

## Antiretroviral Therapy 1

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Antiretroviral Therapy: Use in Sub-Saharan Africa and Common Obstacles Encountered

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Abstract

HIV has become one of the most feared diseases in the world. It has claimed millions of lives, especially in Sub-Saharan Africa. Although it is impossible to cure, studies have shown that using antiretroviral therapy (ART) can greatly improve quality of life and decrease viral load. There are four main classes of ART—NRTIs, NNRTIs, protease inhibitors, and fusion inhibitors. Although access to ART is improving, it is vital that its use is increased in Sub-Saharan Africa, where the prevalence can be as high as 33%.

This thesis explores the current need of ART in Sub-Saharan Africa, as well as the existing coverage. In addition, it addresses the obstacles preventing ART distribution and use—both provider and patient-related. Provider-related obstacles include limited availability of drugs, total cost, lack of healthcare staff and facilities, lack of organization, and government regulations. Patient-related obstacles include cost, transportation, geographic proximity to healthcare facilities, side effects and hunger, pill burden, hospital-related factors, cultural beliefs, social stigma, lack of adequate counseling, and drug resistance. It is important to be proactive, assess ART delivery, consider suggestions for improvement, and tackle the HIV epidemic.

Antiretroviral Therapy: Use in Sub-Saharan Africa  
and Common Obstacles Encountered

The epidemic of human immunodeficiency virus (HIV) has torn apart many families and stolen many lives within the last 20 years. Every day, about 5700 people in the world die from AIDS and 6800 people become newly infected with HIV. Approximately two thirds of people living with HIV reside in Sub-Saharan Africa, making it the most seriously affected region in the world (UNAIDS/WHO, 2007). Providing treatment in this region and throughout the world is a major healthcare concern. There are currently four classes of drugs that have been formulated to target this virus. Even though none of these medications cure HIV, they have proved to drastically decrease viral load and improve the patient's quality of life. In order to provide antiretroviral therapy in Sub-Saharan Africa, healthcare professionals first need to be familiar with HIV itself and the drugs that are available to treat it. Secondly, it is also important for them to assess the current need in their area and compare it with the percent receiving antiretroviral therapy. Finally, since there are many obstacles in distributing and maintaining treatment, it is imperative that they are identified and addressed so that this devastating epidemic can be brought to an end.

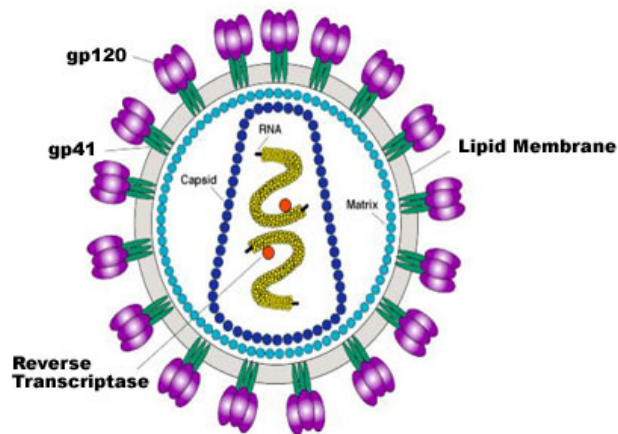
Human Immunodeficiency Virus

There are two different types of human immunodeficiency virus—HIV-1 and HIV-2. HIV-2 is found solely in West Africa, as opposed to HIV-1, which has documented cases worldwide. The majority of research has been done on HIV-1 since it is the more prevalent type of HIV. In order to produce medications to treat this devastating disease, the structure of the virus had to be understood as well as its

mechanism of infection. With this knowledge, particular drugs were devised to inhibit specific steps of the process (Lehne, 2007).

Concerning its structure, the virus contains several main components: a core, a protein capsid and a lipid envelope. The core consists of single-stranded RNA and proteins (Lehne, 2007). See Figure 1.

