Adherence to New HIV Therapies:  
A Research Conference

Summary of Working Group Reports

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Welcome and Introductory Remarks

Judith Auerbach, Ph.D., Chair, Behavioral and Social Science Research Coordinating Committee, the Office of AIDS Research (OAR), on behalf of OAR, the Forum for Collaborative HIV Research (FCHR), and the National Minority AIDS Council (NMAC), welcomed panelists, expressed her appreciation for their participation, and announced the goals and structure for the second day of the conference. The panelists were divided into working groups, each having a facilitator to lead the discussion and a rapporteur to record the ideas conveyed. These working groups were formed to identify research questions and priorities for the following areas of adherence: factors influencing adherence, interventions to assist adherence, and measures of adherence. During the first session, a biomedical and a behavioral working group met to discuss each of the areas. During the second session, the biomedical and behavioral working groups for each of the three areas merged, recognizing the cross-disciplinary nature of adherence research.

Thomas Coates, Ph.D., Director, University of California, San Francisco, AIDS Research Institute/Center for AIDS Prevention Studies, conference cochair, presented the charge to the working groups: (1) identify research priorities in view of current knowledge, gaps, and opportunities; (2) establish a time frame for research with respect to need and feasibility, i.e., immediate, intermediate, or long-term projects; and (3) identify targets of research at all levels: patient, provider, patient-provider relationship, regimen(s), disease, and setting/system/context.

On the first day of the conference, speakers noted that the needs of infants and children are very different from those of adolescents and may be different from those of mothers and women who are not mothers as well as other special populations. The working groups were instructed to note
which population was being targeted in their discussions. The working group reports will be used to develop a research agenda.

Gerald Friedland, Director, AIDS Program, Yale University School of Medicine, conference cochair, noted the focus of the meeting was to create a working document that could be used to develop a research agenda. It was hoped that the product could be quickly transcribed into a document that could be used for both policy and decision-making purposes.

**Working Group Reports: First Session**

*Behavioral Factors Influencing Adherence*

Sheryl Catz, Ph.D., Assistant Professor, Center for AIDS Intervention Research, Medical College of Wisconsin, reported the discussion of the behavioral factors working group. She described a pyramid framework to view adherence on the levels of the individual, health care provider, community, and societal perceptions.

**Important research domains:**

The consensus of the working group was that these domains interact to such a large extent that it was difficult to prioritize them, and that it may be important to prioritize how to bridge these frameworks with particular groups of patients who are on combination therapies.

- Motivation, attitudes, beliefs, and behavioral intentions should be studied on the individual level because they may be very important in determining how self-adherence is defined and how decisions are made on an individual level.
- Also on an individual level, it is important to identify organization strategies, frameworks, coping mechanisms, knowledge of the regimen, cognitive function, recall, lifestyle factors, self-identification, and daily activities such as employment and substance abuse.
- Interpersonal networks are important to explore particularly as they relate to different subgroups of people with HIV. Whether information versus emotional support networks are differentially important predictors of adherence in different groups must be examined, these factors must be refined in order for interventions to be developed.
- The effect of quality of life on adherence should be examined.
The education factor bridges the individual, community, and health care provider levels to a large extent. Identifying what makes patient education work in each of these settings is necessary. What are some of the characteristics of patient-provider interactions and how do they interact with the health care system in terms of insurance, health care setting, location, accessibility? What are the characteristics of successful clinical services including education, attitudes of providers, and attitudes of patients?

The living environment should be viewed in terms of the broader context of a person’s life. What are the person’s beliefs (beliefs about medications or trust of physicians) in his or her self-identified community that may be interacting with the ability to adhere to treatment?

The influence on adherence of patient clinical status, disease comorbidity, dementia, mental illness, and substance abuse must be explored.

Conclusions:

The working group made the following conclusions:

Subgroups that are particular targets of intervention should be identified and tools developed to assess behavioral predictors of adherence based on these groups.

