracker during patient visits for observation (N = 10).

Results: A total of 231 patients were tracked over a period of 12 months. Sixty-four percent (N = 148) were located and 88% (N = 130) of those located returned to clinic. Interview data suggest a theoretical explanation for the high return rate, as follows: Patients initially miss visits because they encounter unanticipated obstacles outside their control. Initial obstacles may resolve themselves, but feelings of guilt and shame at having "defaulted" on obligations as patients persist, resulting in a reluctance to return to care. Tracking intervenes to reduce guilt and shame and offer encouragement. Patients respond to this "gesture of caring" by recommencing clinic visits.

Conclusions: Tracking improves communication and strengthens links between patients and staff at a large urban clinic. Patient tracking is an effective approach to facilitating return to care by patients who have missed clinic visits and been located by a tracking team in Jos, Nigeria.

69967 Identification and Assessment of Adherence-Enhancing Interventions: Results of a Literature Review

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Background: Medication non-adherence is prevalent across all medical conditions that include ambulatory pharmacotherapy, and is thus a major barrier to achieving the benefits of evidence-based drug therapies. The objective of this research is to identify components of adherence-enhancing strategies that successfully improve execution of the prescribed drug dosing regimen and maintain long-term persistence.

Methods: We conducted a systematic review to identify randomized controlled trials that tested the effectiveness of medication adherence-enhancing strategies with self-administered medications. Our review included only studies in which adherence was reliably assessed by electronically compiled drug dosing histories. Adherence-enhancing components were classified in 8 categories. Meta-analysis using random effects models was used to derive global effect on adherence outcomes. Regression analysis was used to identify which intervention component successfully enhanced medication adherence, expressed as % of prescribed doses taken (%PDT).

Results: A total of 67 controlled clinical trials published between 1979 and 2010 were included in the review. 25 (35%) of them were in the field of HIV. Patients randomized to an intervention group had an average %PDT which was 12% [95%CI:9%-16%] higher than that in patients randomized to standard care. Study duration had a negative effect on %PDT ($p = 0.0008$). Intervention strategies that included a focused discussion based on adherence data compiled by electronic monitors were significantly more effective than those that did not include that feedback ($P = 0.0012$). The average %PDT among patients receiving this adherence feedback was 21% [95%CI:10%-32%] higher than among patients randomized to standard care.

Conclusions: Measurement Guided Medication Management (MGMM) is an approach to enhance medication adherence in which reliable and detailed electronically-compiled drug dosing history data are used to provide feedback to the patient on his/her medication adherence. MGMM sets the stage for focused dialogue between the healthcare providers and their patients, resulting in substantive and significantly improved medication adherence.

**69968 Medication Adherence: A Consensus on Taxonomy**

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Background: Four decades of adherence research, however, has not resulted in uniformity in the terminology used to describe deviations from prescribed therapies. The objective of this research is to propose a robust taxonomy which supports quantifiable parameters that are rooted in both behavioral and pharmacological science.

Methods: The first step was to identify the different conceptual approaches to adherence research, through a literature review. A taxonomic approach was subsequently derived, evaluated, and refined via many discussions with international experts. In September 2010, a consensus was reached by the European Commission-sponsored project, Ascertaining Barriers to Compliance (ABC) in collaboration with the European Society for Patient Adherence, Compliance and Persistence (ESPACOMP).

Results: The conceptual foundation for a new, transparent taxonomy relies on 3 elements, making a clear distinction between processes that describe actions through established routines, and the disciplines that study those processes. "Adherence-related sciences," "Medication management," and "Medication adherence" constitute the three pillars of the concept. "Medication adherence," the process by which patients take their medication as prescribed, further divided in three quantifiable phases: "Initiation," which occurs when the patient takes the first dose of a prescribed medication; "Execution," which is the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen, and, "Discontinuation," which occurs when the patient stops taking the prescribed medication.

Conclusions: In response to the proliferation of (often) ambiguous or unquantifiable terms in the literature on medication adherence, this research has resulted in a new conceptual foundation for a transparent taxonomy. The terms and definitions are focused on promoting consistency and quantification in terminology and methodology to aid in the conduct, analysis, and interpretation of scientific studies of medication adherence. The adoption of these terms and definitions will also help standardize the medical literature and, therefore facilitate evidence-based health policy decisions derived from sound measurement.

69969 Improving the Estimation of HIV Treatment-Efficacy by Combining Structural Nested Mean Models with Pharmacokinetic Models of Antiretroviral Drug Exposure

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Background: The aim of treating HIV-1-infected patients is to achieve and maintain suppression of viral load (VL). Achievement of this aim is thwarted by variable adherence to prescribed antiretroviral drugs.

Methods: Variable adherence to an antiretroviral regimen creates variability in the patient's internal exposure to the drugs. Structural nested mean models (SNMM) enabled us to estimate, during the initial phase of treatment, the relationship between variable internal exposure and VL, accounting for measured time-varying confounders and feedback relations using an antiretroviral regimen containing lopinavir/ritonavir (LPV/RTV, LPV/r).

Results: Our final SNMM predicts that the short-term effect of treatment is modified by the most recently past VL, with higher initial VLs being associated with larger treatment-induced reductions for a given internal exposure to the drugs. Variation in internal exposure to LPV/r in the interquartile interval (P25%-P75%) only slightly affects the overall reduction in VL.

Conclusions: Those findings support the conclusion that the relatively long duration of action of LPV/r minimizes the impact on VL of the most frequently recurring intermittent lapses in dosing. In effect, this finding indicates that the ARV agent, LPV/r, gains in forgiveness as prior duration of treatment increases.

* Not CME-certified



69986 Evaluating the Implementation of a Comprehensive Care Coordination Program in New York City

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Introduction: In December 2009, the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) began using Ryan White Part A funding to implement a comprehensive, evidence-based Care Coordination program aiming to improve health outcomes for HIV-infected persons. NYC Care Coordination programs share a standard protocol, designed to provide detailed guidance on program components, including health promotion and support for adherence to antiretrovirals and primary care appointments. Because of the program's complexity and critical importance, the DOHMH evaluated its first year of implementation, specifically assessing protocol fidelity.

Program Description: Using a mixed-methods design, implementation was assessed through program staff surveys, focus groups and chart review. Surveys were distributed to program directors, care coordinators and patient navigators in electronic and paper format. Focus group participants were selected from a representative sample of contracted providers. Using a randomized cluster sampling strategy, charts were selected from among eligible patients at funded agencies. Focus groups and chart reviews are complete and results are being compiled.

Lessons Learned: The five focus groups revealed diversity in program implementation and lack of fidelity to protocol in some areas. Differences emerged in perceptions of program objectives and methods for care team communication. Chart reviews on 796 patients enrolled for at least 30 days revealed some key program components were inconsistently completed at recommended intervals, despite support from independent contract managers and DOHMH technical assistance.

Recommendations: This case study illustrates ways in which process evaluation is essential to implementing a new program, as substantial deviations from protocol may otherwise escape recognition. Successful long-term implementation of a challenging new intervention model requires a combination of initial programmatic guidance, timely and extensive technical assistance, process evaluation to compare protocol intent with real-world delivery of services, adjustments of the protocol where indicated, and integration of process findings into outcomes evaluation.

70002 Adherence is the Major Factor Associated with Virologic Outcomes on a Dual-Class Dual-Drug Regimen of Raltegravir with a Protease Inhibitor

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Background: Novel treatment strategies are needed for HIV-infected individuals with resistance or intolerance to multiple antiretroviral medications. Our goal was to evaluate factors associated with virologic outcomes on novel dual-class dual-active-agent antiretroviral therapy (ART) consisting of raltegravir plus a protease inhibitor (PI).

Methods: Retrospective evaluation of individuals initiating a dual-class raltegravir plus PI regimen. Virologic success was defined by a plasma HIV-RNA level ≤ 200 copies/ml. Adherence was measured using pharmacy refill data for six months prior to the last HIV-RNA level on the included regimen. The association between adherence and virologic failure was assessed utilizing basic descriptive statistics for adherence terciles (thirds) and with bivariate logistic regression.

