5th International Conference on
HIV TREATMENT ADHERENCE

Miami, May 23-25, 2010

Jointly Sponsored By

IAPAC
INTERNATIONAL ASSOCIATION
OF PHYSICIANS IN AIDS CARE

NIMH
National Institute
of Mental Health

PIM Postgraduate Institute
for Medicine

WELCOME LETTER FROM THE CO-CHAIRS

Thank you for joining us in Miami for the 5th International Conference on HIV Treatment Adherence!

On behalf of the conference's co-hosts – the International Association of Physicians in AIDS Care (IAPAC) and the National Institute of Mental Health (NIMH) – we welcome you to a state-of-the-science forum at which health care and human service professionals can examine sound and practical strategies to understand and enhance adherence to HIV/AIDS treatment in a variety of settings.

There is clearly a need for this conference. We base this assertion on the rapid changes that are the hallmark of HIV treatment, the dramatic scale-up of access to HIV treatment around the world, the multifaceted clinical and behavioral issues that remain to be understood in HIV treatment adherence, and your submissions for our Call for Abstracts. This year's oral abstract and poster sessions were drawn from a record number of submissions, representing interdisciplinary research and programs from more than 40 countries.
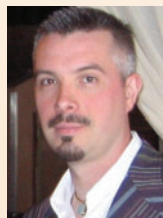
This conference is a unique forum to present the best evidence to understand and improve treatment adherence, but the main reason that we come together is to rapidly translate these scientific advances into approaches that can make a difference in real-world settings. Therefore, the science should guide providers who are treating patients on a daily basis. We strongly believe that increasing our understanding of adherence and the effectiveness of adherence interventions can have a critical and immediate impact on the health of HIV-positive patients worldwide.

We extend our gratitude to the conference's Planning Committee and the Postgraduate Institute for Medicine (PIM). We also sincerely express our appreciation to the NIMH, IAPAC, the Office of AIDS Research (OAR) and the Office of Behavioral and Social Sciences Research (OBSSR) both at the National Institutes of Health (NIH), and the National Institute of Allergy and Infectious Diseases (NIAID), as well as our commercial supporters, for their generous contributions. Finally, a special thank you to our distinguished faculty for what we are sure to be cutting-edge presentations to help advance our educational objectives.

We hope this conference helps to strengthen the dialogue and collaboration among government agencies, treatment providers, and researchers. While maintaining the integrity of the science, we also hope the conference fosters a sense of urgency to this process. We must act now, disseminate research, enhance programs, influence policy, and improve quality of life.

Christopher M. Gordon, PhD
Co-Chair, NIMH

José M. Zuniga, PhD
Co-Chair, IAPAC

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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/PROGRAM OVERVIEW
Adherence to HIV treatment is an essential determinant of treatment success or failure. Yet there is still much to learn about measurement, determinants, and interventions for HIV treatment adherence. These are complex challenges that require multidisciplinary cooperation among providers, researchers, government agencies, and patients.

The goal of this conference is to provide an international forum for the presentation and discussion of state-of-the-science HIV treatment adherence research, as well as current behavioral and clinical perspectives in practicum. Ultimately, achieving the conference goal will translate into evidence-based implementation of approaches for real world clinical and community settings.

EDUCATIONAL OBJECTIVES
After completing this activity, the participant should be better 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, pharmacists, nurses, mental health professionals, adherence specialists)
- Describe the relationships between adherence, pharmacokinetics, viral suppression, and resistance
- Discuss the implications of adherence for HIV prevention and public health
- Identify adherence assessment tolls and interventions that can be integrated into patient care, including in resource-limited settings

GENERAL INFORMATION

MEETING VENUE
The 5th International Conference on HIV Treatment 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 and on the Lower Level (see the Hotel Floor Plan and the Conference Program on page 8 and pages 5-7, respectively).

MEALS
Breakfast will be served from 7:00 A.M. - 8:30 A.M., on Monday, May 24, 2010, and Tuesday, May 25, 2010, in the Lower Level Foyer **and** in the Foyer for the Ocean Tower 1. Neither lunch nor dinner will be provided by the conference. Please visit the Registration Desk for a list of local restaurants.

INTERNET ACCESS
The 5th International Conference on HIV Treatment 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 Abstract Book will be distributed at registration, and an electronic version will be available at www.iapac.org post-conference.

QUESTIONS
If you have any questions during the conference, please locate an IAPAC staff member by leaving a message at the hotel Registration Desk. If you have any questions post-conference, please contact Steve Ketchum at sketchum@iapac.org or (312) 795-4934.

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). PIM is accredited by the ACCME to provide continuing medical education (CME) for physicians.

Credit Designation
PIM designates this educational activity for a maximum of 16.0 *AMA PRA Category 1 Credit(s)*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Disclosure and Conflict of Interest
PIM 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 Abstract 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 Hub in the Mona Lisa Foyer.

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, Gilead Sciences, Abbott Laboratories, nor Boehringer Ingelheim 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, Gilead Sciences, Abbott Laboratories, and Boehringer Ingelheim. 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 7309. Upon successfully completing the evaluation, a CME certificate will be made available to each participant.

PIM Postgraduate Institute for Medicine

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 15 CE Credits. A certificate of attendance will be available at the end of the conference.

ANAC
ASSOCIATION OF
NURSES IN AIDS CARE

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SUNDAY, MAY 23, 2010

TIME	ACTIVITY	PROMENADE A	PROMENADE B	MONA LISA
Noon–2:00 P.M.	Adherence Workshops	**Workshop 1** Building Blocks for Interventions: Explanatory and Delivery Models in Antiretroviral Adherence and HIV Care Utilization	**Workshop 2** Improving Patient Engagement in Care: The Care Coordination Model in New York City	**Workshop 3** Promises and Pitfalls of Directly Observed/Administered Antiretroviral Therapy in Treatment-Naïve and -Experienced HIV-Infected Adults in Developed and Developing Settings
2:00 P.M.–2:30 P.M.	Break – Ocean Tower 1 Foyer			
2:30 P.M.–4:30 P.M.	Adherence Workshops	**Workshop 4** Improving Your Adherence Counseling Skills: Theory and Practice	**Workshop 5** An Introduction to Delivering Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) for Individuals Living with HIV Infection	
4:30 P.M.–5:00 P.M.	Brief Transition			

TIME	ACTIVITY
	OPENING CEREMONY • POMPEII BALLROOM
5:00 P.M.–5:15 P.M.	Welcome from Conference Co-Chairs 　　　Christopher M. Gordon, PhD, 　　　José M. Zuniga, PhD
5:15 P.M.–5:20 P.M.	Introduction to the "Gary S. Reiter, MD, and Andrew Kaplan, MD, Memorial Lecture" 　　　David Bangsberg, MD, MPH
5:20 P.M.–5:50 P.M.	Memorial Lecture: Treatment Adherence as Prevention 　　　Julio S.G. Montaner, MD
5:50 P.M.–6:00 P.M.	Introduction of Local, Domestic, and International Scholarship Recipients 　　　Michael Stirratt, PhD
	OPENING RECEPTION • OCEAN GARDEN
6:15 P.M.–8:00 P.M.	Open Bar and Passed Hors d'Ouevres

MONDAY, MAY 24, 2010

TIME	ACTIVITY	FISHER A (WEST) LOWER LEVEL	FISHER B (EAST) LOWER LEVEL	LA GORCE LOWER LEVEL	SAN MARCO LOWER LEVEL
7:30 A.M.–8:30 A.M.	Breakfast Roundtable Discussions*	Case Study: Facing the Challenges of HIV/AIDS and Substance Abuse Moderators: Deborah Jones, PhD, Evelyn Tomaszewski, MSW	Sub-Saharan Africa: Regional Networking and Discussion Group Moderator: Glenn Wagner, PhD	Nursing: Disciplinary Discussion Group Moderator: Ann Williams, EdD, RNC	What do US Primary Care Guidelines Say About Adherence? What Should They Recommend? Moderators: Christopher M. Gordon, PhD, José M. Zuniga, PhD
7:30 A.M.–8:30 A.M.	*Continental Breakfast Served in Lower Level Foyer and Ocean Tower 1 Foyer (Not Moderated Discussions)				

KEYNOTE ADDRESS • POMPEII BALLROOM

8:45 A.M.–9:15 A.M.	Adherence in "Testing and Linkage to Care Plus" (TLC+): The Sticky Wicket Michael S. Saag, MD

PLENARY 1 • POMPEII BALLROOM

9:15 A.M.–9:45 A.M.	Antiretroviral Regimens as Pre-Exposure Prophylaxis (PrEP): Adherence Considerations Robert Grant, MD
9:45 A.M.–10:15 A.M.	Break – Ocean Tower 1 Foyer

TIME	ACTIVITY	POMPEII BALLROOM	PROMENADE A	PROMENADE B	MONA LISA
10:15 A.M.–11:00 A.M.	Invited Lectures		Emerging Methods and Technologies for Adherence Measurement Jessica Haberer, MD	The Economic Price of Antiretroviral Non-Adherence Jean Nachega, MD, MPH	Quality of Standard of Care Affects Adherence Intervention Trial Outcomes Marijn de Bruin, MD
11:00 A.M.–Noon	**POSTER SESSION • OCEAN TOWER BALLROOM**				
Noon–1:15 P.M.	Lunch				
1:15 P.M.–2:45 P.M.	Thematic Oral Abstract Sessions	Integrating Adherence Monitoring into Clinical Care Moderator: Linda Koenig, PhD	Adherence in the Complex Patient Moderator: James Scott, PharmD	Adherence in Sub-Saharan Africa Moderator: Kata Chillag, PhD	Novel Research on Adherence Determinants Moderator: Cynthia Grossman, PhD
2:45 P.M.–3:15 P.M.	Break – Ocean Tower Ballroom				
3:15 P.M.–4:45 P.M.	Thematic Oral Abstrac Sessions	Antiretroviral Regimens, Adherence, and Virologic Outcomes Moderator: Tia Frazier, RN	Patient-Provider Adherence Communication Moderator: Michael Stirratt, PhD	Engagement in Care in the United States Moderator: Deborah Parham-Hopson, PhD	Pediatric, Child, and Adolescent Adherence Moderator: Susannah Allison, PhD
4:45 P.M.–5:00 P.M.	Brief Transition				

PLENARY 2 • POMPEII BALLROOM

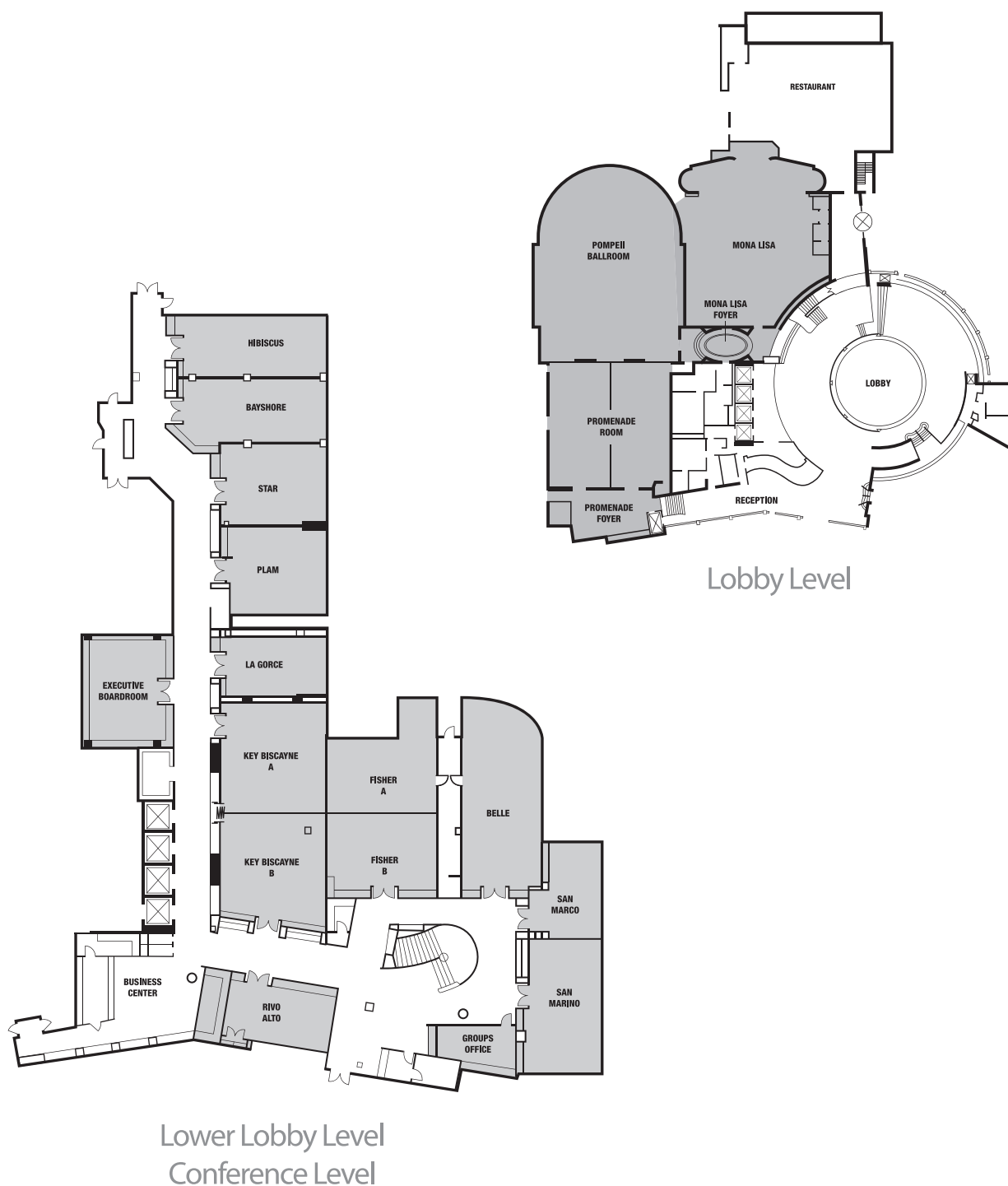|	
5:00 P.M.–5:30 P.M.	Improving Physician-Patient Adherence Communication Ira Wilson, MD
5:30 P.M.-5:45 P.M.	Presentation of 2010 Jonathan Mann Health Human Rights Award to Jean William Pape, MD, Director, Center GHESKIO, Port-au-Prince, Haiti Jozé M. Zuniga, PhD

TUESDAY, MAY 25, 2010

TIME	ACTIVITY	FISHER A (WEST) LOWER LEVEL	FISHER B (EAST) LOWER LEVEL	LA GORCE LOWER LEVEL	SAN MARCO LOWER LEVEL
7:30 A.M.–8:30 A.M.	Breakfast Roundtable Discussions*	Case Study in a Resource-Limited Setting: Presentation and Discussion Moderator: Jean Nachega, MD, MPH	Southeastern US: Regional Networking and Discussion Group Moderators: Michael Mugavero, MD, Deborah Konkle-Parker, PhD	Pharmacists: Disciplinary Discussion Group Moderator: James Scott, PharmD	How Can We Advance the Dissemination and Implementation of Adherence Interventions? Moderator: K. Rivet Amico, PhD
7:30 A.M.–8:30 A.M.	*Continental Breakfast Served in Lower Level Foyer and Ocean Tower 1 Foyer (Not Moderated Discussions)				

PLENARY 3 • POMPEII BALLROOM	
8:45 A.M.–9:15 A.M.	CDC Review and Dissemination of Evidence-Based HIV Treatment Adherence Interventions Mahnaz Charania, PhD
PLENARY 4 • POMPEII BALLROOM	
9:15 A.M.–9:45 A.M.	Who Starts Antiretroviral Treatment in Durban, South Africa? Not Everyone Who Should Ingrid Bassett, MD
9:45 A.M.–10:15 A.M.	Break – Ocean Tower 1 Foyer

TIME	ACTIVITY	POMPEII BALLROOM	PROMENADE A	PROMENADE B	MONA LISA
10:15 A.M.–11:30 A.M.	Invited Panels	Patient Panel: Meeting the Challenge of HIV Treatment Adherence Moderator: Robert Remien, PhD	The Role of Antiretroviral Adherence Data in Monitoring of Patients and Clinics in Resource-Limited Settings David Bangsberg, MD, MPH, John Chalker, PhD, Robert Gross, MD, David Meya, MD	Engaging Patients in HIV Care: Challenges and Successes in Miami-Dade County Lisa Metsch, PhD, Michael Kolber, MD, Rick Siclari, MBA	Drug Development Panel: Powering Antiretroviral Regimens to Ameliorate Adherence Concerns Patrick Clay, PharmD, Kristi Grimm, PharmD, Michael J. Harbour, MD
11:30 A.M.–12:45 P.M.	Lunch				

LUNCHEON SESSION • POMPEII BALLROOM	
Noon–12:30 P.M.	ART in Africa: Is Adherence Really Better? An American Physician's Perspective After Six years Charles Steinberg, MD *(Box Lunches Available for Purchase on the Palm Terrace)*

TIME	ACTIVITY				
12:45 P.M.–2:15 P.M.	Thematic Oral Abstract Sessions	Wireless Adherence Monitoring and Support Moderator: Susannah Allison, PhD	Adherence and Substance Use Moderator: Shoshana Kahana, PhD	Operations Research in Sub-Saharan Africa Moderator: John Chalker, PhD	Measuring Adherence and Engagement in Care Moderator: Khiya Marshall, PhD
2:15 P.M.–2:45 P.M.	Break – Ocean Tower 1 Foyer				
2:45 P.M.–4:15 P.M.	Thematic Oral Abstract Sessions	Adherence and HIV Prevention Moderator: Vanessa Elharrar, MD	Directly Observed Therapy/Transitions from Prison Moderator: Cynthia Grossman, PhD	Adherence Performance Indicators and Quality of Adherence Care Moderator: Michael Stirratt, PhD	Methodological Concerns in Adherence Research Moderator: Mahnaz Charania, PhD
4:15 P.M.–4:30 P.M.	Brief Transition				

CLOSING PLENARY PANEL DISCUSSION • POMPEII BALLROOM	
4:30 P.M.–5:00 P.M.	Key Questions and Directions in Adherence Research in 2010 and Beyond David Bangsberg, MD, MPH Linda Koenig, PhD Jean Nachega, MD, MPH K. Rivet Amico, PhD

EDEN ROC RENAISSANCE HOTEL

RESTAURANT

POMPEII
BALLROOM

MONA LISA

MONA LISA
FOYER

PROMENADE
ROOM

LOBBY

PROMENADE
FOYER

RECEPTION

Lobby Level

HIBISCUS

BAYSHORE

STAR

PLAM

LA GORCE

EXECUTIVE
BOARDROOM

KEY BISCAYNE
A

FISHER
A

BELLE

KEY BISCAYNE
B

FISHER
B

SAN
MARCO

BUSINESS
CENTER

RIVO
ALTO

GROUPS
OFFICE

SAN
MARINO

Lower Lobby Level
Conference Level

SUNDAY, MAY 23, 2010

Noon-2:00 P.M.

