

**Prevention Adherence in the DAIDS HIV Clinical Trials Networks:
Lessons Learned from Treatment Adherence and Future Directions
Meeting Report**

Key messages

- HANC/NIMH co-organized a workshop on adherence in DAIDS clinical trials in July 2008.
- Partial and non-adherence to intervention appears to diminish effect sizes and obscure user and product failures.
- Common challenges to adherence in network trials were identified.
- Recommendations for improving adherence measurement and counseling are offered.

Introduction

This report describes the proceedings of a joint workshop organized by HIV/AIDS Network Coordination (HANC) and the National Institute of Mental Health (NIMH) entitled, “Prevention Adherence in the DAIDS HIV Clinical Trials Networks”, which was held in Bethesda, Maryland on July 15 – 16, 2008. Prevention adherence refers to the extent to which research participants’ behaviors conform to the specific protocols of clinical trials of integrated behavioral and biomedical interventions to reduce the risk of HIV acquisition or transmission. Special emphasis will be placed on such behaviors as taking investigational agents as recommended and for the duration of the protocol (e.g., PrEP, HSV-2 suppressive therapy), reducing HIV transmission risks (e.g., partner reduction, condom use), and adopting or maintaining other healthful behaviors (e.g., reducing alcohol or substance use, taking oral contraceptives). The meeting was borne out of a growing appreciation that partial and non-adherence to treatment and prevention protocols may diminish observed effect sizes and obscure the delineation of user and product failures in network clinical trials.

The meeting objectives were to: 1) facilitate cross-network communication and collaboration, 2) review the relevant adherence literature, 3) explore lessons for improving adherence measurement and counseling, and 4) identify a prevention adherence research agenda for network trials. Following is a brief summary of the invited presentations, discussion, and recommendations for optimizing adherence in the DAIDS clinical trials networks. Meeting attendees included 40 – 45 investigators from the AIDS Clinical Trials Group (ACTG), Adolescent Medicine Trials Network (ATN), HIV Prevention Trials Network (HPTN), HIV Vaccine Trials Network (HVTN), International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT), International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), Microbicide Trials Network (MTN), Family Health International (FHI), and Statistical Center for HIV/AIDS Research and Prevention (SCHARP).

Following introductory comments by **Dianne Rausch** and **Andrew Forsyth** (NIMH), the meeting opened with a presentation by **Norma Ware** (Harvard University), who discussed a multilevel model of HIV treatment adherence in sub-Saharan African communities characterized by economic scarcity. Her data are among the first to explore beyond individual-level analyses to show that HIV treatment adherence is highly valued in these settings and is motivated in part by a desire to reduce the burden of disease on family, friends, providers, and society. The talk expanded on the range of variables thought to influence adherence,

including the preservation of social capital and the role of social networks on individuals' health behaviors.

Adherence Challenges in the Networks

In a session moderated by **Sten Vermund** (HPTN/Vanderbilt), investigators were invited to offer observations about intervention adherence measurement and counseling in order to identify common and unique challenges among their respective networks. Toward this end, **Nancy Reynolds** (ACTG/Yale) discussed the use of multimodal assessment methods that include medication event monitoring system (MEMS) caps, pill counts, pharmacy refills, and the ACTG self-administered questionnaire. The ACTG's focus on assembling evidence for the efficacy of new regimens often proceeds without equal consideration of intervention adherence and it struggles to balance the need for simple, brief measures with more intensive assessments that may yield more precise estimates of behavior. A revised ACTG questionnaire is under consideration but the process has raised questions about cross-dataset comparisons, impacts on analytic plans, capturing intra-individual variability and duration of adherence behaviors, potential risk of confounding parent trials with adherence sub-studies, and the need for both adherence and efficacy trials.