Results: Of 39 included individuals, 10% were female, 41% Hispanic, 10% Black, and 85% men who have sex with other men. Median prior ART exposure was 11 years; 69% were three-class antiretroviral medication experienced. Thirty-six (92%) of 39 individuals achieved an HIV-RNA level ≤ 200 copies/ml; 79% achieved an HIV-RNA level < 50 copies/ml. After a median 328 days (IQR 190-737 days) of follow-up, 74% maintained an HIV-RNA level < 200 copies/ml. Median adherence was 96.4% (terciles: $< 84\%$, 84-99%, $> 99\%$). In the top adherence tercile 92% maintained virologic suppression compared to 82% and 36% in the middle and bottom terciles respectively. For every 10% decrease in adherence, the risk of virologic failure increased by 90% (OR 1.9, 95% confidence interval 1.1 - 3.3, $p = 0.03$). All four individuals having ≥ 2 baseline major PI resistance mutations failed therapy; however, all were in the bottom adherence tercile.

Conclusions: Antiretroviral medication adherence was the major factor associated with successful virologic suppression in this ART experienced population on a novel two-class regimen containing raltegravir plus a PI. Pre-existing major protease resistance mutations may also be a risk factor for virologic failure.



70014 What's Love Got To Do With It? A Relationship Framework for Research on Adherence to Antiretroviral Therapy (ART) as Pre-Exposure Prophylaxis

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Background: Pre-exposure prophylaxis (PrEP), in which an HIV-negative individual takes antiretroviral medication daily as chemoprophylaxis, is a promising biomedical approach to HIV prevention. Adherence is essential to maximize PrEP effectiveness. This presentation offers a conceptual framework for understanding PrEP adherence based on preliminary analysis of data from a qualitative study.

Methods: The study is part of an ongoing, double-blinded, multi-site randomized controlled trial of PrEP efficacy among stable serodiscordant couples in rural southwest Uganda. Adherence is monitored using unannounced pill counts and medication event monitoring system (MEMS) caps. All participants receive individual and couples-based adherence counseling. Using purposive sampling, in-depth interviews are being conducted with individuals taking PrEP (or placebo) and their HIV-1-positive partners. Interview transcripts are content-analyzed for influences on adherence.

Results: Nineteen (5.9%) of 323 monitored individuals at the single, qualitative study site have had adherence rates <80%. Preliminary qualitative results suggest PrEP adherence is mediated by a discordant couple's success in negotiating the dynamics of power, trust and solidarity in intimate relationships. Power: Adherence is affected when study pills are "used" in ways intended to manipulate either partner's behavior. Trust: Perceived breaches of trust in the relationship can result in deliberate adherence lapses. Solidarity: Lack of a sense of solidarity ("we are in this together") can lead to demoralization and missed medication doses by the HIV-negative partner. Couples who employ strategies to cope with serodiscordance can affirm their relationship and counter negative influences on adherence. Regular clinic counseling through the efficacy trial plays a critical role in supporting relationships, and consequently, adherence to PrEP.

Conclusions: Early results suggest PrEP adherence success in stable partnerships is influenced by the quality of the intimate relationship. A social conceptual framework centering on power, trust and solidarity as analytic constructs defines relationship quality and may inform future research.

70018 Closing the Gap between Practice and Research: Collecting Quality Adherence Data in the Real World

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Introduction: The collection of high-quality adherence data for a home-based HIV Directly Observed Therapy (DOT) program presents important challenges. Boston's Prevention and Access to Care and Treatment (PACT) program employs community health workers (CHWs) to deliver DOT to vulnerable patients and improve patients' self-management skills. In 2010, PACT partnered with Dimagi, a health IT firm, to develop a smart phone and web-based application to facilitate collection, analysis, and exchange of complex adherence data from the field.

Description: Throughout the past decade, PACT's DOT program has used paper-based tools to capture and organize patients' adherence data. This system was labor-intensive and error-prone. In particular, it was challenging to standardize interpretation of pillboxes when patients had missed DOT visits and had refilled their pillboxes prior to CHW arrival. PACT collaborated with Dimagi to design an easy electronic system through which CHWs log DOT encounter details into hand-held devices; these data include patient self-reports, pillbox checks, and observed dose information. Adherence scores that combine the three data points and automatically reconcile two weeks of pillbox data are instantaneously calculated. These data inform CHW intervention in real time and are used on a weekly basis by referring clinicians to further direct patient care and by program management for quality improvement (QI) initiatives.

Lessons Learned: Dimagi created an effective data collection, analysis, and exchange system after considerable exposure to CHW practice patterns and participatory multi-cycle field testing. The ability to standardize pillbox interpretation is critical to capturing quality adherence data. Combination adherence scores can be used to direct HIV care and QI initiatives in real time.

Recommendations: Quality adherence data collection and analysis in non-research settings are critical to inform real time and accurate decision-making by adherence interventionists and referring clinicians.



70022 Gaps in HIV Care: An Evaluation of the Association of Gap Length with Virologic and Immunologic Outcomes

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Background: Engagement in HIV care is critical for successful management of HIV infection. We studied the natural history and consequences of gaps in HIV care.

Methods: Retrospective review of medical records for all HIV-infected individuals at Denver Health with a 6-month (≥ 180 -day) gap in HIV care ending between June 2008 and January 2009. Review spanned from 6 months before and after the gap in care. Gap duration was assessed for associations with virologic suppression (HIV-RNA < 50 copies/ml) and changes in CD4 lymphocyte counts. The Pearson correlation coefficient was used to assess the correlation between gap length and CD4 cell count change.

Results: Out of approximately 1400 HIV-infected patients at our institution, 309 (22%) had a ≥ 6 -month gap in HIV care ending during the study period. Median age was 41 years (interquartile range [IQR] 35-47), 11% women, 28% Hispanic, 19% Black, and 68% were men who have sex with men. Median pre-gap CD4 count was 416 cells/ μ l (IQR 281-573). Prior to the gap 232 (75%) were on antiretroviral therapy (ART); 179 (77%) were undetectable. Median gap duration was 8.5 months (IQR 7.2-12.0). In individuals on ART, the proportion undetectable and median CD4 changes at the end of 6-7, 8-9, 10-11, > 12 month gaps were 75%, 63%, 47%, and 42% and median CD4 count changes were -10, +34, -52, and -76 cells/ μ l respectively. In individuals not on ART prior to the gap, there was a significant inverse relationship between gap duration and change in CD4 count ($p = 0.01$).

Conclusions: Gaps in HIV care of 6 months or greater were common, affecting 22% of our cohort. Most individuals on therapy with a gap in HIV care spanning 9 months or less are able to maintain virologic suppression, however outcomes waned for gaps ≥ 10 months in duration. In individuals not on therapy, gap duration inversely correlated with immunologic decline.

70029 HIV Provider's Confidence and Expertise in Treating Depression as a Means of Addressing Antiretroviral Adherence

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Background: Depression is common in HIV patients and can affect antiretroviral adherence and clinical outcomes without proper diagnosis and treatment. HIV providers play an important role in identification and management of depression.

Methods: The SLAM DUNC (Strategies to Link Antidepressant and Antiretroviral Management at Duke and UNC) Study is a randomized trial of a depression treatment intervention's impact on antiretroviral adherence and clinical outcomes in depressed HIV patients. Before study launch, 48 providers at two study sites completed semi-structured interviews about current depression management knowledge and practices.

Results: Interviewees were 26 MD attendings, 15 MD fellows, 4 Physician-Assistants, and 3 Nurse-Practitioners. Years of HIV clinical experience ranged from 1-28 (mean: 12). Providers devoted 10-100% (mean: 38%) of time to clinical work, with 5-100% (mean: 69%) focused on HIV treatment. Only 23% assessed depression systematically; 70% asked only when prompted by the patient's presentation and 7% never assessed depression. Providers expressed high confidence in prescribing an initial antidepressant (mean: 4.0 on 1-5 Likert scale), but lower confidence in changing antidepressants (mean: 3.0). When dosing antidepressants, 64% did not consider interactions with the patient's ARVs. Compared to best-practice treatment guidelines, 36% followed up within 2-4 weeks after starting an antidepressant, 36% would titrate up to the maximum recommended dose, and 27% evaluated improvement in the patient's depressive symptoms to guide dose changes. Most (64%) referred to outside mental health resources if the patient failed a first antidepressant. Providers welcomed receiving decision support from non-prescribing clinical personnel.