Groups identified as priorities for further study include children, adolescents, ethnic groups (particularly African Americans, Latinos, immigrants), women (with and without children), the mentally ill, active drug users, and the homeless.

In integrating these domains and basing them on research with these priority groups, researchers should start on the individual level as a priority, recognizing that there is much interaction between levels.

Biomedical Factors Influencing Adherence

Frederick Altice, M.D., Assistant Professor, AIDS Program, Yale University School of Medicine, reported the discussion by this working group, which focused on the biomedical factors affecting an individual taking medications. Key factors in previous adherence literature that are applicable to the HIV arena are issues related to side effects and tolerability of medication. The severity of the side effects and how the individual perceives those side effects are factors.

Factors related to the medication itself include:

Pharmacokinetics and frequency of dosing
C Route of administration (suppositories, transdermal patches, suppositories for children, long-acting intravenous or depo injections for those who can’t adhere to pilltaking regimens [examples from the contraception literature]).

C Taste of the medication, the number of pills, physical attributes (pill size), and pediatric formulations. These factors might be important to mothers and children taking similar medications.

C Toxicities (related to other medical conditions such as pregnancy)

C Drug interactions (related to increased side effects or decreased efficacy)

C Complexity of the regimen

C Single versus multiple drugs for evaluating adherence (Can people be adherent to two of their drugs and not adherent to the third, and what does that mean in terms of the development of resistance?)

C Refrigeration of medications (How does this affect a person traveling or the homeless?)

C Whether the drug needs to be taken after fasting or with food

C The effect of HIV medications on other medications

C Potency of the medication

C Resistance to the medication

Factors related to the individual include:

C Whether there is a bioassay to give immediate feedback to the individual, clinician, and others to assist in adherence

C Viral load and change, baseline CD4 count or change in CD4 count

C Stage of the disease (Is the patient symptomatic or asymptomatic?)

C Opportunistic infections

C Mental illness and other non-HIV comorbidities

C Substance abuse

C Symptom relief

C Attitude toward disease (Does the individual view HIV as an acute or chronic disease?)

C Cognitive function (ability to adhere to therapy)

C Cultural meaning of disease

Factors related to health care provision include:

C What is the organization of the health care delivery system?

C Are new models of care needed to deliver HIV-related care to individuals who can’t operate within the existing structure?
What are the sites of care (coordination of mother and child care at one site, ways to deliver care to active injection drug users)?

How is home care and home infusion integrated in the system?

What is the interface between managed care, and how may that impede the clinician-patient relationship? Does the organization of care result in the individual receiving fragmented versus integrated care?

What are the communication skills of the clinician and the patient?

What are the amount of time per visit and frequency of visits?

What is the expertise of the clinician?

What are the availability, consistency, and experiential training of the provider? Has the person ever taken AZT and experienced its gastrointestinal side effects? Have they ever tasted the buffer in ddI? Do they have that experience to provide feedback to the individual?

What are the characteristics of other key providers in that health service network, and how do they affect adherence?

Based on that framework, the group developed top priority research questions:

How much adherence is enough? This is known for single drugs and for two drugs taken consistently over time. However, what are the consequences of a person on triple drug therapy if one of those drugs is discontinued for a short period of time?

What are the factors that influence adherence for various populations?

Can the drugs be made easier to take while retaining adequate potency? Related to this was the issue of studying drug interactions with non-HIV-medications and illicit drugs. When the question arose as to who should carry out this research, it was suggested that this was a regulatory issue. One doesn’t want to have the regulatory environment have so many prerequisites that new drugs will be held back from the patients who are failing current regimens. It was suggested to enact regulations that will allow for such postmarketing evaluation. This is a challenge to the regulatory agencies and pharmaceutical companies.

What is the effect of disease state on adherence?

