Staying healthy: Taking Antiretrovirals Regularly

Facilitator Training Manual

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Chapter 1: The STAR Intervention

Section 1: Introduction

I. The STAR Study

The STAR (Staying healthy: Taking Antiretrovirals Regularly) intervention takes the best strategies available from prior adherence and behavior change research and utilizes them in an interdisciplinary adherence intervention trial for HIV-infected individuals having difficulty following their antiretroviral regimen. Through providing for HIV+ patients a tailored, behavioral intervention that includes social support and patient education components, as well as maintenance booster session, the STAR intervention aims to:

- 1. promote medication adherence and effective problem-solving related to medication adherence among HIV+ individuals;
- 2. improve patient self-efficacy and outcome expectancies related to adherence;
- 3. assist patients in dealing with emotional and behavioral distress related to difficulties with adherence, and improve quality of life; and
- 4. improve patient coping methods and health care satisfaction.

II. Background & Significance

Adherence to prescribed medication regimens is critically important for patients with HIV infection. Poor adherence to antiretroviral drugs can result in the development of resistance by HIV to multiple drugs—and to whole classes of drugs. Interruptions in medication adherence permit the virus to resume it's typical rapid replication—and the replication rate is formidable, with as many as 10¹⁰ viral particles produced per day (Ho et al., 1995; Perelson, Neumann, Markowitz, Leonard, & Ho, 1996) – which allows the generation of resistant mutant strains that are no longer responsive to available antiretroviral drugs. Development of resistant strains of HIV poses a potential public health danger (Friedland, 1997). A widespread transmission of resistant HIV strains would threaten to undermine all of the progress made in HIV therapeutics in the past few years.

Over the last three decades, for many different diseases, nonadherence has been a significant problem for medical practice. Several reviews involving hundreds of well-controlled studies have repeatedly emphasized the magnitude and pervasiveness of the problem (e.g., Becker & Maiman, 1982; Eraker, Kirscht, & Becker, 1984). Adherence is defined as the extent to which a patient's health-related behaviors correspond with medical advice. In previous research literature for other diseases, poor medication adherence has been defined as taking less than 75-80% of prescribed medication (Horwitz & Horwitz, 1993), and estimates of nonadherence to therapy for non-HIV illnesses have ranged from 13% to 93%, with an average rate of about 40% (Greenberg, 1984). Moreover, it has been reported that typically only 65% of patients on chronic medical regimens actually take enough of their medication

to achieve therapeutic benefit (Sackett & Snow, 1979). Studies specific to adherence for HIV-infected patients are finding approximately the same rates as those of previous adherence studies for other illnesses. For example, studying zidovudine alone, zidovudine plus didanosine, and didanosine alone, 63% of the patients were found to be compliant, with adherence defined as taking greater than 80% of their prescribed medication (Singh et al., 1996). Due to the rapid development of resistance when doses are missed, HIV+ patients need to strive for "perfect" (100%) adherence, as opposed to previous adherence definitions for other illnesses of approximately 80%.

Currently, treatment guidelines state that the therapeutic regimen for acute HIV infection should include a combination of two nucleoside reverse transcriptase inhibitors and one potent protease inhibitor (Panel on Clinical Practices for Treatment of HIV Infection). Some of these medications require patients to follow special instructions. For example, some require fasting, others need to be taken with high-fat meals. At present for HIV-infected patients taking combination drug treatment, frequent dosing, with up to as many or more than 20 pill per day, is required to maintain suppression of viral replication and prevent resistance (Ickovics & Meisler, 1997). Although researchers are currently working to find ways to simplify medication dosages, such as developing drugs with fewer side effects, combining two drugs in a single capsule, developing longer lasting drugs, or developing drugs with no adverse interactions with food or other drugs, it is clear that HIV-infected patients will continue to be faced with a significant medication adherence challenge. Studies have not yet identified estimates of the number of doses missed before resistance develops, but they have suggested an association between an increase in viral load and notes in individual medical records suggesting nonadherence; a direct relationship between the risk of developing a detectable viral load and delays in refilling prescriptions; and an increase in viral load in those who missed three days of therapy (Roland, 1998).

Overview of the STAR Intervention

Theoretical Basis of the STAR Intervention. Past research has shown that successful interventions include three main components: behavior change strategies; social support; and patient education. The STAR study will incorporate these three components.

Behavioral strategies that include the principles which underlie successful risk behavior change will be incorporated into the intervention: risk education; threat personalization; perceived efficacy of change; intention to act; behavioral skills acquisition; cognitive-problem solving skills for change implementation and maintenance; and reinforcement of behavior change efforts (Kelly, 1995).

In addition to behavior change strategies, the STAR intervention will include a focus on *social support* and on appropriate *patient education*. Social support group intervention is probably the intervention most commonly offered in applied settings to individuals faced with chronic or uncertain illness (Kelly, Murphy et al., 1993). The majority of the social support studies have indicated a positive association between patient social support system and adherence (e.g., Martin & Dubbert, 1986; Rees, 1985). Findings indicate that when patients perceive that they have sufficient levels of social support or when relationships are secure, then adherence levels are high (e.g., Bloom, 1990; Raven, 1988; Sarason et al., 1988).

Finally, the most often used method of enhancing adherence is *patient education* (Crespo-Fierro, 1997). However, the clarity and reading level of materials given to patients regarding treatment adherence may have an impact on level of adherence. Ley (1976) provided two versions of an information brochure designed to help women keep to a low carbohydrate diet: one with a moderate readability level, and a simplified version that contained explicit categorization of information, easy readability, and repetition. Weight reductions at all follow-up points (2, 4, 8, and 16 weeks) were significantly higher for women who received the simplified version. Murphy, O'Keefe, and Kaufman (1998) randomly assigned 141 women at risk for HIV to be presented with one of two versions of an information packet designed to explain an HIV vaccine trial. One version was the standard prototype educational material; the second was a simplified version that included pictures designed to emphasize the key concepts. Women presented with the simplified version understood significantly more information about study visit procedures, potential benefits, and possible risks at both the immediate and the three-month follow-up. Simplified information seems to be desired by patients (Joubert & Lasagna, 1975; Ungvarski, Schmidt, & Crespo-Fierro, 1996). Even if, however, better presentation of patient education materials can somewhat improve adherence, it has been well-documented that information alone does not lead to reliable, regular, or predictable behavior change (Helweg-Larsen & Collins, 1997). Therefore, this component will be utilized within the context of the behavior change strategies that form the core of the intervention.

Multidisciplinary Strategy for the STAR Intervention. The proposed intervention is designed as an interdisciplinary intervention: the intervention group facilitators should optimally include a behavioral psychologist and a nurse. It is essential to place health psychology interventions in the general context of health care systems (Compas et al., 1998), since psychological interventions complement and work in conjunction with biomedical interventions. This is likely to be the most efficacious method of achieving the dual goals of most health psychology interventions: increasing length of patients' lives and enhancing quality of life.

Section 2: Questions Pertinent to STAR

I. What is HIV?

HIV, human immunodeficiency virus, is the virus that causes AIDS. The virus passes from person to person through contact with blood and exchange of bodily fluids during sexual intercourse or sharing of needles during injection drug use. It can also be passed from mother to baby during pregnancy (mostly during delivery) and by breast milk. The virus attacks the immune system. At late stages of HIV infection immune systems do not function well and patients are susceptible to several infections and cancers. This late stage of HIV infection is known as AIDS.

II. What is AIDS?

AIDS, acquired immunodeficiency syndrome, is the late stage of HIV infection. By the time someone develops AIDS, the virus has damaged the body's defenses (immune system). Thus, people with AIDS develop diseases that most healthy people can normally resist or control, such as a parasitic pneumonia, thrush or other fungus infections, or recurrences of childhood infections. They also may suffer from cancers rarely found among people with healthy body defenses. All of these problems are collectively referred to as opportunistic infections (OIs). Since the virus can enter the brain and other organs throughout the body, many people with AIDS have trouble with movement, memory, and body functions. People with AIDS may die, not simply because they have HIV, but because their weakened immune system allows them to develop infections they cannot survive. Recent treatments have substantially prolonged life for people with HIV and AIDS.

III. What is the immune system?

The immune system is a complex group of cells and chemicals (called antibodies and cytokines) that act as the body's defense against anything foreign (against disease agents and other things that can make people sick). When the system works as it should, white blood cells patrol the body and attack any organisms that should not be there. Some of these blood cells attack disease agents directly, by engulfing them; other cells make antibodies in response to invading disease agents.

IV. What does AIDS have to do with the immune system?

AIDS is a result of infection caused by a virus (HIV). HIV affects certain parts of the immune system. They include the following: (1) T-cells that serve many functions such as signaling macrophages and certain other T-cells to attack disease agents, helping to trigger B-cell functioning, and serving as the general control mechanism for slowing or speeding up the immune system; (2) B-cells that make antibodies to defend the body against anything foreign; and (3) Monocytes/macrophages that surround and devour infected cells, disease agents, and dead material.

Although they attempt to fight HIV, white blood cells may be defeated by the virus, which eventually cripples the immune system. One class of T-cells (also referred to as T-helper cells and CD4 cells) often serves as a target (host cell) for HIV. The virus enters the genetic information of the T-cells and never leaves. When activated, HIV multiplies and the new viruses infect many more of the T-cells. By causing them to die or clump together, HIV slowly destroys the functioning of these T-cells and they no longer trigger antibody production or signal attacks on disease agents.