### **Organization of the HIV-1 Virion**



*Figure 1.* Structure of HIV Virion (NIAID, 2004)

Viruses are not technically living organisms due to the fact that they rely on a host to assist in replication. HIV can enter the body through a variety of means. The most common modes of transmission include sexual intercourse, the use of contaminated needles, vertical transmission from mother to child, and breastfeeding (Vella & Palmisano, 2005). Regardless of how the virus is introduced to the body, HIV replicates and spreads in the same manner. Its first task is to locate a CD4 cell—a type of helper T lymphocyte. Once it finds one, glycoproteins (gp120 & gp41) on HIV's envelope attach to specific proteins on the CD4 cells' membrane. The membranes fuse and HIV injects its RNA into its new host (Lehne, 2007). An enzyme called reverse transcriptase transcribes

the viral RNA into DNA. Then this DNA can be incorporated into the CD4 cell's DNA. Therefore, the virus' genetic material is replicated along with the CD4 cell's DNA. This enables the virus to multiply itself. A daughter viron forms when the RNA and proteins migrate toward the edge of the cell and bud off. Final maturation occurs when large polyproteins in the viron are broken into smaller, functional proteins by an enzyme called protease. If this step is not completed, the viron is not infectious (Lehne, 2007).

Once a person is infected with HIV, he or she may live up to 10 years without any signs of the disease. Despite the slow emergence of symptoms, the virus is rapidly replicating and destroying CD4 cells. In the initial phase on infection, there can be up to 10 million virions per milliliter of blood. At this point, the individual has not mounted an immune response yet, allowing the virus to replicate unopposed. In addition, there is still a high CD4 count, which gives the HIV many vulnerable targets. Once the body's immune system begins to attack, the number of virions per milliliter reduces to between 1,000 and 10,000. Yet, this is still an astronomical number (Lehne, 2007).

#### Drugs Available to Treat HIV

As the HIV epidemic spread globally, researchers recognized the immediate need for medicine. By studying the mechanism of the virus described briefly above, four main classes of medications were invented. These include NRTIs, NNRTIs, protease inhibitors, and fusion inhibitors (see Table 1). The treatment of HIV is called ART (antiretroviral therapy). It is generally recommended that patients are on regimens of three or four drugs. Using only one or two drugs is not typically prescribed because the probability of resistance is high. One possible exception is pregnant women (Lehne, 2007). Multiple studies have been conducted in order to determine the most effective regimens. These

have become known as HAART (Highly Active Antiretroviral Therapy) (Justesen, 2005).

Table 1. *Drugs of Antiretroviral Therapy* (Lehne, 2007)

NRTIs	Protease Inhibitors
Abacavir (Ziagen) Didanosine (Videx) Emetricitabine (Emtriva) Lamivudine (Epivir) Stavudine (Zerit) Tenofovir (Viread) Zalcitabine (Hivid) Zidovudine (Retrovir) Acabavir/lamivudine (Epzicom) Acabavir/lamivudine/zidovudine (Trizivir) Emtricitabine/tenofovir (Truvada) Zidovudine/lamivudine (Combivir)	Amprenavir (Agenerase) Atazanavir (Reyataz) Fosamprenavir (Lexiva) Indinavir (Crixivan) Nelfinavir (Viracept) Ritonavir (Norvir) Saquinavir (Invirase or Fortovase) Tipranavir (Aptivus) Lopinavir/ritonavir (Kaletra)
NNRTIs	Fusion Inhibitors
Delavirdine (Rescriptor) Efavirenz (Sustiva) Nevirapine (Viramune)	Enfuvirtide (Fuzeon)

The goals of HAART include the following: to diminish the viral load as much as possible, maximize the number of CD4 cells, restore and preserve immune function (reducing the risk of opportunistic infections), improve quality of life, and decrease mortality. The effectiveness of antiretroviral therapy has been very promising within the last couple of years. A patient on HAART should have a sharp drop in HIV RNA by the end of 8 weeks of therapy. In addition, HIV can often become undetectable (fewer than 50 HIV RNA copies per mL) after 4 to 6 months. Even if this is the case, patients must continue following their drug regimen. Unfortunately, there is no complete cure for HIV or AIDS due to the fact that some virions remain dormant in CD4 cells (Lehne, 2007).