How can HIV care be organized to optimize and enhance adherence? What are the key system factors of the health care delivery system that may impede or improve adherence? This must be linked to health outcomes, including cost effectiveness, health status of the individual, and the effect of nonadherence on the community (development of resistant strains). Should HIV care be provided by an HIV specialist versus a primary care physician? What are the characteristics of clinicians who provide good HIV care, and how can others be trained or encouraged to pursue this field? How do the financial incentives in the managed care environment impede or improve adherence in terms of the organization of care?
Other research questions considered by the working group include:

C Can bioassays be developed to monitor adherence to give feedback to the individual and provider?
C Can individuals be trained to adequately monitor and to prevent side effects to improve adherence?

*Behavioral Interventions To Assist Adherence*

Ms. Julie Davids, Philadelphia FIGHT and ACT UP Philadelphia, reported the discussion of the behavioral interventions group.

Basic principles discussed by the group include:

C Overall context affects adherence; it must be recognized that the individual exists in relationships with the provider, community, society, etc.
C Adherence is not limited to taking medication. There is the decision whether or not to take medications in the first place and then there is the initial act of taking medication, as well as the issue of taking medications over a long term. Interventions must address all three stages.
C It is important to address both people in care and those who are not in care.
C Adherence should be viewed in terms of disease management the ultimate goal is keeping people healthy.

Areas of intervention include:

C Information dissemination
C Behavior change (including stopping further transmission of HIV)
C Patient-provider relationship
C Systemic and structural changes
C Innovative outcome measures (not just pill counts) that allow one to study interventions
C Community-based interventions that may not have been strongly evaluated (Efforts must be made to assist in their assessment as well as to integrate knowledge from new research findings into the community.)
C Individuals and providers who must be asked what is important to them in an effort to design new interventions.
Immediate research goals include:

C Formative research (performing a needs assessment, addressing specific populations, addressing individuals in care and those not in care (why aren’t they in care), asking providers and community support (families, churches, etc.) for their needs, asking good compliers how they manage to adhere to treatment and what they think the evaluation and outcomes should be.

C Pilot programs.

C Development of assessments to determine the ability of individuals to adhere (not based on preconceptions for populations) examining specific individuals in subpopulations labeled as poor adherers to determine what may be generalized.

C Design of new interventions based on what has been used in other diseases.

C Evaluation of existing programs communicating to communities the importance of evaluation of their programs in a nonthreatening way, offering to help set up ongoing research structures, at all stages, collaborating between the community and researchers in implementing interventions, evaluating how the community-based organizations determined what interventions were necessary.

Intermediate research goals include:

C Evidence-based interventions (ethical, randomized controlled trials; quasi experiments that might not have randomized controls, and replication of pilot programs on a larger scale as demonstration projects.

C Combination of multilevel approaches including information dissemination, behavior change, provider-patient relationship (service community as well as medical care providers), and systemic change. (Can we change the delivery of health care or the behavior of the individual health care provider?)

Long-term research goals include:

C Evaluation of research conducted in terms of cost-effectiveness and application.

C The provision of research guidelines so that interventions can be conducted on the local level or so others can aid efforts on the local level without being obtrusive.

C Long-term interventions and research into these interventions to see whether the initial ability to adhere to medications predicts the long-term ability to adhere.

C Interventions that are flexible or adaptable as the medications and formulations change.
Providers must be attuned to their patients’ needs. If speaking with substance abusers, a provider can have a zero-tolerance attitude. He or she needs to think of harm reduction or substance abuse management. Providers should not limit instructions to the act of pill-taking, but should emphasize that if one doesn’t take the pills he or she won’t get results.

**Biomedical Interventions To Assist Adherence**

Mr. Richard Jefferys, Access Project Director, AIDS Treatment Data Network, reported the discussion of the biomedical interventions working group.

Issues and research priorities include:

- **Blood-level monitoring**
  - Can therapy be individualized based on blood-level monitoring? Is it possible to assist adherence with intensive short-term monitoring to make sure that the doses are appropriate to maximize the benefit and to minimize the side effects? Could regular blood-level assays be built in to ensure that people were achieving adherence goals based on blood-level monitoring? (One could build in substudies of that looking at outcome measures such as viral load and development of resistance.) Population substudies and cost effectiveness should be performed to justify the individualization of therapies.