Macrophages also serve as host cells for HIV. The very cells that should destroy HIV carry the virus to other areas of the body, help to spread the infection, and serve as virus reservoirs. B-cells make the HIV antibodies found in the blood of people who have the virus. Instead of destroying HIV, these antibodies may, in fact, permit the virus to cause infection by encouraging macrophages to surround the antibody-HIV complex.

Persistently infected lymphocytes or macrophages serve as reservoirs for HIV even in the face of drug cocktails (combination therapies) that reduce virus levels in blood to very low levels. Thus HIV hinders and often destroys the immune system by crippling its defenses. People with HIV who have developed AIDS have lost much of their protection against the invasion of disease agents.

V. What is a CD4 count?

A CD4 T Lymphocyte count is most commonly used as an index or measurement of total functioning of the immune system. Normal CD4 for adults is 1200 - 1500 and may be much higher for young children. 'Significant' damage to the immune system is considered to be a count of < 500. At 200 or less patients are given prophylactic drugs to prevent OIs. Symptoms of infections indicating "AIDS" may begin at higher levels but frequently begin below 200. The Centers for Disease Control and Prevention and all state health departments define AIDS as any HIV positive individual with a CD4 T lymphocyte count of <200 or having any one of 30 or more OIs. Most people with less than 500 CD4 T lymphocytes begin combination antiretroviral therapy. Many patients and doctors choose to begin combination antiviral therapy at higher CD4 levels.

VI. What is a viral load test?

A viral load test measures the amount of HIV in someone's blood.

Why does someone need a viral load test if they have already had an HIV test? An HIV test indicates whether or not a person is infected with HIV; the virus that causes AIDS. A viral load test measures the amount of virus in an individual's blood. Knowing how much virus is in the blood may affect treatment decisions.

What does a viral load predict? The viral load test helps predict an HIV+ person's future health. If the viral load is low, the individual is less likely to develop AIDS in the near future than someone with a higher viral load.

How is the viral load test different from a T-cell count? A T-cell count (or CD4+ test) measures how well the body is coping with HIV infection. The viral load test measures how much virus is present in the blood, regardless of how the individual's body is dealing with HIV.

What is a normal viral load test? There is no normal value for a viral load test. It's not normal to have HIV in the blood. The lower the viral load, the better. If the results are very low, they may be reported as "undetectable."

What does "undetectable viral load" mean? Usually, undetectable means there are less than 500 viruses per milliliter of the blood. New tests are coming which will measure even smaller amounts of HIV. Undetectable does not mean that there is no virus in the blood. An HIV+ individual can still infect someone else, if he/she shares needles or has unprotected sex. Even with an undetectable viral load, a person is still HIV+.

VII. What can someone do to lower their viral load? What is the goal of antiretroviral treatment?

Many people have successfully used combinations of anti-HIV drugs to lower the amount of virus in their blood. These drugs have helped people who were sick get better, and people who were well stay well. Unfortunately, all of these drugs have side effects. Some people will experience more severe side effects than others. The drugs don't work for everyone and no one knows how long they will work. People have to be prepared for changes in their lives if they take these drugs.

The goal of antiretroviral treatment is to decrease or stop viral replication for as long as possible, reducing the chance that the virus will produce mutations that allow HIV to multiply despite therapy. Taking combinations of antiretroviral drugs is thought to be the best way to accomplish this goal.

Are there any natural or alternative treatments that will lower viral load? There have been small studies of some alternative treatments that have lowered viral load. So far no alternative treatment has been proven to reduce viral load as much as combinations of prescription drugs.

How can anyone tell if treatments are working? An individual cannot tell from a single viral load test if his/her treatment is working. If his/her viral load gets lower and stays consistently lower over several viral load tests, then his/her treatments are working to control the amount of virus in the body. Any consistent decrease in viral load is beneficial. People should discuss with their doctor what an appropriate treatment goal for them would be. Other good signs include rising CD4+ counts, recovery from existing opportunistic illnesses and, of course, feeling better.

What if an individual does not want to take drugs right now? Having a viral load test doesn't mean that someone has to rush into taking drugs or other treatments; now or ever. If someone is considering drug treatment, they should think about how they will deal with treatment side effects and the changes that may be necessary in their daily schedules. They should be prepared for how they will feel if these treatments do not work for them. Having a viral load test may help people get a better perspective on the decisions they want to make right now. Having these tests now will also give them better background information for future decisions.

Is a viral load test always accurate? If someone has the flu or any other short-term illness, their viral load may rise. This increase is temporary. Temporary increases in viral load may also occur after a vaccination such as the flu shot. People should avoid having a viral load test in the week after a vaccination or an illness.

The number value reported for one viral load test and the number reported for the next test 2 or 3 months later can vary. Sometimes a doctor will suggest that an individual have a second viral load test immediately. This may help to sort out whether there was a meaningful change in the viral load, or if the difference was due to small changes in the body or the test procedure.

How does one read a viral load report? Viral load is reported as the number of copies of HIV RNA per milliliter of plasma. This number represents the amount of HIV in the blood. The results of the first viral load test, or the average of the first two viral load tests, are called the baseline viral load. Future viral load tests are compared to this baseline to determine if there has been a change in the viral load. This is one way HIV+ people can monitor the effects of treatment.

All viral load results vary. This is because of tiny changes in the body and in the test procedure. The baseline viral load is actually the middle of a range of numbers. Within this range, increases or decreases are part of the normal variation of the test. Outside of the range, increases or decreases are called significant, meaning they are not due to chance, predictable errors in the test, or usual body variations. The range is calculated using logarithms and is commonly called a "half log change." An easy way to calculate this is to multiply and divide the baseline result by 3. For example, if the baseline viral load is 5,600 copies, then the range is from 1,870 copies to 16,800 copies (5,600 \div 3 = 1,870, 5,600 x 3 = 16,800). This sounds like a lot, but no new result between 1,870 – 16,800 is significantly different from the baseline.

If the viral load results are above the baseline range, it suggests that the amount of virus in the body is increasing. If the viral load results are below the baseline range, it suggests the treatments are reducing the amount of virus in the body.

VIII. What types of antiretroviral agents are available to treat HIV infection?

There are currently three types of antiretroviral agents for treatment of HIV: (1) nucleoside reverse transcriptase inhibitors; (2) non-nucleoside reverse transcriptase inhibitors; and (3) protease inhibitors.

IX. How do nucleoside reverse transcriptase inhibitors (NRTIs) work?

HIV depends on several enzymes in order to make copies of itself inside infected cells. One of these is reverse transcriptase (RT). HIV uses RT to convert HIV genetic code (RNA) into DNA. The integration of this DNA into the host cell is a key step in HIV replication. Once the integration is complete, the host cell becomes chronically infected and is ultimately destroyed. The nucleoside reverse transcriptase inhibitors (NRTIs), also known as "nukes," inhibit this replication process by incorporating themselves into the DNA produced by the virus. This prevents the infection of new cells. The NRTIs have been considered the foundation of therapy for HIV infection.

X. How do non-nucleoside reverse transcriptase inhibitors (NNRTIs) work?

The non-nucleoside reverse transcriptase inhibitors (NNRTIS) also interfere with the action of RT. They do this by binding directly onto reverse transcriptase and thus preventing the conversion of RNA to DNA. Thus, the NRTIs and NNRTIs interfere with HIV replication at the same point, using different mechanisms. Antiretroviral therapy often incorporates medications of both types, to increase effective viral suppression and to reduce development

of resistant strains. However, while the NRTIs and NNRTIs prevent infection of new cells, they cannot prevent the production of new HIV virus by already-infected cells.

XI. How do protease inhibitors (PIs) work?

The Protease Inhibitors (PIs) interrupt the process of viral reproduction at a later stage, preventing the production of a viable HIV virus by already-infected cells. Protease is another enzyme that assists in the HIV replication process, but it operates towards the end of the process, when the HIV has already entered the cell's nucleus and has made long chains of proteins and enzymes that will form many new copies of HIV. Before these chains can begin to start working correctly, they have to be cut into smaller pieces. The HIV protease enzyme is like a "chemical scissors" because it cuts the long chain into shorter pieces. PIs are drugs that resemble pieces of the protein chain that protease normally cuts. They interfere with the cutting of the long chains of proteins and enzymes into the shorter pieces that HIV needs to make copies of itself. New copies of HIV are still made and still leave the infected cell. But these short copies of HIV are defective and cannot go on to infect other cells. Thus, the PIs provide a vital addition to the antiretroviral armament, preventing the production of viable HIV by infected cells. It is important to remember that all the antiretrovirals are subject to the development of resistance, and that, with protease inhibitors, viral resistance will develop very quickly if suboptimal doses are given or if exposure to the drug is erratic, such as when patients are nonadherent.

XII. What are the names of the antiretroviral medications currently approved to treat HIV infection?

Drug Name	Brand Name	Medication Type
1. Zidovudine (AZT, ZDU)	Retrovir	NRTI
2. Didanosine (DDI)	Videx	NRTI
3. Zalcitabine (ddC)	Hivid	NRTI
4. Stavudine (d4T)	Zerit	NRTI
5. Lamivudine (3TC)	Epivir	NRTI
6. Saquinavir (hard capsule)	Invirase	PI
7. Ritonavir	Norvir	PI
8. Indinavir	Crixivan	PI
9. Nevirapine	Viramune	NNRTI
10. Nelfinavir	Viracept	PI
11. Delavirdine	Rescriptor	NNRTI
12. Zidovidine/Lamivudine	Combivir	NRTI
13. Saquinavir (soft capsule)	Fortovase	PI
14. Sustiva (efavirenz)		NNRTI

As of December 22, 1998, there were 15 drug products (13 drug substances) approved by the Food and Drug Administration for the treatment of HIV infection.