Conclusions: Systematic identification and best practices of depression management were uncommon. Providers generally initiated a first antidepressant but lacked in adjusting doses and medications. Depression management support allows for opportunities to improve treatment in clinic with potential benefits to HIV outcomes.



70058 Predicting the Emergence of Antiretroviral Therapy (ART) Side Effects: The Role of Psychological Variables

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Background: Treatment side effects are frequently associated with non-adherence to ART, however little is known about the pre-treatment determinants of side effects. We examined differential effects of clinical (type of regimen, CD4 count and viral load), demographic (age, sex, employment status) and psychological variables (pre-treatment beliefs about medicines, anxiety and depression) on the emergence of treatment side effects.

Methods: In a prospective, follow-up study, consecutive patients attending HIV clinics in Brighton, UK, completed validated questionnaires assessing pre-treatment concerns about ART, beliefs about medicines in general, perceived sensitivity to adverse effects of medicines, depression and anxiety before initiating ART (baseline). Self-reported ART side effects were measured at 3 (3M) and 6 months (6M). Self-reported adherence was assessed at 6M and 12 months (12M). Clinical, treatment and demographic data were recorded from medical files.

Results: Eighty five people initiated treatment and provided data. Of those 62 (73%) reported high adherence (taking at least 95% ART as prescribed) and 23 (27%) reported low adherence (taking <95% as prescribed) at 12M. Low adherence at 12M was associated with a greater number of moderate-severe ART side effects at 6M ($p < 0.05$). The emergence of side effects at 6M was associated with psychological variables at baseline including pre-treatment concerns about ART, ($p < 0.0001$), perceptions of personal sensitivity to adverse effects medicines ($p < 0.05$), higher rates of depression ($p < 0.0001$) and anxiety ($p < 0.0001$). The emergence of side effects was associated with a longer diagnosis of HIV ($p < 0.05$), but not with any other clinical or demographic characteristics. Pre-treatment concerns about ART were associated with negative beliefs about medicines in general (all $p < 0.001$).

Conclusions: The emergence of ART side effects was associated with psychological variables including pre-treatment concerns about medicines, anxiety and depression, which may be amenable to change. These results therefore have implications for the development of interventions to support patients and facilitate adherence.

70063 Feasibility of a Test and Treat Approach in Routine HIV Care

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Background: Test and treat strategies depend on viral suppression (VS) shortly after diagnosis, but few studies assess outcomes from the time of diagnosis. We sought to determine success rates for linkage to care, retention in care, receipt of ART, and VS (<400 copies/mL) one year after diagnosis for patients cared for in routine settings.

Methods: STEPS was a prospective observational cohort study of patients newly diagnosed with HIV infection at public facilities in Houston, TX. Participants were enrolled within 3 months of diagnosis and excluded if they had already completed an HIV primary care visit. Participants were surveyed at baseline and every 3 months. Medical record review was done at 2 years at all sites used by the participant, plus nearly all Ryan White clinics in the area and VA facilities, accounting for about 90% of the care of uninsured patients in Houston.

Results: There were 183 evaluable participants; median CD4 cell count 200 cells/mm³. 78% attended a visit within 90 days of diagnosis. 32% attended a visit in all 4 quarter-years after diagnosis. 56% of the 132 participants known to be alive and in the Houston area at 12 months attended visits in both the 3rd and 4th quarter-years. 65% of participants had baseline CD4 <350 cells/mm³, and 73% of those received ART within one year. By 12 months, 32% of all participants had VS. 132 participants were known to be alive and in Houston at 12 months, 42% had VS. 108 participants had a 12-month VL done, 54% had VS.

Conclusions: A substantial portion of patients does not suppress virus one year after diagnosis due to losses at all steps of care. A test and treat model, with the goal of a low VL in all patients, will require significant additional resources to link, treat, and retain patients in care.



70064 Depression - Evidence of its Key Role for ART Adherence in Sub-Saharan Africa

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Background: Studies of the determinants of HIV antiretroviral therapy (ART) adherence in sub-Saharan Africa have generally focused on practical and structural barriers. With Social Cognitive Theory as a theoretical framework, this is among the few studies to conduct a comprehensive evaluation of cognitive, psychosocial, and behavioral factors that may influence adherence.

Methods: Self-report surveys, including measures of ART adherence, physical and mental health, social environment and support, and adherence self-efficacy, as well as chart-abstracted medical characteristics, were collected over the first 12 months of ART among clients at two HIV clinics in Uganda. Baseline measures were examined in relationship to suboptimal adherence (at least one missed dose during the week prior to month 6 or month 12); significant bivariate correlates were included in logistic regression analysis.

Results: Approximately one-third of the sample (33%) reported suboptimal adherence (36% at month 6 and 31% at month 12). In bivariate analysis, suboptimal adherence was associated with urban location, younger age, not working, WHO disease stage 3 or 4, lower physical functioning, and greater depression and internalized HIV stigma. In multivariate analysis, depression (other than urban location) was the sole predictor of suboptimal adherence. When change in depression from baseline to month 12 was added to the model, decreased depression was associated with improved adherence. Adherence self-efficacy responses were highly skewed, largely uniform and thus not included in analyses.

Conclusions: The study findings reveal a similar level of non-adherence as that found in other studies in sub-Saharan Africa as well as the developed world. While depression is often found to be a key predictor of adherence, this is one of few studies to provide evidence on the role of both the level and change of depression over time in sub-Saharan Africa. Further research is needed to elucidate the pathways through which depression influences adherence.

70065 An Adherence Intervention to Support HIV Pre-Exposure Prophylaxis (PrEP) Adherence in Serodiscordant Couples in Uganda

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Introduction: PrEP is a promising biomedical HIV prevention method, and adherence counseling will be key to its success. The Partners PrEP Study is an ongoing phase III, double-blind, three-arm, randomized, placebo-controlled trial of daily oral PrEP among 4700 HIV-1-uninfected members in serodiscordant African couples, which includes an ancillary adherence study in Uganda at three of the nine study sites.

Description: Individuals with = 80% adherence (measured by unannounced pill count) in the prior = 1 month(s) receive standardized adherence counseling based on a social problem-solving model of treatment adherence. We are using an iterative process of intervention development based on data collected from the counselors and recipients of the intervention.

Lessons Learned: As of November 2010, 544 participants have data available for analysis (48% female, mean age 36.5 years [SD 8.7]). Adherence <80% has been found in 51 participants (9.4%), 37 (72.5%) of whom received the intervention. Training took place in local group meetings; ongoing supervision involves monthly telephone calls and yearly site visits. Sample intervention topics include assessment of sexual behavior, motivational interviewing, and an optional couples session. Counselors report high levels of intervention acceptability. Counselor-reported barriers to adherence include sexual behavior changes, partner discord, and travel. Participants report high levels of motivation to adhere to PrEP, driven by wanting to improve HIV prevention for future generations. Initial follow-up adherence has improved to >80% in 86.5% of the 37 participants.

Recommendations: Adapting evidenced-based treatment adherence interventions to PrEP adherence, with culturally relevant topics is feasible and acceptable to counselors and participants. Further follow-up will address efficacy and sustainability of increasing adherence after this intervention in those with <80% adherence to daily PrEP. Such work will increase confidence in interpretation of results from biomedical HIV prevention trials and will facilitate adherence and proper use of these strategies should they become widely available.



70075 Defining and Predicting Detection Rates of Intracellular Emtricitabine-Triphosphate (FTC-TP) and Tenofovir-Diphosphate (TFV-DP) in the iPrEx HIV Pre-Exposure Prophylaxis (PrEP) Trial

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Background: Quantifiable drug in viably cryopreserved PBMCs (v-PBMCs) powerfully predicted HIV acquisition in iPrEx, but how to best quantify daily adherence with v-PBMCs, what predicts quantifiable drug, and how measures of adherence (self-report, refill measures) perform in relation to drug detection is relatively unknown yet critical in facilitating accurate monitoring of and signaling potential problems with adherence.

Methods: Expected detection rate in v-PBMCs with daily FTC/TDF dosing was first determined using PBMCs from 10 suppressed HIV-positive individuals outside of iPrEx. Drug detection was then determined in a sample of 179 HIV-negative active arm iPrEx participants at week 24 stratified by adherence level. Detection was defined as above the limit of quantification for FTC-TP (0.1 pmol/sample) and TFV-DP (2.5 fmol/sample). Overall rates of adherence by indicator were established for the full cohort (N = 2045) at week 24 and examined for positive predictive and negative predictive value (PPV, NPV) in the stratified random sample with v-PBMCs (N = 179).