Promenade A
Building Blocks for Interventions: Explanatory and Delivery Models in Antiretroviral Adherence and HIV Care Utilization

Primary Presenter: K Rivet Amico, PhD

Other Presenters: Thomas Giordano, MD; Michael Mugavero, MD; Steve Safren, PhD; Jane Simoni, PhD; Laramie Smith, MA; Ira Wilson, MD

Purpose: Presentation and review of leading explanatory models and theories of antiretroviral adherence and HIV care utilization, and the delivery models and systems that have been, or can be, used as methods to influence change in these behaviors, or the theory-based core determinants of the behavior.

Promenade B
Improving Patient Engagement in Care: The Care Coordination Model in New York City

Primary Presenter: Luz Rivera, MPA

Purpose: To provide assistance with navigating the healthcare and social services systems; coordinate logistics such as transportation and childcare to ensure that they have ready access to their care providers. Provide home visits on a weekly, monthly or daily basis.

Mona Lisa
Promises and Pitfalls of Directly Observed /Administered Antiretroviral Therapy in Treatment-Naive and -Experienced HIV-Infected Adults in Developed and Developing Countries

Primary Presenter: Jean B. Nachega, MD, MPH

Other Presenters: David Bangsberg, MD, MPH; Robert Gross, MD; Heidi Louise Behforouz, MD; Frederick Altice, MD; Ed Mills, PhD

Purpose: Critical review and discussion of recent evidences for the effectiveness of directly observed/administered antiretroviral therapy in developed and developing countries as well as in various patient populations.

2:30 P.M.-4:30 P.M.

Promenade A
Improving Your Adherence Counseling Skills: Theory and Practice

Primary Presenter: Ira Wilson, MD

Other Presenters: Mary Catherine Beach, MD

Purpose: The purpose of this workshop is to introduce participants to some evidence based, practical adherence counseling skills and to give them a chance to practice those skills.

Promenade B
An Introduction to Delivering Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) for Individuals Living with HIV Infection

Primary Presenter: Steven Safren, PhD

Other Presenters: C. Andres Bedoya, PhD; Conall O'Cleirigh, PhD; Meghan Pinkston, PhD

Purpose: The purpose of the workshop is to train individuals in how to deliver an evidenced-based approach (CBT-AD) to treating depression and increasing adherence in individuals living with HIV infection.

CONCURRENT WORKSHOP SCHEDULE

MONDAY, MAY 24, 2010

Oral Session 1
Integrating Adherence Monitoring into Clinical Care
1:15 P.M. - 2:45 P.M. / Pompeii Ballroom

62019 An Electronic-Monitoring Based Intervention Improves HIV-Treatment Adherence
de Bruin M presenting

62145 Evaluating Integration of an HIV Medication Adherence Computer-Assisted Self-Administered Interview (CASI) with Routine Patient Care
Crane H presenting

61589 Novel Approaches to HIV Medication Adherence: Development and Testing of a Touch-screen Patient Adherence Tool with Targeted Adherence Counseling
McInnes K presenting

61205 Patient-Reported Outcomes Predict Antiretroviral Adherence: A Transformative Health Informatics Technology for Research and Patient Care
Kozak M presenting

Oral Session 2
Adherence in the Complex Patient
1:15 P.M.m - 2:45 P.M. / Promenade A

61391 Double-Burden: The Challenges of Coping with TB and HIV Therapy on HIV/TB Co-Infected Persons
Oladapo O presenting

61419 Hepatitis C Treatment Adherence Over Time and Virologic Response Among HIV/Hepatitis C-Coinfected Patients
Lo Re V presenting

61841 Differences in Treatment Adherence, Illness Perceptions, and Beliefs About Medications in Co-Morbid HIV and Type 2 Diabetes Mellitus
Batchelder A presenting

62133 Bipolar Medication Use and Adherence to Antiretroviral Therapy among Patients with HIV/AIDS and Bipolar Disorder
Akincigil A presenting

Oral Session 3
Adherence in Sub-Saharan Africa
1:15 P.M. - 2:45 P.M. / Promenade B

63513 What Makes People Living with HIV/AIDS (PLWHA) Refrain From Seeking Timely and Proper Care in Health Care Institutions in Port Harcourt, Nigeria?
Mbonu N presenting

62157 Group Counseling Achieves High Adherence to Antiretroviral Therapy: Results of the CAPRISA 058 Randomized Controlled Trial Comparing Group Versus Individualized Adherence Counseling Strategies in Durban, South Africa
van Loggerenberg F presenting

62213 A CBPR-Designed Adherence Intervention Using Multimedia and Social Support: A Promising Tool for Resource-Poor Settings
Remien R presenting

Oral Session 4
Novel Research on Adherence Determinants
1:15 P.M. - 2:45 P.M. / Mona Lisa

62255 Is Race/Ethnicity Associated with ART Adherence? Findings from the MACH14 Study
Simoni J presenting

61131 Longitudinal Relationships of HIV-, Race-, and Sexual Orientation-related Discrimination to Medication Adherence among African-American Men with HIV
Bogart L presenting

61685 Assessing the Information, Motivation, and Behavioral Skills (IMB) Model of Antiretroviral Adherence Among a Sample of Internet-Using People Living with HIV/AIDS
Horvath K presenting

61265 General Versus Specific Social Support: Which Better Explains adherence?
Taylor K presenting

Oral Session 5
Antiretroviral Regimens, Adherence, and Virologic Outcomes
3:15 P.M. - 4:45 P.M. / Pompeii Room

62223 Are Once-Daily Regimens Really the Magic Bullet?
Glass T presenting

61881 People with Intermediate Level of Adherence Taking PI or NNRTI Have Different Viro-Immunological Outcomes
Murri R presenting

62047 Comparison of Ritonavir-Boosted Atazanavir and Unboosted Atazanavir in HIV Patients on a Stable HAART Regimen Containing Tenofovir
Marx K presenting

61629 A Novel Population Pharmacokinetic Adherence Measure (PPAM) Among 3-Class-Experienced Patients in the Darunavir Outcomes Study
Mugavero M presenting

Oral Session 6
Patient-Provider Adherence Communication
3:15 P.M. - 4:45 P.M. / Promenade A

61403 Patient Portal to Support Adherence: Acceptability and Feasibility Pilot Findings
Catz S presenting

61339 Impact of a Patient and Provider Intervention to Improve the Quality of Communication About Medication Adherence Among HIV Patients
Beach M presenting

62289 Implementation and Evaluation of a Pharmacy-Based Medication Therapy Management Program to Improve Provider Communication and Patient Adherence to Therapy
Thompson M presenting

MONDAY, MAY 24, 2010 (CONTINUED)

Oral Session 7
Engagement in Care in the US
3:15 P.M. - 4:45 P.M. / Promenade B

62049 Statewide Analysis of Engagement and Transitions in HIV Care for a Newly HIV-Diagnosed Cohort
Gardner E presenting

61501 Factors Associated with Missed Visits among Patients Establishing Initial HIV Care: First Steps towards a Clinical Prediction Rule
Orr M presenting

61859 A Qualitative Study of the Barriers and Facilitators to Retention-in-Care among HIV-Positive Women in the Rural Southeastern U.S.: Implications for Targeted Interventions
Kempf M presenting

61557 The Situated Information Motivation Behavioral Skills Model of HIV Care Initiation and Maintenance (sIMB-CIM): Preliminary Support for Characterizing Gaps in HIV Care
Amico K presenting

Oral Session 8
Pediatric, Child, and Adolescent Adherence
3:15 P.M. - 4:45 P.M. / Mona Lisa

62165 HIV-Infected Children Who Default Care in Western Jamaica
Evans-Gilbert T presenting

62137 Patterns and Influencing Factors of Adherence to ART in HIV-Infected Children in Rural Uganda
Haberer J presenting

61381 Determinants of Adherence to Highly Active Antiretroviral Therapy Among HIV-Infected Children in Rwanda
Binagwaho A presenting

62199 Centralization of HIV Services in HIV+ African American and Hispanic Youth Improves Retention in Care
Davila J presenting

TUESDAY, MAY 25, 2010

Oral Session 9
Wireless Adherence Monitoring and Support
12:45 P.M. - 2:15 P.M. / Pompeii Room

62061 Real Time Adherence Monitoring for HIV Antiretroviral Therapy in a Developing Setting
Haberer J presenting

61413 The Use of Mobile Phone Intervention Based on Short Message System (SMS) for Assisting HIV-Infected Non-Adherent to Comply with Antiretroviral Therapy. HI-Vision Project
Ammassari A presenting

62059 Challenges in Using Mobile Phones for Collection of Antiretroviral Therapy Adherence Data in a Resource-Limited Setting
Haberer J presenting

62127 The Power of Narratives: Using Video to Build Community for Non-Urban Patients with HIV
Winstead-Derlega C presenting

Oral Session 10
Adherence and Substance Use
12:45 P.M. - 2:15 P.M. / Promenade A

61321 Methamphetamine Use and HIV Medication Adherence Among MSM: Day-Level Associations
Parsons J presenting

61347 Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in HIV-Infected Injection Drug Users in Substance Dependence Treatment
Safren S presenting

62215 ART Adherence Changes Among Patients in Community Substance Use Treatment: A Preliminary Analysis from MACH14
Rosen M presenting

61097 Structural Ecosystem Therapy for HIV Medication Adherence and Substance Abuse Relapse Prevention
Feaster D presenting

Oral Session 11
Operations Research in Sub-Saharan Africa
12:45 P.M. - 2:15 P.M. / Promenade B

61421 Structured Treatment Preparation and Patient Readiness Improves Retention In Care Rates In Nigeria
Ugoji C presenting

61331 Effects of Strengthening Appointment and ART Patient Tracking Systems on ART Adherence: A Pilot Study in Tanzania
Sando D presenting

61209 Improved Patient Retention Rates with the Integration of Electronic Patient Monitoring System in Large Workplace ART Program in Lesotho
Asiimewe F presenting

TUESDAY, MAY 25, 2010 (CONTINUED)

62173 Feasibility and Effectiveness of a Mobile Antiretroviral Pharmacy in Rural Southwestern Uganda
Sethi A presenting

Oral Session 12
Measuring Adherence and Engagement in Care
12:45 P.M. - 2:15 P.M. / Mona Lisa

62095 A Four-Item Measure of Motivation to Adhere that Predicts MEMS Adherence over 48 Weeks
Goggin K presenting

62271 Validating Five Questions on Antiretroviral Non-Adherence in a Decentralized Community-Based ART Programme in Rural South Africa
Chaiyachati K presenting

62045 Validity of Self-Report Measures in Assessing Antiretroviral Adherence of Newly Diagnosed, HAART-Naïve, HIV Patients
Buscher A presenting

Oral Session 13
Adherence and HIV Prevention
2:45 P.M. - 4:15 P.M. / Pompeii Room

61291 Daily Covariation in Substance Use, HIV Medication Adherence, and Sexual Transmission Risk: Neuropsychological and Psychosocial Moderators
Golub S presenting

61405 Behavioral Intervention to Accompany HIV Treatment for Prevention: Reducing Transmission and Improving Adherence
Kalichman S presenting

62191 Barriers and Facilitators to Prevention Pill Use in iPrEx: Capturing the Experience of MSM PrEP Study Participants in the United States
Liu A presenting

62253 Developing an Innovative Approach to Adherence Counseling and Assessment in a Pre-Exposure Prophylaxis (PrEP) Trial: Next Step Counseling and Neutral Assessment in the iPrEx Study
Amico K presenting

Oral Session 14
Directly Observed Therapy/ Transitions from Prison
2:45 P.M. - 4:15 P.M. / Promenade A

62097 Outcomes of Project MOTIV8: A RCT of Novel Behavioral Interventions for ART Adherence
Goggin K presenting

61245 Benefits of DOT for Improving Adherence and Suppressing Viral Load Do Not Persist During the 12-Months After DOT Discontinuation
Arnsten J presenting

61397 Feasibility of Monitoring and Addressing Antiretroviral Adherence Among Persons Recently Released From Prison
Catz S presenting

59735 The Bridge Program (BP): Building a Mental Health (MH) Care Network for HIV+ Inmates with Mental Illness (MI) Recently Released from the Virginia Department of Corrections (DOC)
Rollison M presenting

Oral Session 15
Adherence Performance Indicators and Quality of Adherence Care
2:45 P.M. - 4:15 P.M. / Promenade B

61913 Using Antiretroviral Therapy without Monitoring Viral Load in the United States
Akincigil A presenting

61553 Adherence Support Services for Antiretroviral Therapy (ART) in Rwanda
Horowitz D presenting

61805 Adherence Performance in Health Facilities Providing Antiretroviral Therapy in Kenya – Pre-Intervention Assessment of Quality of Care
Kagai D presenting

61795 Antiretroviral (ART) Adherence and HIV RNA (VL) Control as HIV Quality Measures in Kaiser Permanente (KP)
Horberg M presenting

Oral Session 16
Methodological Concerns in Adherence Research
2:45 P.M. - 4:15 P.M. / Mona Lisa

62221 Heterogeneity Among Studies in Rates of Declines of Antiretroviral Therapy (ART) Adherence Over Time: Findings from MACH14
Wilson I presenting

61393 Value of Multi-Modal Standard Care Assessment in ART Adherence Research
Banderas J presenting

61387 Analyzing Medication Adherence: a Powerful Alternative to Logistic Regression
Saberi P presenting

62225 A "Honeymoon Effect" when Initiating the Use of Electronic Drug Monitoring (EDM) in Clinical Studies: Findings from MACH14
Wilson I presenting

59735 The Bridge Program: Building a Mental Health Care Network for HIV+ Inmates with Mental Illness Recently Released from the Virginia Department of Corrections

Michael Rollison[1] **(presenting)**, Steven Bailey[2], Rachel Rees[2]

[1] Virginia Commonwealth University Medical Center, Richmond, VA, United States
[2] Virginia Department of Health, Richmond, VA, United States

Introduction: A recent American Public Health Association study (Nov 2007) indicates >50% of HIV+ inmates in the US have mental illness (MI), with half undiagnosed. Pre-incarceration, inmates with MI have substantial unmet needs and increased needs upon release. They demonstrate poor capacity to cope with challenges related to accessing HIV and mental health (MH) care. A pilot program, was collaboratively developed by the Virginia Department of Health and the VCU Medical Center's Infectious Disease Clinic (IDC), identifying recently released HIV+ persons returning to IDC for HIV care, assisting with care transition, providing MH evaluation, assessment and treatment as indicated. Components of Bridge Program (BP) services include neurological and psychological evaluative testing relevant to incarceration, HIV, depression, cognitive function, post traumatic stress disorder, and bio-social history. Other supportive MH services provided: psychiatric follow-up, MH counseling and intensive case management. Projections: Approximately 50 HIV+ Department of Correction (DOC) released annually that are then followed in the IDC.

Description: Objectives are to (1) Assist in HIV care transition post DOC release, (2) Offer and provide extensive MH evaluation, assessment and treatment. Objective outcomes: Maintain or improve HIV health parameters achieved during DOC incarceration, identify and treat MH conditions appropriately towards increasing compliance to and retention in medical care, and lastly reduce recidivism back to DOC.

Lessons Learned: By the end of the second quarter (October 2009), 35% met Social Security criteria for disability related to MI (7/20), while 80% (16/20) were found with clinically diagnosable MI conditions deemed moderate to severe. Only one BP client has been re-incarcerated and two lost to care, indicating an 85% retention rate to HIV and MH care.

Recommendations: DOC release planning should include identifying HIV+ inmates with MI, addressing this group's elevated needs upon release regarding intensive medical case management, MH screening and treatment to facilitate the successful care transition into community HIV care sites.

61097 Structural Ecosystem Therapy for HIV Medication Adherence and Substance Abuse Relapse Prevention

Daniel Feaster[1] **(presenting),** Victoria Mitrani[2], Myron Burns[3], Brian McCabe[2], Ahnalee Brincks[1], Allan Rodriguez[1], Deshratn Asthana[1], Michael Robbins[1]

[1] University of Miami, Miami, FL, United States
[2] University of Miami, Coral Gables, FL, United States
[3] Nevada State College, Henderson, NV, United States

Background: Substance abuse is associated with adverse consequences for women with HIV/AIDS. Structural Ecosystems Therapy (SET) seeks to encourage medication adherence and prevent drug relapse among HIV+ women by strengthening family support, helping woman distance themselves from drug-using family members, and developing a family plan to respond to drug relapse.

Methods: An NIH-funded randomized trial tested the efficacy of SET relative to a psycho-educational health group (HG) intervention in 126 HIV+ women in drug abuse recovery. The interventions lasted four months. Research assessments were conducted for 12 months. Women were assessed for drug use and medication adherence at two-month intervals. CD4 T-cell count and HIV viral load were assessed at four-month intervals. Family members were assessed on a range of psychosocial factors to examine the family mechanisms of SET.

Results: Levels of drug use did not differ by condition. Women in SET were more likely to separate from drug using household members and increase substance abuse services in response to relapse than women in HG. These changes explained the decline in drug use observed within SET between six and 12 months. SET showed declines in medication adherence but increases in CD4 T-cell count relative to HG. The increase in CD4 T-cell count in SET was related to increasing proportions of women in SET taking antiretroviral medications. A sub-analysis of children (n = 42) demonstrated that SET resulted in a significant decrease in internalizing and externalizing symptoms in the children, an increase in positive parenting, and reduced psychological distress and drug use of mothers.