Drug Name	Brand Name	Medication Type
15. Ziagen (abacavir)		NRTI

XIII. Why do HIV-positive patients have to take combinations of antiretroviral medications?

The primary goal of antiretroviral therapy is to reduce viral load in the infected patient. This is accomplished most effectively by interrupting the viral replication cycle wherever possible. The use of combination therapy with two or more drugs that have different mechanisms of action (i.e., a drug that prevents infection of target cells with a drug that blocks production of infectious virus) has proven the most effect technique to date in the battle against HIV. Combination therapy usually consists of two NRTIs and a Protease Inhibitor, though NNRTIs may be used instead of or in addition to NRTIs. These combinations have proven effective in reducing replication of drug-resistant strains, prolonging antiretroviral effects, increasing CD4+ cell counts, and slowing disease progression.

XIV. What are some common combination therapy regimens? How many pills per day for each?

Patients' regimens vary for many reasons, including what medications patients have taken previously, experiences with side effects, etc. Combination therapy can range from two medications to up to four or five different medications. The following are three examples of common combination therapy regimens.

	Medication/Type	Dose	Special instructions
1.	Ritonavir (PI)	6 capsules, 2 x day	Refrigerate. Take with meals.
	AZT (NRTI)	2 capsules, 3 x day	None.
	3TC (NRTI)	1 tablet, 2 x day	None.
2.	Nelfinavir (PI)	3 tablets, 3 x day	Take with meal or light snack.
	AZT (NRTI)	2 capsules, 3 x day	None.
	3TC (NRTI)	1 tablet, 2 x day	None.
3.	Ritonavir (PI)	6 capsules, 2 x day	Refrigerate. Take with meals.
	D4T (NRTI)	1 capsule, 2 x day	None.
	DdI (NRTI)	2 tablets, 2 x day	Take on empty stomach. Avoid alcohol.

XV. What is "resistance?"

HIV is a virus that produces variants of itself, or mutations, at a rapid rate. In response to antiretroviral therapy, HIV mutations may include versions of HIV that are resistant to, or unaffected by antiretroviral medications, allowing the virus to continue the process of replication, even in the presence of the drugs that normally kill it. The higher the rate of viral reproduction, the greater the chance for resistant strains of the virus to emerge and reproduce

themselves. Adherence to a regimen of combination therapy is thought to provide the best chance of reducing viral mutation, minimizing the possibility that a mutation resistant to the medications will replicate in sufficient numbers to challenge the therapy. Resistance has been shown to develop to all classes of antiretroviral medications, but seems to develop especially quickly to the protease inhibitors if low doses are given or if patients are nonadherent.

XVI. What is "cross-resistance?"

Cross-resistance is a phenomenon characterized by HIV genetic material changing in response to one drug to resist its effects and consequently making other drugs ineffective in the body (because of structural similarities in the drugs). Thus, a patient who is nonadherent in taking one antiretroviral medication may develop resistance not only to that medication, but to other antiretroviral medications of the same type.

XVII. What are the side effects for some of the common antiretroviral medications?

Dru	ig Name	Side Effects
1.	Stavudine (d4T)	peripheral neuropathy (tingling in the hands and feet)
2.	Saquinavir (hard capsule)	diarrhea, painful burning and tingling, upset stomach
3.	Ritonavir	diarrhea, nausea
4.	Indinavir	diarrhea, kidney stones, nausea and vomiting, headache
5.	Nevirapine	fatigue, nausea, headache, vomiting, fever
6.	Nelfinavir	diarrhea, hyperglycemia, nausea, flatulence, rash
7.	Zidovidine/Lamivudine	anemia, nausea, muscle weakness, headaches, malaise
8.	Saquinavir (soft capsule)	nausea, diarrhea, upset stomach, heartburn

XVIII. Changing Medication Regimens

The decision to change an antiretroviral regimen is complex and should be made by the primary care provider and the patient, working together. Continuous monitoring of the CD4 count, viral load and clinical status provide the physician with information about the effectiveness of a current treatment regimen. Indications that a change in regimen is advisable include: (1) the initial viral response is less than 1.0 log 10 decrease in plasma HIV RNA after 1-2 months of therapy and the viral load is not under the limit of detection after 2-4 months; (2) the viral load remains detectable after 4-6 months of therapy; (3) virus is detected repeatedly after initial suppression to undetectable levels, indicating the development of resistance: (4) a reproducible increase, threefold or greater, occurs from the lowest HIV RNA plasma level attained by that patient and it is not attributable to infection, vaccination, or test methodology; (5) the patient is receiving double nucleoside therapy, with no protease inhibitor, and has achieved undetectable viral level (most people on double nucleoside therapy who do not modify the regimen to include at least one PI eventually

experience treatment failure); (6) CD4+ T-cell counts, measured on at least two separate occasions, persistently decline; and (7) clinical deterioration occurs.

All regimen changes must be made on a case-by-case basis and should take into consideration both clinical indications and patient characteristics. Patients and their health care providers should take into account a number of important factors when making this decision, including the patient's clinical history, viral load and CD4 count, remaining treatment options, adherence patterns, and readiness of the patient to deal with implications of the new regimen, such as side effects, drug interactions, dietary requirements, etc.

The nature of the change in medication regimen will vary, depending upon the reason for the change. If a regimen is being changed because of drug intolerance (e.g., medication side effects), the health care provider may recommend substitution of one or more alternative drugs of the same class and potency as the medication that caused the side effects. If the regimen is being changed because of treatment failure, providers may recommend changing the entire regimen to drugs that the patient has not taken before, as it is generally considered inadvisable to change only one medication of a regimen to which the HIV seems to have become resistant. If an apparently successful regimen is being changed because it contains only one or two antiretroviral medications (usually two nucleoside analogues), most providers will simply add new medication (usually a PI) against the likelihood that the patient will develop resistance to the nucleoside analogues.

*Note: Chapters 2 - 4 have been adapted from two sources, which we would like to reference here. These are as follows.

- 1. NIMH Multisite HIV Prevention Trial Project Light Intervention Manual, January 1994
- 2. Centers for Disease Control; Woman-to-Woman HIV/STD Prevention Intervention Fernández, Gay, & Bowen; University of Miami School of Medicine, 1999

Chapter 2: Research Issues

Section 1: Interventionist Role^{*}

I. The Interventionist as a Researcher

It is very important to remember that the STAR Project is first and foremost a research study. One of the primary goals of this study is to determine whether this intervention program is effective in helping HIV+ patients on antiretroviral therapy adhere to their medication regimen. In order to determine whether the program is effective, the interventions described in this manual must be administered in a standardized way. The interventionists play a pivotal role in achieving this goal. In a very real sense, the interventionist makes or breaks this program. The researcher's ability to interpret the results from this study and determine the project's success depends upon the interventionist's ability to deliver the information and conduct the exercises contained in this manual with fidelity.

Every part of this manual was designed with a special purpose in mind. Interventionists should take the time to read and understand the basic principles, the key elements, and the content of each chapter. The interventionist should be attentive during the training and should not deviate from this manual when administering the interventions.

II. The Interventionist Is Not a Counselor/Therapist

The role of an interventionist is very different from that of a counselor or therapist. Counselors talk to people about whatever may be bothering or troubling them and often allow the individual to guide the course of the discussion. The role of an interventionist differs from that of a counselor because the role is limited to helping the patient acquire behaviors that will improve medication adherence and address barriers to medication adherence. In addition, interventionists have a fairly specific script that they will be following as they administer the intervention. While this is a counseling intervention and some of the interactions are tailored to the individuals' situations, the sessions are not designed to be therapeutic encounters. There are specific guidelines regarding the content of the interventions, what should and should not be covered, and how long each session should last. Deviating from these guidelines will contaminate the research findings and prevent us from determining whether the interventions are effective in improving adherence to antiretroviral medications.

Sometimes interventionists encounter difficulties in adhering to the manual and keeping the session focused on adherence issues. The participant may be more interested in talking about side issues such as family and relationship problems or financial difficulties. There may be times when the interventionist feels that talking about these issues would be very helpful for the participants. However, this is not the interventionist's role. These issues should only be discussed with respect to how they affect participants' adherence to their antiretroviral medications. These issues should not dominate the entire session. The interventionist must

keep the session focused on medication adherence. Of course, interventionists should give the participant a list of referrals (which will be provided for them) so that he or she can address side issues with an appropriate professional. If the interventionist feels that the participant needs to see someone urgently (i.e., the participant indicates that he or she is considering hurting themselves or others or is experiencing bodily harm), they should notify the Project Director immediately.

Because this is a research project designed to test a specific intervention, it is very important to adhere to the instructions contained in this manual. If interventionists deviate from the manual and start administering therapy to the participants, we will be testing whether the interventionists' "therapy" affects patients' adherence.

III.Interventionist Responsibilities

Because the STAR Project is a research study, the most important responsibility of the interventionist is to administer the program as described in this manual. In addition, the following duties are included in the interventionist's role.

- 1. Be on time for all scheduled intervention sessions.
- 2. Be prepared for all scheduled intervention sessions.
- 3. Be sure you are administering the appropriate module and session to each participant.
- 4. Administer the intervention according to the protocol.
- 5. Maintain accurate records of all your appointments and activities.
- 6. Complete checklists and ratings forms immediately following each session.
- 7. Attend and participate in all supervision meetings.
- 8. Abide by project rules and specified timetables.
- 9. Maintain confidentiality of participant information at all times.
- 10. Assist in other project activities as requested by the research team.