- **Levels of adherence**
  - How much adherence is enough? How much adherence is enough to get clinical benefit?

- **Formulations and dosing**
  - What are the possibilities of developing pediatric formulations and formulations for adults who can’t take pills? Is there a way to survey innovative drug delivery companies to look at formulations (for example, transdermal patches) to improve adherence? Can dosing be improved, and can companies be encouraged to develop once-a-day or b.i.d. [please spell] formulations?

- **Better monitoring**
  - Viral load is being used by people as a biomedical intervention to assist with adherence. Can this be improved by more frequent monitoring of viral load in a practical way so that people catch themselves when there is breakthrough? Does this help people set adherence goals? Can the reproducibility of the assays be improved to make those goals more achievable?

- **Side-effect management**
  - The community could get involved in this aspect of the research agenda because they hear about efforts to manage side effects. Can this information be collected, and can those interventions be studied in a rational way? Can managing side effects be used as a medical intervention?
Systems issues

If a refill cannot be obtained on time, is an intervention needed to make that happen? The broader systems issues addressed by the behavioral factors working group were echoed.

Behavioral Measures of Adherence

Sandra Geletko, Pharm.D., Associate Professor, University of Rhode Island, College of Pharmacy, reported on the discussion of the behavioral measures working group.

Issues and challenges considered include:

- Identification
  Medications taken by the patient must be correctly identified. There is variability in how patients are asked about taking medications. The way questions are asked must guarantee an accurate picture of what medications are taken for what symptoms or conditions. This is particularly important for pediatric patients whose parents or grandparents organize their medications.

- Characterization
  How to characterize the patients and their readiness to adopt a new behavior, their perceived benefit of therapy, and their attitudes about pill-taking were discussed.

- Self-report
  Recall and the assessment of adherence patterns over time were discussed.

- Electronic monitoring
  Challenges include the limitations of this mechanism to certain formulations, financial issues, patient acceptance, and the question of whether or not this changes behavior. Should there be a direct comparison of self-reports versus electronic monitoring?

- Accuracy
  How can one obtain the patient’s permission in order to get an accurate picture of adherence? If patients don’t respond to therapy, can providers ask questions in a manner that lets the patient know the therapy isn’t working while acknowledging that there are several reasons why this might be, including malabsorption, resistance, and missed doses? Can providers ask the patient for assistance to identify which of these reasons is causing the drug to be ineffective at this time?

- Monitoring
  Paging or calling the patient to determine if medication is being taken was discussed. Although more obtrusive, the group didn’t discount this option.

- Computer technology
  One may get a different assessment if the patient answers questions with use of a computer rather than verbally. An evaluation of which method is more accurate should be conducted.

- Incentives
  Incentives for patients to give the correct measurement would be important. All sectors should be involved in addressing these issues. Partnerships are definitely needed. There is a need for a quick tool to assess adherence before a patient begins therapy and to use if a
breakthrough occurs. Other needs include measures for those with disabilities (actual drug levels might be necessary as well as viral load to confirm self-reports).

Top-priority immediate research goals include:

C Enhancement of self-report and the need to address the patient’s misunderstanding of medication identification.
C Alternatives to self-report.

Intermediate and long-term research goals include:

C Developing other unobtrusive measures of adherence.
C Developing a clinician assessment tool to ascertain patient adherence behavior before therapy and at the time of breakthrough (similar to a CAGE questionnaire).
C Determining how one can use these measures and factors clinically to enhance adherence.

**Biomedical Measures of Adherence**

David Wheeler, M.D., Infectious Diseases Physicians, Inc., reported the discussion of the biomedical measures working group.

Key issues/challenges/questions include:

C There are no good biomedical markers of adherence.
C Many biomedical markers that might be chosen are actually outcome measures as well.
C Adherence may be only one component of determining success or failure of outcomes.
C It is very difficult to separate measurements of adherence versus contributing factors and some of the interventions that one might use.
C Methodological issues include trying to explain adherence as opposed to using adherence to explain other outcomes.
C It is difficult to separate biomedical measures from behavioral ones, and any successful attempt to measure adherence will probably combine the two.