Conclusions: Results of the trial were mixed, although SET showed significant effects on theoretical mechanisms of action on drug relapse. Drug use prevalence among women post-drug treatment (38.9% at baseline, 56.1% at 12 months) highlights the need for intervention. Implications for enhanced intervention potency and targeting are discussed.

ORAL ABSTRACTS

61131 Longitudinal Relationships of HIV-, Race-, and Sexual Orientation-Related Discrimination to Medication Adherence among African-American Men with HIV

Laura Bogart[1] **(presenting)**, Glenn Wagner[2], Frank Galvan[3], David Klein[4], Martin Lee[5]

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[2] RAND, Santa Monica, CA, United States
[3] Charles Drew University of Medicine and Science, Los Angeles, CA, United States
[4] Children's Hospital Boston/Harvard Medical School, Boston, MA, United States
[5] UCLA School of Public Health, Los Angeles, CA, United States

Background: HIV-infected African-American men who have sex with men (MSM) are at the nexus of multiple stigmatized identities related to race/ethnicity, HIV, and sexual orientation. Although prior work documents associations of perceived discrimination with poor health and health behavior, research has not investigated how intersecting stigmas act in concert over time. We examined longitudinal effects of multiple forms of discrimination on antiretroviral treatment (ART) adherence among African American MSM.

Methods: 152 African-American MSM on ART completed interviews measuring adherence and discrimination due to HIV, race/ethnicity, and sexual orientation at baseline and monthly for six months. Discrimination since the last assessment was measured at every follow-up. Adherence (% of doses taken) was electronically monitored for six months. Separate generalized linear random effects models tested effects of each type of discrimination on adherence over time, controlling for baseline self-reported discrimination and adherence, and treating individual as random. A full random effects model (with main and interactive effects) tested whether all three discrimination types were simultaneously associated with adherence over time.

Results: Mean six-month adherence was 60%. In separate models, greater perceived discrimination due to HIV [b(SE) = -0.01(0.01), p <.05] and race/ethnicity [b(SE) = -0.02(0.01), p <.05] were significantly associated with lower adherence over time; the sexual orientation discrimination effect was marginal [b(SE) = -0.01(0.01), p <.10]. In the full model, only perceived discrimination due to race/ethnicity was significantly related to lower adherence over time [b(SE) = -0.04(0.02), p <.01].

Conclusions: Chronic experiences with discrimination can contribute to worse treatment adherence among African-American MSM with HIV. Culturally tailored interventions to promote adherence should focus on coping skills for discrimination-related stress, especially racism.

61205 Patient-Reported Outcomes Predict Antiretroviral Adherence: A Transformative Health Informatics Technology for Research and Patient Care

Michael Kozak (presenting), Michael Mugavero, Jiatao Ye, Inmaculada Aban, Sarah Lawrence, Christa Nevin, James Raper, Cheryl McCullum-Smith, Joel Schumacher, Michael Saag, James Willig

University of Alabama School of Medicine, Birmingham, AL, United States

Background: Computerized collection of psychometrically validated measures of patient reported outcomes (PRO) provides a novel paradigm for data capture at the point of clinical care. Comparisons of PROs and traditionally captured clinical data recorded by providers (chart diagnoses) in the prediction of health behaviors and outcomes are lacking. We compare PRO vs. chart diagnosis capture of psychosocial domains in the prediction of adherence to antiretroviral therapy (ART).

Methods: This retrospective study includes HIV-positive patients at an urban, Southern HIV clinic who completed PRO assessment April 2008-July 2009. The questionnaire includes measures of depression (PHQ-9) and substance abuse (ASSIST) categorized as current, prior, and absent. Self-reported ART adherence (ACTU-4) was modeled using separate logistic regression analyses (PRO vs. chart diagnosis models) controlling for age, sex, insurance, CD4 and prior ART experience.

Results: Of 782 study participants, mean age was 45±10 years, 78% male, 53% white, 54% MSM, 42% private insurance, 18% uninsured, and 17% self-reported ART non-adherence. Chart vs. PRO diagnosis of current substance abuse was 13% (n = 99) vs. 6% (n = 45) (p <0.0001) and current depression was 41% (n = 317) vs. 12% (n = 97) (p <0.0001). In the chart diagnoses model, neither substance abuse (OR = 1.25; 95%CI = 0.70-2.21) nor depression (OR = 0.93; 95%CI = 0.62-1.40) was significantly associated with ART adherence. Conversely, in the PRO model, current substance abuse (OR = 2.78; 95%CI = 1.33-5.81) and current depression (OR = 1.93; 95%CI = 1.12-3.33) were associated with poor ART adherence.

Conclusions: The explanatory characteristics of the PRO model correlated best with known factors associated with poor ART adherence including substance abuse and depression. The computerized capture of PROs as a part of routine clinical care may prove to be a complementary and potentially transformative health informatics technology for research and patient care.

61209 Improved Patient Retention Rates with the Integration of Electronic Patient Monitoring System in Large Workplace Antiretroviral Therapy (ART) Program in Lesotho

Fred Asiimwe[1] (presenting), Limakatso Phatsoane[1], Limakatso Phatsoane[1], Mabereng Letsie[1], Mabereng Letsie[1], Majoalane Mokone[1], Tema Nthejane[1], Mantai Ramangoela[2], Bart Vander Plaetse[1]

[1] Apparel Lesotho Alliance to Fight AIDS (ALAFA), Maseru, Lesotho
[2] Ministry of Health, Maseru, Lesotho

Background: The growing number of patients in chronic HIV care and progressively on ART is a management challenge for clinical teams in resource constrained settings. The aim of the present study was to describe the factors associated with loss to follow up (LTFUP) among HIV-infected apparel workers in the ALAFA (Apparel Lesotho Alliance to Fight AIDS) HIV care program and evaluate the effect of integration of electronic patient monitoring systems on patient retention in the program.

Methodology: All HIV-infected apparel workers enrolled in the program since June 1, 2006, were included. A patient was considered LTFUP if the last visit was more than six months. Associations between indicator variables and the dichotomous outcome LTFUP were determined using odds ratios and 95% confidence intervals (CI).

Results: Of 6,293 HIV-infected apparel workers from different factories within Lesotho were included and a total of 648 (10.3%) patients had been LTFUP. Loss to follow up was higher among patients who had never initiated ART (14%; n = 3800) compared with those who ever been on ART (6.8%, n = 1685). Subsequent analyses showed that patients LTFUP were likely to be of younger (28 vs. 33, p <0.015). The median CD4 cell count on the last visit was lower among LTFUP (321 vs. 388, p = 0.008). Having no workplace clinic was associated with an increased likelihood of being LTFUP (OR 3.3 [p <0.003, 95% CI 1.4-1.8]). With the electronic patient visit triage system, there has been an increase in the number of patients who attend their scheduled visits from 37.3% to 61% in November 2009. The program attrition rates have also stayed below 11%.

Conclusion: Linkage of paper based patient monitoring system with electronic system at facility level improves clinic attendance and improve treatment adherence. The electronic triage systems reduces the lead time for action on patients that would be lost to follow up and improves patient retention in large HIV care programs.

61245 Benefits of Directly Observed Antiretroviral Therapy (DOT) for Improving Adherence and Suppressing Viral Load Do Not Persist During the 12-Months After DOT Discontinuation

Julia Arnsten (presenting), Karina Berg, Alain Litwin, Xuan Li, Moonseong Heo

Albert Einstein College of Medicine, Bronx, NY, United States

Background: In a randomized trial of directly observed antiretroviral therapy (DOT) provided at methadone clinics, we recently demonstrated that six months of DOT was more efficacious than self-administered highly active antiretroviral therapy (HAART) for improving adherence and suppressing viral load (VL). Whether these beneficial effects persist for 12 months after DOT discontinuation is unknown.

Methods: At enrollment there were no differences between treatment groups [DOT v. treatment as usual (TAU)]. Pill count adherence and VL were assessed frequently during the six-month trial; after DOT discontinuation at six months, we continued monthly adherence assessments for 12 months and also assessed VL at the three-, six-, and 12-month follow-up points. Paired and unpaired t-tests assessed group differences in adherence and VL 12 months after DOT discontinuation.

Results: 65 participants completed the six-month intervention. Median age was 47, 59% were female, 31% Black, 35% Hispanic. Substance use was common: 26% (heroin), 29% (cocaine), and 36% (crack). Median duration of methadone maintenance was 8 yrs (IQR 3-19), and of HIV infection was 13 years (IQR 9-17). All participants were HAART-experienced. At completion of the six-month trial, adherence was higher among DOT (86%) than TAU (54%, p <0.0001) participants, and more DOT than TAU participants had VL <75 copies/ml (71% v. 44%, p = 0.03). After 12 months of additional follow-up, these differences had extinguished: adherence was 55% for DOT and 60% for TAU (p = .31) and the proportion of participants with undetectable VL in DOT and TAU was the same (36% for DOT v. 34% for TAU, p = 0.92). For both outcomes, differences between groups were non-significant as early as the three-month post-trial follow-up point.

Conclusions: Among HAART-experienced substance users, the beneficial effects of DOT on adherence and VL did not persist after DOT discontinuation. Future studies should examine sustainability, including cost-effectiveness, of implementing DOT programs in methadone clinics.

61265 General Versus Specific Social Support: Which Better Explains Adherence?

Kelly Taylor (presenting), Torsten Neilands, Samantha Dilworth, Mallory Johnson

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

Background: Social support has been linked to better antiretroviral therapy (ART) adherence. This study explored which of two types of social support is more associated with ART adherence: perceived availability of general support or receipt of HIV-treatment specific support.

Methods: Using binary logistic regression with cross-sectional baseline data from a clinical trial of a coping intervention, we examined associations among self-reported ART adherence (using VAS & AACTG), general social support (Social Provisions Scale) and treatment-specific social support. The Social Provisions Scale is a general support measure that assesses level, type, and perceived satisfaction with social support from one's social network. The Regimen Specific Support scale measures reports of actually receiving specific support from significant others for disease specific self-care (e.g. help refilling prescriptions).

Results: The 290 respondents were 89.7% male, 18.6% African American, 16.9% Hispanic, and mean age of 46.3 (SD = 7.86). Over 70% of the participants reported >90% adherence. General social support was not associated with adherence (OR = 1.04, 95% CI = .742, 1.46), whereas higher reports of receipt of regimen specific support were associated with lower adherence (OR = .703, 95% CI = .510, .968).

Conclusions: We detected two puzzling findings. First, unlike in the literature, the perception of available general social support was not associated with better adherence in our sample. This suggests that general measures of social support may not be sensitive indicators of ART adherence. Second, reporting receiving specific support for HIV self-care was associated with poorer adherence than when such help was not provided. This association may be explained by the following: a) those individuals were receiving more practical help due to adhering poorly from the outset and/or b) the help may have been unwelcome or disempowering, resulting in unintended negative effects on adherence.

61291 Daily Covariation in Substance Use, HIV Medication Adherence, and Sexual Transmission Risk: Neuropsychological and Psychosocial Moderators

Sarit Golub (presenting), Jeffrey Parsons

Hunter College of the City University of New York, New York, NY, United States

Background: Near perfect treatment adherence significantly reduces the risk of sexual transmission of HIV. Substance users are less likely to adhere to HIV medication regimens and more likely to engage in high-risk sexual behavior, but few studies have examined daily associations among substance use, HIV transmission risk, and missed pills. This study used Hierarchical Linear Modeling (HLM) to examine daily covariation in these behaviors, and identify potential moderators.

Methods: Participants were 76 HIV-positive methamphetamine-using MSM enrolled in an ongoing RCT to improve adherence to antiretroviral therapy. Participants completed a daily assessment of adherence, substance use, and sexual behavior in the past 14 days and a computer-assisted survey capturing psychosocial factors in adherence behavior. A subset (n = 54) completed a neuropsychological battery measuring decision-making deficits and attention/response inhibition.

Results: HLM models were run to predict HIV transmission risk, i.e. unprotected sex with a serodiscordant partner. Methamphetamine use on a given day increased the odds of transmission risk by 6.7 (p <.001). The association between methamphetamine use and transmission risk was moderated by decision-making impairment, increasing the likelihood of risk on meth days (p = .01). Controlling for methamphetamine use, the odds of transmission risk increased 4.4 times (p <.001) on days in which participants also missed pills. The association between non-adherence and transmission risk was moderated by positive attitudes toward medication adherence; individuals with more positive attitudes demonstrated less of an association between the two behaviors (p <.05).

Conclusions: There are day-level associations between non-adherence and sexual transmission risk, even controlling for substance use. Both behaviors may be seen as a release from disease burden for HIV-positive individuals, and their relationship may be moderated by complex psychosocial and neuropsychological factors.

61321 Methamphetamine Use and HIV Medication Adherence among Men Who Have Sex with Men (MSM): Day-Level Associations

Jeffrey Parsons (presenting), Sarit Golub

Hunter College of the City University of New York, New York, NY, United States

Background: Methamphetamine users are less likely to be adherent to HIV medication regimens, but few studies have examined specific day-level associations between meth use and missed pills. This study compared the association between meth use and adherence at aggregate and day levels to examine both mechanisms and moderators of their relationship.

Methods: The present investigation used baseline data from HIV-positive MSM (N = 76) on antiretroviral therapy (ART) whom were enrolled in a randomized controlled trial. All participants reported at least three days of methamphetamine use in the past 90 days. Participants completed a detailed calendar assessment of medication adherence and methamphetamine use (in the last 14 days) and a computer-assisted survey capturing psychosocial factors in adherence behavior.

Results: Participants reported an average of 3.9 missed medication days, i.e. 73% day adherence (range 1-14; IQR 1-5) and 2.3 methamphetamine use days (range 1-14; IQR 1-3) in the past 14. At the aggregate level, there was no correlation between the number of methamphetamine use days and the number of missed medication days ($r = -.01$, $p > .9$). Hierarchical Linear Modeling (HLM) was used to examine daily associations between methamphetamine use and non-adherence. Compared to days in which no methamphetamine was used, methamphetamine use on a given day increased the odds of non-adherence by 2.9 (95% CI = 1.9-4.5, $p < .001$). Consistent with past research, depression was associated with greater non-adherence and methamphetamine use at the aggregate level, but did not moderate day-level associations between the two behaviors. Perceived costs of adherence significantly moderated the association between methamphetamine use and non-adherence, such that more negative attitudes made non-adherence more likely on methamphetamine days ($p < .05$).

Conclusion: Methamphetamine use impacts non-adherence by increasing the likelihood of missed pills at the day level. Attitudes toward adherence may be critical moderators of daily associations between methamphetamine use and non-adherence.

61331 Effects of Strengthening Appointment and Antiretroviral Therapy (ART) Patient Tracking Systems on ART Adherence: A Pilot Study in Tanzania

David Sando (presenting)

Tanzania National AIDS Control Program, Dar es Salaam, Ilala, Tanzania

Background: By October 2009, 298,000 patients had been started on antiretroviral therapy (ART) in Tanzania; however, little has been done to measure or sustain treatment adherence. This study's objectives are to establish baseline ART adherence levels and evaluate the effectiveness of a systems-improvement intervention on clinic attendance and adherence.

Methods: The study uses a quasi-experimental, interrupted time series with comparison group design in two regions. The study population, drawn from three clinical treatment centers (CTCs) in each region, includes experienced patients (n = 600) who initiated ART at least 10 months before baseline and all new patients (expected n >600) who initiated ART from seven months before the baseline survey through the end of the follow-up period. The comparison population will come from CTCs not participating in the intervention. Interventions include: establishing a standardized appointment register and a system of negotiated appointments; strengthening patient tracking and follow-up and linking CTC and home-based care programs to help track clients who missed appointments; and building CTC staff capacity to self-monitor through performance indicators. Study indicators in all facilities include attendance on the scheduled day, time from missed clinic visit to re-attendance, and ART adherence via days covered by dispensed medicine; clinic waiting time and success in contacting patients missing appointments is being measured only in intervention CTCs.

Results: Patient attendance in the scheduled appointment blocks improved dramatically during the first four months (68%, 89%, 99.8%, 97%). Clinic staff report that the new appointment system has decreased clinic crowds, resulting in them being able to close the clinic early now.

Conclusions: The systems improvements are low cost, feasible, and well-received by clinic staff and patients. If proven successful in the long-term, the intervention should be scaled up to all CTCs nation-wide.

ORAL ABSTRACTS

61339 Impact of a Patient and Provider Intervention to Improve the Quality of Communication about Medication Adherence among HIV Patients

Mary Catherine Beach[1] **(presenting)**, Ira Wilson[2], Somnath Saha[3], P. Todd Korthius[3], Victoria Sharp[4], Jonathon Cohn[5], Richard Moore[1]

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2 Tufts-New England Medical Center, Boston, MA, United States
3 Oregon Health Science University, Portland, OR, United States
4 St. Lukes-Roosevelt, New York, NY, United States
5 Wayne State, Detroit, MI, United States

Introduction: Medication adherence is essential for the health of HIV-infected persons, and yet provider communication about adherence is not optimal. We sought to improve patient-provider communication about HIV medication adherence.

Methods: We randomized providers at three HIV care sites to receive or not receive communication skills training based on the principles of motivational interviewing applied to dialogue about medication adherence. Post training, non-adherent patients of intervention providers were coached to discuss adherence issues. Patients of control providers did not receive coaching. We audio-recorded and coded patient-provider interactions using the Roter Interaction Analysis System (RIAS). We compared control vs. intervention differences in targeted communication behaviors.

Results: Providers (n = 24) had a mean age of 46 years; 59% were female and 69% were white. Patients (n = 140) had a mean age of 45 years; 67% were male and 46% were African American. There were no control vs. intervention differences in any patient or provider characteristics. There was a greater total amount of dialogue about therapeutic regimens in intervention vs. control encounters (167 vs. 128 statements, p = 0.003). Intervention vs. control providers engaged in more positive talk (44 vs. 38 statements, p = 0.039), emotional talk (26 vs. 18 statements, p <0.001), asking patient opinion (3 vs. 2 statements, p = 0.009), and brainstorming solutions to nonadherence (41% vs. 22% encounters with brainstorming, p = 0.026). Intervention patients did not engage in more of therapeutic dialogue, nor did they ask more questions.