*Nucleoside/Nucleotide Reverse Transcriptase Inhibitors*

Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) were the first HIV medications to be discovered. They have been considered the “backbone” of all antiretroviral regimens. They are convenient pills and have few drug interactions. The prototype of this class is zidovudine, which has been known to reach the CNS better than any other ART drug. Collectively, NRTIs are effective medications as a result of their structure—they are chemically similar to nucleosides (the building blocks of DNA). They can act as competitive inhibitors of reverse transcriptase. During transcription, reverse transcriptase uses the drug as a nucleoside, incorporating it into the DNA strand. This prevents other nucleosides from binding, which in turn terminates transcription (Lehne, 2007 & Justesen, 2005).

*Non-nucleoside Reverse Transcriptase Inhibitors*

A second class of ART that also inhibits reverse transcriptase is called a non-nucleoside reverse transcriptase inhibitor (NNRTI). Instead of acting like a nucleoside, it binds to an active site on reverse transcriptase, directly inhibiting it. Currently, efavirenz is the only NNRTI preferred for treating HIV. Typically, NNRTIs are given in combination with NRTIs and are administered in pill form. There are a couple disadvantages and limitations with the use of NNRTIs. First of all, resistance to this drug occurs more frequently than with any of the other classes. This is due to the high rate of mutation. It is estimated that 10 incorrect base pairs are incorporated into viral DNA during every replication. Secondly, it is only used for HIV-1; it is ineffective in treating HIV-2 (Lehne, 2007 & Justesen, 2005).



### *Protease Inhibitors*

Protease inhibitors (PIs) are known as the most effective antiretroviral drugs. They are also given in pill form. When given in combination with NRTIs, the viral load is often undetectable. Sometimes it will also be given with a second PI, which boosts its effects. Concerning their mechanism of action, they inhibit the last step of viral replication (when an enzyme called protease breaks large polyproteins into smaller, functional proteins). If a patient is on a protease inhibitor, the drug binds to active sites on protease which makes it inactive. This leaves the viron immature and unable to become infectious. There are many positive aspects about using a PI—it is less selective than some of the other drugs, treats both HIV-1 and HIV-2, and can be used to treat children. Lopinavir can be used in infants as young as 6 months old and nelfinavir in children at least two years old. Another valuable use for PIs is in some resistant cases. Tipranavir/ritonavir (a combination drug) is flexible and is able to adapt the shape of HIV as it mutates. Therefore, it can effectively halt viral replication in resistant cases. A negative aspect of protease inhibitors is that it can cause multiple drug interactions by increasing other drug levels (Lehne, 2007 & Justesen, 2005).

### *Fusion Inhibitors*

The only fusion inhibitor is enfuvirtide, also known as T-20. Unlike all of the other classes of antiretroviral drugs that work by inhibiting enzymes, this one actually stops HIV from entering into the CD4 cells. It binds to gp41 on the virus, stiffening the glycoprotein. Since it is no longer able to mold into other shapes, it is unable to fuse with the CD4 cells' membranes. This halts infection. The positive aspects of using a fusion inhibitor is that it is often very effective, it can be useful for patients with a resistant

strain of HIV, and it has few known drug interactions. Unfortunately, this medication is not as widely used because it is inconvenient and expensive. It takes 106 steps to make this drug (in contrast to the 8-12 steps required for NRTIs, NNRTIs and PIs). Therefore, the cost is high—approximately US\$20,000 per year. In addition, fusion inhibitors are inconvenient because they require two subcutaneous shots every day. It is also limited to HIV-1 and children over age 6 (Lehne, 2007 & Justesen, 2005).