Sharon Mannheimer (INSIGHT) shared similar concerns about the requirements and limitations of adherence assessment and the need for standardization across protocols, noting that INSIGHT has often relied on a 7-day self-report instrument yielding categorical data known to correlate with biomarkers (e.g., CD4 counts). INSIGHT has also encountered challenges using adherence data to inform "when to start" treatment trials and to analyze primary endpoints. As principal investigator for the HPTN, **Sten Vermund** described a number of network protocols that incorporate adherence centrally (e.g., 039, 043, 052, 058). It is a priority in the HPTN to utilize design elements that enable investigators to distinguish user- and product failures.

Beryl Koblin (HVTN) identified a number of circumstances leading to the discontinuation of product in HIV vaccine clinical trials, including the occurrence of pregnancies due to non-adherence to contraceptives or failures to report relevant medical histories at baseline. In addition, the network has considered the need to enhance its counseling protocols in order to avert the emergence of risk compensation over time due to exaggerated beliefs of the protection conferred by experimental products. **Ann Coletti** (MTN/FHI) reiterated others' concerns about the collection and use of adherence data, but added that successful integration of behavioral and social science expertise into protocol teams has served the MTN well toward this end. An ongoing challenge for the network is providing clear, consistent, and comprehensive adherence counseling for range of prevention products used concurrently (e.g., microbicides, condoms, and another contraceptives). Other challenges include addressing the interpersonal and social context that affect microbicide adherence (e.g., partner resistance, reproductive planning), as well as the need to develop standardized counseling protocols that remain fresh and relevant in longitudinal trials.

Isa Fernandes (ATN) discussed steps taken by the ATN to employ core adherence assessment items across protocols, and acknowledged the challenge of collecting and analyzing variability in adherence over time and circumstance. The salience of adherence messages delivered in the context of meaningful patient-provider relationships is an important factor affecting adolescent behavior and the successful transition of health care responsibilities from parents to independent adolescents during later developmental stages remains understudied. **Pat Flynn** (IMPAACT) raised drug palatability and dosing as challenges in adherence research with HIV-infected children. The transfer of responsibility for medication adherence from caretakers to

adolescents is an obstacle, one that is complicated further by the risk of HIV disclosure for those taking antiretroviral regimens. In addition to ethical questions about the acceptable limits of non-adherence in pediatric samples, it is imperative for IMPAACT investigators to provide counseling on sexual transmission risks and substance use in increasingly autonomous adolescents.

General discussion covered a range of topics, including the potential to bias results toward the null if enrollment criteria result disproportionately in adherent samples. Similarly, studies may limit the generalizability of findings to higher risk samples that are non-adherent to a number of related health behaviors. In addition to individual-level factors, upstream influences on adherence were examined, including interpersonal, social, and structural influences on adherence. Among these are staff and provider influences on participant behavior. Methodological considerations, such as run-in trials, were explored as a way to screen and enroll persons reporting greater difficulties with established prevention modalities (e.g., condoms, partner reduction). Attendees also considered ways to enhance counseling and informed consent procedures to ensure accurate reporting and to clarify for participants that partial or non-adherence may not necessarily result in expulsion from trials.

State of the Science of Adherence Assessment

The first series of presentations was moderated by **Margaret Chesney** (UMD – SOM) and highlighted key lessons learned from HIV treatment adherence assessment. **Ira Wilson** (Harvard) discussed the cognitive processes involved in reporting adherence, the difference between behavioral recall vs. estimation in retrospective behavioral self-reports, and recent findings using rough estimates of ARV adherence show greater correspondence to MEMS data than did adherence data collected using frequencies or percentages. Wilson highlighted the benefits of using 30-day retrospective reporting periods, the importance of a multi-modal strategy for behavioral assessment, and the need to advance the science of self-report. **David Bangsberg** (Harvard) reviewed the strengths, weaknesses, and future directions of electronic monitoring and other tools for adherence assessment, including the use of hair assays as a biomarker of medication exposure and the new XHALE breath monitoring device. He noted that these methods may detect absence of drug, but they offer few insights into individual patterns of adherence that effect intra-individual variability in drug levels. He also reminded attendees that non-adherence is the common for health-related behaviors of all sorts and that assessing non-adherence directly may be more informative than assessing adherence. **Seth Kalichman** (UCT Storrs) discussed the adaptation and implementation of telephone-based, pill count methodology in an adherence study in Atlanta, Georgia. Unannounced home visits were conducted within minutes of each telephone-based assessment and provided compelling evidence of concurrent validity. The results have direct implications for use in international and other settings in which unannounced home visits are infeasible due to resource limitations. **Nancy Padian** (RTI) examined adherence assessments across a range of biomedical strategies to curb the spread of HIV, including microbicides, and discussed the strength of evidence needed to demonstrate product efficacy and effectiveness at the individual and population levels, respectively.