Results: FTC-TP and TFV-DP were detectable in 100% of v-PBMCs in the suppressed HIV-positive sample. Among the 179 iPrEx participants, FTC-TP and TFV-DP were detected in 50% and 62% of specimens. Correlates of detection included age ≥ 25 years, US site, and recent unprotected receptive anal intercourse. Adherence indicators at week 24 characterized the sample as highly adherent (mean 96%, 91%, 92%, and 1.31, for interview, CASI, pill count, and medication possession ratio [MPR]). PPVs were 68%, 62%, 59%, and 75% for drug detection among those in the highest adherence strata, and NPV among those classified in the lowest strata for no drug detected were 88%, 78%, 85%, and 100% (respectively for interview, CASI, pill count, and MPR).

Conclusions: Age, site, and recent sexual activity associated with drug detection. Although the sample was characterized as highly adherent by all indicators, drug detection rate suggested consistent adherence in only 60% of participants. NPV was strong for all indicators, while MPR appeared to generally outperform other measures.

70076 Appointment Keeping Medication Adherence and Clinical Outcomes in Patients with HIV

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Background: Effective disease management requires that patients with HIV schedule and keep clinic appointments and follow their prescribed medication regimen. These activities are two different ways to assess degree of patient adherence and potentially improve clinical outcomes.

Methods: Using baseline data, this study examined the relationship between appointment keeping and adherence to antiretroviral medications in a sample of patients living with HIV/AIDS participating in a randomized control trial designed to improve medication adherence. Measures included medical record review, electronic event monitors (for adherence summarized as the total number of doses of antiretroviral medication taken [dose] and the number of days with correct intake [days] over 14 days), self-report of adherence, and a demographic questionnaire.

Results: The sample included 269 subjects with medical record review data; 4 (1.5%) were excluded as they lacked appointment data. About half the sample (n = 147, 54%) had no missed appointments recorded during the 6 months prior to baseline data collection. The sample included 182 males (67.7%); 107 (39.8%) subjects were white. Self-reported adherence was 9.81 (SD = 2.53), dose adherence was 77.53 (SD = 27.81), and days adherence was 67.92 (SD = 32.14) for the total sample. Compared to those who missed appointments, subjects with no missed appointments had higher mean self-reported adherence (10.34 vs. 9.12, $p < .0001$), greater mean dose (82.59 vs. 71.0, $p < .0001$) and days (73.91 vs. 59.91, $p < .0001$) adherence, and higher mean CD4 counts (490.2 cells/mm³ vs. 416.0 cells/mm³, $p = .045$). Subjects with no missed appointments had 1.72 times the odds of having an undetectable viral load compared to those with missed appointments (95% CI = [1.04, 2.85], $p = .036$).

Conclusions: The findings demonstrate that appointment keeping and medication adherence are associated with improved patient outcomes. Regular clinic visits offer opportunities for health providers to monitor and reinforce the importance of medication adherence to decrease HIV disease progression.



70077 Factors Affecting Enrollment of Newly Diagnosed HIV-Positive Persons into ART Services in India: An Observational Cohort Study

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Background: India has around 2.31 million people living with HIV (PLHIV). By March 2009, the ART program was treating 217,781 PLHIV. A major challenge has been to increase enrolment into ART services. We present findings from a multi-site cohort study done to understand factors influencing the uptake of ART services in India.

Methods: Data were collected from 27 Integrated Counseling/Testing Centers (ICTCs) and nine corresponding ARTCs across six states. Individuals testing HIV-positive were interviewed at selected ICTCs, followed prospectively and interviewed again when they registered at a referral ARTC. Those who did not register at ARTC were interviewed in the community. Ethical approvals were obtained.

Results: 1057 newly diagnosed PLHIV (52% females, mean age 34.7 years) were recruited from 27 CTCS. 73.5% (n = 777) PLHIV registered at referral ARTCs within 2 months; 17.9% (n = 189) did not register and were interviewed in the community, 5.6% (n = 60) were traced but could not be interviewed and 3% (n = 31) were lost to follow-up. Reasons cited by unregistered PLHIV (n = 189), for not visiting referral ARTCs, were mainly a perception of good health (30%), work/family engagements (22%), fear of disclosure (9%) and financial difficulties (9%). Other reasons included family opposition, lack of transport, no one to accompany or being very sick. On multivariate analysis younger clients (AOR: 0.97; 95%CI:0.95-1.00; p = 0.057); single clients (AOR:1.90; 95%CI:1.02-3.52; p = 0.041); clients who disclosed their HIV status to someone (AOR:2.79; 95%CI:1.90-3.96; p <0.001); clients who knew a PLHIV (AOR:2.2; 95%CI:1.54-3.16; p <0.001); clients from households with principal occupation of manual labour (AOR:2.46; 95%CI:1.03-5.85; p = 0.041) and economically weaker clients (AOR:2.00; 95%CI:1.33-3.01; p = 0.01) were more likely not to register at ARTCs.

Conclusions: While stigma and financial difficulties are barriers, a perception of good health also prevents PLHIV from accessing services. Addressing these barriers through focused counseling, follow-up in the community, support in dealing with stigma and bringing ARTCs closer to clients should be considered.

70078 Definitive Medication Adherence Monitoring is Unaffected by Potential Food Interferents

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Background: We previously described a breath-based system that definitively documents adherence to prescribed medications using a miniature gas chromatograph (mGC). GRAS flavorants, termed "taggants" (e.g., secondary alcohol: 2-butanol), are ingested along with an active pharmaceutical ingredient and the metabolite of the taggant (corresponding ketone: 2-butanone) is detectable in the breath shortly after gastrointestinal absorption. Because these taggants are also present in specific foods, we evaluated whether foods known to contain the highest concentrations of 2-butanol or 2-butanone among foodstuffs interfere with the adherence monitoring system.

Methods: After IRB approval 11 healthy subjects (M = 6, F = 5; 22-61 years) were consented and enrolled in a crossover observational study. The study had 2 limbs: fasted and fed (Jimmy Dean sausage muffin). Each limb contained four study groups: control (empty capsule), ingestion of 40 mg of 2-butanol in a capsule, ingestion of 500 ml of black tea (contains 2-butanol) and ingestion of 1 tomato (contains 2-butanone). Therefore, each subject had a total of 8 visits with at least a one day wash-out between visits. Breath samples were collected in Tedlar bags and analyzed by GC-MS and mGC. After a baseline breath sample, capsules or food were ingested and samples obtained at time 0 and 11 additional times up to 60 min.

Results: Very low levels of 2-butanone were detected in breath from baseline and control samples (<3 ppb) and following ingestion of black tea and tomato (<6 ppb). In contrast, after ingestion of 40 mg of 2-butanol in fasting and fed subjects, the average concentrations of 2-butanone in breath were 150-250 ppb at 7.5-10 min, 300-600 ppb at 10-20 min, and 100-150 ppb at 60 min.

Conclusions: Ingestion of foods known to contain the highest concentrations of 2-butanol and 2-butanone among foodstuffs does not appear to interfere with the function of the adherence monitoring system.

* Not CME-certified



70087 Patterns of Non-Adherence and Impact on Viral Load among HIV-Positive Patients from the MACH-14 Study

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Background: While it is known that non-adherence is associated with viral load (VL), little is known about how patterns of non-adherence vary in their effect on VLs. We hypothesized that a greater number of consecutive non-adherent days would be associated with higher VL, even after adjustment for total non-adherence.

Methods: The MACH-14 study includes data pooled from 16 studies across the US. The current analysis was restricted to 768 individuals with 2,399 VL measures. The analysis focused on patterns of non-adherence in the 28 days prior to VL measurement. Non-adherence was defined as: 1) total number of non-adherent days; 2) number of short (27-48 hours), intermediate (2-6 days), and long (>7 days) interruptions in medication-taking; 3) length of the longest non-adherent period; and 4) time between the longest non-adherent period and VL measurement. We used generalized estimating equations to determine the effect of non-adherence on log-transformed VL.