### *Preferred Regimen*

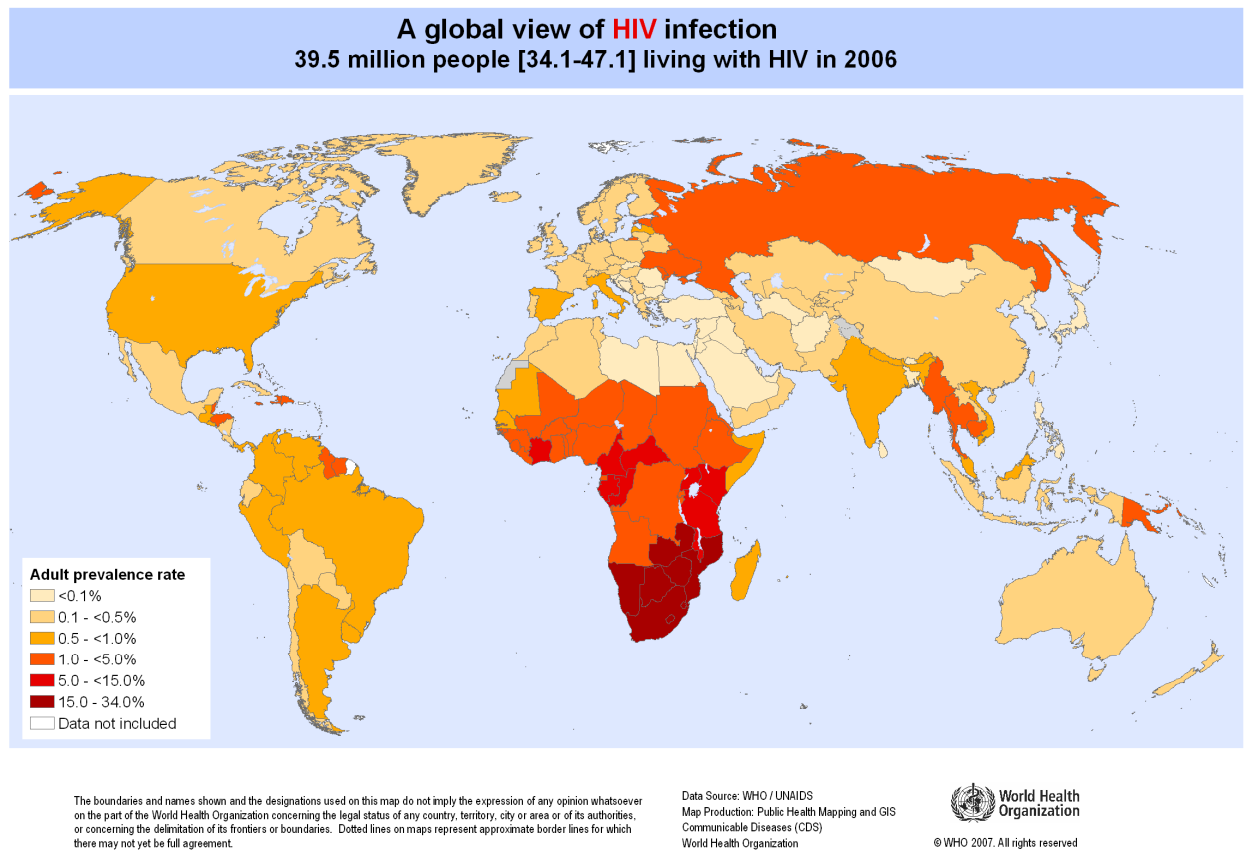
The preferred HAART regimens are listed below in table 2 (Lehne, 2007).

Table 2. *Preferred HAART Regimens* (Lehne, 2007)

Regimen	Drugs of the Regimen
NNRTI based (1 NNRTI + 2NRTIs)	Efavirenz + (lamivudine or emtricitabine) + (zidovudine or tenofovir)
PI based (1 PI + 2 NRTIs)	Lopinavir/ritonavir (Kaletra) + (lamivudine or emtricitabine) + zidovudine

### The Need for Antiretroviral Therapy in Sub-Saharan Africa

In order to provide HIV treatment, healthcare professionals need to assess the need in their area and compare it to the percent of patients who are receiving ART. The United Nations Programme of HIV/AIDS (UNAIDS) and the World Health Organization (WHO) have compiled statistics to provide healthcare providers with this information. The map in Figure 2 displays the prevalence of HIV/AIDS throughout the world.