Areas to consider include the following.

Pharmacologic measurements:
Measurement of drug levels versus compartments

Pharmacologic markers
Many drugs have short half-lives.
High cost is associated with these measurements.
There is a change in pharmacokinetics over time.
Monitoring the pharmacologic levels might adversely affect the therapeutic relationship between the provider and the patient.

Virologic measurements:

Viral load measurement
Measurements of drug resistance
Baseline measurements
Are they necessary before patients start therapy?
Expense
High cost is associated with these measurements.
Effectiveness
There are little data to show whether these are markers of adherence.
Outcome
This is also an outcome measure.

Immunologic measurements and clinical measurements:

The group did not address immunological or clinical factors as measurements of adherence but broached the issue of the relative contribution of adherence measures and trying to determine their effects on outcome.
The importance of behavioral measurements was reiterated.

Research questions include:

Pharmacologic measurements:

What is the role of therapeutic drug monitoring as a measurement of adherence?
What is the role of pharmacologic additives in measuring adherence? Is there a long-acting drug that could be included in the formulation for which blood-level monitoring could be performed?
Is there a marker, such as change in the color of urine, to give biologic feedback?

Virologic measurements:

What is the role of viral load measurements? What is the role of the nadir? What is the role of time below level of detection in measuring nonadherence?
C What is the role of emerging resistance (whether phenotypic or emergence of specific mutations) in measuring adherence?

Methodologic issues:

C How are various methods of monitoring adherence best combined?
C How can some measures of subsets of members of a group be used to infer results within the whole group?
C Adherence or nonadherence may be thought of as a nonrandomized intervention (something that happens after intervention). How can one make causal inferences? The relative role of adherence as a measurement must be looked at in any study that is conducted.
C Clinical and virologic successes versus clinical and virologic failures should be studied. Using some of the measurements that were addressed, the relative component of adherence in contributing to that success or failure should be determined.
C The relative role of adherence must also be studied in different populations since this role might vary.

Working Group Reports: Second Session

Combined Factors Influencing Adherence

Dr. Frederick Altice reported the discussion of the combined factors group.

Key issues include the following:
C A combination of sociobehavioral and biomedical predictors will be important determinants for adherence.
C There is a body of non-HIV-literature on adherence, but there may be additional factors for the various HIV populations. A top priority is to define what the issues are for each population. This might be done by using existing observational databases and nested case-control studies and by looking at successes and failures of HIV therapy.
C Outcome studies and cost analysis will be needed to develop interventions that will use these factors. Potentially alterable factors such as health beliefs, individual factors, and health care systems, must be examined. Other questions about these factors include
C What should be the timing of initiation to therapy? What needs to be factored into visits and discussions prior to beginning therapy?
C What is the meaning of adherence for individuals? Should patients have trial runs before they start therapy?
Is it possible to develop a common assessment tool that crosses different cultures and populations so that comparison between groups can be made?

The definition of adherence should be broadened to include not only medication adherence but also such related activities as adherence to the prevention of HIV transmission and adherence to doctor appointments.

From a methodologic standpoint the difference between acceptance of therapy and adherence to therapy must be distinguished. Factors associated with acceptance to therapy may be different from those associated with adherence to therapy. If an intervention is targeted to get a person to adhere to therapy, their acceptance of therapy might need to be addressed first.

Patients enrolled in studies that are observational might not be reflective of the whole or of the patients that might need to be studied the most. Therefore, one must exercise caution in interpreting data from these studies.

Issues of trust must be explored from the societal, institutional, and physician levels.

Issues of social support must be explored.

The factors associated with nonadherence should be investigated.

Research should include the kinds of tools that can be used at all levels to help guide both initiation and continuation of therapy.