Results: The sample was 73% male, 42% African-American, 34% White, 17% Hispanic/Latino, with a median age of 40 years (IQR: 35-46), and 31% treatment-naïve at baseline. The median VL was 400 copies/mL (IQR: 400-1454). After adjusting for socio-demographics, total non-adherent days, and time since longest interruption, a dose-response relationship between the length of the longest treatment interruption and increased VL was observed: there was no association between interruptions <14 days in length, while interruptions between 14-20 days ($z = 3.24$, $p < 0.001$) and >21 days ($z = 8.15$, $p < 0.0001$) were associated with incrementally higher VLs.

Conclusions: The results suggest that recent patterns of non-adherence impact viral suppression. We observed a threshold effect whereby interruptions in medication-taking >14 days increased VL, even after adjusting for time since long interruption, while shorter interruptions and overall medication-free time did not. Future analyses will adjust for regimen type. Clinicians should focus efforts to improve adherence on reducing longer consecutive interruptions in medication-taking.

70094 Psychosocial Distress and Treatment Failure in HIV-Positive African Youth

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Background: Psychosocial problems among children and adolescents have the potential to cause HIV treatment failure if they disrupt adherence to antiretroviral therapy. Rapid screening tests for psychosocial dysfunction may allow for recognition of children and adolescents at the highest risk of adherence problems in busy clinics in resource-limited settings. The Pediatric Symptom Checklist (PSC) has been used extensively in high resource settings for the rapid identification of at-risk youth in clinics and schools. We sought to determine whether high PSC scores are associated with treatment failure in HIV-infected children in Africa.

Methods: We translated, culturally-adapted and validated the PSC in HIV-infected 8-16 year olds in Botswana. ROC analysis comparing PSC scores to other indicators of child distress determined optimal cut-off scores for the PSC. We used logistic regression to assess whether children on HAART for ≥ 6 months were more likely to have virologic failure if they had high scores on the PSC.

Results: We enrolled 637 participants (median age = 12 years, range = 8-<17 years, 50.1% male) from Northern Botswana. 155 (24.3%) had a history of virologic failure. The high score cut-off on the PSC was 20 with 111 (17.4%) having high scores. Those with PSC scores >20 were significantly more likely to have had virologic failure (OR 1.67, 95% CI 1.07-2.62). Adjusting for sex, age, grade in school, baseline and current CD4 counts, and orphan status did not indicate confounding.

Conclusions: Psychosocial dysfunction as measured by the PSC is related to treatment failure among HIV-infected youth in Botswana. Psychosocial dysfunction may be a cause of reduced adherence, leading to treatment failure. Accurately measuring adherence in children and adolescents is often challenging. The PSC may be a useful tool to help identify youth at risk of adherence problems and treatment failure and needs to be assessed in longitudinal studies.



70095 Barriers and Facilitators to Pill-Use among MSM at Risk for HIV: Lessons for Pre-Exposure Prophylaxis (PrEP) Programs in the United States

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Background: The iPrEx trial recently demonstrated efficacy of PrEP for HIV prevention among men who have sex with men (MSM); non-adherence was a significant challenge in this study. As PrEP implementation programs are being planned, understanding facilitators/barriers of pill-use among at-risk MSM will be critical in developing effective strategies to support PrEP in community settings.

Methods: In November-December 2010, we administered an online survey to MSM in the US recruited from Facebook and Black Gay Chat. Topics included experience with pill-taking, self-reported adherence (5-point rating scale), and facilitators/barriers to pill-use. We used logistic regression to describe factors associated with medication use and nonadherence.

Results: 1,482 HIV-uninfected MSM completed the survey. Median age was 28; 70% were white, 9% African-American, 13% Hispanic; 35% completed college; 34% had anal sex in the past week, and 28% had unprotected anal intercourse at last sex. Over half (55%) reported taking a daily medication, including vitamins/supplements (46%), and medications for hypertension/hyperlipidemia/diabetes (33%) and mood disorders (33%). Daily medication use increased with age (p for trend <0.0001) and higher education (AOR 2.0; 95%CI 1.42-2.84) and was lower in African American (AOR 0.47; 95%CI 0.30-0.73) and uninsured (AOR 0.57; 95%CI 0.44-0.74) men. While most rated their medication-taking as excellent/very good (73%), 27% reported a lower rating, and nearly two-thirds (64%) missed ≥ 1 dose in the past month. Lower adherence was associated with younger age (p for trend <0.0001) and being uninsured (AOR 1.75; 95%CI 1.18-2.59). Common barriers included forgetting (63%), change in daily routine (34%), and being busy (33%); facilitators included establishing a routine (25%), keeping medications visible (19%), and using a pill-box (6%) or cell-phone/digital alarm (4%).

Conclusions: Younger and uninsured MSM had less experience and more difficulties with medication-taking. Adherence supports for men taking PrEP should address challenges cited by younger MSM, and address establishing routines.

70096 Medication Adherence Outcomes are Mediated by Treatment-Related Changes in Depression among People with HIV in Treatment for Opiate Dependence

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Background: Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in patients with HIV improved both adherence and depression outcomes relative to enhanced treatment as usual (ETAU). This treatment model presupposes that successful treatment of interfering mental health issues (i.e., depression) enables patients with HIV to reap additional benefits in the practice of health behaviors (i.e., medication adherence). The purpose of this analysis was to evaluate this treatment model and determine whether or not treatment related changes in depression mediated treatment-related (randomized) changes in medication adherence.

Method: HIV-infected adults in treatment for opioid dependence ($n = 89$) were randomly assigned to CBT-AD or ETAU. Treatment outcomes for depression and adherence were assessed 3-months. HLM was used to model slope of medication adherence (9 treatment sessions). The requirements for mediation were evaluated within successive HLM models. Adherence was assessed using Medication Event Monitoring. Treatment-related changes in depression were assessed using the MARDS administered by assessors blind to treatment condition.

Results: Previous reports established the first condition for mediation that treatment was associated with significant increases in adherence ($\hat{\alpha}(\text{slope}) = 0.717$, $t(87) = 2.01$, $p < .05$) and with decreases in depression ($F(1, 79) = 6.52$, $p < .01$). Change in depression also significantly predicted adherence ($\hat{\alpha}(\text{slope}) = 0.038$, $t(87) = 2.51$, $p = .01$), establishing the second condition of mediation. In the final HLM model the previously significant relationship between random assignment and adherence was no longer significant ($\hat{\alpha}(\text{slope}) = 0.48$, $t(86) = 1.35$, $p = .18$) and the relationship between depression and adherence maintained its significance ($\hat{\alpha}(\text{slope}) = 0.032$, $t(86) = 1.98$, $p = .05$), thus establishing the final condition for mediation.

Conclusions: As mediation is established here in the context of a randomized design these results provide good evidence in support of the treatment model and suggest that integrating treatment for medication adherence in to mental health treatment may increase the efficacy of adherence interventions.



70101 Relation of Chronic Disease Treatment Adherence to Antiretroviral (ART) Adherence

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Background: The association of other (non-HIV) chronic disease treatment adherence with antiretroviral adherence is understudied, and will be an issue of increasing importance as more people live with HIV into old age.

Methods: 452 HIV-positive adults aged 50 and older completed telephone surveys prior to enrolling in an adherence trial. The sample (70% men; 57% AA; 36%W; 7% other; 6% H/L) was recruited from community-based organizations in 10 US cities. Correlations between non-HIV chronic disease adherence (Morisky Adherence Questionnaire; MAQ) and ART adherence were computed. Stepwise regression analyses were performed to predict missed ART doses and late ART doses from MAQ intentional and unintentional nonadherence subscales for chronic disease treatments.

Results: Overall chronic disease nonadherence was more strongly associated with 30-day missed ART doses ($r = .46$) than with 30-day late ART doses ($r = .28$). Intentional chronic disease nonadherence accounted for greater variability in missed ART doses than did unintentional chronic disease nonadherence. For late ART doses, intentional and unintentional MAQ subscales accounted for similar variability.

Conclusions: Among older persons who are likely to have multiple chronic conditions, brief measures of non-HIV chronic disease treatment adherence may be useful for predicting ART adherence. In particular, the 2-item intentional nonadherence Morisky subscale was strongly associated with missed ART doses. Older persons with HIV may benefit from interventions that address reasons for both intentional chronic disease nonadherence and antiretroviral treatment nonadherence.