Conclusion: A brief provider training combined with patient coaching increased important provider communication behaviors and dialogue regarding medication adherence. However, most of the increase in adherence dialogue was provider not patient talk, indicating that further training is required to help providers engage patients effectively.

61347 Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in HIV-Infected Injection Drug Users in Substance Dependence Treatment

Steven Safren[1] **(presenting)**, Conall O'Cleirigh[2], Jacqueline Bullis[3], Michael Otto[4], Michael Stein[5], Mark Pollack[2]

1 MGH/Harvard Medical School and Fenway Health, Boston, MA, United States
2 Massachusetts General Hospital and Harvard Medical School, Boston, MA, United States
3 Massachusetts General Hospital, Boston, MA, United States
4 Boston University, Boston, MA, United States
5 Butler Hospital/Brown University Medical School, Providence, RI, United States

Background: Depression and substance use disorders, two of the most common psychosocial comorbidities with HIV, are both associated with worse treatment adherence.

Methods: We conducted a two-arm, RCT (N = 90) comparing cognitive behavioral therapy for adherence and depression (CBT-AD), to enhanced treatment as usual (ETAU) in triply comorbid (HIV, depression, IDU) individuals who were in substance abuse treatment. Both groups received a single session adherence counseling intervention, and the intervention condition also received nine sessions of CBT-AD.

Results: Hierarchical Linear Modeling was used to estimate the change in adherence (MEMS) over time across 11 study visits and the significance of the difference in slope between study conditions. The CBT condition showed significant improvement compared to ETAU condition from baseline to the post-treatment assessment ($\_$ = -0.717, t (87) = -2.01, p <.05). Additionally, at post-treatment outcome, those in the CBT-AD condition showed significant improvement in depression scores compared to ETAU. These outcomes, assessed by independent (blinded) assessor, were significant for both the MADRS (F (1, 78) = 6.38, p <.02) and the CGI (F (1, 79) = 12.99, p <.01). Follow-up data revealed that although depression gains maintained after the intervention was discontinued at six- and 12-months of follow up, adherence gains did not.

Conclusions: In patients managing the multiple challenges of HIV, depression, substance dependence, and adherence, CBT-AD is a useful way to integrate treatment of depression with an intervention to increase adherence. Although there is good evidence support its efficacy during treatment, continued adherence counseling is likely needed, however, to maintain adherence gains in this multiply comorbid, complicated population, even after depression improves.

61381 Determinants of Adherence to Highly Active Antiretroviral Therapy (HAART) Among HIV-Infected Children in Rwanda

Agnes Binagwaho[1] (presenting), Gisanura Ngabo[2], Mawuena Agbonyitor[3], Immacule Murekatete[4]

[1] Ministry of Health Rwanda, Kigali, Rwanda
[2] Kanombe Military Hospital, Kigali, Rwanda
[3] Harvard Medical School, Boston, MA, United States
[4] Faith Victory Association, Kigali, Rwanda

Introduction: Since 2005, Rwanda's Ministry of Health and National AIDS Control Commission have increased the number of children under highly active antiretroviral treatment (HAART). The objective of this study is to identify the factors associated with adherence to HAART among Rwandan children.

Methods: This study will assess HIV-infected children's adherence to HAART through: the evaluation of adherence by measuring the number of missed doses; the identification of obstacles to full adherence; and the identification of problems faced by caregivers. Five health foundations were visited that treated HIV-infected children with HAART for at least 12 months. 88 children were visited and interviewed at home. Inclusion criteria were children under 15 years, who were treated with HAART for at least 12 months. A questionnaire was given to the caregiver for data collection. Non-adherence is defined as missing at least one dose during a 12 month period of HAART treatment.

Results: Most of the children surveyed (56.8%) were between 6 and 12 years old: 59.1% were girls, 40.9% were boys. 34% of children had missed at least one dose of HAART in the past 12 months, with forgetfulness (38%) as the most common reason. Children and caregivers who were members of an association for people living with HIV or AIDS (PLWHA) were more likely to be adherent than those who were not (p = 0.031). Caregivers who were satisfied with the health care their children were receiving were more likely to have adherent children, compared to those who were unsatisfied (p = 0.001). Also, the more time it took for children to be served at health centers, the less likely they were to be adherent (p = 0.043).

Conclusion: In conclusion, for Rwanda to increase full pediatric adherence to HAART, it must: review the counseling protocol to provide caregivers and children with tools to combat forgetfulness; sensitize caregivers to join associations of PLWHA; and promote good customer care for patients at health centers.

61387 Analyzing Medication Adherence: a Powerful Alternative to Logistic Regression

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Background: In addition to challenges surrounding the best measure of antiretroviral therapy (ART) adherence, there is much debate regarding a standard method to operationalize this measure for analysis. Many studies have investigated appropriate methods of determining ART adherence; however, these data are highly skewed and difficult to analyze. Dichotomizing this continuous variable, at arbitrary cut-points of 90%, 95%, or 100%, leads to loss of power and valuable information. Here we contrast analyses of one study using a dichotomized adherence measure versus an innovative method of adherence analysis.

Methods: We utilized baseline data from the Healthy Living Project to demonstrate the difference in analyzing adherence data using logistic regression (operationalized as non-adherence dichotomized at cut-points of 0% non-adherence versus greater than 0% non-adherence) in comparison to the use of generalized linear models (GLM) assuming a gamma distribution (treating percent non-adherence as a continuous variable). Self-reported ART non-adherence was calculated using the ACTG three-day adherence measure. The same established predictors of ART non-adherence were utilized in both models.

Results: In one example using logistic regression (N = 2543), odds ratios for age categories 35-44 and ≥45 were 0.99 (95% CI = 0.78-1.27; p = 0.96) and 0.76 (95% CI = 0.58-0.99; p = 0.05), respectively, with age category <34 as the reference. In comparison, using GLM, exponentiated coefficients for age categories 35-44 and ≥45 were 0.81 (95% CI = 0.65-1.01; p = 0.06) and 0.67 (95% CI = 0.53-0.85; p = 0.001), respectively. Predicted mean ART adherence using GLM were computed at 88.6% for 0-34 year of age, 90.7% for 35-44 years, and 92.6% for 45 years and above.

Conclusion: Using GLM we were able to preserve and analyze ART adherence as a continuous variable, gain statistical power, and avoid arbitrary adherence categories. Adopting this methodology may enhance future medication adherence research.

ORAL ABSTRACTS

61391 Double-Burden: The Challenges of Coping with TB and HIV Therapy on HIV/TB-Coinfected Persons

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Introduction: As one third of the world's population is estimated to be infected with tuberculosis (TB), there is greater risk of latent TB in people living with HIV (PLHIV) being activated due to their reduced immune status. TB therefore poses the greatest danger and burden to PLHIV.

Description: Ibadan-based Positive Life Association of Nigeria (PLAN) conducted a focused group discussion in March 2009 on the challenges of coping with TB and HIV treatment among 36 persons living with HIV who have had TB infection at least once. Some of the challenges identified by the participants include increased morbidity due to TB/HIV coinfection, increased pill burden occasioned by combining TB treatment with antiretroviral therapy; reluctance of HIV home-based care team and health care workers to visit PLHIV coinfected with TB for fear of TB infection; low levels of TB treatment success rates among PLHIV; as well as doubled stigma and discrimination against coinfected patients leading to increased mortality among PLHIV due to TB disease.

Lessons Learned: Inadequate knowledge about TB coping mechanisms among PLHIV; inadequate or non-existent referral linkages between HIV/AIDS and TB treatment programmes; inadequate adherence support services targeting TB/HIV co-infected patients

Recommendations: There is the need for establishment of TB/HIV collaborative activities especially with regards to accessing treatment support services. Groups of PLHIV need to be empowered with information on TB treatment; the activities DOTS centres and antiretroviral therapy services need to be linked for improved management of TB/HIV coinfected clients. Adherence support and treatment literacy services need to be designed to meet the needs of TB/HIV coinfected. Effective referral and follow mechanisms should be devised for patients on TB and HIV treatment.

61393 Value of Multi-Modal Standard Care Assessment in Antiretroviral Therapy Adherence Research

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Background: Discussion of antiretroviral (ART) adherence intervention studies often neglect to address the impact of the underlying standard care (SC) provided to patients. It is critical to evaluate SC in multisite and long term studies. Identifying possible contamination of groups and exploring potential moderating effects on adherence outcomes are important steps in the process of translating research interventions into practice.

Methods: Three methodologies (medical record abstraction, provider survey, and patient survey) were used to measure the SC delivered by two clinics where participant recruitment was conducted for Project MOTIV8, a randomized controlled ART adherence intervention study. Department of Health and Human Services Antiretroviral Guidelines for Adults and Adolescents were used to establish the reference SC for clinical care and ART adherence education. SC was assessed twice during a five-year period (pre and post recruitment).

Results: End of study (EOS) data showed that SC practice followed nine changes in guidelines throughout the study period. Results from 150 pre-study and 100 EOS patient medical records demonstrated >80% compliance with SC guidelines and no difference in compliance between clinics or from pre-study to EOS. (p's >.05). Findings from 60 patient surveys (40 pre-study, 20 EOS) demonstrated no difference between clinics, however did show change in SC adherence education over time. Adherence tools and education were more frequently provided at EOS (p's <.05).

Conclusions: SC guidelines and SC delivered by study clinics changed over the duration of this adherence trial. It was necessary to utilize a multi-modal assessment of SC in order to identify changes in different aspects of SC from beginning to EOS. The SC delivered to study participants in the context of an ART adherence intervention trial must be measured to fully evaluate the study results.

61397 Feasibility of Monitoring and Addressing Antiretroviral Adherence among Persons Recently Released from Prison

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Background: Release from prison is a time of high risk for reincarceration, relapse to substance use, risky sexual activity, loss to medical follow up, and medication adherence lapses. For these reasons, intervention during this period is both critical for public health and inherently challenging to carry out.

Method: We tested the feasibility of delivering and evaluating an antiretroviral therapy (ART) adherence intervention immediately prior to and following release from a state-wide prison system. 41 HIV+ men and women prescribed ART while incarcerated were enrolled in person. We attempted one telephone survey and three intervention calls prior to release and three follow up telephone surveys and four intervention calls after release. Feasibility of collecting ART refill data from community record sources was assessed.

Results: 91% of those approached enrolled in the study. Mean number of intervention calls completed in prison was 2.6 (range = 1-3) and in the community was 3.5 (range = 0-6). With intensive tracking, 88% of one-week, 66% of three-month, and 56% of five-month post-release surveys were completed. 20% were reincarcerated by three months. ART supplies at release ranged from one-eight weeks, with 30/41 (73%) having at least one confirmed refill. 26/35 (74%) filled ART prescriptions according to state drug assistance program records, with six records unavailable (five moved out of state; one ineligible for assistance); five/six of these completed surveys. 18/34 (53%) filled ART prescriptions according to community pharmacy records, with seven records unavailable (two pharmacies refused to release data; five pharmacies unknown).

Conclusions: Tracking procedures must be intense and include immediate post-release contact. Retention might be improved by more frequent and front-loaded incentivised surveys. Methods for measuring community medication adherence upon reincarceration are needed. For this population, a combination of self-report and multiple state ADAP databases are likely to yield the most accurate ART adherence data.

61403 Patient Portal to Support Adherence: Acceptability and Feasibility Pilot Findings

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Background: Scalable antiretroviral therapy (ART) adherence interventions are needed. A potential intervention platform is the use of patient Websites that allow shared access to electronic medical records (EMR) and secure online communications between patients and providers. This study examined acceptability and feasibility of these tools in supporting ART adherence.

Methods: Adult HIV+ patients enrolled in two health plans were screened for adherence lapses, new or changed regimens, and detectable viral loads. Patients with and without prior portal experience were eligible. Of 42 screened eligible, 29 (69%) completed online consents and baseline Web surveys. Participants were randomized to receive 6 secure messages from an adherence intervention nurse (n = 20) or 6 attention control emails (n = 9). Adherence Information-Motivation-Behavioral Skills (IMB) baseline survey responses were used to individually tailor intervention messages. 26 participants (89%) completed 3-month post-intervention surveys and acceptability interviews.

Results: Common adherence barriers included deficits in information [how ART works (38%), ART side effects (26%), ART interactions with alcohol and drugs (21%)], motivation [concerns about ART hurting health (79%), frustration with lifelong treatment (72%)], and behavioral skills [managing side effects (59%), adapting to changes in routine (52%)]. 82% of intervention respondents found messages useful and 94% would recommend the study to others. Bi-monthly messages were acceptable, with all respondents opening study messages. Web services found most useful were e-mailing doctors, ordering medications, setting appointments, and viewing labs.

Conclusions: It was feasible to generate individualized intervention algorithms from IMB model based Web surveys. Retention was good and Web services appeared to offer added benefits to participants. EMR patient portals show promise as an acceptable and feasible intervention delivery vehicle for supporting patient adherence.

ORAL ABSTRACTS

61405 Behavioral Intervention to Accompany HIV Treatment for Prevention: Reducing Transmission and Improving Adherence

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Background: Antiretroviral therapy (ART) can be used to prevent HIV transmission by reducing infectiousness. Behavioral interventions are needed to address poor medication adherence, co-infection with other STI, and behavioral risk compensation that will otherwise undermine HIV treatment for prevention.

Methods: Men and women living with HIV/AIDS (N = 436) participated in a randomize clinical trial testing a five-small group two-individual session behavioral intervention aimed at reducing HIV transmission risks compared to an attention control condition. Computerized interviews measured risk behaviors and unannounced pill counts monitored ART adherence.

Results: The Integrated transmission risk reduction intervention demonstrated less unprotected intercourse with non-concordant partners at three and six-month follow-ups as well as fewer new STI diagnoses over the nine-month follow-up period. The Integrated intervention also demonstrated increased ART adherence and reductions in behavioral risk compensation beliefs.

Conclusions: A theory-based integrated behavioral intervention can reduce HIV transmission risks and improve HIV treatment adherence. HIV treatment for prevention should be bundled with behavioral interventions to maximize effectiveness.

61413 The Use of a Mobile Phone Intervention Based on Short Message System (SMS) for Assisting HIV-Infected Non-Adherent Patients to Comply with Antiretroviral Therapy (ART)

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Objective: To determine whether an intervention based on the delivery of short message system (SMS) on mobile phone improves adherence to antiretroviral therapy (ART).

Methods: A multi-site single-arm prospective study was conducted. Inclusion criteria: treatment with cART, availability of a mobile phone, and reported non-adherence. Non-adherence behaviors were investigated through a self-reported questionnaire: % of therapy taken in the last month; <100% doses taken over the last week; timing deviation; drug holidays over the last month. The SMS (short text with slogan or smile) were anonymously sent as a reminder every time the patient had to take the medication. The perceived intrusiveness or helpfulness of receiving SMS was also investigated. Participants were evaluated at baseline, and at month (M) 3, 6, 9, and 15. Only subjects with at least one follow-up (FU) were considered. Differences in adherence behaviors were evaluated by the mean of paired t-test for continuous and x-square McNermar test for categorical variables.

Results: A total of 71 participants had at least one FU , 41 had three-month FU, and 14 were evaluated at six-month FU (75% were male; 34% MSM, 32% heterosexual, 18% ex-IDU, 10% active-IDU). Mean percentage of doses taken over the last month raised from 79.59% at baseline to 94.27% at month 3 (3M) (P <0.0001), 93.9% at month 6 (6M) (P <0.0001), and 93.2 at month 9 (9M) (P = 0.003). Prevalence of patients reporting <100% doses taken over the last week decreased from 63.4% to 25.4% at 3M (P <0.0001), 36.6% at 6M (P = 0.01), and 28.6% at 9M (P = 0.03). Prevalence of reported drug holidays also significantly decreased from 42.3% to 15.5% at 3M (p <0.0001), 14.6% at 6M (p <0.0001), and 7.1 at 9M (P = 0.03). Timing deviations did not seem improve with the intervention (P = n.s. for all assessment).

Discussion: These preliminary results support the hypothesis that a structured mobile phone intervention based on SMS can help people to correctly take their medications.

61419 Hepatitis C (HCV) Treatment Adherence Over Time and Virologic Response among HIV/HCV-Coinfected Patients

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Background: Adherence to PEG-interferon (IFN) + ribavirin has been incompletely examined in HIV/hepatitis C patients. We evaluated relationships between adherence and early (EVR) and sustained virologic response (SVR) in coinfected patients and examined changes in adherence over time.

Methods: We conducted a retrospective cohort study among HIV/hepatitis C patients treated with PEG-IFN + ribavirin in the National VA Clinical Case Registry: Hepatitis C between 2001-2007. Eligible subjects had: 1) HIV; 2) hepatitis C genotype 1-4; 3) at least one prescription for PEG-IFN + ribavirin; 4) a pre-treatment HCV viral load; 5) a viral load after treatment initiation. Adherence to each drug was calculated over 12-week intervals using pharmacy refills. EVR (2 log drop in viral load at 12 weeks) and SVR (persistently undetectable viral load after treatment end) were main outcomes. Logistic regression estimated associations between adherence and EVR and SVR. Mixed effects models estimated mean changes in adherence over time.

Results: Among 368 patients (288 genotype 1/4), EVR was higher with higher levels of ribavirin adherence (genotype 1/4: 0.13, 0.21, 0.32 EVR at 50%, 70%, 90% adherence; genotype 2/3: 0.36, 0.50, 0.64 EVR at 50%, 70%, 90% adherence). However, SVR did not increase with ribavirin adherence (genotype 1/4: 0.26, 0.24, 0.23 SVR at 50%, 70%, 90% adherence; genotype 2/3: 0.26, 0.24, 0.22 SVR at 50%, 70%, 90% adherence). Results were similar for PEG-IFN adherence associations with EVR and SVR. There was a 6.2% points mean decline in ribavirin adherence (p <0.001) and 4.8% points mean decline in PEG-IFN adherence (p <0.001) per 12-week interval.

Conclusions: Adherence to PEG-IFN + ribavirin declined over time, but more so for ribavirin. Higher adherence to each drug was associated with higher EVR, but not SVR. Immunologic, metabolic, and viral characteristics warrant exploration to determine why greater magnitudes of adherence do not confer higher SVR rates in HIV.