Section 2: Professional Ethics and Participant Rights

Research conducted at the Health Risk Reduction Projects of the University of California, Los Angeles Department of Psychiatry is based on the highest ethical and technical standards. These standards are applied from the earliest steps of deciding whether to participate in a study to the final steps of analyzing and reporting information obtained. Strict precautions are built into the design of a study and observed at all times to protect the confidentiality of participants. Interventionists are expected to maintain these same professional standards, to collect information with scientific objectivity and to maintain confidentiality of all observations and participant responses.

Successful and meaningful research is dependent on establishment of trust between the researchers and the participants throughout the data collection phase of the study. Another necessity in research is to maintain strong professional ethics and to present an image of integrity and honesty. As researchers, interventionists must display high ethical standards in all contacts with the public and study participants. Verbal or written assurances given to participants have little meaning if they are violated or contradicted by the actions of any member(s) of the research team. The research procedures developed are designed to protect individual rights and to comply with all applicable laws.

All research follows strict ethical guidelines to protect the rights of the research participants. These rights are not only important to us as individuals, but are equally important to us as professionals engaged in research and evaluation. The following guidelines must be followed by all researchers to ensure that participants are not harmed by their participation in this project.

- Participants must be informed that they have the right to refuse to enter the study.
- Participants must be informed that they have the right to withdraw from the study at any time.
- Participants must be informed about the general purpose of the study.
- Participants must be informed about what they will be asked to do if they agree to participate in this study.
- Participants must be informed of the potential risks associated with participation in the study.
- Participants must be informed of potential benefits associated with participation in the study.
- Participants must be informed about the extent to which confidentiality will be maintained.
- Participants must be informed about whom they can call if they have any questions about the study.
- Participants must sign a Study Consent Form to indicate that they have been informed of their rights as research participants.
- Participants have the right to referral information upon request.

Section 3: Confidentiality

All participants in research studies must be assured that the information they provide will be kept confidential to the extent permitted by law. Sometimes researchers can provide participants with an assurance of anonymity as well. It is important to understand the

difference between anonymity and confidentiality so that you can clearly explain it to the participant. An anonymous response is one whose identity is revealed to no one, not even the researcher. This requires the research to be conducted without knowledge of the participant's name. This study <u>does not</u> assure that responses are anonymous.

Confidentiality refers to the identity of the study participants. It means that the identity of the study participants cannot be related to the data collected by anyone outside of the research team, it also means that information is not shared outside the setting where it was obtained. As a researcher on this study, you will know the names of the participants. However, we have developed procedures to safeguard our participants' confidentiality and ensure that the participants' names will not be shared with anyone outside the research team. Specifically, participants' names will never appear on our data collection forms or our data disks; special study identification numbers will be used to track the data. Only our research team will have access to the information that matches our participants' data with their names.

In all research efforts, protection of an individual's privacy is mandatory. Both the federal and the state governments have rules and regulations protecting the privacy of an individual. Violation of the principle of confidentiality is reason for immediate dismissal from the project. It is also a misdemeanor offense under Federal law (Privacy Act of 1974).

Several types of confidentiality are important to this study.

- 1. <u>Employee confidentiality</u> means that any personal information that researchers and other study team members share about themselves, during and after training, will not be shared outside of the Health Risk Reduction Projects.
- 2. <u>Participant confidentiality</u> means that the names of the participants in the study will not be revealed. When the results of the study are shared with others, no individual's responses will be identified. For the STAR study staff, this means that no one will discuss or reveal names of participants to anyone except other STAR staff members. It also means that no one will discuss any personal information learned during the course of the program with anyone except for other STAR staff and then, only when absolutely necessary.
- 3. <u>Exceptions to confidentiality</u> occur when participants may be dangerous to themselves or others. In addition, if a participant reports that he/she is abusing a child, staff members are required to report this to Department of Children and Families.

Standard procedures for maintaining confidentiality are:

- 1. No data collection forms and interview materials may be visible in any public place. Review confidential forms in the research study's office.
- 2. Do not discuss the contents of the questionnaires or anything said in the interviews with anyone. If there is a need to discuss a participant with other staff, it must be done in private.
- 3. Retain copies of all completed forms in a locked storage file. Keep all study documents locked and secured when not using them.
- 4. Turn in completed interviews to appropriate staff according to protocol.
- 5. <u>Never put a participant's name on a data form</u>. Only use the study identification number.

Section 4: Suggestions for Responding to Participants' Concerns about Confidentiality

As a researcher, one important challenge interventionists will face is assuring participants that the information they provide will be held in strict confidence. If the participants are concerned about confidentiality, assure them that only authorized research staff will have access to the information provided.

Reassure the participants by telling them that:

- 1. Everything they tell you will be absolutely confidential.
- 2. All of their answers will be combined with those of other people like them and will only be released as statistical data (or in group or aggregate form).
- 3. Their names will never be used outside the study offices. No personal identifying information will be used in any report.
- 4. As a researcher on this study, you pledge to maintain confidentiality for all data you will collect.

*Adapted from Woman-to-Woman Intervention Manual, M. Isabel Fernández, Ph.D., Caryl L. Gay, Ph.D., G. Stephen Bowen, M.D., M.P.H., University of Miami School of Medicine (1999).

Chapter 3: Theoretical Framework

Section 1: Social-Cognitive Principles Underlying Behavior Change

Principle 1: Personal Vulnerability (Personal Risk)

Before people will change their behavior, they must have a reason, or source of motivation, to do so. If people don't see how they can personally benefit from doing something differently (for example, being adherent to their antiretroviral medication regimen), then no amount of skill will be enough to produce change.

When it comes to adherence, the behaviors are not in-and-of-themselves appealing: remembering at regular intervals to take medications that remind you that you are HIV-infected; putting up with unpleasant side effects; and having to arrange food or sleep schedules around medication-taking, for example. Therefore, people must have other reasons to adhere. Probably the most likely reason a person will have for trying to be adherent is to avoid disease progression. However, many people do not think about the fact that they will have disease progression if they are not adherent, or that they may become resistant to some antiretrovirals. There are several reasons for this sense of invulnerability. For one thing, they may have seen others who aren't 100% adherent, but whose viral loads remain undetectable. They may be at undetectable levels themselves, and have missed some doses. Finally, almost all people have a natural tendency to believe that bad things will not happen to them, and they underestimate their chances of experiencing negative consequences from their behavior. One goal of this program, then, is to increase participants' sense of personal risk.

Principle 2: Consequences of Non-Adherence

If people are to be motivated to change their behavior, they must believe that if they are not adherent to their medications, their disease will progress and their physical condition will deteriorate. They must also believe that there may not always be another drug to take the place of one to which they've developed resistance, and that, despite all of the recent medical advances, there is still no cure for AIDS. While most of the participants will know these things, it is important that the program make these points clearly just in case some participants are not aware of these basic facts.

Principle 3: Behavioral Strategies Are Effective In Improving Adherence

Even if the participants believe that they are at risk for nonadherence, and that this is problematic, they will not make the changes that we recommend unless they also believe that these changes will work. Participants must believe that behavioral strategies will effectively assist them in adherence. If they do believe that behavior change will help them adhere, which will help them stay healthy, then they are likely to make the changes. Believing that disease progression and resistance can be held off or prevented will also make people react less fearfully to the information described above.

Principle 4: Adherence Strategies are Acceptable

It is also important that the behavior changes recommended by the interventionist be acceptable to the participants. If participants believe that consistent adherence is overwhelming their life, or that the reminder of being HIV-positive when they take their medications is a negative thing, it is less likely that they will change their behavior to improve adherence. The interventionist's role is to help the participants view adherence more positively.

Principle 5: Adherence Will Increase Self- and Social-Respect

Everybody has standards for behavior. When people behave in accordance with their standards, they feel good about themselves, and when they do not, they feel guilty, afraid, or depressed. Much of what people come to value in their own behavior is shared by community, friendship and family networks, and people are often influenced in what they value by others in their networks. The intervention should begin to affect standards by strengthening the belief among the participants that adherence is "the right thing to do," and focusing on how self-respect and self-worth are improved when the participants are dealing with the daily responsibilities of their medications and taking care of themselves.

Principle 6: "I Can Adhere" (Self-Efficacy)

Many people find it difficult to adhere to their medication regimen, and to do it consistently. The interventionist will increase the participants skills through skills training, assisting participants in developing individualized adherence plans, modeling appropriate behaviors, and by providing the opportunity for participants to practice the skills and receive feedback on how to improve their plans. All of these will facilitate patients' self-efficacy regarding adherence.

Principle 7: "I Can Be a Partner in My Health Care" (Self-Efficacy – Assertiveness & Negotiation)

The interventionist must be sensitive to participants' desires to maintain good relationships with their health care providers and to avoid conflict with them. At the same time, the interventionists need to provide the participants with the skills necessary to discuss issues with their health care providers in order to obtain a thorough understanding of what their treatment regimens are and what to expect in terms of side effects, to learn how to discuss untenable side effects, and to be able to discuss nonadherence without fear. This program will provide opportunities to practice these skills through the use of role plays and other exercises.

Principle 8: "I Can Control My Nonadherence" (Self-Efficacy, Self-Control) People need to be able to control their urges to take "drug holidays," to "forget about all of this HIV for a while," and to lapse to nonadherence. These skills will also be provided in the program.