*Figure 2. Prevalence of HIV/AIDS in 2006*

(Retrieved from the WHO website: <http://gamapservr.who.int/mapLibrary/Files/Maps/HIVPrevalenceGlobal2006.png>).

Concerning total need, they estimated that there were 33.2 million people in the world living with HIV in the year 2007. 22.5 million of these people (two thirds) were from Sub-Saharan Africa. In addition, nearly 90% of the children in the world infected with HIV live in this region. Concerning mortality, 2.1 million of people in the world died of AIDS in 2007. 1.6 million of these people were Sub-Saharan Africans. This means that three quarters of all deaths from AIDS were in this region. In fact, AIDS is the *leading* cause of death in Sub-Saharan Africa. (UNAIDS/WHO, 2007). HIV/AIDS has drastically reduced the life expectancy in some of these countries. For instance, in South Africa, the

male life expectancy dropped from 61.5 in 1994 to 49.2 in 2000. This decline was mainly due to the increasing prevalence of HIV/AIDS cases (Kapp, 2004).

Approximately 5% of people in Sub-Saharan Africa are infected with HIV, which is drastically higher than the rest of the world (<1%). However, the prevalence varies greatly county to country (see table 3) (UNAIDS/WHO, 2007).

Table 3. *Prevalence of HIV Reported in the 2006 WHO Report on the Global AIDS Epidemic* (UNAIDS/WHO, 2007)

Country	% of Population	Country	% of Population	Country	% of Population
Benin	1.8	Ethiopia	1.4	Senegal	0.9
Botswana	24.1	Ghana	2.3	Sierra Leone	1.6
Burkina Faso	2.0	Guinea	1.5	South Africa	18.8
Burundi	3.3	Kenya	6.1	Swaziland	33.4
Cameroon	5.4	Lesotho	23.2	Uganda	6.7
Central African Republic	10.7	Malawi	14.1	Tanzania	6.5
Chad	3.5	Mali	1.7	Zambia	17.0
Cote d'Ivoire	7.1	Niger	1.1	Zimbabwe	20.1
Equatorial Guinea	3.2	Rwanda	3.1		

The majority of the countries in Sub-Saharan Africa that have a high prevalence of HIV are in located in southern Africa. Countries of particular concern include Swaziland (who has a prevalence of 33.4%), Botswana (24.1%), Lesotho (23.2%), Zimbabwe (20.1%), South Africa (18.8%), and Zambia (17%). The prevalence of HIV in the countries of East Africa have been relatively stable, and are even beginning to decline. This is the same for many of the countries in West and Central Africa (UNAIDS/WHO, 2007). Organizations such as the WHO and UNAIDS use this information to narrow in on the areas with the greatest need.

## Use of ART in Sub-Saharan Africa

As a result of increased awareness and funding, the distribution of ART in Sub-Saharan Africa has been improving substantially. This has greatly improved the clinical outcome of the disease and reduced the death rate. Although the patients will have to remain on ART for the rest of their lives, their ability to live and function in society is greatly improved. Many patients make a complete turnaround and no longer display outward signs and symptoms of HIV. In addition, many patients' viral loads diminish to undetectable levels. However, one of the major problems in Sub-Saharan Africa is that the majority of people are not tested for the disease. In fact, less than 10% of HIV-infected people in this region know that they are HIV positive. Most people with HIV are not tested for it until they are admitted into the hospital for opportunistic infections (Colebunders, Ronald, Katabira, & Sande, 2005).