Improvement of health care delivery is also an issue. Barriers in existing systems that need to be removed to improve adherence should be identified. This might have important implications for financing medical services for people with HIV. If it takes 30 minutes to speak to a patient about HIV therapy, will the physician be reimbursed for this as opposed to a 10-minute visit?

An overarching issue and clear charge from the group was the need to look at funding adventurous and flexible studies with regard to factors associated with adherence. This may mean involving people from the community on review panels to evaluate studies from community-based organizations.

How much adherence is enough is a question that must be answered to have an operational definition of adherence.

With the paradigm of factors influencing adherence at the individual, health care provider, community, and societal levels, several questions were raised:

How can therapy be made easier to take without losing potency?

How can we influence the drug development process, and how can information on drug development be simplified to educate the patient?

Research questions include:

What are the factors of adherence and use of medication among various populations (substance abusers, injection drug users, women, pregnant women, the homeless, etc.)?
What is the relationship between antiretroviral therapy adherence and public health adherence (safer sex, transmission of virulent strains or resistant strains)?

What are the knowledge, attitudes, and beliefs of adherence as they relate to self-efficacy and motivation?

What are the disease states, and how do they relate to adherence?

What factors are associated with provider education and antiretroviral therapy?

What are the issues related to the health care provider?
  What can be done to help health care providers improve the patient-provider relationship?
  Should there be teaching about side-effects monitoring?
  What is the impact of managed care?
  Can time be made available for continuing medical education credits?
  Who are the other staff who should be involved in this effort?

What is the impact of informational networks and alternative therapies on adherence in different populations?

What are the factors associated with stabilization (housing, drug treatment, etc.) that affect adherence?

What are the determinants of the health care delivery system on adherence for various populations?

What are the key educational components that must be provided? Who should provide these? How should this information be provided for the cognitively impaired?

What are the factors that influence the health care provider’s decision to administer antiretroviral therapy?

What are the predictors of resistance on the part of the community? What role does adherence play in the emergence of resistance if you can control other factors, such as viral load and potency of therapy?

Combined Interventions To Assist Adherence

Ms. Julie Davids reported the discussion of the combined interventions group.

Key issues and questions include:

A randomized trial should be conducted to see how different reimbursement mechanisms influence adherence and medical outcomes.

An evaluation of community programs should be initiated. The group strongly believed that this should be a priority for NIH to fund.
Various elements of the patient-provider relationship should be examined.

- Define behaviors of providers that affect adherence.
- Define partnerships that affect adherence.
- Use interventions to build partnerships between patients and providers (include a range of providers and settings such as nutritional counselors and methadone clinics).
- Train both providers and patients in communication skills.

Develop assessment tools to help patients and providers (defining provider broadly) decide the following issues: Is the patient ready to start therapy? This could be turned into an intervention by assisting the patient in starting therapy. Based on the individual's life and priorities, what actual regimen would the patient best be able to adhere to?

Observational outcome studies are needed involving both clinical and community settings looking at adherence measures and clinical and virologic outcomes. Such studies are ongoing by the Centers for Disease Control and Prevention, Health Resources and Services Administration, and Glaxo-Wellcome. A standard instrument to evaluate adherence is needed for use in these studies in order to compare them. Continuous variables would be required since it is not known how much adherence is enough.

Will individualized therapy enhance adherence?

- How much adherence is enough (defined by clinical and virologic outcomes)? Is it better or worse to completely stop drugs if doses are missed? Observational studies were suggested. Will individual feedback affect compliance (including computerized compliance tools)?
- Will side-effects management affect compliance? This includes more research exploring this issue and treatments for side effects as well as assisting patients in managing side effects.
- Perceptions of persons in the community regarding treatments should be ascertained.

Once-a-day or b.i.d. [spell b.i.d.] treatments, liquid formulations, and combinations of drugs should be formulated even if the individual components aren't owned by the same company.