Ensuing discussion raised key questions about whether or how to utilize trial adherence data in real time to improve counseling protocols, address participants' therapeutic or other misconceptions, or emphasize the importance of adherence in efficacy trials. Accessing these data expeditiously and making them available to site staff raises several operational and methodological challenges. Concerns about the potential for reducing variability in adherence behavior because of improved counseling protocols highlight the need to distinguish the goal of demonstrating efficacy of a product versus the efficacy of an

intervention to improve adherence (see Chesney, 2006). Attendees discussed the need for multi-method assessment strategies such as self-reported adherence, MEMS caps, plasma blood levels, or hair assays to detect exposure to product.

State of the Science of Adherence Counseling

The second series of presentations was moderated by **Thomas Coates** (UCLA) and highlighted advances in the science of adherence counseling. **Jane Simoni** (University of Washington) discussed her recent meta-analysis on adherence to antiretrovirals, noting that methodologically rigorous trials have demonstrated significant improvements in self-reported adherence and achievement of undetectable viral loads. The study identified a range of correlates associated with non-adherence, including characteristics of patients, provider-patient relationship, treatment regimen, and contextual factors. **Bill Fisher** (University of Western Ontario) provided a review of the Information-Motivation-Behavioral Change (IMB) model and its application to risk behavior change and adherence to microbicides and antiretrovirals across a range of samples (e.g., MSM, minority youth). The evidence shows that brief interventions can be efficacious in facilitating behavior change but that greater attention is needed to risk compensation and factors that influence differentially the initiation and maintenance of behavior change. Fisher commented briefly on contributors to suboptimal oral contraceptive adherence, including environmental and personal factors (e.g., age, marital status), and cited evidence of risk compensation in reported associations between the initiation of oral contraceptives, nonuse of barrier methods, and an increased risk of sexually transmitted infections in studies of young Canadian women. **Nancy Reynolds** (Yale) reviewed her findings from a short-term, telephone-based intervention with significant improvements in medication adherence at 12-month follow-up that were credited to a person-centered approach tailored to patients' daily lives and adherence-related cognitions. **Claude Mellins** (Columbia) discussed her research on perinatally-infected youth who are aging into developmental stages characterized in part by sexual risk taking, drug use, psychiatric disorders, and social pressures to conform. She noted the need for new evidence-based interventions that address individual and contextual challenges during these developmental transitions and offered recommendations that included addressing mental health, family stresses, and developmental needs using multi-faceted, systemic approaches with a focus on long-term outcomes.

In the general discussion, attendees acknowledged the unique challenges associated with enhancing adherence for the purpose of preventing HIV infection as compared to treatment adherence. Several attendees noted that partial and non-adherence behaviors generally are common to health behavior and that it needs to be anticipated and planned for in the design of HIV clinical trials. Some attendees questioned whether further improvements in adherence counseling and assessment were possible, advocating instead for focusing on developing and testing higher efficacy biomedical prevention strategies that can withstand effects from suboptimal adherence. Unfortunately, even the most efficacious pregnancy and STI/HIV prevention strategies are vulnerable to attenuated effectiveness due to suboptimal adherence. Others noted that greater attention to the science and practice of dissemination is indicated, given that a sufficient body of literature has accumulated attesting to the capacity to affect behavior change. Additional questions were raised about best strategies for incorporating in adherence data into the provision of counseling, which may entail the development of novel approaches to monitor counselor behavior and participant adherence, and adjust counseling messages accordingly (cf., Celum's PARTNERS study).