70115 A Culturally Adapted Intervention to Treat Depression and ART Nonadherence on the US-Mexico Border: Feasibility and Initial Results from a Pilot RCT

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Background: The sister cities of El Paso, Texas, and Ciudad Juarez, Chihuahua, situated on the US-Mexico border face a potential explosion in the HIV epidemic. Although antiretroviral therapy (ART) is increasingly available and accessible, preliminary studies indicate that poor adherence and depressive symptomatology detract from its potential success.

Methods: We culturally adapted Safren's empirically supported cognitive-behavioral therapy program for adherence and symptoms of depression (CBT-AD) and then evaluated its feasibility and initial efficacy. Participants were clients of Mexican descent at a community-based HIV primary care clinic in El Paso, Texas, who reported depressive symptomatology and less than optimal adherence. Intervention participants received at least 12 sessions of CBT-AD in English or Spanish over 6 months; control participants received the clinic's usual care. Assessments were conducted at baseline, post-intervention, and 9-month follow-up and included self-reported adherence according to the visual analog scale (VAS), the Beck Depression Inventory (BDI), and the clinician-administered Montgomery-Asberg Depression Rating Scale (MADRS).

Results: [Results reported here are based on data from 16 participants; findings from the full cohort of 40 at post-intervention will be available for presentation at the conference.] The intervention proved to be highly feasible, with much interest and low attrition though variable attendance. Challenges included literacy and language issues, with cognitive restructuring and thought records homework requiring adaptation. Repeated measures ANOVAs indicated improvement from baseline to post-intervention was greater in the intervention than the control arm for all three outcomes: BDI (intervention M/SD = 27.4/9.6 to 14.3/9.5 vs. control 16.0/4.7 to 13.0/6.7), $F(1,13) = 6.47$, $p = .025$; MADRS (intervention 28.8/9.4 to 18.2/12.3 vs. control 21.0/5.2 to 23.6/10.6), $F(1,13) = 4.03$, $p = .066$; VAS (intervention 81.4/19.4 to 89.3/11.0 vs. control 95.4/7.1 to 81.6/20.4), $F(1,12) = 3.60$, $p = .080$.

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



70129 Association between Disclosure of Children's HIV Infection Status and Adherence

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Background: Disclosure of HIV status by caregivers to children has been related to good adherence primarily in the US and European experience with little data emerging from Africa and Nigeria in particular. Guilt about transmission and associated sexual taboos in Nigeria are factors that make parents reluctant to disclose. This study sought to explore impact of disclosure of HIV status to children and medication adherence in the Nigerian setting.

Methods: Pediatric patients from 19 AIDSRelief ART sites in Nigeria and their caregivers were interviewed using a structured adherence survey. Disclosure status was determined by the question "Has the child been informed of his/her status?" with three possible response categories "Yes," "No," and "I Don't Know," while missed doses was assessed using one week and one month missed ARV doses recall. Data was analyzed with SPSS 17.0. One way ANOVA was used to determine difference in number of doses missed over the one week and one month period by disclosure status.

Results: Respondents were 232 129 (54.4%) males and 103 (44.6%) females. Age ranged from 1-15 years. 129 (56.6%) responded Yes, 100 (43.1%) No, and 3 (1.3%) I Don't Know. Mean missed doses for one week was 0.11, 0.42, 0.00 for Yes, No, and I Don't Know, respectively. Mean missed doses for one month was 0.28, 0.68, 0.33 for Yes, No, and I Don't Know. There was a statistically significant effect of disclosure status on missed ARV doses over a one week and one month recall period. (F (2;229) = 4.929, P <0.01) (F (2;229) = 3.038, P <0.05).

Conclusions: Pediatric patients who knew their HIV status tended to miss less ARV doses compared to those who did not. This suggests disclosure of HIV status to pediatrics patients in the Nigerian setting is desirable to improve adherence.

70353 Epidemiology and Subsequent Engagement in Care for a Cohort of Known HIV-Infected Individuals who Undergo Repeat HIV Testing

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Background: Engagement in HIV care is critical for successful HIV treatment outcomes. Data on engagement in HIV care has mostly focused on newly diagnosed individuals. We were interested in understanding the characteristics of repeat testers and to evaluate subsequent engagement in HIV care.

Methods: Retrospective review of all positive HIV antibody tests at Denver Health from 2005-2007. Data review included medical records from Denver Health, the University of Colorado Hospital, and the Children's Hospital Denver. In addition, we reviewed mandated Colorado state laboratory reporting databases for HIV testing results, CD4 cell counts and HIV-RNA levels. Successful linkage to care required having an outpatient clinic visit or HIV labs within 180 days of diagnosis. Full retention-in-care required no gaps in visits/labs lasting >180 days.

Results: Of 471 positive HIV tests, 119 (25%) were from individuals previously diagnosed with HIV. Forty-three (36%) did not disclose their prior positive HIV test. Most others were retested for clinical verification of infection (34%), to access HIV care or services (13%), or to re-check their HIV status (13%). Median age was 37 years (interquartile range [IQR] 30-44), 21% were female, 41% White, 29% Black, 29% Hispanic, 49% men who have sex with other men, and 30% heterosexual. Median baseline CD4 count and viral load were 295 cells/ μ l (IQR 136-469) and 4.6 log₁₀ copies/ml (IQR 4.0-5.1), respectively. Compared to the 352 newly diagnosed individuals, the re-testers were more often female (21% vs. 8%, p <0.001), Black (29% vs. 14%, p = 0.001), and had heterosexual risk for HIV transmission (30% vs. 12%, p <0.001). Median baseline CD4 count was lower in repeat testers (295 vs. 409 cells/ μ l, p = 0.003). Time to linkage for repeat testers compared to newly diagnosed individuals was a median of 21 days (IQR 11-59) vs. 35 days (IQR 19-77, p = 0.33). Median follow-up was the same (2.6 years) in the two groups. Retention in care during the entire follow-up period was similar among repeat testers (29%) and the newly diagnosed individuals (29%, p = 0.98).

Conclusions: It is common for individuals to re-test for HIV after a prior HIV-positive test result. Repeat testers had different demographic characteristics than newly diagnosed individuals; more were female, black, and had heterosexual HIV transmission risk. After an HIV-positive test result, engagement in HIV care was similar in repeat testers and newly diagnosed individuals.



70356 Using Prescription Refills May Overstate Actual Adherence Because Patients Fail to Pick Up the Prescription That Have Been Filled

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Background: Prescription refills often are used to measure adherence to antiretroviral therapy (ART). However, adherence based on refills has not strongly correlated with other measures of adherence. A reason may be that, even though prescriptions are filled, they are not picked up by patients. This study examined the effect on refill-based adherence of patients' not picking up their prescriptions.

Methods: 63 patients who failed to pick up >1 ART prescription during September-December 2008 were identified from pharmacy data. Adherence was first calculated as the percent of required prescription that were requested by patients and filled by pharmacists. A second measure was based on the percent of required prescriptions that were actually picked up by patients.

Results: The 63 patients had an average age of 44 years and were 71% male. The group was 14% white/Asian, 68% African American, and 18% Hispanic. 25% of the patients were current substance abusers and 18% were former users. 33% had a history of psychiatric illness. The average CD4 count recorded within the six months prior to the study was 421 (N = 56). 47% of 55 patients had undetectable viral loads for their last viral load in the six months before the study. Adherence measured by percent of required prescription that were filled averaged 58.1%. Percent of required prescriptions actually picked up averaged 35.7%. Fourteen of the patients who had measureable adherence using a refill-based measure were found to be totally non-adherent when adherence was measured by medications that were actually picked up.

Conclusions: Researchers who use prescription renewals as a measure of adherence must verify that the prescriptions were actually picked up. Otherwise, they may significantly inflate the level of adherence in their studies.

70365 Pooled Week 48 Safety, Efficacy, and Adherence Results from ECHO and THRIVE Phase 3 Trials Comparing TMC278 vs EFV in Treatment-Naïve HIV-1-Infected Patients Receiving FTC/TDF

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Background: TMC278 (rilpivirine, RPV) can be combined with FTC/TDF into a single tablet regimen (STR). The pooled 48-week primary analysis results of the subset of subjects receiving FTC/TDF as a background regimen in two double-blind, randomized, double-dummy RPV versus EFV Phase III studies, ECHO and THRIVE will be presented.