Section 2: Key Elements of Behavior Change from a Social-Cognitive Perspective

Common Element 1: Reinforcement

Reinforcement is used in the program in several ways. Participants can be reinforced through their interactions with the interventionist. When a participant enjoys the experience of talking to you about how to adhere and has success with their individualized adherence plan, the experience itself becomes reinforcing. Therefore, whenever a participant shares experiences or attempts to achieve a goal (whether successfully or unsuccessfully), it is important for the interventionist to thank that person and emphasize the positive aspects of their contribution. People feel reinforced when they receive respect, positive regard, and appreciation from others, and providing this will enhance their pleasure and participation in the program. Another source of reinforcement will come from the other group members—who become a social support group for this person during the course of the intervention group meetings; the person's fellow members will encourage them and reinforce them when they succeed. Another source of reinforcement will come from successfully achieving changes in behavior, as reflected in the results of self-monitoring and goal-setting, described below.

Common Element 2: Modeling

Modeling refers to the process of setting an example for others through the interventionist's own behavior. When they see the interventionist providing examples of behavior change effectively, whether it be adherence reminder strategies, thinking of a good re-framing of a negative self-thought, or how to be persistent with a health care provider to obtain information while maintaining appropriate tone and expression, they will be learning from the interaction.

This raises the issue of sharing personal experiences. Because this is a standardized intervention, it is important that all interventionists use similar examples and give similar messages. Therefore, it is important that the interventionist does NOT share personal experiences with the participants.

Common Element 3: Goal-Setting

The purpose of goal-setting is to test the program in the real world, where participants will encounter the barriers that really exist in their environments. It is often difficult to translate enthusiastic plans formed during sessions into behavior change in the outside world because one cannot always predict what barriers will be encountered. Through goal-setting, participants will select an attainable behavior change to achieve by the following session. Then, at the next session, they report and assess how well the plans went. If the goal was achieved, then the next one selected should be more difficult. If it was not achieved, then the interventionist tries, with the participant, to identify what went wrong and to brainstorm solutions to the problem. A slightly easier goal, particularly one that addresses the problems encountered, should be selected for the next time. It is essential that unmet goals *not* be viewed as failures, but rather as learning opportunities. This will create an environment where participants feel free to report problems encountered honestly and without embarrassment.

The ultimate purpose of the goal-setting procedure is to enable participants to adhere to their medication regimen consistently. However, some participants will not be ready to accomplish this goal. They need to set a series of intermediate goals, which should be moderately difficult for them. Achieving these intermediate goals should ultimately lead the participant to consistent adherence. Goals that are too easy do not promote growth, and ones that are too challenging are unlikely to be achieved and may lead to a sense of failure. Goals must also be specific and concrete so that it is easy to know within a week whether they have been achieved.

Common Element 4: Self-monitoring

Self-monitoring is the process of keeping track of one's behavior and behavior change. It goes hand-in-hand with goal-setting because it provides a means for reflecting on one's actual behavior. This can help the participants to identify their problem areas ("I didn't adhere on Tuesday--why was this? It was the only day I drank alcohol last week.") so that they can choose appropriate goals, and it also serves as a record for whether, and when, goals were met, day by day. In the long term, it provides concrete feedback and reinforcement for how far the participants have come: how much more adherent they are behaving than when they started the program.

Common Element 5: Role Playing

Role-playing allows the participants the opportunity to practice the skills they acquire in the program. The interventionist asks the participant to act out a difficult situation, for example, asking a friend to participate in a reinforcement program with them to help them adhere, or being persistent with a health car provider to obtain information or express concerns. The participant should act realistically and without resolving the conflict at first. Participants should really think through all of the possible options. Make every effort to avoid stereotyped role playing.

Common Element 6: Problem Solving

When appropriate, participants are encouraged to apply problem solving to a situation. Typically, problem solving involves five steps. Those steps are:

- a. Identify the problem
- b. Identify the goal (i.e., adherence)
- c. Think of different possible strategies or steps to handle obstacles
- d. Evaluate the steps and pick the best solution
- e. Act on the best solution

While the steps of problem solving appear quite logical, problem solving is often not successful because of a wide variety of human biases and limitations. Examples of biases include paying attention to things presented first or last rather than in the middle, getting sucked into competition, being trapped by superficial elements, and trying to gain or protect against a loss. Limitations refer to a lack of information, time pressures, limited resources, imperfect perceptions, short-term memories, and levels of complications that are difficult to handle. These biases and limitations must be considered and avoided while practicing problem solving.

Chapter 4: Interventionist Tools^{*}

The STAR intervention strives to help participants improve their antiretroviral adherence. The intervention is predicated on the assumption that behavior change is a process. The role of the interventionist is to help the participant initiate, adopt, and maintain the process of behavior change. The intervention consists of four essential components: (1) motivation; (2) skill-building; (3) practice; and (4) reinforcement.

Motivating the participants includes convincing them of the importance of adhering to the antiretroviral medications. It also involves helping the participants to make a commitment to taking the antiretroviral medications correctly, each and every time. In short, the interventionist strives to convince the participants of the importance of adherence and to persuade them to make a commitment to improve their own adherence.

For the change process to be successful, the participants must also believe that there are specific things (i.e. using a pillbox or carrying pills with them when they are away from home) which they can do to improve their antiretroviral adherence. They must also have confidence in their abilities or skills to perform these adherence behaviors. The participants must learn to reward themselves for behaving in ways that improve their adherence.

Because adherence requires both technical competencies (i.e. taking pills at correct times) as well as the ability to communicate effectively about adherence problems (i.e., knowing how to talk to one's doctor about problematic side effects), the intervention works on building both technical skills and communication skills. Communication skills consist of the ability to: (1) <u>initiate</u> the topic of adherence with health care professionals; (2) <u>tell</u> one's primary care provider if adherence problems occur; and (3) <u>negotiate</u> a more manageable regimen with one's provider, if need be. Technical skills consist of teaching assorted ways to improve adherence through demonstrations and hands-on training. The interventionist allows the participant to practice these skills and provides positive reinforcement.

To build the participants' communication skills, the interventionist provides many opportunities to practice these skills by using role plays. The interventionist provides feedback, encouragement, and positive reinforcement to all attempts made by the participants. The interventionist uses classic behavior change techniques (i.e. modeling, role plays, practice with feedback, and reinforcement) to help the participants to acquire the skills and confidence that they need to take their antiretroviral medications as prescribed.

To assist the participant through the process of behavior change, the interventionist will use a number of skill building tools. These tools are designed to support the activities listed in the intervention sessions. The interventionist should know these tools and should be ready to use them as needed during the delivery of the intervention.

I. Tool #1: Motivating the Participant to Adhere

Objective: To motivate the participants to adhere by helping them to reflect on the reasons they have for wanting to stay healthy.

The interventionist helps the participants to explore reasons why it is important for them to stay healthy (i.e., having children, watching children grow up, wanting to go to school, wanting to be there for their partners, etc.). The interventionist should make a list of each of the reasons for staying healthy on the checklist so that the he/she can refer back to them throughout the session. The interventionist should use these reasons as reinforcements and motivators during the course of the intervention.

Taking antiretroviral medications as prescribed helps you to stay healthy. What are some reasons why you would want to stay healthy?

Factors such as wanting to obtain and develop a long-term relationship, wanting to follow through on school or career plans, or wanting to watch children grow up can motivate the participants and can show her/him how these goals go with staying healthy.

Motivation is an important tool that will be used throughout the intervention sessions. The interventionist should assess the participants' motivation regularly. If motivation is faltering, the interventionist should work on enhancing their motivation to change.

II. Tool #2: Practice with Coaching, Feedback, and Reinforcement

Objective: To increase the participants' technical skills in adhering to antiretroviral regimens; to increase the participants' skills in communicating with health care professionals about adherence; to increase participants' abilities to overcome barriers to adherence.

Practice with coaching and feedback is used throughout the intervention to help build participants' technical and communication skills. Role plays and behavioral demonstrations are the two main strategies that will be used to build competence. This tool box contains a number of standardized role plays and scenarios that the interventionist can use to help build skills. Always present role play scenarios in increasing order of difficulty. This will help the participants to successfully complete the role plays, the interventionist should also ask the participants to present their real world scenarios. After the participants have generated a scenario, the interventionist will play the role of the participant and he/she will ask the participants to role play other actors in the situation (e.g., partners, children, co-workers). The interventionist models appropriate responses; the participant can generate the reactions of others. After this scene is completed, the roles are reversed and the practice is repeated. Throughout these enactments, the interventionist coaches the participants as needed and provides feedback. The interventionist uses reinforcement to reward the participant for all of their attempts.

III. Tool #3: Defining Obstacles to Adherence

Objective: To increase the participants' understanding of their personal obstacles to antiretroviral adherence and increase their skills in overcoming the obstacles.

Many things can influence people's actions. Recognizing the things that influence people's behavior is an important element in behavior change. This tool is designed to help the participants recognize the things that prevent them from taking their antiretroviral medications as prescribed. When something prevents a person from behaving in a certain way, it is called an obstacle or a barrier. In this intervention, these are defined as those <u>people</u>, <u>places</u>, <u>situations</u>, <u>moods/feelings</u>, and <u>substances</u> that prevent participants from adhering to their regimens. Ask the participants to think about their obstacles to adhering to their antiretroviral medication regimens.

What are some obstacles that keep you from taking your antiretroviral medications as prescribed?

For instance, some possible reasons for not taking one's antiretroviral medications as prescribed include believing that: (1) missing a dose here or there is not a big deal; (2) "resistance can't happen to me;" (3) taking pills in public is a sign to everyone around that you are HIV-positive; (4) the side effects are too troublesome; (5) taking "drug holidays" gives your body a needed break from the pills; and (6) it's too difficult to take the pills with the right amounts or types of food.