Still, as education and prevention are promoted, more and more patients are being tested for HIV. Once HIV is diagnosed and the patient's disease is staged, the physician determines the patient's need for antiretroviral therapy. The World Health Organization (WHO) recommends that in resource-limited settings, ART is given to patients who fall in one of these categories:

- Stage I or II HIV with a CD4 cell count below  $200/\text{mm}^3$
- Stage III HIV with a CD4 cell count below  $350/\text{mm}^3$
- Stage IV HIV

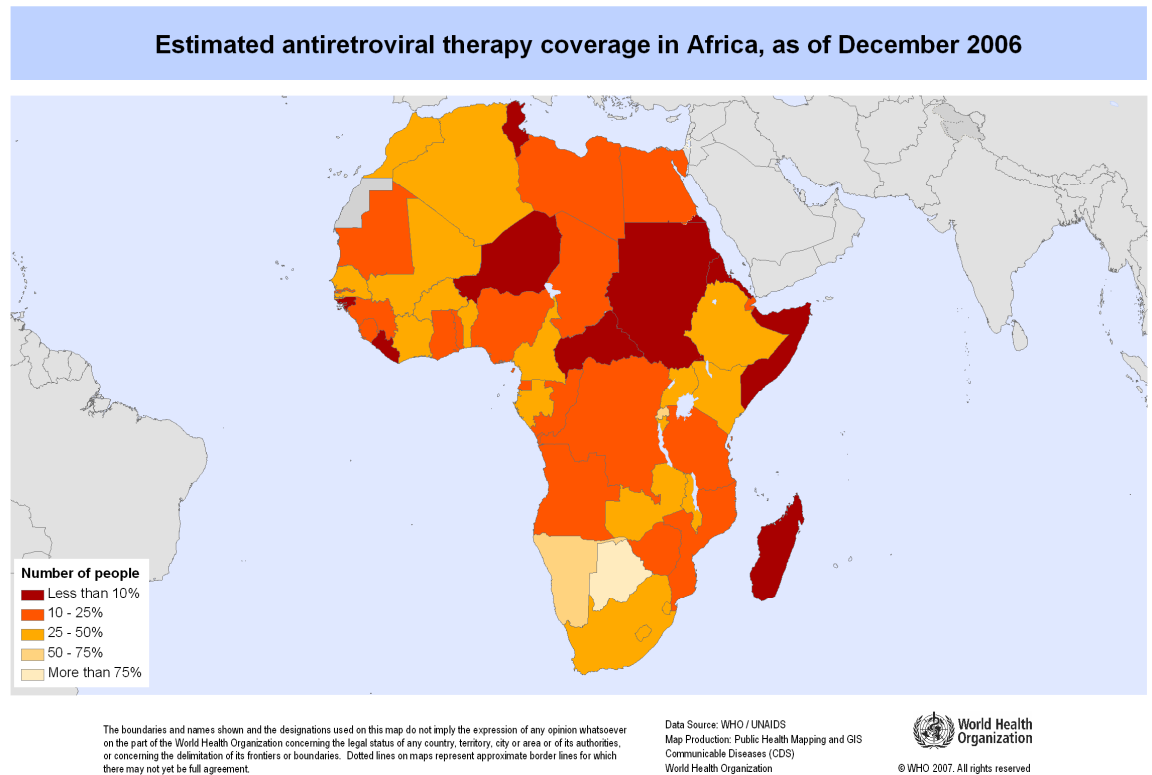
These recommendations are in place to help guide physicians in providing ART in areas where there are not enough resources and for every HIV patient to receive therapy (WHO, 2003).

The recommended regimens for Africa usually include one NNRTI and two NRTIs. These drugs are cheaper and more accessible in developing countries (Colebunders, Ronald, Katabira, & Sande, 2005). The WHO recommends using one of the following regimens:

- stavudine + lamivudine + nevirapine
- zidovudine + lamivudine + nevirapine
- stavudine + lamivudine + efavirenz
- zidovudine + lamivudine + efavirenz (WHO, 2003)

A study in Botswana collected information and compiled statistics about the use of the different types of ART. Of ART receivers, 31% were taking a combination of at least three drugs (18% on PI regimen plus 13% on NNRTI regimen). From the rest of the patients, 52% were only able to afford one drug or a combination of two drugs. The most common class of drug given by itself was an NRTI. The remaining regimens (17%) were unclear (Weiser, Wolfe, Bangsberg, Thior, Gilbert, Makhema, 2003). Studies such as this one are important because they provide data that can be further researched to determine effectiveness of drug regimens.