Methods: Treatment-naïve adult patients (N = 1096) received RPV 25mg qd or EFV 600mg qd in combination with FTC/TDF in ECHO (n = 686) and THRIVE (n = 410, subset of study). The primary objective was to demonstrate non-inferiority (12% margin) of RPV to EFV in confirmed virologic response (ITT-TLOVR) at week 48. Adherence was measured using a visual analog scale M-MASRI (modified medication adherence self-reported inventory).

Results: RPV in combination with FTC/TDF was non-inferior to EFV in combination with FTC/TDF overall (ITT-TLOVR VL <50 copies/mL 83.5% vs. 82.4%) and across all categories of baseline VL. Adherence was the strongest predictor for response for RPV+FTC/TDF and EFV+FTC/TDF; for patients with >95% adherence 86.5% vs. 88.2% achieved a VL <50 copies/ml, while for patients with < 95% adherence 65.6% vs. 72.9% achieved a VL <50 copies/ml, respectively. Among subjects receiving FTC/TDF, incidences of the following tolerability measures were significantly lower in the RPV group than in the EFV group: adverse events leading to discontinuation, grade 2-4 AEs possibly related to treatment, rash, dizziness abnormal dreams/nightmare, and grade 3/4 laboratory abnormalities for lipids. There were fewer virologic failures in the EFV group.

Conclusions: At Week 48, RPV+FTC/TDF demonstrated a high virologic response rate and was non-inferior to EFV+FTC/TDF across a broad range of treatment-naïve patients, with adherence playing an important role as one of the primary reasons for response to both arms. Overall, the data support the clinical benefit of FTC/RPV/TDF currently in development as a once-daily, STR for the treatment of HIV-1 infection.



70366 Antiretroviral Adherence Interventions from Randomized Trials using Electronic Monitors of Adherence

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Background: Interventions to improve ARV adherence have been shown to be effective however little is known about the components of such interventions.

Methods: This study seeks to describe characteristics of ARV adherence interventions and assess the impact of intervention completion. ARV adherence descriptions submitted by MACH 14 investigators (a multi-study HIV/AIDS collaborative) who conducted RCTs to assess intervention effectiveness were included; descriptive analyses were used to identify features of the interventions. Adherence levels of individual in each study were measured using MEMS caps and compared for completers and noncompleters.

Results: Eleven of 14 MACH studies involved interventions. Average study intervention session length ranged from 8 to 45 minutes with a mean of 31. Of the 11 interventions, only 3 included boosters. Four provided general HIV education and 7 adherence specific education. Nine programs included skills building, 7 of which addressed self-efficacy. While 8 enhanced social support, only 2 addressed stress reduction and 3 motivation, 3 studies using contingency management, 3 reminders, and directly observed therapy in one. The number of components each intervention contained ranged from 0-9 with three studies having 5, three having 6. The mean adherence level was 0.67 for those that completed the adherence intervention compared with 0.59 for those who did not ($p < 0.001$).

Conclusions: Although ARV adherence interventions vary considerably with regard to their content, session duration, complexity and number and type of components involved, individuals who complete adherence interventions have better adherence than those who do not.

70488 HIV Treatment Adherence Levels, Patient Literacy, and Health Care Provider-Patient Communication: A Global Survey of 2,035 Adults

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Background: Adherence to HIV medications is critical to the effective management of the disease and the avoidance of drug-resistance and disease progression. However, on a global scale, little is known about patients' health literacy in relation to the consequences of treatment non-adherence and drug resistance.

Design & Methods: A cross-sectional study (the AIDS Treatment for Life International Survey [ATLIS]) was undertaken from January-March 2010 in 12 countries in North America, Latin America, Europe, Africa and Asia/Pacific, to investigate patients' health literacy with issues such as antiretroviral therapy (ART) adherence and drug resistance, and to assess patient-health care provider communication about these topics. A 20-minute survey was conducted either in-person, by phone, or via Internet. Each participant was required to give his/her informed consent.

Results: 2,035 HIV-infected adults were recruited: 63% male and 40%; 53% and 6% of participants were aged 18-39 years, 40-60 years, and >60 years, respectively. Overall, 57% of responders reported 100% ART adherence; highest in Latin America (89%) and Africa (73%) and lowest in North America (45%) ($p < 0.01$). Forgetfulness was the most common reason reported for sub-optimal adherence (74%). Running out of medication was more commonly mentioned in Côte d'Ivoire (25%) compared to France (16%), United States (13%), Germany (7%), Italy (10%), or Korea (2%) ($p < 0.01$). While most participants (87%) agreed their health care providers (HCPs) stress the importance of ART adherence, only 71% cited practical recommendations from their HCPs to maintain optimal adherence, with the lowest in the United States (62%) and the highest in Latin America and Africa (both 80%) ($p < 0.01$). Individuals who reported having discussed adherence with their HCP were more likely to understand the meaning of drug resistance and its health implications and to report 100% ART adherence (83% vs. 72%, $p < 0.01$). Overall, independent predictors of sub-optimal ART adherence in multivariate logistic regression model were: not belonging to an HIV support group (OR: 1.24; $p < 0.001$); experience of ART side effects (OR: 1.23; $p < 0.001$); and living in North America (OR: 1.68, $p < 0.001$), Europe (OR: 1.65, $p < 0.001$), or Asia/Pacific (OR: 2.20; $p < 0.001$).

Conclusions: This study underscores the global heterogeneity in ART adherence levels and barriers. There is an urgent need to disseminate best practice ART adherence guidelines and promote patient-HCP communication around the detrimental consequences of ART non-adherence.



70489 Pharmacy Refill Data Combined with Self-Report Adherence Questions Improves Prediction of Boosted Protease Inhibitor Regimen Failure

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Background: Studies evaluating the accuracy of simple, low-cost ART adherence monitoring tools, used singly or in combination, to predict treatment success or failure are sketchy. This knowledge is critical, especially in patients on second line antiretroviral therapy (ART), since it is last regimen option, available in the public sector of most resource-limited settings.

Methods: In a pilot cross-sectional study, we investigated thirteen self-reported questions regarding frequency and pattern of adherence (missed doses and treatment interruptions); 12-month pharmacy refill; and 30-day pill-counts as predictors of virologic failure in two South African public service settings. Logistic regression was used to test which ART adherence monitoring tool or combination, dichotomized at prespecified cut offs, optimized the classification of patients as having detectable viral load (VL >50 copies/mL). Receiver Operative Characteristic (ROC) analysis was used to identify the most discriminant tool(s).

Results: 93 adults answered adherence questions of which 49 (53%) had detectable viral loads. Median (IQR) adherence by pill-count and pharmacy refill were 100% (98.7-100) and 99.7% (98-100), respectively. The optimal combination of adherence measures included 11 of the self-report questions plus pharmacy refill data yield the following diagnostic test characteristics (%; 95% CIs): sensitivity (93; 83-100); specificity (90; 77-100); positive predictive value (93; 83-100); negative predictive value (90; 77-100). In addition, the positive and negative likelihood ratios for self-report questions plus pharmacy refill data were: 9.27 and 0.08, respectively. ROC's Area Under the Curves (AUCs; 95% CIs) for this optimal combination was: (0.97; 0.92-100, $p < 0.001$) as compare to pill count alone (0.64; 0.50-0.79, $p < 0.001$) or pharmacy refill alone (0.75; 0.57-0.85, $p < 0.001$).

Conclusions: Pill count performed poorly while the combination of pharmacy refill and 11 self-report adherence questions had excellent diagnostic accuracy in this setting. Further validation of this simple combination of measures is warranted in large prospective studies.

70490 Alcohol Abuse, Depression, and Adherence to Antiretroviral Therapy in HIV-Infected Adults in Africa: A Systematic Review and Meta-Analysis

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Background: Prevalence estimates of alcohol abuse, depression and their association with antiretroviral therapy (ART) adherence is unclear in ever expanding ART programs in sub-Saharan Africa. We aimed to determine the point estimates and variability in prevalence rates of depression symptoms, major depression and alcohol abuse as well as their association with ART adherence in sub-Saharan Africa.

Methods: Data Sources: Studies that documented prevalence estimates of depression symptoms, major depression, and alcohol use disorders among HIV positive individuals using ART were identified through PubMed, CINAHL and PsychINFO and Pubmed Central, for the period until October 2010. Study Selection Studies that reported identified cases within the selected time frame were included, yielding a total of 28 studies for the systematic review and 24 for the meta-analysis involving 9,893 participants. Data Extraction Information on prevalence rates of depression symptoms, major depression, and alcohol use disorders among HIV positive individuals using ART was extracted independently by 2 raters. Effect sizes were reported as event rates and odds ratios. Random-effects models of event rates were used because of significant heterogeneity.