Key needs identified include:

- Structural support for real collaborative research (funding and coordination of these mechanisms).
- Evaluation of research and community-based findings (not waiting for publications).
- Information dissemination between the community and researchers.
- Health care delivery. (Efforts should be made to remove obstacles impeding medication delivery. If one is in arbitration over welfare and prescription filling is denied, alternatives should be available.)
**Combined Measures of Adherence**

Dr. David Wheeler reported the findings of the combined measures group. If the group sets an appropriate research agenda for measuring adherence, the answer to the overriding question of how much adherence is enough will be answered.

The key issues for measurement include the following:

- Biomedical and behavioral measures of adherence must be evaluated in concert.
- Measurements must be studied in different populations.
- Varied methodology must be considered. Certain studies could be nested in clinical trials, others that are cross-sectional could be used to obtain quick answers, and longitudinal studies could be used to study adherence over the long term.
- Treatment and treatment dosing are going to change over the coming years. If answers about measures of adherence to regimens that are being used now are desired, then studies will have to be done rapidly to be relevant to problems people are facing today.

Key research questions include these topics:

**Pharmacologic measurements:**

- What is the role of therapeutic drug monitoring as a measure of adherence?
- What is the role of pharmacologic additives, and what are the ethical and feasibility implications of putting markers in medicines?

**Virologic measurements:**

- Can we use viral load to measure emergence of resistance at either the phenotypic or genotypic level as measurements for surrogates for adherence?

**Reporting:**

- What is the role of self-report in measuring adherence?
- How can one optimize some of these self-report tools to be more pertinent to adherence?
- How valuable is clinician assessment in measuring adherence?
- How valuable are measures by other people (partners, family members, parents of children) in obtaining true measures of adherence?
C More research is needed on the role of electronic monitoring in adherence (both as an influence and as a measure).

Social support:

C Are there markers?
C How valuable are measures of social support in predicting adherence or serving as surrogates for measuring adherence?

Methodologic research:

C How does one best combine the various methods of monitoring adherence?
C When multiple components are measured, how can the relative contributions of each of these components be separated to determine the single best predictor of adherence?

The group agreed that outcome measures (virologic) are not direct measures of adherence. For a true picture of adherence, these somewhat useful measures (genotypic testing, viral load, behavioral instruments) should be combined. If used together, perhaps a correlation to predict adherence would be obtained.

Next Steps and Closing Comments

Dr. Coates noted that adherence to medications was as crucial as the development of the drugs themselves because the drugs won't do any good if people can't use them properly. He reflected on Dr. Andrew Moss's presentation on Day 1, remarking that the health care system might resent paying $5 to people to get them to keep their appointments to take medication; however, the system is spending millions of dollars to develop the medications. He thanked the FCHR, NMAC, and OAR for bringing the group together and focusing on the topic of adherence. He thought the ideas presented by the working groups were excellent and will provide the basis for a research agenda. If HIV-related issues are addressed through adventurous and flexible studies, the field of adherence might be pushed forward.

Dr. Gerald Friedland stated that a great deal of energy on behalf of the organizers and the participants resulted in a successful meeting. The problem of adherence to HIV therapies is one that benefits us all to solve. The collaboration of patients, community, industry, providers, and systems should have a major effect on helping people with HIV disease.
Dr. Auerbach noted that a document produced from the working group deliberations will be shared with panelists as soon as possible after the Planning Committee and sponsoring organizations finish drafting one. The research agenda developed from this meeting should be used by organizations to push the adherence field forward. The summary of Day 1 of the conference as well as the research agenda will be made available as widely as possible. She thanked the panelists on behalf of NIH and was pleased by the representation across various sectors.

Mr. David Barr echoed Dr. Auerbach’s comments and stated that the goal of FCHR is to identify issues and gaps in the HIV research effort. The adherence question was one of the first such issues identified. The role of FCHR is to facilitate discussion of people from the various disciplines, communities, and constituencies to address the problems identified. He thought that assembling a diverse group representing these sectors was useful for addressing the topic of adherence to new HIV therapies. The panelists will receive a research agenda as the outcome of this meeting, and Mr. Barr implored them to implement it in their particular settings.