Obstacles to adherence fall under 5 main categories:

1. <u>People</u> who influence a participant's behavior can be obstacles to antiretroviral adherence. For example, a close friend may have very strong beliefs about using only alternative therapies (i.e., acupuncture, massage, etc.), and may influence the participant's decision to stop taking his/her antiretroviral pills. Ask the participants to reflect on who some of the people are that influence them (i.e., boyfriend, neighbor, family, wife).

People are some of the hardest obstacles to overcome because the participant may find it difficult to talk about adherence with people they care about. Encourage the participant to brainstorm some possible reasons why certain people might be obstacles to adherence. For instance:

- Not wanting co-workers to know about their HIV status
- Not wanting to be on a different eating or sleeping schedule than their partners
- Not wanting to take pills in front of one's kids because the kids do not know the participant's HIV status
- Not wanting to look "different" in front of friends
- 2. <u>Places</u> may influence the participants' behavior and prevent them from adhering to their antiretrovirals regimens. For example, participants may not want to take antiretroviral medications when they are in public, such as at a restaurant or bar. Encourage the participants to brainstorm some possible places where adherence behavior may be influenced:
 - Work
 - A bar or club
 - A party
 - Their date's apartment
 - Their parent's home
 - A place that makes them feel very good about themselves, or very bad

- 3. <u>Situations</u> can be obstacles that influence participants' behavior but are not always obvious. For example, a participant might go away for the weekend and decide to stay an extra day, but not have enough antiretroviral pills. Encourage the participants to brainstorm some possible situations that may negatively affect their adherence.
 - Being away for the weekend
 - Being somewhere without enough pills
 - Being out late and missing a scheduled dose of pills
- 4. <u>Moods/feelings</u> may be powerful obstacles to adherence. For example, if participants are feeling upset and lonely they may be more likely to miss doses of their antiretroviral medications. Feelings and thoughts could be obstacles to adherence. For instance: (1) feeling depressed; (2) feeling like the antiretroviral medications are too toxic; (3) believing that they deserve a break from their adherence schedules; (4) believing that they will get sick with AIDS in the future anyway; (5) wishing that they could eat and drink whatever they want to, whenever they want to, like "normal people" do. Encourage the participants to brainstorm some moods/feelings they felt before they missed doses of their antiretroviral regimens.
 - Fear (of the future, of the toxicity of the medications)
 - Depression
 - Confusion
 - Happiness
 - Anger (that they have to take so many pills, that they are "different")
- 5. <u>Substances</u> can be obstacles to adherence. For example, if participants are drunk or high on drugs they may be less inclined to take their antiretroviral medications as prescribed. The need to get drugs or alcohol can also influence a participant's behavior.

Encourage the participants to think about ways in which drugs and alcohol affect their adherence:

- When a person gets high, s/he doesn't think about anything else.
- When a person is drinking, s/he may forget to eat the right sorts of food with the antiretroviral doses.
- When a person is high, s/he feels like nothing can touch her/him, not even HIV.
- When people get drunk or high, they may not want to take their antiretroviral medications for fear of having too many toxic substances in their systems at one time.

IV. Tool #4: Identifying Personal Obstacles to Adherence

Objective: To assist the participants in identifying their personal obstacles to antiretroviral adherence.

This tool is designed to help the participants learn how to identify their obstacles to adherence. Identifying personal obstacles to adherence includes: (1) teaching the participants to identify when they are missing their pills or taking them incorrectly; (2) understanding what influences participants to nonadhere and their personal obstacles to adherence (i.e. people, places, situations, moods/feelings, and substances); and (3) using slips to learn about personal obstacles and influences so the participants can develop plans for avoiding them. Using the

last episode of nonadherence, the interventionist helps the participants to identify their obstacles to adherence.

Let's think back to the last time you had problems adhering to your antiretroviral regimen.

- Where were you?
- Who were you with?
- What led up to the situation?
- What were you thinking or feeling?
- Were you using alcohol or drugs?

We are all important, and we all have reasons to stay as healthy as we can be. We need to learn how to take care of ourselves. We need to work towards being as healthy as we can be by making healthy choices. If you realize what obstacles prevent you from taking your antiretroviral medications, you can learn to overcome these obstacles and make healthier behavior choices.

Reminder list for interventionists (any of these could be given as an example):

- Sleeping through a scheduled dose time
- Drinking alcohol or being high on drugs
- Having trouble taking the medicines with the right amount/type of food
- Not carrying antiretroviral medications with them when they leave the house
- Being away for the weekend
- Being depressed
- Having to take pills in public
- Feeling like the antiretroviral medications are too toxic
- Being frustrated with the strict pill-taking schedule
- Feeling like missing a dose or two won't make a difference

V. Tool #5: Using the Problem Solving Approach to Control Obstacles to Adherence

Objective: To increase the participants' skills in controlling and overcoming obstacles to adherence.

This tool is designed to teach the participants how to use the problem solving approach to control their obstacles to adherence. An obstacle doesn't automatically make nonadherence happen. However, an obstacle can make nonadherence more likely if the obstacle isn't handled correctly or avoided. So, learning to handle obstacles in ways that preserve patients' adherence is an important part of successfully taking antiretroviral medications. One of the goals of this intervention is to help the participants identify all of their obstacles and barriers to antiretroviral adherence. The process we use for controlling obstacles is called the problem solving approach. There are five steps to problem solving to control obstacles:

- 1. Identify the problem
- 2. Identify the goal (i.e., adherence)
- 3. Think of different possible strategies or steps to handle obstacles
- 4. Evaluate the steps and pick the best solution

5. Act on the best solution

The interventionist should refer to these steps while helping the participants to brainstorm solutions to participants' experiences and personal obstacles. The interventionist should use the following example to illustrate the problem solving approach.

It's a Friday afternoon and the phone rings. Joe is calling to invite Maria to go out to dinner. Maria and Joe have been out several times before. She cares about him but has not yet told him about her HIV status. She is scheduled to take a dose of her antiretroviral medications at 8:00pm—the time when they would be at the restaurant. Maria does not like to take her medications in front of people who do not know her HIV status, but she likes Joe and would like to have dinner with him.

Let's see if we can approach the problem that Maria faces from a problem-solving perspective.

1. What is the obstacle or problem that Maria faces?

Ask the participants, and guide discussion to identify the problem as being able to take antiretroviral medications as scheduled, when one is in public, in the company of people who do not know their HIV status.

2. What do you think Maria's goal is in this situation if she is to remain adherent?

Guide discussion and identify goal as taking antiretroviral doses on schedule, but also not staying home bored all weekend.

When faced with almost any problem, there are a lot of steps that someone can take to handle the problem. Some may be good and others may not be so good for handling a problem, but there are always many possible actions to take.

Let's try to brainstorm different things that Maria could do in this situation. Let's think of a few steps Maria could take to reach the goal of taking her doses on schedule, but also not being bored with nothing to do.

Have the participants identify different potential courses of action. These might include: going out to dinner with Joe and taking the antiretroviral dose in the privacy of the restroom; postponing the time of the date so that it doesn't conflict with her medication schedule; telling Joe about her HIV status if he asks why she is taking pills at the table in the restaurant; or meeting Joe for a drink later in the evening, but eating dinner and taking her pills at home.

Good. Now, not every plan is equally likely to work well, and some might have better success, cause fewer problems for Maria, or be easier to manage. Let's try to evaluate each solution.

3. Which solution do you think is best for Maria to take, and why?

Ask the participant to think of the pros and cons of each option and then decide which strategy is best for Maria to follow.

4. What, exactly, does Maria need to do to implement this plan of action?

Ask the participant to identify behavioral steps to implement solutions, writing down what Maria needs to do to put the strategy into effect.

Now, I'd like you to try this out, and do just what we did with Maria.

The interventionist should select an appropriate scene from the selection below:

Scene 1: You are going away to Las Vegas for the weekend with a bunch of your "wild and crazy" friends. You know that the weekend is apt to include a lot of late nights, and little sleep. You need to take your antiretroviral medications on a strict time schedule and worry that this may be difficult to do in a place like Las Vegas, where there are no clocks in the casinos.

Scene 2: On Saturday nights, you usually visit a club in your neighborhood for a few drinks. The last three Saturday nights you went to the club, you had a lot to drink, stayed out late and missed your 10:00pm dose of antiretroviral medications. It's Saturday night and you are thinking about going out to the club.

Scene 3: You had a difficult time falling asleep this evening and really need to catch up on your rest. All you want to do is sleep in as late as you can in the morning, but you are scheduled to take a dose of antiretrovirals at 6:30am.

Scene 4: You are a salesperson who is out on the road a lot making sales calls. The medications you take cause many unpleasant side effects, most notably severe diarrhea. This isn't that big of a problem when you are at home, since you are close to the bathroom. But, when you're out on the road for business, it's hard to predict if there is going to be a public restroom handy when you need it. Sometimes it's just easier to not take your pills during the day than to take them and have to worry about finding a restroom.

Ask the participants to practice how they would problem-solve the situation, following the problem-solving process (identify problem, identify goal, generate steps, evaluate steps, action plan) described and modeled earlier. The interventionist prompts, encourages, reinforces, and otherwise helps the participants through the process. If the participants have trouble, the interventionist can model the process, then ask the participants to perform the same enactment.

VI. Tool #6: Assertive Talk Skills

Objective: To increase the participants' skills and confidence in initiating conversations about adherence with their primary care professionals, contacting their providers if adherence problems occur, and negotiating more manageable regimens with their providers, if need be.