61421 Structured Treatment Preparation and Patient Readiness Improves Retention in Care Rates In Nigeria

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Background: The ACTION project, a comprehensive HIV/AIDS care and treatment program implemented by the Institute of Human Virology–Nigeria, provides antiretroviral therapy (ART) to over 60,000 patients. However, adherence and retention in care challenge optimal patient outcomes. In 2008, we restructured our treatment preparation so that patients starting ART receive three weeks of HIV education, disclosure support, treatment buddy encouragement, adherence counseling and linkages to community and support groups. Pre-ART, patients are assessed by trained counselors and given certificates applauding their commitment to participate in their care management. Adherence support is continued by supportive counseling, home visits, tracking and back-to-care linkages if appointments are missed. We assessed retention in care rates at University of Benin Teaching Hospital, one of our sites after intervention implementation.

Methods: Appointment and lost-to-follow up (LTFU) tracking data were abstracted from standard clinic registers for 238 patients who started ART between May and October 2009. Data were analyzed using STATA10 and LTFU rates were compared using the Z-test.

Results: Historical program data showed that of 1,140 patients who commenced ART between March 2005 and August 2006, 251 (22%) were LTFU after three months. After the intervention, only 27 (11%) of 238 patients commencing ART were LTFU after three months (p = 0.0002). 126 (53%) were on time (<7 days) to their appointments. Of the 112 who were >7 days late, two died; one transferred; 48 were linked back to care within 30 days, 34 linked back within 30-90 days; and 27 were still LTFU after 90 days.

Conclusions: Structured treatment preparation interventions can increase retention in care rates. Improved tracking and documentation of patients who miss appointments also likely prevents misclassification of transfers and deaths as LTFU. Our data show that tracking efforts need to be pursued for more than 1 month to ensure optimal retention in care.

ORAL ABSTRACTS

61501 Factors Associated with Missed Visits among Patients Establishing Initial HIV Care: First Steps Toward a Clinical Prediction Rule

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Introduction: Missed visits are common among patients in the first year after establishing outpatient HIV medical care and have been linked to delayed receipt of antiretroviral medications and a three fold increased risk of mortality. Identification of patients at risk for missed visits in the first year of care may allow for targeted interventions to improve appointment adherence and clinical outcomes.

Methods: A prospective cohort study at an urban, Southern HIV Clinic included patients establishing initial outpatient HIV care from January 2007-December 2008. At first contact, patients completed a semi-structured interview and questionnaire that captures a range of socio-demographic and psychosocial variables using validated instruments. Multivariable logistic regression modeled a "no show" visit in the first year of care with variables selected based on a theoretical model, clinical relevance, and statistical significance in unadjusted analyses.

Results: Among 177 patients (mean age 37 years, 66% black, 76% male), 83 (47%) had a "no show" visit in the first year of care. Out of 18 variables screened, seven were included in the multivariate model (unadjusted p-value): age ($p = 0.03$), racexsex ($p = 0.27$), HIV risk factor ($p = 0.06$), health insurance status ($p < 0.01$), education ($p = 0.01$), depression (PHQ-9, $p = 0.08$) and anxiety (PHQ-4, $p < 0.01$). The final model demonstrated reasonable discriminative capacity in predicting missed visits in the first year of care (c-statistic = 0.73), good model fit (Hosmer-Lemeshow chi-square test, $p = 0.29$), sensitivity (68%) and specificity (52%).

Conclusions: This study represents an important first step towards developing a missed visit prediction rule. Successful development of an externally validated prediction rule building upon these findings has key implications for appointment adherence research and for the efficient allocation of limited supportive service resources (e.g., psychological services) to HIV-infected patients in greatest need.

61553 Adherence Support Services for Antiretroviral Therapy (ART) in Rwanda

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Background: Strict ART adherence is associated with better patient outcomes. Little is known about the availability and composition of adherence support amid HIV service scale-up in Africa.

Methods: During a study examining levels and predictors of ART adherence in Rwanda, availability of related services was assessed through interviews with clinic managers. Twenty clinics, stratified by funding (public n = 14; faith-based n = 6), were randomly selected from 113 providing ART since February 2007. Significant associations between services and site characteristics (e.g., type, location, enrolment) are presented below.

Results: Most clinics were rural (11/20), in primary health centers (HCs) (14/20) with median (range) cumulative adult enrollment of 850 (265-4,903) for care and 331 (152-2,065) for ART. Per national guidelines, all required a "treatment buddy" before ART initiation. Most provided outreach after missed visits (18/20), appointment cards (17/20), pill counts (17/20), or support groups (17/20). Fewer offered routine home visits (10/20), pill boxes (9/20), calendars/checklists (9/20), peer educators (PEs) (6/20), or ART-specific support groups (5/17). Outreach after missed appointments was more common among HCs (13/13) vs. secondary (5/6)/tertiary (0/1) facilities ($p = 0.03$). Rural (vs. urban) clinics were more likely to conduct outreach ≤3 (vs. >3) days after missed visits ($p = 0.01$). Most provided nutritional counseling (16/20) but rarely food support (4/20), income generation activities (2/20), or vitamins/minerals (1/20). All offered HIV status disclosure counseling. Only one screened/referred for substance abuse.

Conclusions: Coverage of important adherence support strategies was high among a random sample of Rwandan HIV clinics, though some services believed to impact adherence (e.g., PEs, food support, substance abuse screening) were rarely provided. To optimize adherence and reduce the risk of drug resistance, outreach should be initiated ≤3 days after missed visits.

61557 The Situated Information Motivation Behavioral Skills Model of HIV Care Initiation and Maintenance (sIMB-CIM): Preliminary Support for Characterizing Gaps in HIV Care

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Background: Gaps in HIV-care are associated with poorer health outcomes. Correlates of retention in HIV care have been examined in the literature, but explanatory models and their evaluation are comparatively lacking. In response, we provide an initial evaluation of a comprehensive model; the situated-Information-Motivation-Behavioral Skills model of Care Initiation and Maintenance (sIMB-CIM).

Methods: 130 HIV-positive adults (age 47, 49% male) in care completed semi-structured interviews including a small number of sIMB-CIM items for maintenance in care. The sIMB-CIM model's adequacy in characterizing gap/no-gap in HIV care was evaluated using logistic SEM (integration for estimating paths and comparative fit; WLSMV for model fit).

Results: Of 127 participants providing complete data, 40 (31%) reported a period of time when they failed to attend HIV care (average gap of 18 months), most were in the past five years. Validity of self-report was generally supported by analyses of a subset of individuals' clinic-use data. Maintenance-related motivation and behavioral-skills had univariate negative association with self-reported gap in care. Path models supported associations between maintenance-in-care related information and motivation, motivation and behavioral skills, and behavioral skills to not having reported a historical or recent gap. Behavioral skills mediated the relation between motivation and gap in care. Information did not covary significantly with behavioral skills or gap in care in this experienced sample, though retaining information in the model produced a better fit. Mediated model fit was good (ns Chi-square, CFI .99, RMSEA .04), demonstrating higher levels of behavioral skills increased odds of having had no-gap (OR = 2.0; [1.17 to 4.0]).

Conclusions: Results provide preliminary support for the role of information, motivation, and behavioral skills in characterizing HIV care utilization when situated for content specifically relevant to maintaining one's involvement in HIV care. Results are discussed in light of measurement limitations and in relations to theory development.

61589 Novel Approaches to HIV Medication Adherence: Development and Testing of a Touch-Screen Patient Adherence Tool with Targeted Adherence Counseling

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Background: Providers overestimate patient adherence to antiretroviral therapy (ART) and, even when they identify non-adherence, often lack skills to help patients overcome adherence barriers. We describe an intervention – and pilot results – that combines an adherence assessment tool, with feedback to patients and providers, and a telephone adherence care manager (ACM).

Method: The Medication for Chronic HIV: Education and Collaboration (MedCHEC) intervention starts with patients using computer assisted self-interviewing (CASI). CASI elicits patients' understanding of their ART, estimates of 30-day adherence, and reasons for missing doses, including underlying depression and substance use. Printed patient and provider reports summarize the data collected. A software algorithm identifies patients with adherence problems, who are referred to the ACM. Seventy-two patients taking ART completed the MedCHEC intervention.

Results: Provider judgment of 30-day adherence differed from patients' in 46% of cases. Notably we detected "missed non-adherence" in 22% of patients; it was more common in older (OR = 3.4) and more educated (OR = 9.0) patients. Additionally, 54% of patients made at least one error in reporting their medication dose instructions. As expected, providers overestimated patients' adherence. Patients attributed their non-adherence to forgetfulness, running out of pills, and interruptions to usual routine.

Conclusions: MedCHEC's pilot test identified patients, previously unidentified, who were non-adherent and/or making medication errors. It shows that incorporating MedCHEC into clinical workflow is feasible, and suggests that ACMs are likely to be behavior-change agents for patients identified by MedCHEC as needing assistance. This, combined with the mismatch between patient adherence behavior and provider assessment of adherence, supports further study to assess if MedCHEC achieves adherence-related process and outcome improvements.

ORAL ABSTRACTS

61629 A Novel Population Pharmacokinetic Adherence Measure (PPAM) among Three-Class Experienced Patients in the Darunavir Outcomes Study

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Introduction: We evaluated the relationship between a novel pharmacokinetic (PK) adherence measure with self-reported adherence and viral load (VL) suppression in treatment-experienced HIV-infected patients receiving darunavir (DRV)-containing ART.

Methods: The DRV Outcomes Study is a single-site prospective cohort study of three-class experienced patients changing regimens after 7/1/2006. At routine visits, an adherence self-report measure (ACTU-4) and blood sample collection for research purposes was completed. Plasma DRV levels were measured in each sample and characterized as to whether they fell within an expected DRV range (10-90%) based on population PK data. A population PK adherence measure (PPAM) was calculated for each study patient by dividing their number of samples with DRV in the expected range by their total samples (e.g., 80% if 4/5 samples in expected range). The relationship between both adherence measures (PPAM and self-report) and VL suppression (VL <400 c/mL) were evaluated with logistic regression.

Results: Among 33 patients with available samples (mean age 47±8 yrs, 67% white, 97% male, mean CD4+ T-cells 185±155 cells/mm^3, 39% VL >100,000 c/mL), 82% (n = 27) achieved 48-week VL ≤400 c/mL. Mean PPAM and self-reported adherence were 0.59±0.30 and 0.65±0.30 in those with VL <400 c/mL, and 0.40±0.41 and 0.50±0.18 among those with VL >400 c/mL. Higher PPAM (OR = 1.20 per 0.10; 95% CI = 0.90-1.61) and adherence self-report scores (OR = 1.21 per 0.10; 95% CI = 0.86-1.70) exhibited trends towards increased VL suppression. However, there was no significant correlation between adherence measures.

Conclusions: Behavioral (self-report) and biologic (PPAM) adherence measures were associated with a trend towards improved VL suppression in this exploratory pilot study. PPAM represents a novel PK adherence measure with comparable prognostic value to self-report. Future studies with larger sample sizes are needed to evaluate the correlation among these measures.

61685 Assessing the Information, Motivation and Behavioral Skills (IMB) Model of Antiretroviral Adherence among a Sample of Internet-Using People Living with HIV/AIDS (PLWHA)

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Background: The Information, Motivation, Behavioral Skills (IMB) model has been applied to a number of health domains, including the prevention and treatment of HIV. The aim of this study is to determine the extent to which this model can explain antiretroviral treatment (ART) adherence in a sample of Internet-using people living with HIV/AIDS (PLWHA) in the United States.

Methods: As part of a larger study to develop an online HIV medication adherence intervention, 312 PLWHA (Mdn age = 43; 84% male, 69% Caucasian, 73% gay) completed an online survey between July and November 2009. Participants completed socio-demographic items, antiretroviral adherence in the past 30 days, a modified IMB-AAQ measure, as well as measures of depression, life chaos, and substance use in the past 30 days. Participants were categorized as either having low (adherence <95% in the past 30 days; n = 164) or high (adherence >94% in the past 30 days; n = 148) adherence. Path analysis was used to assess the IMB model of ART adherence after adjusting for depression, life chaos, and substance use.

Results: The measurement model overall showed satisfactory fit (Chi-square = 403.19, df = 198, p <.001; CFI = .92; RMSEA = .058, 95% CI = .05, .06). As predicted, greater adherence information (beta[b] = .26, 95% CI = .14, .38), personal motivation (b = .19, 95% CI = .13, .25), and social motivation (b = .14, 95% CI = .06, .23) were significantly associated with greater behavioral skills, which, in turn, was significantly associated with higher adherence (b = 1.94, 95% CI = 1.40, 2.48). Unexpectedly, personal motivation had a significant negative independent association with adherence (b = -0.45, 95% CI = -0.77, -0.14).

Conclusions: Overall, the IMB model appears to be a useful predictive model of ART adherence in this sample of PLWHA. The negative independent association between personal motivation and adherence may reflect a group of PLWHA with high personal motivation who lack the behavioral skills to enact high adherence behaviors.

61795 Antiretroviral Therapy (ART) Adherence and HIV RNA (VL) Control as HIV Quality Measures in Kaiser Permanente (KP)

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Background: High ART adherence and maximal VL control are critical to achieving best outcomes for HIV+ patients. Measuring these outcomes as quality indicators on a system-wide basis has gained momentum in HIV care in the United States. We determined feasibility of such measurements in our system utilizing electronic clinical data.

Methods: KP is a large integrated healthcare system in eight states plus the District of Columbia (DC), providing HIV care to >19,000 HIV+ patients annually. Using electronic data only, we measured ART adherence in six of eight states plus DC (excluding Colorado and Hawaii) for all HIV+ patients active within KP for ≥9 months and on ART for ≥3 months. All six states plus DC provided data for 2007, while only three states provided data for 7/1/2005-6/30/2006 (California [CA], Oregon [OR], Georgia [GA]). Adherence was calculated using pharmacy refill data and included all ART medications the patient was taking. We captured VL data from laboratory databases. We determined the percentage of patients with ≥90% adherence and the percentage of patients with VL <75 copies/mL ("blq") ever and at last measurement.

Results: For 2005/2006, we reviewed 13,064 HIV+ records with 8,520 on ART and eligible for analysis. For 2007, we reviewed 16,037 records with 10,729 on ART and eligible. Median adherence was 92.8% (2005/2006) and 93.8% 2007. 58.2% had ≥90% adherence in 2005/2006and 61.8% in 2007 (all six states plus DC) and 63.6% for CA, OR, GA only in 2007. VL results showed 86.1% ever blq in 2005/2006 and 79.4% blq at last measure; for 2007 these were 88.8% ever and 84.2% last (all); 89.9%/85.5% for CA, OR, GA only in 2007. All comparisons between time periods for all measures presented (either all or just CA, OR, GA) was statistically significant (p <0.001 chi-square).

Conclusions: Quality measurement through electronic medical records is feasible beyond claims data. Quality improvement (QI) in adherence and viral control continues to improve. While we have high adherence and VL blq, data not shown indicate regional variation and QI projects need to be targeted locally.

61805 Adherence Performance in Health Facilities Providing Antiretroviral Therapy (ART) in Kenya – Pre-Intervention Assessment of Quality of Care

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Background: Weak health systems continue to be a barrier to antiretroviral therapy (ART) adherence in resource-limited settings. Many health facilities do not routinely measure their own validated adherence indicators, nor do they make use of such measurements when available. Quality improvement interventions are needed. The aim of this study was to collect data on patient attendance and adherence monitoring in selected facilities in Kenya and to explore barriers for improvement.

Methods: We randomly selected six facilities with a patient load of 100 to 500 from three provinces. A retrospective cohort design was used to assess adherence trends as measured by four core outcome variables related to adherence and clinic appointment-keeping. We collected data from 600 patient records and interviewed 15 health workers and 15 patients to qualitatively assess perceptions on adherence monitoring and barriers to adherence.

Results: The results showed that: a) 29% of patients attended their clinics after their appointment dates; b) the average percentage of days covered by ART dispensed was 80%; c) 20% of patients experienced a gap of 30 days or more in their treatment; and d) patients self-reported less than perfect adherence 7% of the time. Interviews indicated that the procedures and roles for adherence monitoring were not clearly defined, and that it was uncommon for clinics to make use of timely adherence monitoring information for operational management.

Conclusions: Routine monitoring of adherence indicators and tracking of clinic appointments are strategies that can be used to promote adherence to ART and prevent treatment failure, and thereby strengthen the health system.

ORAL ABSTRACTS

61841 Differences in Treatment Adherence, Illness Perceptions, and Beliefs About Medications in Co-Morbid HIV and Type 2 Diabetes Mellitus

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Background: Among HIV-infected individuals, morbidity and mortality from cardiovascular disease and related risk factors is increasing. Better medication adherence is associated with improved clinical outcomes for both HIV and type 2 diabetes but little is known about variations in adherence across conditions. We hypothesized that adherence is higher for antiretroviral than hypoglycemic medications and that illness perceptions and beliefs about medication differ across conditions. Specifically, we hypothesized that HIV is associated with greater negative consequences, treatment efficacy, and medications concerns.

Methods: Surveys were conducted with 54 participants prescribed medications for both HIV and diabetes. Adherence to antiretroviral and hypoglycemic medications was measured using a seven-day visual analog scale. Using validated questionnaires, we measured domains of illness perception (e.g., consequences and treatment efficacy) and beliefs about medications (i.e., necessity and concerns) for both HIV and diabetes. We analyzed adherence both continuously and dichotomized at 100%, and used paired t-tests and general linear models to examine differences in adherence and illness perceptions between HIV and diabetes.

Results: The sample was 52% female, 43% Black, and 33% Hispanic with a mean age of 53. Antiretroviral adherence was higher than hypoglycemic adherence (90% versus 85%; p = 0.007) and more participants were 100% adherent to antiretroviral than hypoglycemic agents (50% versus 39%; p = 0.013). Overall, 23% of those classified as adherent to antiretroviral were non-adherent to hypoglycemic agents. HIV was perceived as having more negative consequences than diabetes (p = 0.004) and antiretroviral were perceived as of greater necessity than hypoglycemic agents (p = 0.018). There were no differences in treatment efficacy or medication concerns.

Conclusions: Among people with HIV and diabetes adherence varies across conditions, and this may be partly related to differences in illness perceptions and beliefs about medications. Future research should examine the causes and clinical impact of differences in adherence, and the efficacy of adherence interventions across conditions.