Results: Studies displayed consistent rates of depression symptoms, major depression and alcohol abuse in the past month with a pooled proportion of 33.3% (95% CI, 26-40%, Tau² = 0.39); 20.4% (95% CI, 14-28%, Tau² = 0.26) and 12% (95% CI, 8-18% Tau² = 0.37), respectively. The association between depression symptoms and adherence to ART indicated a 54% (95% CI 26-71%, Tau² = 0.23, p -value = 0.001) reduction in adherence.

Conclusions: Depression symptoms, major depression and alcohol use are a substantial burden among HIV-infected adult patients in Africa, leading to poor adherence. There is an urgent need for screening services and interventions to improve mental health and adherence in this setting.



70492 Adherence Patterns to Raltegravir (RAL)-Based Regimens and Their Influence on Virologic Outcome: A Prospective Cohort Study (RAL-TECAPS Study)

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Background: Treatment interruption of 15 days was associated with a 50% probability of virological failure (VF) among HIV-infected subjects on an NNRTI-based regimen. This study aimed to assess this relationship in the context of low genetic barrier and short half-life, such as RAL.

Methods: We are currently conducting a 6-month prospective multicenter cohort study among consecutive RAL-based treated individuals in France. First available data are reported here. Adherence patterns were measured with MEMS caps validated by PK RAL dosages. Primary endpoint was virologic control (VC) at the end of adherence measurement period. Several pre-defined MEMS adherence patterns were tested to predict outcome.

Results: Fifty RAL-treated subjects (64% male) were followed for 124 d +/- 63. RAL was not discontinued during the study. Age was 49 y +/- 11. At baseline, CD4 was 497 +/- 269 cells/mm³; eight patients were ARV naive. 6/50 (12%) subjects had VL >40 copies/mL at the end of the study. Considerable inter-individual variability was observed in the PK of RAL (Median [IQR]: 510 ng/mL [93-1,004.5]). Adherence rate was consistently high (95.8% +/-5) and not associated with VC (Odds Ratio for 10% increase: 1.0, 95% confidence interval [0.1-4.0], p = 0.98). Drug holidays (>48 hours of treatment interruption) occurred more frequently before VF (2/6 versus 6/44 before VC, p = 0.24 by Fisher exact test). Longer treatment interruption during follow-up significantly predicted VF (median [IQR]: 55.4 hours [47.7-158.6] before VF versus 30.8 h [24.4-45.9] before VC; p <0.03 by Wilcoxon test). By logistic regression analysis, we estimated that the probability of VF is 50% after RAL interruption of 5 days.

Conclusions: Adherence and persistence to RAL are particularly high. In these preliminary findings, RAL appears highly susceptible to treatment interruption. Chaotic behaviour of RAL PK may explain these results for some patients.

70494 The Impact of Routine Clinical Care Assessment of Patient-Reported Outcomes (PROs) with Same-Day Pre-Visit Provider Reports

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Background: This study examines the impact of point-of-care PRO reports to providers on provider awareness and behavior.

Methods: At the UW CNICS site, patients complete PRO assessments immediately prior to seeing their provider. In 1/2009, the clinic began delivering PRO results to providers prior to providers entering the patient's examination room. Chart reviewers, blinded to whether providers had received PRO reports, reviewed same-day provider documentation for the window defined by 8 months before and after initiation of provider feedback reports. Charts were selected for review based on inadequate adherence (missing antiretroviral doses in the last 4 days), at-risk alcohol use (AUDIT-C scores ≥ 5 for men, ≥ 4 for women), or moderate-to-severe depression (PHQ-9 scores ≥ 10).

Results: 205 patients reported inadequate adherence. Before initiation, 81% of provider documentation mentioned adherence vs. 85% after initiation of provider reports (p = 0.5). Before initiation, provider documentation disagreed with PRO data ("perfect adherence, missed no doses") in 42% vs. 24% after (p = 0.02). Before initiation, provider documentation indicated some action in response to inadequate adherence in 23% vs. 38% after (p = 0.07). There were 156 patients who reported at-risk alcohol use. Before initiation of reports, provider documentation acknowledged alcohol use in 42% vs. 64% after (p = 0.04). Before initiation, providers documented some action in response to alcohol use (e.g., health educator referral) in 13% vs. 29% after (p = 0.09). There were 317 patients who reported moderate-to-severe depression. Before initiation, provider documentation mentioned depression in 74% vs. 87% after (p = 0.02).

Conclusions: These findings suggest PRO collection with point-of-care provider reports improves provider awareness, and that the impact of reports differs by domain. Provider reports increase accuracy of adherence assessments and awareness of at-risk alcohol use and moderate-to-severe depression. However, there is still room for substantial improvement. Additional studies are needed to assess impact on patient outcomes, and to integrate interventions to further improve care.



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6th International
Conference on
**HIV TREATMENT
AND PREVENTION
ADHERENCE**

May 22-24, 2011

To Whom It May Concern:

This letter is a confirmation that _____ attended the 6th International Conference on HIV Treatment and Prevention Adherence, held May 22-24, 2011, 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,

A handwritten signature in black ink that reads "José M Zuniga". The signature is fluid and cursive.

José M Zuniga, PhD, MPH
President/CEO, IAPAC



A D H E R E N C E 2 . 0**Integrating Advances in HIV Treatment and Prevention Adherence into Clinical Practice**

3:00 pm - 4:30 pm, Sunday, May 22, 2011

Mona Lisa Ballroom • Eden Roc Renaissance Hotel

MODERATOR

Jeffrey J Weiss, PhD, MS
Assistant Professor of Medicine
Mount Sinai School of Medicine
New York, NY, United States

PRESENTERS

Where is the Science in
Implementation Science?

Bruce R Schackman, PhD
Associate Professor of Public Health
Weill Cornell Medical College
New York, NY, United States

Integrating HIV Treatment Adherence
Self-Report into Routine Practice

Heidi M Crane, MD, MPH
Assistant Professor of Medicine
University of Washington
Seattle, WA, United States

Implementing HIV Guidance
in a Managed Care Setting:
Implications for PrEP

Daniel B Klein, MD
Chief, Division of Infectious
Diseases and HIV Services
Kaiser Hospital
Hayward, CA, United States

STATEMENT OF NEED

Given fast-paced advancements in the field of HIV treatment and prevention, there exists an urgent need to translate and integrate HIV treatment and biomedical prevention adherence advances into clinical practice to achieve individual, community, and public health goals. Implementation science and a review of treatment and prevention intervention adaptations made pre- and post-implementation will be reviewed during this symposium from academic medicine and managed care perspectives.

TARGET AUDIENCE

Physicians, nurse-practitioners, physician-assistants, researchers, adherence specialists

LEARNING OBJECTIVES

After attending this activity, participants will be able to:

- Explain current state-of-the-art regarding implementation science
- Describe current directions in HIV treatment and biomedical prevention adherence
- Discuss integration of HIV treatment and biomedical prevention advances into clinical practice
- Identify opportunities/challenges posed by HIV treatment and biomedical prevention advances

DISCLOSURE POLICY

It is the policy of the National Association for Continuing Education to ensure fair balance, independence, objectivity and scientific rigor in all activities. All faculty members participating in CME activities sponsored by the National Association for Continuing Education are required to present evidence-based data, identify and reference off-label product use, and disclose all relevant financial relationships with those supporting the activity or others whose products or services are discussed. Faculty disclosure will be provided in the activity materials.

COMMERCIAL SUPPORT

We wish to acknowledge commercial support from Gilead Sciences, which provided an educational grant in support of this activity.

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 through the joint sponsorship of the National Association for Continuing Education and the International Association of Physicians in AIDS Care. The National Association for Continuing Education is accredited by the ACCME to provide continuing medical education for physicians.

CREDIT DESIGNATION

The National Association for Continuing Education designates this live event for a maximum of 1.5 *AMA PRA Category 1 Credit(s)*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

REGISTRATION

Registration is free-of-charge. Send an email to iapac@iapac.org to register.





The 6th 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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