It is very important that HIV drug coverage is analyzed and evaluated on an annual basis. The number of HIV-infected people living in Sub-Saharan Africa needs to be compared to the number of patients that are receiving ART. This will provide data regarding the current state of ART distribution. Therefore it helps to ensure that distribution is increasing and maintenance is improving. Figure 3 shows the coverage in Sub-Saharan Africa in the year 2006.



*Figure 3.* ART Coverage in Sub-Saharan Africa in 2006

(Retrieved from the WHO website: [http://gamapservers.who.int/mapLibrary/Files/Maps/Africa\\_ARV\\_Coverage\\_A4\\_100407.png](http://gamapservers.who.int/mapLibrary/Files/Maps/Africa_ARV_Coverage_A4_100407.png)).

In 2003, the WHO declared a goal of reaching 3 million HIV patients by the year 2005. It was called the “3 by 5” initiative. Although, the goal was not met, there was a drastic improvement in the distribution of antiretroviral therapy. In 2003, only about 400,000 HIV patients from low or middle-income countries were receiving ART. By the year 2005, this increased to 1.3 million people. In Sub-Saharan Africa, the number of patients on ART increased drastically from 100,000 to 810,000 between 2003 and 2005 (see table 4) (WHO/UNAIDS, 2006). In the year 2007 1.3 million people in this region were on ART. This is approximately 28% of their HIV population. Currently, the WHO and UNAIDS are pushing towards universal access by 2010. (WHO/UNAIDS, 2007).

Table 4. *Estimated Distribution of ART in Sub-Saharan Africa for 2005*

Country	HIV patients in need of ART	HIV patients who received ART	ART coverage
<b>SOUTHERN AFRICA</b>			
Angola	52,000	2500-3500	6%
Botswana	84,000	67,000-77,000	85%
Lesotho	58,000	7,500-9,000	14%
Madagascar	20,000	<200	0%
Malawi	169,000	31,000-35,000	20%
Mauritius	---	<200	---
Mozambique	216,000	19,000-21,000	9%
Namibia	41,000	27,000-31,000	71%
South Africa	983,000	178,000-235,000	21%
Swaziland	42,000	12,000-14,000	31%
Zambia	183,000	45,000-52,000	27%
Zimbabwe	321,000	22,000-27,000	8%
<b>EAST AFRICA</b>			
Burundi	46,000	6,000-7,000	14%
Eritrea	11,000	<1000	5%
Ethiopia	278,000	19,000-22,000	7%
Kenya	273,000	60,000-72,000	24%
Rwanda	49,000	18,000-20,000	39%
Somalia	6,000	---	1%
Uganda	148,000	71,000-79,000	51%
United Republic of Tanzania	315,000	20,000-23,000	7%
<b>WEST AFRICA</b>			
Benin	14,000	3,500-6,000	33%
Burkina Faso	34,000	7,500-9,000	24%
Cameroon	108,000	21,000-26,000	22%
Cote d'Ivoire	111,000	18,000-19,000	17%
Gambia	1,500	<200	10%
Ghana	61,000	4,000-5,000	7%
Guinea	23,000	2,000-2,500	9%
Liberia	15,000	<500	3%
Mali	22,000	5,500-9,000	32%
Niger	12,000	<1,000	5%
Nigeria	636,000	37,000-45,000	7%
Senegal	9,000	3,000-5,500	47%
Sierra Leone	9,600	<500	2%
Togo	25,000	5,000-8,000	27%
<b>CENTRAL AFRICA</b>			
Central African Republic	49,000	1,500-2,000	3%



Chad	38,000	5,000-8,000	17%
Democratic Republic of the Congo	209,000	7,000-8,500	4%

(WHO/UNAIDS, 2006).