Clarifying the Prevention Adherence Science Agenda

Two breakout sessions ran concurrently that sought to clarify the science agenda for adherence measurement and counseling in the context of the DAIDS HIV clinical trials networks. In the **Adherence Measurement** group, meeting attendees discussed the need to identify applicable lessons from treatment adherence that may be applied to improving assessment of prevention adherence, paying careful attention relevant factors to each domain. The importance of integrating reliable and valid measures of behaviors was emphasized, particularly in light of recent biomedical trials with null findings that may be attributable in part to imperfect adherence. Attendees also discussed the need for experimental manipulation checks that document exposure to intervention, the need for a multi-method approach for measuring target behaviors, and the importance of careful examination the determinants of key behavioral endpoints (e.g., substance use, partner resistance, and social norms). Also, there is a need for innovative approaches that permit the comparison of subjective (e.g., self-reported adherence) and objective measures (e.g., hair assays, genetic analyses of semen exposure, blood levels) that are optimized for clinical trial settings. In a similar vein, attendees suggested the development of innovative, technological solutions to improving the assessment of intra-individual variability in adherence behaviors that may affect study endpoints. Broader availability of mobile and smart phone technology in developing country contexts, as well as other innovations in the technology sector, may offer drastic improvements retention, tracking, behavioral assessment, and prevention counseling. Finally, greater attention to potential barriers to adherence was suggested, with perceptions of treatment group assignment, side effects, and substance use suggested as important determinants of partial or non-adherence to regimen or risk reduction counseling.

A concurrent breakout session focused on the burgeoning scientific agenda for **Prevention Counseling** and endorsed the view that careful consideration of adherence measurement and counseling should be a central component of network supported trials. It reiterated the importance of being able to distinguish user- and product-failures, as well as the potential for quality behavioral data to shed important light on null findings. Attendees also discussed the potential for conducting adherence pre-screening and intensive assessments (e.g., cognitive interviews, exit interviews) with subsets of participants, noting that together these additional steps may help to recruit those most likely to benefit from new prevention technologies, minimize confusion about prevention messages, emphasize the need for honest and accurate reporting of imperfect adherence, and elucidate facilitators of and barriers to adherence, including individual-, dyadic-, social-, and structural factors. The role of well-trained study counselors was discussed at length and included such suggestions as improving quality assurance for initial and ongoing training; use of case studies, blogs, staff meetings, and other tools for training purposes; and taking better account of lessons learned by other protocol teams. Toward these ends, Fuchs and colleagues' risk reduction counseling curriculum may be an important model for counselor training for other networks. Methods for monitoring adherence in real-time were also explored as an opportunity to intervene early in the face of poor adherence, particularly if product efficacy – rather than improving adherence, per se – is the primary goal. Broad discussion ensued about the need to include manipulation checks and to ensure that sound behavioral and social science is incorporated appropriately into network-supported protocols, as determined by the DAIDS Prevention Science Review Committee (PSRC). Finally, several attendees highlighted the importance of integrating behavioral expertise early into the protocol development process, and of attending to structural issues in networks that impede better quality adherence assessment and intervention (e.g., time, resources, and priorities).