61859 A Qualitative Study of the Barriers and Facilitators to Retention-in-Care among HIV-Positive Women in the Rural Southeastern United States: Implications for Targeted Interventions

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Background: Retention in HIV medical care has been recognized as critical for long-term favorable clinical outcomes among HIV-positive patients. However, relatively little is known about specific factors related to HIV medical care adherence among HIV-positive women in rural areas in the United States, where the epidemic is rapidly growing among minorities and women. The objective of the current study was to assess the barriers and facilitators to HIV clinic visit adherence among HIV-positive women in the rural Southeast of the United States through the use of focus groups.

Methods: Forty HIV-positive women were recruited from four outpatient clinics providing health care and social services to people living with HIV in 23 predominately rural counties located in the South of Alabama. Four focus group sessions were conducted ranging from 5-16 participants. Content analysis was used to analyze and interpret the data. Data coding and sorting was conducted by using QRS NVivo 8© software.

Results: Participants were predominately African American (37/40) ranging in age from 29 to 69 years (mean = 46.1 years). On average, participants reported living with HIV for a total of 8.8 years. Factors that impacted participants' ability to maintain clinic visits appointments included personal, contextual, and community/environmental factors, including: women's current health status, patient/provider relationships, family support, access to transportation, organizational infrastructure of the healthcare facility visited and perceived HIV stigma within their communities.

Conclusions: Findings from the current study highlight the myriad of retention-in-care barriers faced by HIV-positive women living in rural areas in the Southeastern United States. Innovative multilevel interventions that address these factors are sorely needed in order to increase long-term retention-in-care among HIV-positive women residing in rural areas.

61881 People with Intermediate Level of Adherence Taking a PI or an NNRTI Have Different Viro-Immunological Outcomes

Rita Murri (presenting), Antonella Cingolani, Andrea De Luca, Simona Di Giambenedetto, Giuseppe Marasca, Giuseppe De Matteis, MassimilianoFabbiani, Carmela Pinnetti, Enrica Tamburrini

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Objective: To evaluate differences in virological and immunological efficacy between protease inhibitor (PI)- and non-nucleoside reverse transcriptase inhibitor (NNRTI)- based regimens according to adherence levels.

Methods: Prospective, cohort (Ad-UCSC), monocenter study. A short questionnaire on adherence to combined antiretroviral therapy (cART) was longitudinally administered to any outpatient taking cART at Catholic University, Rome, Italy. Self-reported adherence was estimated on a 0-100 scale. Patients were stratified according to the self-reported adherence level (A <75, B between 75 and 90 and C >90). Virologic failure was defined if, at the moment of the survey, HIV RNA was >50 copies/ml. CD4 cell count and other epidemiological and clinical characteristics were also collected.

Results: At December 2009, 903 patients filled the questionnaire. 32.5% females, mean age 47 yrs (SD 8.5), IDU 20%, median log HIV RNA 1.7 copies/ml (IQR 1.7-1.7), median CD4 count 563 cells/mm^3 (IQR 405-745). 504 (57%) were taking a PI and 269 (29.7%) an NNRTI. Mean SelfAdher was 80 (SD 18). 26% were grouped in A, 39% in group B and 33% in group C. While for people in group A and C, no statistically significant differences were found in virological failure between people taking a PI or an NNRTI (group A: 21.3% for PI and 20.5% for NNRTI; p = 0.91; group C: 15.3% for PI and 9% for NNRTI; p = 0.13), in group B 18% people taking a PI had a virological failure compared to 6.6% for people taking an NNRTI (p = 0.007). Similarly, mean of CD4 cell count was not different in people of group A and C (group A: 500 cells/mm^3 [SD 254] for PI and 573 cells/mm^3 [SD 192] for NNRTI; p = 0.09; group C: 596 [SD 246] for PI and 636 [SD 232] for NNRTI; p = 0.19) but was different in group B (595 [289] for a PI and 714 [363] for an NNRTI; p = 0.002).

Conclusions: Differences in virological and immunological outcomes were found for people taking a PI or an NNRTI only within the intermediate strata of adherence (between 75 and 90).

61913 Using Antiretroviral Therapy (ART) Without Monitoring Viral Load in the United States

Ayse Akincigil (presenting), James Walkup, Cecilia Huang, Siegel Michele, Stephen Crystal

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Background: Highly active antiretroviral therapy (HAART) requires frequent laboratory monitoring for optimal outcomes. Preventing viral evolution of drug resistance requires suppressing viral replication to undetectable levels. Monitoring improves patient outcomes and is cost effective. Clinical guidelines for the use of antiretroviral agents in HIV infected adults and adolescents recommend monitoring of HIV viral load every 3-4 months.

Objective: Describe rates of viral load monitoring in a large privately insured population; explore factors that are associated with guideline consistent monitoring. Design: A retrospective, observational study of laboratory, pharmacy and other medical care claims submitted to private insurance companies between 2003 and 2007. Setting and Patients: Privately insured adults with HIV/AIDS who received antiretroviral therapy through a prescription drug benefit (N = 13,234). Patients were enrolled in over 80 different health plans provided by large employers throughout the United States.

Measure: Guideline consistent monitoring, operationalized as having no more than 150 days between laboratory claims for HIV-1-RNA testing.

Results: Only 28% of the patients achieved guideline consistent levels of laboratory monitoring. Significant variations were detected by region. Patient demographics were not significantly associated with monitoring.

Conclusion: Among privately insured individuals with HIV/AIDS, monitoring is suboptimal. These results suggest there are significant missed opportunities to improve outcomes and prevent drug resistance in this population. Further studies are necessary to understand patient, provider and health care system level causes of the lack of proper monitoring, and to identify and implement interventions for improvement.

62019 An Electronic-Monitoring Based Intervention Improves HIV Treatment Adherence

Marijn de Bruin (presenting)

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Background: Suboptimal adherence to HAART is an important cause of treatment failure and disease progression among HIV-infected patients. Evidence-based interventions that can be easily implemented in HIV-clinics are needed. This study investigated the effectiveness of an adherence intervention (AIMS) designed to fit HIV clinics' routine care procedures.

Methods: Through block randomization, consenting patients were allocated to the intervention or the control group. The study included two months baseline measurement, three months intervention, and four months follow-up. Adherence was measured objectively with electronic pill-bottle caps (MEMS caps) and viral load data were collected. HIV nurses delivered a minimal intervention (i.e., 'adherence sustaining') to patients scoring >95% timing adherence at baseline, and an intensive intervention to patients with <95% timing adherence ('adherence improving'). The control group received care as usual.

Results: 133 patients were included (67 control, 66 intervention), 60% had <95% adherence at baseline, and 87% (116/133) completed the trial. Intent-to-treat analyses showed that adherence improved significantly in the complete intervention sample. Subgroup analyses showed that this effect was caused by the participants scoring <95% at baseline (mean difference = 15.20%; p <.001). These effects remained stable during follow-up. The number of patients with an undetectable viral load increased in the intervention group compared to the control group (risk difference [95% CI] = -0.11 [-0.24, 0.01]; controlling for baseline viral load: OR = 2.96, p <.05). The treatment effects on viral load were mediated by the improvements in adherence.

Conclusions: The AIMS-intervention was effective and has the potential to become an integral part of routine clinical care for HIV-infected patients. Discussion will also focus on the continuation of this research in a multi-center cost-effectiveness trial in The Netherlands and the use of patient feedback from Medication Event Monitoring Devices in adherence interventions.

62045 Validity of Self-Report Measures in Assessing Antiretroviral Adherence of Newly Diagnosed HAART-Naïve HIV-Positive Patients

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Background: Few studies have compared the performance of self-report instruments to assess adherence to ART in naïve patients starting ART.

Methods: Of 184 patients in a prospective observational cohort study of newly diagnosed patients, 54 were given MEMS caps for their boosted protease inhibitor (PI) or non-nucleoside reverse transcriptase inhibitor (NNRTI). Every three months for up to 18 months, patients completed three self-report adherence instruments: a four-week visual analogue scale (VAS), the AACTG four-day recall instrument, and a one-month qualitative single item from Lu et al. Participants had a median (IQR) of 445 (292-490) days of MEMS monitoring. Electronic pharmacy records provided HIV medication refill dates. The Fisher Z-transformation of Pearson correlation coefficients was used to improve comparisons of correlation estimates between adherence measures.

Results: Of 46 patients with MEMS data, 80% were male; 52% Hispanic, 39% African American, 9% Caucasian; 52% had heterosexual sex as their HIV risk factor, and 39% were men who have sex with men (MSM). Median (IQR) HIV viral load was 263,330 copies/mL (141,254-587,489 copies/mL). Median (IQR) adherence was 89.2% (78.3-99.1) by MEMS, 92.9% (80.7-98.2) by pharmacy, 98.3% (92.0-99.8) by VAS, 100% (93.8-100) by AACTG, and 95.0% (75.0-100.0) by qualitative single item. The correlation coefficient (CC) of MEMS with pharmacy was 0.30 (p <0.01). The CC of VAS with MEMS was 0.40 (p <0.01) and with pharmacy was 0.35 (p <0.01). For the AACTG, the CC with MEMS was 0.28 (p <0.01) and with pharmacy was 0.37 (p <0.01). For the qualitative single item, the CC with MEMS was 0.22 (p <0.01) and with pharmacy was 0.28 (p <0.01). The VAS-MEMS CC did not change over time, and in Spanish speakers, the VAS-MEMS CC was 0.41 (p <0.01).

Conclusions: The VAS performed as well as the AACTG and a qualitative single item, compared to MEMS and pharmacy data; it also performed well in Spanish-speaking patients. A VAS can assess adherence in newly diagnosed patients starting ART.

62047 Comparison of Ritonavir-Boosted Atazanavir and Unboosted Atazanavir in HIV Patients on a Stable HAART Regimen Containing Tenofovir

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Background: A clinically significant drug-drug interaction occurs between tenofovir (TDF) and atazanavir (ATV), which results in decreased ATV levels. As such, ATV must be boosted with ritonavir (RTV) in patients on a TDF-containing regimen. However, many patients are intolerant of RTV due to side effects. As a result, some medical providers have used a FDA non-approved combination of unboosted ATV with TDF to increase adherence. Anecdotal reports suggest that this dosing of ATV with TDF usually results in undetectable viral loads.

Methods: This retrospective study compares 50 subjects on regimens containing TDF and unboosted ATV (400mg and 600mg) to case-matched subjects on regimens containing TDF and boosted ATV (300mg ATV and 100mg RTV). Subjects are excluded based on age <18 years old, HAART regimens not containing both TDF and ATV, recent changes to their ART regimen, and creatinine clearance <50mL/min. Effectiveness is compared using changes in viral loads and CD4 counts. Adherence rates are determined using pharmacy refill data (which has previously been shown to reflect adherence at our clinic). Bilirubin, serum creatinine, and diagnoses of diarrhea while on the regimens are also compared.

Results: Data collection for this residency project is currently ongoing. We will compare the effectiveness, adherence, and tolerability between the two arms. Adherence rates will be measured as the total number of days supply of medication picked up, divided by the total number of days provided. Tolerability will be compared using changes in bilirubin levels and creatinine clearance, and diagnoses of diarrhea.

Conclusions: We anticipate showing that unboosted ATV TDF regimens are effective at suppressing HIV and will offer an alternative for patients who are intolerant of RTV.

62049 Statewide Analysis of Engagement and Transitions in HIV Care for a Newly HIV-Diagnosed Cohort

Edward Gardner[1] (presenting), Elaine Daniloff[2], Daniel Reirden[3], Mark Thrun[1], Arthur Davidson[1], Ralph Wilmoth[2], Steven Johnson[4], Elizabeth Connick4, William Burman[1]

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Background: Poor engagement in HIV care is associated with poor treatment outcomes. The contribution of changes in HIV care site to poor engagement is unknown. Prior studies of care engagement have been limited to single healthcare systems.

Methods: Retrospective review of engagement in care among persons with an initial HIV diagnosis at Denver Health, 2005-2007. Data sources included clinical data from three public HIV care providers and two clinical trials groups. For statewide evaluation we utilized mandated Colorado state laboratory reporting databases for CD4 and HIV-RNA. Linkage to care required having follow-up CD4 count or HIV-RNA, and was deemed successful if it occurred within 180 days of diagnosis. Full retention in care required no gaps in visits or labs lasting >180 days. Loss to follow-up was defined as having no visits or labs during the last six months of follow-up: July through December 2009.

Results: 351 individuals were included; 8% were women, 30% Hispanic, 15% Black, and 74% men who have sex with men (MSM). Median baseline CD4 count and HIV-RNA were 408 cells/mm^3 and 4.6 log10 copies/ml, respectively. Initial linkage occurred in 303 (86%) individuals, median time to linkage was 36 days (interquartile range 19-80 days); 255 (73%) linked within 180 days. Over 2.7 years median follow-up, 102 (29%) individuals had no gaps in care >180 days. At the end of 2009, 198 (56%) individuals remained in care. Transitions between health care providers were documented in 131 (37%) individuals, including 42 (12%) who were incarcerated. Out of state care was documented in 48 (14%) individuals. Overall, only 58 (17%) of 351 individuals had successful linkage to care, retention in care, and were not lost to follow-up.

Conclusions: Using data sources that allowed tracking of patients across multiple care systems, we assessed linkage and retention in a cohort of patients with newly-diagnosed HIV. Gaps in HIV care and transitions in HIV care were common. Detailed multisystem analyses are needed to further understand HIV care dynamics and their impact on treatment outcomes.

ORAL ABSTRACTS

62059 Challenges in Using Mobile Phones for Collection of Antiretroviral Therapy Adherence Data in a Resource-Limited Setting

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Background: Frequent antiretroviral therapy adherence monitoring could detect incomplete adherence before viral rebound develops, potentially allowing for timely intervention to prevent treatment failure. Mobile phone technologies are becoming ubiquitous in developing settings, making frequent, brief adherence interviews possible; however, feasibility and acceptability are unknown.

Methods: Interactive voice response (IVR) and short message service (SMS) text messaging were used to collect adherence data from 19 caregivers of HIV-infected Ugandan children. IVR calls or SMS quantifying missed doses were sent in the local language weekly over four weeks. IVR calls were repeated up to nine times and SMS were repeated up to three times each week. Qualitative interviews were conducted to assess impressions of the technologies. IVR call and SMS completion rates were analyzed using descriptive statistics and logistic regression to explore potential predictors. Qualitative interviews were systematically examined for themes.

Results: Median caregiver age was 36.0 (interquartile range 28.8-39.8) years, 90% were female, 79% completed more than primary school, and 65% were literate. Forty-eight weekly IVR call cycles were initiated: six (12.5%) were successfully completed, 36 (75%) were unsuccessful, and six were incomplete (i.e., busy signal, network congestion, non-answer). The most common reasons for unsuccessful calls were problems with the personal identification number (PIN; 46%) and inappropriate responses to the research question (29%). Twenty-four SMS cycles were initiated; 18 (76%) of which were not answered (i.e. no response to the PIN prompt). Sex, primary school education, and literacy did not predict successful IVR calls and SMS, although increasing age trended toward significance (odds ratio 0.9; p = 0.16). Two qualitative themes emerged: 1) poor understanding of proper responses to prompts, and 2) inadequate training.

Conclusions: Despite much promise for mobile phone technology in resource-limited settings, individual level collection of healthcare data presents challenges. Further research is needed for effective training and incentive methods.

62061 Real Time Adherence Monitoring for HIV Antiretroviral Therapy in a Developing World Setting

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Background: Current adherence monitoring methods typically detect missed doses long after they occur. Real-time, wireless monitoring strategies for antiretroviral therapy (ART) may provide novel opportunities to proactively prevent virologic rebound and treatment failure. Because cellular network coverage is becoming ubiquitous, the technical infrastructure now exists for real-time adherence monitoring in developing settings.

Methods: Wisepill is a wireless pill container that transmits a cellular signal to a web-based server when opened. We piloted Wisepill in ten HIV-infected adults in rural Uganda who had been participating in a prospective ART adherence cohort for at least one year. Adherence levels were measured for two three-month periods by Wisepill, unannounced pill count, and self-report; adherence values were truncated at 100%. Acceptability was assessed by questionnaire.

Results: Median age was 37.3 (interquartile range 34.1-46.0) years, 80% were female, 90% took ART twice daily, and 80% took a three-drug combination pill. Signal transmission problems decreased from 30 in the first three months to one in the second three months after increasing battery life and upgrading the signal forwarder. In the second three-month period, mean adherence levels were 90% by Wisepill, 99% by unannounced pill count, and 100% by self-report, as well as 87% by medication event monitoring system (MEMS) during the three months prior to this pilot. Three interruptions of unclear cause occurred in the first three months and two occurred in the second three months. Four individuals developed transient, low-level viremia unassociated with interruptions. All participants described Wisepill as "easy/very easy" or "convenient/very convenient" and felt the monitoring system was "ok" or "liked it."

Discussion: After overcoming technical challenges, real-time adherence monitoring is feasible in resource-limited settings. Interruptions of unclear cause may reflect missed doses. Further studies are needed to understand causes of adherence interruptions, their association with viral load, and scalability of this approach.

62095 A Four-Item Measure of Motivation to Adhere that Predicts MEMS Adherence Over 48 Weeks

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Background: Clinical practice would benefit from being able to determine which patients require intensive antiretroviral therapy (ART) adherence support. However, brief screening tools that can predict patient adherence over time are lacking. We examined the predictive validity of a novel measure of motivation to adhere in Project MOTIV8, a multi-site randomized clinical trial of novel behavioral interventions for ART adherence.

Methods: Drawing on motivational counseling process research of predictors of clinical outcome, a 4-item scale of motivation for ART adherence was developed. Patients (N = 203; 74% male, 57% African American, average age 41 years) rated how strongly they Need, Had Good Reasons, Are Ready, and/or Are Committed to always stick to their medication schedule using an 11-point scale ("Not at All" to "Extremely"). Adherence was assessed with MEMS. Percentage of doses taken and percentage of doses taken on time were based on total possible doses for the 30-day period after each evaluation session (i.e., 12-, 24-, 36-, 48-week).