Improving participants' communication skills is an essential component of the intervention. Making a commitment to adhere is an important first step to having excellent adherence. However, if participants cannot initiate a discussion about adherence problems (e.g., side effects) with their primary care providers, they may have trouble sticking with their regimen or may even stop taking medicines on their own. Similarly, negotiating a more manageable regimen with one's health care provider is essential if the current one is so difficult that participants are missing doses regularly. This tool is designed to help participants to understand that assertive communication is the most appropriate way to speak and to act in the health care setting by: (1) emphasizing the differences between speaking passively, aggressively, and assertively; and (2) understanding the differences in nonverbal ways of communicating passively, aggressively, and assertively.

People have different ways of talking to people. You talk to your close friends differently than you might talk to someone you've just met. When we talk with health care professionals, how we talk can affect whether we are successful at communicating our needs and/or questions. Communication involves more than just the words we use or say. We communicate a lot with our bodies - our tone of voice, our eye-contact, our posture, and our hands. In short, there is word talk as well as body talk. There are three different ways of communication that we want to demonstrate today: Passive, Aggressive, and Assertive. One of these three ways is a very effective way to talk; the other two are not. Let's take a look.

There are three ways to say things:

- *Passively with too little attitude*
- Aggressively with too much attitude
- Assertively with the right attitude

Passive talk or talk with "too little attitude" means you fail to state your goal, need, or view, ignoring your own needs and wishes. Passive talk doesn't respect your own feelings and ideas. When you use passive talk, you simply aren't going to get your way, meaning, you probably won't be able to express adherence concerns fully to your provider.

- 1. Being unable to tell someone how you really feel about a situation or what you want or need.
- 2. Going with the crowd when you are unsure of a situation.
- 3. Saying yes when you really want to say no.
- 4. Acting this way so that you will be liked, to be nice to someone or not to hurt the other person's feelings.

The nonverbal ways in which you communicate passively involves:

- Speech: say nothing at all, saying "um" a lot, skipping around the subject
- Voice: soft, whining
- Eyes: not looking at the person, looking down or away
- Posture: shoulders drooping, head down, unable to stand or sit without fidgeting
- Hands: shaking

Aggressive talk, or communicating with "too much attitude" means communicating in such a way that doesn't show respect for the other party's feelings and ideas. You may get your way when you use aggressive talk, but you may not have a good quality relationship with the other person once you're through.

- 1. Expressing yourself, standing up for yourself in a way that is punishing, demanding or threatening to someone else.
- 2. Trying to get your way by putting someone else down.

- 3. Taking or getting what you want without considering the feelings and rights of the other person.
- 4. Threatening or forcing a person to give you something.

The nonverbal ways in which you communicate aggressively involve:

- Speech: cursing, name calling, put downs, hostile remarks
- Voice: loud, tense, shouting
- Eyes: cold, staring, angry, calculating, glaring
- Posture: stiff, rigid, hands on hips, turning your back to/head away from someone while engaging in conversation
- Hands: pointing finger, waving fist, throwing hands up in a manner that dismisses that person ("talk to the hand syndrome")

Assertive talk or communicating with the "right attitude" means saying what you want, in a way that is respectful of the other person's feeling. It can be the most effective way to talk because it allows you to express yourself clearly without alienating the other person.

- 1. Communicating your feelings and opinions in a direct and honest manner instead of hoping the other person will figure out what is on your mind.
- 2. Saying "No" to things you don't want or things that put you in a situation that is undesirable.
- 3. Acknowledging the other person's feelings, telling him/her that you hear him/her, not being demeaning or threatening, yet telling him/her how you truly feel.
- 4. Using "I" statements to let the other person know how you feel helps keep you in control and responsible for the situation. It is very difficult to argue with an I-statement. Also, when you tell your provider "I hear you" this means that you were listening to what they said and your respecting their feelings. Statements that begin with the word "You" can sound very blaming.

The nonverbal ways in which you communicate assertively involve:

- Speech: honest, direct words
- Voice: clear, firm, confident, loud enough to be heard but not too loud
- Eyes: direct eye contact but not glaring
- Posture: head and shoulders raised
- Hands: relaxed

Exercise 1: To make sure we're clear on assertive, aggressive, and passive talk styles, let's practice picking out these different types of talk.

Assertive:

Doctor:	Hello. Have you had any trouble with the medications since I saw you last?
Patient:	Well, I have missed doses a couple of times.
Doctor:	What was going on when you missed the doses?
Patient:	Well, I really have a problem with the taste of the medications. Sometimes
	just thinking about taking them makes me feel sick to my stomach.
Doctor:	Okay. Other people have had some luck taking their pills with a beverage such as Ensure, which helps to mask the unpleasant taste. Why don't you try that and see how it works?

Patient: All right, I'll give it a try.

Was that assertive, aggressive, or passive?

Aggressive:

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Was that assertive, aggressive, or passive?

Passive:

Doctor:	Hello. Have you had any trouble with the medications since I saw you last?.
Patient:	Not really.
Doctor:	Great, let's take a look at your lab results.

Was that assertive, aggressive, or passive?

Exercise 2: Now let's practice talking assertively. Pretend that I am your doctor and I am going to ask you about your adherence. Your job is to use assertive talk to convey your difficulties with adherence and need for assistance.

The interventionist should pick a few of the following statements that seem relevant to the participants' experiences. Then, have them suggest a few of their own.

Doctor: Have you had any problems taking the medicines since I say you last?

- I have missed doses because of problems taking the pills with an empty stomach.
- I sometimes fall asleep before taking the last dose of the day.
- I sometimes sleep through the morning dose.
- I forget to carry the medications with me when I leave the house.
- I get so busy I just forget.
- I am having terrible side effects.
- I feel so depressed about having to take all these pills.

For all of the above: I would like to do a better job taking my pills. Do you have any suggestions that may help me?

Always use assertive communication skills to discuss adherence problems with your primary care provider. Let's practice assertive communication skills in the following exercises.

Exercise 3: Initiating a discussion about adherence

David is at a visit with his doctor. He went on vacation earlier this month and the change in his schedule led to several missed doses of his antiretroviral pills. David is worried that this may make him resistant. The visit is almost over and the doctor hasn't asked her about missed doses. David wants to talk to the doctor about the missed doses but he is afraid that the doctor will think he is a bad patient if s/he does so.

David:	I have something I need to talk to you about. I'm a bit worried about what your reaction is going to be, but I need to get this off my chest.
Doctor:	What is it?
David:	I missed about three total doses of my pills this month when I was away on vacation.
Doctor:	I'm glad you told me. Sometimes it is hard to take all of your pills when you are away from home. Your lab tests seem okay, so I don't think this caused any permanent damage. But, in the future, try to be extra careful about taking all of your pills when you're away from home. You might even want to try using the alarm on your watch to remind yourself about taking the pills when you're away from home.

The interventionist asks the following questions and provides reinforcement and appropriate feedback.

- 1. How did David talk and act assertively when initiating the topic of adherence?
- 2. What other strategies could David have used?

Now let's try a personal situation in which you can initiate discussion about adherence with your primary care provider.

Exercise 4: Negotiating a more manageable antiretroviral regimen

Sometimes when we cannot take our antiretroviral pills as prescribed, it may be helpful to switch to a more manageable regimen. Now we will role play several skits that show us how to negotiate this with your providers.

Kevin had been taking antiretroviral medications for about 3 months. During that time, he had been feeling nauseous, had experienced extreme fatigue, and had had excruciating headaches. Kevin was so disgusted with these side effects that he was considering stopping taking the medicines all together. He decides to at least call his doctor before he stops taking the pills on his own.

Kevin:	I am feeling so sick. I am sick to my stomach, am tired and my head hurts. I really don't think I can take much more of this. I want to stop taking the pills.
Doctor:	Slow down. We can work this out. A lot of people have side effects when they first begin taking these pills. Usually these side effects go away eventually.
Kevin:	But I feel so bad I don't think I can take even one more day of this. I feel that I need to switch to a different regimen. Are there any other medicines that you could give me that would have fewer side effects?
Doctor:	Well, there may be. I think I would like you to come into the office and we can talk about this more in-depth. Can you come in first thing in the morning?
Kevin:	Well, okay, I guess.

Now let's try a personal situation in which you negotiate a more manageable antiretroviral regimen

VII. Tool #7: Reframing

Objective: To increase the participants' skills and confidence in adhering to antiretroviral medications by turning their negative attitudes into a positive reason for sticking with their regimens.

This tool is designed to increase the participants' skills and confidence in adherence through reframing. Reframing involves turning a negative attitude into a positive reason for adhering to the antiretroviral regimen. Reframing involves: (1) identifying a positive motivator underlying the negative attitude; and (2) using that positive motivator to underscore what the participant wants (i.e. adherence).

The interventionist reads the difficulty and the participant generates the reframing statement. If the participant cannot generate his/her own solution the interventionist should give some examples.

Excuse: Comeback:	I feel so down, often I forget to take my pills. When I forget to take my pills, I feel even more depressed than usual. Taking all of my doses makes me feel better about myself.
Excuse: Comeback:	I am so overwhelmed about having to deal with this whole thing. Taking my medicines as prescribed makes me feel like I am in control of my health. Adhering makes me feel less overwhelmed and more in charge of my destiny.
Excuse: Comeback:	No one knows if these medicines are going to work forever anyway. No one can predict the future; taking the antiretroviral medicines is the best way that doctors and scientists know of right now to keep people healthy.

VIII. Tool #8: Creative Negotiation

Objective: To increase the participants' skills and confidence for adhering under difficult situations.

It is possible that some participants may have real concerns about taking their antiretroviral medications at work or other places where people may not know about their HIV status. For example, participants may be concerned that if they openly take their medicines at work, their boss or co-workers will find out about their HIV status and they will be discriminated against or possibly even fired. This tool is designed to help participants to find a solution to protect their adherence under these sort of difficult situations. Creative negotiation is a tool that should be used in special circumstances, and when all other techniques have failed.