Future Directions

The final session, moderated by **Ken Mayer** (Brown/Fenway Community Health), provided a forum for the discussion of future directions for prevention adherence measurement and counseling in the HIV clinical trials networks. These included:

NIH-level

- Enlist support from NIAID and co-sponsoring partners for improving adherence research within networks. Utilize HANC to facilitate cross-network and cross-institute dialogue about adherence, managing adherence working groups, and organizing sessions on adherence in future network meetings. NIMH & HANC will work to identify participants who should be part of the dialogue – either on the Steering Committee in any working groups going forward (statisticians, other IC representatives).
- Funding for improved adherence science. Explore funding requirements to support preliminary, follow-up, and ancillary adherence research relevant to parent trials. Identify which networks face the greatest need and review CTU awards processes to permit preliminary research prior to trial initiation.
- Prevention Science Review Committee procedures. Examine PSRC procedures for evidence that behavioral science is integrated appropriately into relevant network studies and to ensure the presence of behavioral expertise on PSRC when appropriate. Identify the systemic barriers to the incorporation of appropriate adherence measures and expertise.

Network Level

- Establish a Cross-Network Working Group for Network Investigators. The establishment of a working group would facilitate ongoing cross-network communication and collaboration on adherence research within the networks, and facilitate progress toward permanent products such as white papers, manuscripts, meeting or workshop planning, semi-standardized measures, as well as other joint projects appearing below. Networks should consider collaborating with Fuchs et al. on a trans-network risk reduction curriculum.
- Incorporate Experimental Manipulation Checks into Network Trials. Adherence data might be better utilized to demonstrate that experimental manipulations worked as intended – e.g., whether prevention counseling improves adherence to regimens for the duration of protocols, use of microbicides when condoms are not, or reduces exposure to cofactors that increase HIV transmission risk (See Watson-Jones' [2008] use of random subset of urine aliquots to confirm acyclovir adherence). Doing so may help to distinguish user- and product-failures
- Conduct Targeted Reviews. Conduct targeted literature reviews on adherence behaviors for key groups to better inform new protocols (e.g. commissioning a full analysis of how adolescents adhere to ARVs, contraception, and other prevention measures).
- Create a Measurement Repository. Establish a repository of adherence and other measures that can be shared across networks. Consideration of standardizing core elements of select measures may permit tailoring to individual need while retaining the capacity to conduct cross-protocol comparisons. Conduct a systemic inventory of the adherence measures being used in ongoing trials/what has been done in various contexts and create a repository of adherence measures and tools. This may inform the implementation of a multimethod approach to adherence assessment that may help to triangulate behaviors using subjective and objective measures. .
- Adherence Sessions at Network Annual Meetings. Invite networks' adherence experts to conduct sessions at annual meetings to discuss new developments and their implications for network science, take stock of lessons from related domains, provide new and ongoing adherence counseling training, elicit community working group input on adherence measurement and counseling, etc.
- Real-time adherence data to inform trials. Develop procedures to permit adherence data to be used in real time to improve protocol implementation related to adherence measurement and counseling.

- Enlist technological solutions. Consider technological advances that may be deployed to improve adherence counseling (e.g., cell phone) and measurement (e.g., electronic data capture, breath and hair assays).

In summary, adherence remains at the margins of many trials supported by the DAIDS clinical trials networks, although significant progress was reported in integrating behavioral science expertise into protocol teams. Ongoing tension remains between the need for brief, screening tools and more comprehensive and resource intensive assessment strategies capable of providing precise estimates of adherence. Utilizing behavioral data in primary analyses remains a challenge, even though their potential explanatory value for fleshing out null findings is increasingly apparent. There remains considerable variability in the extent to which networks anticipate and remediate partial or non-adherence and other unintended events (e.g., risk compensation, contradictory prevention messages). More fundamentally, investigators recognized that imperfect adherence is the norm in health behavior, and that the field would do well to anticipate it and to plan accordingly, particularly in trials that seek to demonstrate the efficacy of biomedical strategies to curb HIV transmission.

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Send questions or comments to: Andrew D. Forsyth, Ph.D., National Institute of Mental Health. E-mail: af183p@nih.gov.