Results: The motivation scale demonstrated good internal consistency (Cronbach's alpha = .841) and several forms of validity. A mixed model revealed that motivation scores were predictive of MEMS adherence (both doses taken and doses taken on time) during the 30-day period following (p = .0001) evaluation visits. Additional models revealed that motivation ratings remained a significant predictor (all p's <.005) of adherence over 48 weeks independent of, and with a similar magnitude of effect as, self-efficacy.

Conclusions: This brief self-report measure has the potential to be a useful tool to identify patients who will likely experience adherence difficulties. Its ability to independently predict adherence above self-efficacy, which is historically one of the strongest behavioral predictors, suggests that it might be an ideal measure to determine when additional treatment support is warranted.

62097 Outcomes of Project MOTIV8: A RCT of Novel Behavioral Interventions for ART Adherence

Kathy Goggin[1] (presenting), Mary Gerkovich[1], Karen Williams[1], Julie Banderas[1], Delwyn Catley[1], Jannette Berkley-Patton[1], Andrea Bradley-Ewing[1], Nikki Thomson[1], Tara Carruth[2], Kirsten Kakolewski[1], David Martinez[1], Robin Liston[1], Megan Pinkston-Camp[3], Kristine Clark[1], James Stanford[2], Sally Neville[4], Vinutha Kumar[5], David Bamberger[2], Lisa Clough[1]

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Background: Although there have been studies of combined Motivational Interviewing and cognitive-behavioral techniques and studies of modified Directly Observed Therapy (mDOT) to promote antiretroviral therapy (ART) adherence, no studies have assessed the combined effect of MI-based CBT enhanced counseling and mDOT approaches.

Methods: This study reports the findings of Project MOTIV8, a three-armed, multi-site RCT of Motivational Interviewing-based Cognitive Behavioral Therapy (MI-CBT) counseling with modified Directly Observed Therapy (MI-CBT/mDOT) vs. MI-CBT counseling alone vs. standard care (SC). The ART adherence of 204 HIV-infected community clinic patient volunteers was assessed at baseline, 12, 24, 36, and 48 weeks. The primary outcome was MEMs adherence and secondary outcome was viral load.

Results: Mixed effects Poisson regression models were fitted to test the effect of intervention group on MEMs adherence defined as Percent Taken and Percent Taken on Time over 48 weeks. There was a statistically significant main effect of intervention for Percent Taken (IRR 1.18, 95% CI, 1.01-1.38, p = .032) and Percent Taken on Time (IRR 1.25, 95% CI, 1.05-1.49, p = .012) favoring the MI-CBT/mDOT group as compared to SC. Treatment failed to significantly predict viral load, but adherence mediated the relationship between treatment group and the likelihood of having an undetectable viral load. Treatment dose effects were also examined. Combined Dose (number of completed counseling sessions, mDOT visits) was a significant predictor of Percent Taken and Percent Taken on Time (p's = .0001), with adherence increasing by 0.3% (95% CI, 1.1-1.5) and 0.4% (95% CI, 1.2-1.6), respectively for each percentage increase in amount of intervention dose.

Conclusions: Results suggest a combined MI-based CBT counseling with mDOT intervention can be more effective than standard care in increasing MEMs adherence and thereby favorably impacting viral load. Treatment dose effects suggest that frequent and sustained contact is beneficial for enhancing adherence.

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62127 The Power of Narratives: Using Video to Build Community for Non-Urban Patients with HIV

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Background: Mobile technologies provide opportunities to promote engagement in HIV care. Rural populations living with HIV often report isolation that may be exacerbated by the "digital divide." One strategy to diminish patients' isolation is to provide access to video-taped narratives presented by persons living with HIV.

Methods: The Ryan White Clinic at the University of Virginia serves approximately 700 patients. A convenience sample of patients was surveyed during clinic hours. Participants completed a pre-survey and were given an Apple IPOD Touch to watch videos of persons discussing HIV-related topics down-loaded from thepositiveproject.org. Participants were instructed to watch at least two of the videos. At the end of the intervention, participants completed a post survey with questions regarding their reactions to the videos.

Results: Thirty participants completed the survey, 18 (60%) were male, 25 (83%) were over age 40, and 21 (70%) reported living in a small town or a more rural environment. The mean number of videos watched was 10.7. Twenty-two (73%) participants endorsed wanting to watch more videos. The surveys did not identify a significant change in participant perception related to HIV engagement in care or self-disclosure/stigma. However, many of the participants reported that the videos "hit home" and that they enjoyed hearing others speak about issues related to living with HIV.

Conclusions: This pilot project found that using video to reach a non-urban HIV-infected population was feasible and acceptable. Although pre and post surveys did not demonstrate a change in attitudes related to engagement in care and self-disclosure, the videos chosen by participants were heterogeneous and not always focused on these issues. Further research should evaluate the technology's ability to facilitate patient-to-patient HIV health messages as well as the effect of viewing more specific video messaging for longer periods of time on attitudes, behaviors and outcomes related to HIV.

62133 Bipolar Medication Use and Adherence to Antiretroviral Therapy among Patients with HIV/AIDS and Bipolar Disorder

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Objective: To describe relationships between bipolar medication treatment and adherence to antiretroviral therapy (ART) in patients diagnosed with bipolar disorder and HIV.

Methods: A retrospective longitudinal study of eight-state Medicaid claims data (2001-2004), focusing on ART adherence among adults diagnosed with bipolar disorder and HIV. A person-month analysis was performed that controlled for the non-independence of repeated observations within individuals and several background characteristics.

Results: We observed 1,505 patients for an average of 33.4 months. ART prescriptions were filled in 81% of these months and were significantly more common in months covered by a prescription for bipolar medication (84.3% vs. 74.9%, P <.0001). Months with current supply of bipolar medicines were associated with 61% higher odds of ART use.

Conclusions: Active psychiatric care may improve ART adherence among patients with bipolar disorder and HIV.

62137 Patterns and Influencing Factors of Adherence to ART in HIV-Infected Children in Rural Uganda

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Background: Adherence to antiretroviral therapy (ART) among children in developing settings is poorly understood. Hypothesized influences include social-structural factors, child characteristics, and caregiver characteristics.

Methods: We are conducting a prospective observational study of HIV-infected children taking ART in Mbarara, Uganda. Adherence is measured monthly by caregiver report (three-day recall; 30-day visual analog scale [VAS]), medication event monitoring system (MEMS), and unannounced pill count/liquid weights (UPC). Adherence values were censored at 100%. We used t-tests to compare continuous variables and logistic regression to assess predictors of >90% MEMS adherence. We examined baseline social-structural factors (child care, travel to clinic, food insecurity, HIV disclosure to community, stigma), child characteristics (age, sex, enrollment CD4, ART experience, HIV disclosure to child), and caregiver characteristics (relationship to child, alcohol use, HIV status, ART use, education, employment, literacy).

Results: Of 119 children recruited, 47% are female, mean age is 6.6 (+/- 2.3 standard deviation) years, and 15% started ART at enrollment. Median enrollment CD4 count was 1,089 cells/mm3 (interquartile range [IQR] 650-1,501), 57% of children taking ART for >3 months had <400 HIV RNA copies/ml, and baseline ART backbone was nevirapine in 78% and efavirenz in 22%. Over the first six months, median adherence was 100% (IQR 100-100%) by three-day recall, 100% (IQR 93-100%) by 30-day VAS, 93% (IQR 82-97%) by MEMS, and 95% (IQR 89-99%) by UPC (MEMS versus UPC p <0.0001). Median intra-subject standard deviation for MEMS adherence was 9.4% (IQR 6.9-15.1%). Only travel time to clinic of >30 minutes was significantly associated with >90% MEMS adherence (OR 2.9, 95% confidence interval, 1.4-6.2, p = 0.004).

Conclusions: Median ART adherence among children in rural Uganda is sufficient to achieve viral suppression with currently prescribed regimens; however, variation in adherence suggests sporadic treatment interruptions may increase risk for viral rebound. Further analysis is needed to assess factors influencing adherence.

62145 Evaluating Integration of an HIV Medication Adherence Computer-Assisted Self-Administered Interview (CASI) with Routine Patient Care

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Introduction: We evaluated the integration of a computerized clinical assessment into routine patient care using multiple methods including stakeholder interviews, workflow analysis, and software usability testing using the think-aloud protocol.

Description: A web-based CASI was developed to assess patient-reported symptoms and behaviors, including HIV medication adherence. Providers use assessment results during clinic visits to inform care related to adherence, depression, and other domains. Data are also used for clinical research. The CASI is deployed on securely-networked touch-screen tablet computers presented to patients prior to seeing their providers. Study staff initially recruited patients opportunistically and administered the CASI in the clinic lobby. Clinic staff redesigned clinic workflow and space to allow co-location of research staff, activities, and equipment in patient care areas. Patient scheduling practices were also modified so that patients were scheduled for pre-appointment CASI sessions and roomed in advance of their provider encounters.

Lessons Learned: Ongoing observational workflow studies, provider and staff interviews, and patient interviews that incorporate software usability testing protocols indicated that the CASI clinical and adherence assessment web application was well accepted by patients; the CASI response reports and suicidal ideation alerts are valued by providers; and the CASI assessment activities have been successfully integrated with and are minimally disruptive to routine care processes. Ongoing challenges include reducing variability in CASI completion times; optimizing the timing and presentation of CASI response reports to providers in advance of patient encounters; and integrating the CASI with the clinic's electronic medical record and patient web portal systems.

Recommendations: Self-reported HIV medication adherence data collection and reporting at the point of care using CASI and tablet computer technologies is feasible and valued by patients, providers, and staff. Investigators should participate in study sites' local process improvement initiatives to optimize integration of adherence research and improvement innovations with routine patient care.

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62157 Group Counseling Achieves High Adherence to Antiretroviral Therapy: Results of the CAPRISA 058 Randomized Controlled Trial Comparing Group Versus Individualized Adherence Counseling Strategies in Durban, South Africa

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Background: Optimal adherence to antiretroviral therapy (ART) is essential for therapeutic success. The purpose of this trial was to assess an enhanced adherence support program (E-ASP) compared to standard adherence counseling (SAC) on virological suppression in a resource-constrained setting.

Methods: Between August 2007 and August 2009 we conducted a randomized controlled trial in ART-naïve patients in Durban, South Africa. Control group patients received three group-counseling sessions prior to ART initiation, while the intervention group patients received two of the group-counseling sessions plus five one-on-one motivational interviewing sessions post-initiation. Ad hoc counseling support was provided as indicated in both arms. Outcome was proportion of all patients (excluding deaths prior to three months) with suppressed viral load (<400 copies/ml) at nine months after ART initiation.

Results: 149 SAC patients were similar at baseline to 148 E-ASP patients (mean age 36.4 vs. 35.3 years, 38.5% vs. 44.4% male, median CD4 124 [IQR 60-252] vs. 123 [IQR 54-220] cells/mm[3]). All SAC participants received group counseling, and 92.4% of S-ASP patients in the study until six months received at least four of the individual counseling sessions. The arms did not differ in terms of loss to follow-up, relocation, withdrawal, defaulting or death (Fisher's exact p = 0.431). Viral load suppression was achieved in 85.3% of SAC patients and 81.1% of E-ASP (OR 0.74, CI95% 0.37 - 1.45, p = 0.379) with no evidence of enhanced adherence from the E-ASP. In multivariate logistic regression analysis, only baseline CD4 count >50 cells/mm[3] was associated with virological suppression (OR 2.37, CI95% 1.03-5.46, p = 0.042).

Conclusions: Standard adherence counseling provided routinely in groups is as good as the more intensive individual counseling. These data provide reassurance that group counseling as conducted in this programme is not inferior and should be widely promoted as the preferred standard for adherence support in ART services.

62165 HIV-Infected Children Who Default Care in Western Jamaica

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Background: We describe a cohort of HIV-infected Jamaican children who returned after defaulting care.

Methods: A retrospective study was conducted on HIV-infected children at the Cornwall Regional Hospital from March 2004-March 2009. We reviewed the demographic, clinical and laboratory outcomes of defaulters and compared them with non defaulters using chi-square analysis and student's t-test. Default was defined as failure to keep more than 2 scheduled appointments.

Results: Among 66 HIV infected children identified at median age 36 months (range 1-107; IQR 14, 62), 38 (55 %) were male, and 18 % received nevirapine prophylaxis. There were seven (11%) children with delayed therapy, 46 (70%) on first-line, 11 (16%), on second-line and two (3%) on salvage therapy. Time to second-line was 27.2± 13.8 months (95% CI 18.4, 35.9). Of 56 children on HAART, 42 (75%) had immune recovery with median CD4+ percent of 30% (range 5-59%, IQR 24, 43) before and 53% (range 29 -57 %, IQR 37, 57) after therapy. Two children died on second-line therapy. Sixteen children (23%) defaulted. Twelve (75%) returned for care after 18.7 ± 11 months (95% CI 12, 25) after social worker intervention. Six (50%) were immune class 1, three were immune class 2 and 3 were immune class 3 upon return to care. Six (50%) had been on HAART for a median of 15 months (range 3-36) before default and all are now on second-line therapy. Four who were restarted on first-line therapy had immune failure and the two started on second-line had immune recovery and undetectable viral loads. Two of six defaulters not previously on highly active antiretroviral therapy (HAART) met criteria to start therapy and have an undetectable viral load. Characteristics between defaulters and non-defaulters were similar. Non-defaulters were more likely to achieve immune recovery and undetectable viral loads (p <0.0001)

Conclusions: Aggressive detection of defaulters maximizes the benefit of HAART and limit treatment failure in settings with limited treatment options and unavailable resistance testing.

62173 Feasibility and Effectiveness of a Mobile Antiretroviral Pharmacy in Rural Southwestern Uganda

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Background: In rural Southwestern Uganda, HIV-infected patients must travel long distances every month to attend HIV care and pick-up refills of antiretroviral therapy (ART). Reliable transportation is both expensive and difficult to access.

Methods: We employed a quasi-experimental study design to evaluate a Mobile ART Pharmacy and HIV Care (MAP-HC) at two district-level hospitals in rural Southwestern Uganda. We hypothesized that MAP-HC would result in: 1) improved HIV care attendance; 2) improved ART adherence; 3) increased probability of suppression of HIV replication; 4) improved patient satisfaction with HIV care received; 5) decrease patient waiting room time; 6) improved health-care worker (HCW) satisfaction with delivery of HIV care; and 7) decrease patient expenditure on HIV care. Both qualitative and quantitative methods were used.

Results: Our intervention improved HIV care attendance and eased patient burden in picking up refills of ART. There was decreased patient waiting time and decreased patient expenditure on HIV care. Both HCWs and patients expressed high-level satisfaction with MAP-HC. Convenience and savings in transportation costs were major reasons for patient satisfaction. At an average monthly cost of 0.88 USD per patient, MAP-HC resulted in an average monthly net savings of 10.70 USD per patient.

Conclusions: In rural Southwestern Uganda, where patients live long distances away from healthcare facilities, MAP-HC is a feasible, effective and satisfactory intervention to deliver HIV care and antiretroviral therapy.

62191 Barriers and Facilitators to Prevention Pill Use in iPrEx: Capturing the Experience of MSM PrEP Study Participants in the United States

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Background: Adherence to study regimen and the accurate reporting of pill-use are critical to the success of pre-exposure prophylaxis (PrEP) trials. We conducted qualitative research to explore the context of pill-taking and reporting of missed pills among MSM in iPrEx, a study evaluating the efficacy of daily oral FTC/TDF for HIV prevention.

Methods: A sample of iPrEx participants enrolled in San Francisco, California, was interviewed in focus groups (FGs) or in-depth semi-structured interviews (IDIs). Topics explored included participants' experiences with the study; barriers/facilitators to pill-use; reliability of self-reported adherence; and strategies to promote adherence. Interviews were transcribed, coded, and analyzed for themes.

Results: We conducted 22 IDIs and three FGs (49 MSM) in November and December 2009 (median age 40; 61% white, 18% Latino, 12% African American, 8% Asian/Pacific-Islander). Participants described iPrEx staff as personable, helpful, and non-judgmental and appreciated health-monitoring provided by staff. For some, this trust in staff developed over time. Participants joined the study for altruistic and/or economic reasons. Common barriers to pill-use included changes in routine; co-occurring illnesses; stress; stigma of being seen with pills, particularly in men of color; and side effects. Common facilitators included establishing a routine; taking the study pill with another daily medication; and morning dosing. Several participants found the seven-day pillbox helpful in promoting adherence to the daily regimen. Barriers to accurate reporting included feeling embarrassed, perfectionism, and fear of removal from study; facilitators included understanding the importance of accurate data, feeling "safe," and non-judgmental support from staff.

Conclusions: Establishing a routine facilitated daily pill-use, while trust and nonjudgmental support promoted accurate reporting. PrEP studies should consider counseling and assessment strategies that promote a safe, non-judgmental environment. Client-centered adherence counseling may help achieve this aim while working with participants to establish a routine, maintain privacy, and feel part of a larger prevention effort.

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62199 Centralization of HIV Services in HIV+ African-American and Hispanic Youth Improves Retention in Care

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Background: African-American and Hispanic HIV+ youth are one of the highest risk groups for not remaining in care. We examined differences in retention in HIV care among African-American and Hispanic youth who presented for primary HIV care at Thomas Street Health Center during eras of decentralized youth services, centralized youth services, and centralized youth services with enhanced case-management.

Methods: HIV+ youth between 13-23 years who entered HIV care between 1/1/2002 and 8/31/2008 were identified using administrative data. Based on date of entry into care, patients were divided into three service eras: decentralized, centralized, and centralized with enhanced case-management. During the decentralized era (1/2002-2/2004), no youth-specific services were available. Youth services in the centralized era (3/2004-3/2007) included a multi-disciplinary clinic staffed by adolescent care providers and youth case-manager. The youth program was enhanced in 4/2007 to provide intensive case-management using motivational interviewing to improve self-efficacy and increase healthcare navigation skills. Group activities were added as a venue for education and to build support networks. Demographic, clinical, and attendance data for the subsequent 12 months were collected. Retention in care was measured with visit constancy, i.e., the number of quarter-years with at least one medical visit during follow-up.