Let's think about this scenario:

Leo works at a large insurance firm. Although he has been HIV-positive for over 5 years, he has never disclosed his status to anyone at work. He worries that his co-workers might discriminate against him or be uncomfortable working with him if they knew the truth. Sometimes, he hears them make jokes about AIDS and about people who are gay. His antiretroviral medications must be taken on a strict time schedule, so he must take some of his

doses at work. His co-workers sometimes see him taking so many pills and ask, "Leo, are you sick? Why are you taking all of those pills?"

Example Strategies:

I've been learning that many vitamins and minerals can help you stay healthy as you age. I'm taking these to boost my health.

You know, I have really bad allergies, so have to take a bunch of allergy medicines during the day.

I recently started taking a bunch of different herbs to make me feel healthier. My acupuncturist says I need to take them every 4 hours to get the maximum benefit.

IX. Tool #9: Benefits of Adherence

Objective: To increase the participants' positive attitudes toward antiretroviral adherence.

This tool is designed to motivate the participants to make a commitment to adhere to their antiretroviral regimens by helping them to understand the benefits of adherence.

The interventionist should have the participants think of benefits of adherence, such as:

- 1. The more adherent you are, the less likely you are to have viral resistance
- 2. When you are adherent to your regimen, the antiretroviral medications are working at their full strength to fight HIV
- 3. Adherence can make you feel safer, healthier, and less worried
- 4. Adherence can make you feel good about yourself because you are taking care of yourself
- 5. You can feel proud knowing that you are doing the best thing possible to fight the HIV in your body
- 6. You won't have to feel bad about missing doses or taking them incorrectly

X. Tool #10: Breaking Down Barriers to Adherence

Objective: To increase the participants' skills and confidence in breaking down their own barriers to adherence.

This tool is designed to motivate the participants to make a commitment to adhere by breaking down their own barriers to adherence.

The interventionist presents an argument against adherence, and asks the participant to try to refute the argument using assertive talk skills

Argument		Response
I hate to take my pills in public because I am worried about what people think.	a. b. c.	I understand what you are saying, but you can find ways to get around this, such as taking your medicine in the privacy of the restroom. Most people in public aren't paying attention to you anyway! There are things you can do to make taking pills in public as unobtrusive as possible, such as quickly putting the pills in your mouth when no one else is looking.
I never seem to have any food in the house and I need to take my pills with a full stomach.	a. b. c.	I know of a program that delivers free meals to AIDS patients. I can go to the grocery store once a week and get food to last through the week. I can ask my doctor to give me a prescription for a supplement such as Ensure, so if I don't have any food, I can at least take the pills with the Ensure.
I hate the idea of having to take these pills forever.	a. b.	Although no one knows for sure, someday scientists may figure out a way for patients to stop taking the antiretroviral medications without experiencing any problems. I need to take my pills as prescribed for the time being if I want to be around for such a time. If I don't take the pills as prescribed, I won't have a long future to look forward to anyway. I may get sick and die of AIDS.
I don't like to carry my medications with me when I leave the house.	a. b. c.	Carrying the medications can be a bit of a pain, but your life is worth it! If I get a pill case, fill it up once a week, and put it in my backpack, I can make sure to always have the pills I need with me when I go out. If I carry the medications with me, I won't feel bad or guilty about missing doses when I'm away from home.

XI. Tool #11: Relapse Prevention and Coping with Slips

Objective: To increase the participants' skills and confidence in maintaining adherent behaviors over the long term. To increase the participants' skills and confidence in managing slips.

Once participants have improved their antiretroviral adherence, it is important for them to develop strategies to avoid slips and to cope with slips if a slip occurs. The purpose of this tool is to help them to accomplish these two objectives.

The first step in preventing a slip is to recognize situations that might lead to relapse. The second step is to develop a strategy to avoid these situations or to have a strategy to prevent the slip. The next exercise is designed to help the participant to identify the situations that might lead to slips and to develop an approach for preventing the slip.

Exercise 1: Preventing Slips

Many times people learn a new skill — losing weight, stopping smoking, exercising — but they don't keep it up. Let's talk about how you can continue being adherent to your antiretroviral medications even after you finish this program. Let's assume that you have been doing a great job taking your pills as prescribed. But then something happens that could put you in danger of falling backwards. What could that situation be?

- When you start a new job and have to take pills at work during the day.
- When you are depressed because a love relationship has ended.
- When you are drunk or high.
- When you are on vacation.
- When your friends quit their antiretroviral medications in order to concentrate just on alternative therapies such as acupuncture.

Discuss problem-solving strategies for controlling these kinds of situations (preferably ones the participants generated themselves). Perhaps a participant will mention being at her parent's house for the holidays as a situation in which she will not want to take her medications as prescribed. In this situation, you might discuss the possibility of staying at a motel, to give herself a bit more privacy during her visit, or the option of disclosing her status to her family, so that she can feel free to take her medications in front of them.

The next exercise is designed to help the participant to cope with slips.

Exercise 2: Coping with slips

A big problem in maintaining adherence comes in dealing with slips. A slip is any episode of nonadherence to the antiretroviral regimens, after having made a commitment to adhere. However, one slip doesn't mean total failure. Slips are to be used as opportunities for learning how to keep adhering to the medications.

If you say to yourself, "Well that shows I can't adhere, so I might as well forget about it," you will have trouble continuing to adhere. Or if you say something like, "Oh, I feel terrible. How could I do such a thing? I guess I'm just not worth the effort," you will have trouble continuing.

People are only human and mistakes can happen with regimens as complicated as the antiretroviral medications.

Use one of the scenarios in which the participants feel they would be tempted to return to nonadherent behaviors (generated in previous section) to answer the following question:

Let's suppose you do slip in _____ situation and you don't take your medication as prescribed. What things might you say to yourself?

Role Play 1: Dealing with a slip

Now I am going to read you a script to give you some more practice coping with slips.

Lynn:	What's the matter?
Sheila:	I am so upset.
Lynn:	Why?
Sheila:	<i>I had a really busy day, filled with doctor's appointments and other errands.</i>
Lynn:	What's so bad about that?
Sheila:	Well, about two months ago I finally started taking my antiretroviral
	medications on the right schedule, but today I missed my 2:00pm dose and
	didn't end up taking it until 6:30pm. I was doing so well with adherence.
Lynn:	Don't start bad-mouthing yourself.
Sheila:	I don't know after today. I could have prevented it, but I didn't. I am so

How should she finish the sentence? What are some constructive thoughts she could have instead of ones that make it harder for her to adhere?

Role Play 2: New Job Scene

Janet had been doing a great job at adhering to her antiretroviral regimens when she got a new job as a receptionist at a busy dentist's office. During the first week on the job, she missed several doses of her medication, because she got busy answering the phone at work and interacting with the patients who came to the clinic. Moreover, she did not feel comfortable taking her medication in front of the patients and other staff members and never seemed to have the water and food handy to take her pills. She now feels upset about spoiling her adherence record.

Examples of what Janet could learn:

- 1. Always carry water and food to work.
- 2. Take short breaks during the day to take her pills in a "safe" place, such as in the ladies' room or else outside the office.
- 3. Practice taking pills unobtrusively at home, to feel more able to do this without drawing unwanted attention to herself while at work.
- 4. Tell herself that she had been doing a good job and one slip isn't a reason to stop adhering (in fact it's an excellent reason to keep adhering!).

Role Play 3: Depression role play

Diane and Fred have been living with each other for two years and decided to get married in a year. Without any warning, Diane decided she did not want to marry Fred and moved out of their apartment. Up until this time, Fred had done a great job at adhering to his antiretroviral medications. But, after their relationship ended, he got very depressed and started missing his doses. He felt guilty about his nonadherence, but just couldn't seem to stay on his pill schedule.

Examples of what Fred could learn:

- 1. Sometimes people need professional help to deal with depression.
- 2. Just because you are adherent at one time does not mean that you will never have problems taking your pills as prescribed.

Examples of what Fred could do:

- 1. Correct his thinking by saying something like, "Yes, it was a slip, and you feel badly. But you had done well up to this point and can get back on track."
- 2. Telling his doctor about his depression and missed doses might help him find some solutions, such as obtaining counseling to feel better about himself.
- 3. Having a trusted friend remind him to take his doses may help him adhere during this difficult period.

Role Play 4: Alcohol and drugs

Adolfo had been taking his antiretroviral medications for about 3 years. He had not missed one dose in over 6 months. He was invited to a party with some of his old friends from high school. At the party, he drank a lot of alcohol and smoked some pot, things that he normally does not do. He was so drunk and high that he forgot to take his antiretroviral medication before he went to sleep that night, and then slept through his morning dose the next day. Adolfo feels terrible and guilty when he realizes what he's done, and is worried that he may become resistant to the medications.

Examples of what Adolfo could learn:

- 1. Drinking and taking drugs can lead to poor adherence.
- 2. Be more careful about identifying risky situations.

Examples of what Adolfo could do:

- 1. Correct his thinking by saying something like, "Yes, it was a slip, and I feel badly. But, I have to move on. I've done well adhering up to this point and I can do well again."
- 2. Have him begin his normal pill-taking schedule as soon as possible.
- 3. Make a commitment not to get drunk or high.

*Adapted from Woman-to-Woman Intervention Manual, M. Isabel Fernández, Ph.D., Caryl L. Gay, Ph.D., G. Stephen Bowen, M.D., M.P.H., University of Miami School of Medicine (1999).