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PARTICIPANT CONTACT INFORMATION:

Albert Liu

Director, HIV Prevention Intervention Studies
San Francisco Department of Public Health
(415) 554-9104
Albert.Liu@sfdph.org

Alissa Johnson

HANC
Program Manager
Office of HIV/AIDS Network Coordination
(206) 667-1719
ajohns@fhcrc.org

Andrew Forsyth

NIMH
Chief, Primary HIV Prevention & Behavior Change Program,
Center for Mental Health Research on AIDS
National Institute of Mental Health
(301) 443-8403
aforsyth@mail.nih.gov

Anne Coletti

MTN
Senior Scientist
Family Health International
(781) 874-1208
AColetti@fhi.org

Ariane Van Der Straten

MTN
Senior Research Scientist
RTI International
(415) 848-1324
ariane@rti.org

Beryl Koblin

HPTN/HVTN

Head, Laboratory of Infectious Disease Prevention
Member, Lindsley F. Kimball Research Institute
New York Blood Center
(212) 570-3105
bkoblin@nybloodcenter.org

Betsy Tolley

FHI/MTN
Senior Scientist, Behavioral and Biomedical Research
Family Health International
(919) 544-7040 ext 334
btolley@fhi.org

Carl Dieffenbach

NIAID
National Institute of Allergy and Infectious Diseases
(301) 496-9112
cdd@nih.gov

Chris Gordon

NIMH
Branch Chief,
Secondary HIV Prevention and Translational Research
National Institute of Mental Health
(301) 443-1613
cgordon1@mail.nih.gov

Christie Villa

HANC
Training & Evaluation Program Coordinator
Office of HIV/AIDS Network Coordination
(206) 667-4811
cvilla@fhcrc.org

Claude Ann Mellins

PHACS
HIV Center for Clinical and Behavioral Studies,



New York State Psychiatric Institute
(212) 543-5383
cam14@columbia.edu

Connie Celum

ACTG
Professor, Global Health and Medicine
Adjunct Professor, Epidemiology,
University of Washington
(206) 520-3800
ccelum@u.washington.edu

David Bangsberg

MGH
Harvard University
(617) 495-8222
DBangsberg@partners.org

David Burns

NIH
Chief, Prevention Research Branch
Program Officer HPTN Core Leadership Grant
National Institutes of Health
(301) 435-8896
burnsda@niaid.nih.gov

Dianne Rausch

NIMH
Deputy Director, Center for Mental Health Research on AIDS
National Institute of Mental Health
(301) 443 6100
drausch@mail.nih.gov, dr89b@nih.gov

Ed Gardner

INSIGHT, ACTG
Denver Public Health
Assistant Professor of Medicine in Infectious Diseases
University of Colorado at Denver
(303) 602-8740
edward.gardner@dhha.org

Ellen Stover

NIMH
Director, Center for Mental Health Research on AIDS

Director, Div. of Mental Disorders, Behavioral Research, and
AIDS National Institute of Mental Health
(301) 443-6100
estover@mail.nih.gov

Ira Wilson

Lifespan/Tufts/Brown CFAR
Professor
Tufts Department of Medicine
Institute for Clinical Research and Health Care Policy
(617) 636-8672
iwilson@tufts-nemc.org

Isa (Maria) Fernandez

ATN
Dept. of Public Health & Preventive Medicine
Nova University
(954) 262-1598
mariafer@nova.edu

Jane Simoni

Professor, Department of Psychology
University of Washington
(206) 685-3291
jsimoni@u.washington.edu

Jared Baeten

MTN, Partners in Prevention
Fellow, Infectious Diseases, Seattle HIV Prevention Trials Unit
(206) 520-3808
jbaeten@u.washington.edu

Jonathan Fuchs

HPTN/HVTN
Co-PI of the San Francisco Vaccine & Prevention Unit,
San Francisco Dept. of Public Health/UCSF
Co-Chair of the HVTN Training and Education Committee
(415) 554-4234
jonathan.fuchs@sfdph.org