Results: 174 youth (decentralized: n = 36; centralized: n = 90; enhanced centralized: n = 48) entered care. 87% were 18-23 years and 60% male. No significant differences in baseline CD4 <200 cells/mm^3 were observed (decentralized = 20%; centralized = 28%; enhanced centralized = 17%; p = 0.29). Visit constancy improved by era: 31% in the decentralized era had good constancy compared to 57% in the centralized era and 65% in the enhanced centralized era (p <0.0057). Adjusting for patient factors, good constancy remained significantly higher in the enhanced centralized (OR = 2.8; 95% CI 1.04-7.38) era.

Conclusions: Centralizing youth-specific care and expanding youth-specific services are powerful health services delivery tools to increase retention in care among HIV+ youth.

62213 A CBPR-Designed Adherence Intervention Using Multimedia and Social Support: A Promising Tool for Resource-Poor Settings

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Background: While antiretroviral treatment (ART) is increasingly accessible in resource-poor settings, the lack of professional adherence counselors contributes to poor clinical outcomes for many patients. Using community-based participatory research (CBPR) methodology, a six-session intervention, "Masivukeni" ("Let's Wake Up!" in Xhosa), was developed as a multimedia-based adherence tool for lay counselors to engage patients and support partners in care. Pilot-testing is underway in South Africa.

Methods: Poor adherers (based on pharmacy refill records) are recruited and undergo a psychosocial/psychiatric/neurocognitive assessment prior to intervention or standard care randomization. Intervention arm participants identify a treatment support partner in session one; participant plus support partner undergo five sessions together. Participants' adherence is assessed at post-intervention and three-month follow-up, as well as their most recent biological markers. The intervention tool facilitates counselors' use of interactive multimedia activities (e.g., enhanced text, imagery, animations, audio, and video) that teach how HIV and ART affect health and problem-solving skills to overcome adherence barriers.

Results: Counselors have embraced the intervention tool and are able to deliver the intervention in a manner that is engaging, culturally relevant, and standardized. Fifty-three participants (and support partners) have been randomized (target N = 60). Preliminary results show >90% retention rate for participants after completion of session one. The most frequent adherence barriers identified and addressed include alcohol abuse, stigma and inadequate support, poor understanding of treatment benefits, and clinic waiting time. Increasing support and learning to address barriers through problem solving are effective strategies for improving adherence. Additional analyses will be presented.

Conclusions: Utilizing CBPR to develop culturally-salient intervention content has fostered ownership and commitment to "Masivukeni" on the part of clinic staff, lay counselors, and study participants. Multimedia technology is a useful tool to empower and enable lay counselors to deliver an enhanced adherence intervention with fidelity and ease in resource-constrained settings.

62215 ART Adherence Changes Among Patients in Community Substance Use Treatment: A Preliminary Analysis from MACH14

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Background: Considerable evidence suggests that current illicit substance use is associated with worse antiretroviral therapy (ART) adherence; however whether illicit substance abuse (SA) treatment improves adherence is unknown.

Methods: Data from the Multi-site Adherence Collaboration on HIV (MACH 14) were used for this longitudinal analysis of ART adherence. Altogether, N = 287 individuals with illicit SA and post-baseline SA treatment enrollment data were classified as in treatment (current or recent) or not in treatment. Weekly percent of prescribed ART doses taken was calculated using microelectronic monitoring for the four weeks before and after assessment of treatment enrollment. Illicit drug use, measured at the same time as treatment enrollment, was coded as use or no use of an illicit drug other than THC. Starting values and change over time in adherence for patients in and out of treatment were compared.

Results: Controlling for differences in substance abuse, estimated mean adherence at week 1 was not significantly different for individuals in, and not in, SA treatment (intercept = .74 and .83, respectively; p = .19). For individuals using an illicit drug, the intercept adherence estimate was significantly lower than for those not using drugs (intercept differential = -.38; p <.0001). Both patients in, and not in, treatment adhered less over time. Being in treatment was associated with a faster rate of decline in adherence (slope differential = .02, p = .03) A preliminary quadratic model indicates that change in adherence is not linear.

Conclusions: After controlling for differences in illicit drug use, individuals in substance use treatment decreased their adherence to antiretroviral medication at a significantly faster rate over eight weeks than those not in treatment. In additional analyses we will assess whether other covariates account for this finding. Results will address the clinically important question of how best to improve adherence among patients with current substance abuse.

62221 Heterogeneity Among Studies in Rates of Declines of Antiretroviral Therapy (ART) Adherence over Time: Findings from MACH14

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Introduction: Adherence to antiretroviral therapy (ART) tends to decline over time, but there are few large studies that have used objective measures of adherence to quantify the rate or describe the correlates of the declines.

Methods: This study reports on 12 months of Electronic Drug Monitoring (EDM) data from the Multi-site Adherence Collaboration in HIV Study (MACH14), a collaboration between 14 sites (16 studies); five of these studies were observational, and 11 were interventions. To examine the natural history of ART adherence, these analyses only use data from the observational studies or from the control arms of intervention studies (N = 1,221). Data from 15 of the 16 studies could be used for this analysis. Adherence was calculated as the percent of prescribed doses taken of the monitored medication(s). A summary adherence measure was created for each study for each month of follow-up. To understand whether adherence changed over time we used repeated measures linear mixed effects models, with an interaction between month and study that indicated the change in adherence over time for each individual study. We tested age, gender, race/ethnicity, education, and antiretroviral regimen as potential confounders.

Results: In unadjusted models that pooled data across studies, adherence declined 1.3% per month (p <0.001) with additional analyses revealing considerable between-study heterogeneity. In adjusted models, four of 15 studies showed significant declines in adherence compared with the reference study (p <0.05). Race/ethnicity was the only covariate that was significantly associated with adherence. Compared with Whites, African Americans had worse adherence (8 points, p <0.05) and Hispanics were not significantly different.

Conclusions: Pooling across studies with very different study populations and study designs can hide important between-study heterogeneity in declines in ART adherence over time. Covariate adjustments reduce but do not eliminate this heterogeneity, and efforts to better understand the sources of this heterogeneity are needed.

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62223 Are Once-Daily Regimens Really the Magic Bullet?

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Background: Even with simpler and better tolerated regimens, adherence will continue to be one of the crucial issues in successful clinical management of individuals receiving antiretroviral therapy (ART).

Methods: Naïve patients initiating ART between January 2003 and May 2009 who answered at ≥1 adherence questionnaire before November 2009 were included. Outcomes were viral rebound and mortality. Exposure was time-varying self-reported non-adherence to ART (missing 0, 1, 2, or >2 doses) in the previous four weeks. Marginal structural models were used to assess the causal effect of missed doses on outcome. Baseline covariates were gender, age, education, ethnicity, AIDS, physician experience, and time since HIV diagnosis. Time varying covariates were intravenous drug use, CD4 cell count, class of antiretroviral drug, depression, stable partnership, and living alone. Results were stratified by dosing frequency.

Results: During the study period, 2410 eligible individuals initiated ART and were followed for a median of 2.7 years (IQR: 1.4-4.4) and contributed 79,893 person-months of observation. Almost 30% reported missing ≥1 dose of ART, 191 (7.9%) experienced viral rebound and 65 died (2.6%). In marginal structural Cox models in those starting once daily regimens, any missed doses significantly increased the risk of viral rebound (1 dose: hazard ratio (HR) 5.46, 95% confidence interval (CI): 1.69-17.67; 2 doses: HR 6.87, 95% CI: 1.07-44.01; >2 doses: HR 9.26, 95% CI: 2.26-37.99). Missing >2 doses of ART significantly increased the risk of death in those on a once-daily regimen (HR 2.90, 95% CI: 1.09-7.72). No effect of missing doses of ART and viral rebound or death could be detected in those on twice daily regimens.

Conclusions: Missing doses of ART after initiating a once-daily regimen resulted in significant increases in the risk of poor outcomes. Clinicians should carefully consider the consequences of non-adherence which choosing a regimen for patients starting ART.

62225 A "Honeymoon Effect" When Initiating the Use of Electronic Drug Monitoring (EDM) in Clinical Studies: Findings from MACH14

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Introduction: Little research examines whether being given an Electronic Drug Monitoring (EDM) device as part of a study is itself an intervention that acts to improve observed adherence.

Methods: This study reports on 12 months of Electronic Drug Monitoring (EDM) data from the Multi-site Adherence Collaboration in HIV Study (MACH14), a collaboration between 14 sites (16 studies); five of these studies were observational, and 11 were interventions. To evaluate whether EDM use, independent of other study interventions, affects adherence, these analyses only use data from the observational studies or from the control arms of intervention studies (N = 1,221). Data from 15 of the 16 studies could be used for this analysis. Adherence was calculated as the number of openings divided by the doses prescribed of the monitored medications. We constructed repeated measures linear mixed effects models of adherence that included a variable for month (from one to 12) and dummy variable for study. We examined the slope of the change in EDM adherence per month, in models that included all 12 months with models that included months 2-12, 3-12, 4-12, and 5-12.

Results: Median adherence, pooled across all studies in months 1-5 was 89%, 80%, 79%, 82%, and 79%, respectively. The slope (% change) of the adherence decline changes from -0.0134 to -0.0113 (16%), to -0.010 (8%), to -0.0097 (6%), to -0.0094 (3%) in models that use data from months 1-12, 2-12, 3-12, 4-12, and 5-12, respectively. That is, dropping month 1 from the analysis changes the decline in adherence by 16%, from 1.34% to 1.13% per month. Later declines are smaller.

Conclusions: These data suggest that there is a small but clinically important "bump" in adherence associated with the first month of EDM use. Investigators should be aware of this potential effect, and take account of it in both study designs and analytic plans.

62253 Developing an Innovative Approach to Adherence Counseling and Assessment in a Pre-Exposure Prophylaxis (PrEP) Trial: Next Step Counseling and Neutral Assessment in the iPrEx Study

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Introduction: Adherence to study-drug in pre-exposure prophylaxis (PrEP) trials, and the accurate assessment of it, has a clear history of relevance in these trials, but has only recently become well-recognized as essential. With this growing recognition is the need to develop intervention and methodological approaches to promote PrEP use and its accurate assessment. In recognition of these needs within the iPrEx study (a blinded trial of daily oral emtricitabine [FTC]/tenofovir [TDF]), we developed and implemented a two-arm approach, guided by formative research and, where appropriate, antiretroviral therapy (ART) adherence literature.

Description: We developed: 1) Next-Step Counseling to support pill-taking and 2) Neutral Assessment to promote accurate adherence assessments. We disseminated this approach via workshop-trainings to international study teams. Next-Step Counseling is an eight-step client-centered discussion that explores contextual facilitators and barriers to PrEP use, identifies one's next-step in making pill-taking easier, and engages participants in selecting a strategy to try before the next visit. The Neutral Assessment approach relies heavily on skills to maintain a neutral, nonjudgmental stance and the separation of counseling from assessment. Each approach is based on an Information, Motivation, Behavioral Skills model adapted for PrEP-use and missed-pill reporting.

Lessons Learned: Pre-/post-assessments of attitudes and confidence in conducting pill-taking counseling and assessment suggested a positive impact of participation in the training workshops. Subsequent semi-structured interviews with counselors in the Andes who had implemented the approach in over 2000 intervention visits also provided support for the approach and identified areas for further improvements and training. Assessors also provided feedback on the implementation of the Neutral Assessment approach.

Recommendations: As iPrEx sites continue to roll-out the two-arm approach it is clear that entire team buy-in is necessary and can be achieved through full team involvement in implementation support. Participant acceptability and impact of the approach on adherence will be evaluated at study-end.

62255 Is Race/Ethnicity Associated with ART Adherence? Findings from the MACH14 Study

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Background: In prior research, race/ethnicity has been inconsistently associated with antiretroviral therapy (ART). Many studies, however, have been limited by small samples, subjective adherence measures, and failure to adequate control for the possible confounded effects of key sociodemographic indicators. Determining whether race is associated with adherence is an important first step in decreasing racial disparities in HIV outcomes and in identifying potential targets for intervention.

Methods: Analyses employed data pooled from 15 adherence-focused clinical trials in the NIMH-funded Multi-site Adherence Collaboration on HIV (MACH14). Adherence, measured by percent of prescribed doses taken, was computed as a single point estimate of electronically monitored adherence data from the first 12 (monthly) waves of data in each study. The analytic sample included the 1899 participants who self-identified as African American (n = 960), Latino (n = 273), or White (n = 666).

Results: Analysis of variance (ANOVA) indicated unadjusted adherence data differed by race, with Latinos (unadjusted M/SD = .63/.29) adhering worse than African Americans (.67/.29) and Whites (.70/.29) (p <0.001). A subsequent analysis of covariance (ANCOVA) controlling for the socio-demographic correlates of gender, age, education, and income indicated adherence remained significantly different by race (p <0.01): Latinos (Least Square Mean/SE = .65/.02, 95% CI [0.61,0.69]), African Americans (.65/.01, [0.63, 0.68]), and Whites (.70/.01, [0.68, 0.73]). There were independent effects for age (p = 0.012) and education (p = 0.0001).

Conclusions: Compared to White individuals, African Americans and Latinos appear to be at great risk for nonadherence – even after controlling for key socio-economic indicators. Findings suggest the need to be particularly diligent in assessing adherence among African Americans and Latinos and providing culturally relevant assistance to promote optimal adherence. Further MACH14 analyses will examine other variables that might explain the residual variance in adherence, such as substance use, time on ART, and ART regimen.

62271 Validating Five Questions on Antiretroviral Non-Adherence in a Decentralized Community-Based ART Programme in Rural South Africa

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Background: Accurately measuring HIV antiretroviral therapy (ART) adherence and biologic markers are critical for identifying patients needing treatment support. While patient self-report is easiest for screening non-adherence, studies validating adherence questions are rare in sub-Saharan Africa. We validate the performances of five different adherence questions in detecting treatment failure in a public-sector, decentralized ART programme in rural South Africa.

Methods: Five different questions were administered during a nine-month prospective study at KwaMsane clinic, KwaZulu-Natal: seven-day recall of missed doses, seven-day recall of doses missed by ≥ 2 hours, Likert rating-scale of adherence, 30-day visual analogue scale (proportion of pills missed). These questions were validated against patient-record extracted CD4 counts and viral load (VL) within 45-days of adherence self-reports. Immunologic failure was defined as CD4 <100 cells/mm^3 after six months of ART and virologic failure as VL >4.0-log$_{10}$ after six months of ART or VL >2.6-log$_{10}$ after previously undetectable VL.

Results: At study entry, 272 individuals were on ART for a median 12 months (interquartile range (IQR) 6.5-23). Of the 165 with ≥ 1 time-matched CD4 counts, 12 (7%) had immunologic failure and of 137 with 1 time-matched VL, 34 (25%) had virologic failure. The Likert rating-scale performed best with sensitivity/specificity of 100%/5%, 42%/55%, and 25%/95% for immunologic failure when individuals reported either less than "excellent," "very good," or "good" adherence, respectively. The remaining four questions had sensitivities <17%, even when the least strict cut-offs defined non-adherence.

Conclusion: Adherence measures require high sensitivity to identify treatment failures related to imperfect adherence, and high specificity to target interventions without wasting resources. Of five common adherence measures used in resource-poor settings, even the best-performing question was inadequate, irrespective of cut-off. The remaining questions had unacceptably low sensitivity, including seven-day recall of missed doses routinely used by public-sector ART programmes in KwaZulu-Natal – well performing measures are urgently required.

62289 Implementation and Evaluation of a Pharmacy-Based Medication Therapy Management Program to Improve Provider Communication and Patient Adherence to Therapy

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Background: Implementation and evaluation of a pharmacy-based Medication Therapy Management Program involving more than 170 HIV-infected patients enrolled in a local AIDS Drug Assistance Program (ADAP) is described.

Methods: The program was based on results obtained from a retrospective needs assessment of patient records to determine medication pick-up rates from the ADAP Pharmacy, percentage of patients with undetectable viral loads, percentage of patients receiving adequate opportunistic therapy management and patient perceptions about adherence. In addition, an extensive consultation program was developed to communicate patient findings to Providers and to facilitate therapeutic interventions.

Results: The number of undetectable viral loads increased dramatically. In addition, proper opportunistic therapy management was realized in 100% of patients. Although medication pick-up rates from the pharmacy improved dramatically, educational efforts were intensified to seek out those patients seemingly "lost" to therapy. An extensive interview and educational program was developed to identify causes for poor adherence and a referral system was developed to assist in removing obstacles that prevent adherence to therapy. At present, 30 such patients have been identified and the major reasons for nonadherence were found to be financial and mental health issues (anxiety and depression).

Conclusions: The referral program has been successful and continues to be evaluated to determine if removal of obstacles will improve viral control long term. The provider consultation program has been successful in communicating patient concerns to providers and assisting in therapeutic management of these patients.

63513 What Makes People Living with HIV/AIDS (PLWHA) Refrain from Seeking Timely and Proper Care in Health Care Institutions in Port Harcourt, Nigeria?

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Background: Despite an increasing awareness of and publicity given to HIV/AIDS, many problems have continued, especially for people living with HIV/AIDS (PLWHA) in developing countries such as Nigeria. These include the problems that prevent PLWHA from utilizing care in health care institutions leading to suboptimal effectiveness of available treatment.

Aim: The aim of this study is to describe why people living with HIV/AIDS (PLWHA) refrain from seeking timely and proper care in health care institutions in Port-Harcourt, Nigeria, while using the explanatory model of the role of stigma in care-seeking behavior of PLWHA to derive predictions.

Methods: In-depth semi-structured interviews, lasting 60-90 minutes, were conducted with 100 People (health care professionals, the general public and PLWHA) in Port Harcourt, Nigeria. One focus group discussion was held. Interviews were tape-recorded and transcribed verbatim. The Nvivo seven-computer package was used to manage the data. We compared data from the general public, society, and healthcare providers. In addition, we used the explanatory model to analyze the findings.

Results: Using the explanatory model for interpretation, we identified determining and moderating factors affecting PLWHA seeking care. Knowledge, beliefs, self-efficacy were important factors. In addition, poverty, age, policy, gender and religion were found to be important in coping with HIV/AIDS and making care choices which affect utilization of health care institutions.

Conclusions: In conclusion, the results presented confirm the hypothesis that certain variables in addition to stigma prevent PLWHA from seeking care. The study identifies variables associated with care seeking choices. The explanatory model relating stigma to these processes is useful in structuring the problems associated with seeking care. Policy implications are discussed and are recommended.

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