Ken Mayer

HVTN
HPTN Chair of the Scientific Review Committee



HVTN Site PI

Professor of Medicine and Community Health,

Brown University

(401) 793-4711

Kenneth_Mayer@Brown.edu

Lynda Marie Emel

HPTN

SCHARP Senior Project Manager

(206) 667-5803

lemel@scharp.org

Margaret A. Chesney

Professor of Medicine & Associate Director,

Center for Integrative Medicine,

University of Maryland School of Medicine

NIAID Strategic Working Group, External Advisor

(410) 448 6493

mchesney@compmed.umm.edu

Maria Gallo

FHI

Senior Service Fellow, CDC

(919) 308-0144

mgallo@cdc.gov

Michael Stirratt

NIMH

Program Officer, Adherence Program,

Secondary Prevention and Translational Branch,

Center for Mental Health Research on AIDS

National Institute of Mental Health

(301) 443-6802

stirrattm@mail.nih.gov

Nancy Padian

MTN

RTI International

(415) 848-1321

npadian@rti.org

Nancy Reynolds

ACTG

Professor, School of Nursing

Yale University

(203)737-2313

nancy.reynolds@yale.edu

Niru Sista

FHI/HPTN

HPTN Project Director

Associate Director,

Family Health International

(919) 544 7040 ext 590

nsista@fhi.org

Norma Ware

Associate Professor

Harvard Medical School

(617) 432-2554

norma_ware@hms.harvard.edu

Pamina Gorbach

MTN

Associate Professor, Department of Epidemiology,

Behavioral Epidemiology Research Group, UCLA

(310) 794-2555

pgorbach@ucla.edu

Pat Flynn

IMPAACT

IMPAACT Scientific Oversight Committee,

CTU PI & Department of Infectious Diseases,

St. Jude Children's Research Hospital

(901) 495-2338

pat.flynn@stjude.org

Robert Gross

ACTG



Assistant Professor of Medicine and Epidemiology
University of Pennsylvania School of Medicine
(215) 898-2437
rgross@cceb.med.upenn.edu

Seth Kalichman

University of Connecticut
Professor, Psychology Dept
University of Connecticut
(860) 208-3706
seth.k@uconn.edu

Sharon Mannheimer

INSIGHT, ACTG, HPTN
Associate Professor of Clinical Medicine,
Columbia University College of Physicians and Surgeons,
Harlem Hospital Center, Division of Infectious Disease,
Director of Clinical and Programmatic Affairs
(212) 939-2948
sbm20@columbia.edu

Sheryl Zwierski

DAIDS
Prevention Sciences
(301) 402-4032
zwierskis@niaid.nih.gov

Sibyl Hosek

ATN
Department of Psychiatry - Child & Adolescent Division
Stroger Hospital of Cook County
(312) 864:8030
sybilhosek@earthlink.net

Sten Vermund

HPTN
Amos Christie Chair in Global Health
Professor of Pediatrics, Medicine, Preventive Medicine,
Obstetrics & Gynecology
Director, Vanderbilt University School of Medicine Institute for
Global Health
(615) 322-9374
sten.vermund@vanderbilt.edu

Susan Cohn

ACTG
Associate Professor of Medicine, Infectious Diseases Division
University of Rochester Medical Center
(585) 275-2590
Susan_Cohn@urmc.rochester.edu

Thomas Coates

HPTN
Michael and Sue Steinberg Professor of Global AIDS Research
Division of Infectious Diseases
UCLA David Geffen School of Medicine
(310) 794 3580
tcoates@mednet.ucla.edu

Wil Strain

ACTG/CP
NCAB Member, Community Partners Representative
(213) 351-8124
wstrain@ph.lacounty.gov

William (Bill) Fisher

Department of Psychology, Department of Obstetrics and
Gynaecology
University of Western Ontario
(519) 661-2111 ext 84665
fisher@uwo.ca