### Obstacles for Providing Treatment

In order to effectively treat HIV patients in Sub-Saharan Africa, it is important to tackle the common obstacles to providing ART. There are two main types of obstacles: provider-related obstacles and patient-related obstacles. Provider-related obstacles include limited availability of drugs, total cost, lack of healthcare staff/heavy workloads, lack of healthcare facilities, lack of organization, and government regulations. Patient-related obstacles are typically related to adherence to the drug regimen. They can include cost, transportation, geographic proximity to healthcare facilities, side effects and hunger, pill burden, hospital-related factors, cultural beliefs, social stigma, lack of adequate counseling, and lastly, drug resistance. Addressing these obstacles will help to provide successful treatment to the maximum number of patients.

In order to supplement my research, I attempted to administer a survey (see Appendix A) to healthcare providers in Africa. Unfortunately the response was poor. I sent ten surveys to healthcare providers within a missions organization; I only received one survey back. Despite the fact that this eliminates my ability to compare obstacles between different countries, it did provide specific information on a hospital in Benin. The government in Benin had begun to provide ART to this hospital in 2005; since then, 57 patients had been treated. Although they had access to NNRTIs, NRTIs and protease inhibitors, their most common regimen was a NNRTI plus a NRTI. The obstacles encountered in this hospital will be provided throughout the remainder of this thesis in

conjunction with a review of existing studies.

### Provider-Related Obstacles

#### *Limited Availability of Drugs*

As mentioned above (see Table 4), there are more HIV patients than the current resources, drugs and healthcare facilities can supply. Only a limited number of patients can be treated. This is one of the obstacles in providing antiretroviral therapy. In the hospital in Benin that participated in my survey, approximately 80% of people seeking HIV treatment were able to receive it through the hospital. This percent does not include people with HIV who do not seek treatment. The reason why 100% of HIV patients were not able to receive treatment is because the supplies and medications were limited. It is also important to note that if patients become resistant, there is an even lower chance that the second-line drugs will be available for them. Many of these patients will progress quickly in the disease due to a lack of effective treatment.

#### *High Cost*

Since finances are an obvious limitation to providing drug therapy in resource-poor settings, multiple organizations have published an estimate of the total cost. Gutierrez, et. al. compiled information on what it would cost to see “3 by 5” come to completion. They calculated the costs for the 34 countries that made up 90% of the overall need. The estimate that they arrived at was a range from \$5.1 billion to \$5.9 billion. This was just to include the money that would be spent between 2003 and 2005. They also included a chart of the distribution of this money: 43% for ART, 17.8% for treating opportunistic infections, 12.2% for support costs (training health personnel, supervision, etc), 10.1% for universal precautions, 9.1% for palliative care, 3.9% for

program costs, 1.8% for opportunistic infection prophylaxis, 1.4% for ART monitoring and laboratory costs, and 0.6% for testing and counseling. Concerning the costs of ART in resource poor settings, first line therapy ranged from US\$140 to US\$304 per patient per year. Second line therapy ranged from US\$510 to US\$1108. The costs then increased even more for patients who were also diagnosed with TB or were pregnant (Gutierrez, Johns, Adam, Bertozzi, Edejer, Greener, et al., 2004).

An even higher estimate has been released by the World Health Organization. They estimated that for the year 2007, it would cost approximately \$18.1 billion to treat HIV globally. However, it was estimated that only about \$10 billion dollars would be available. The budget for the World Health Organization's HIV/AIDS work has also been short. From their needed \$281 million, they were \$120 million short. Therefore, their research and impact was limited as well (WHO, 2006).

Concerning the current source of the needed money, many governments, organizations, and outside donors contribute to the funding. The WHO estimated that in the year 2006, about \$8.9 billion came from existing pledges and commitments, and \$2.8 billion came from domestic sources. In some middle- and upper-income countries, the government covers 80-95% of HIV costs through public health programs and social security. Financial support is crucial for some low- to middle- income countries. However, even after combining the government's own funding and outside funding, only about 25-50% of the costs are typically covered. The rest has to be covered by the patients or their families (WHO, 2006). This shows how finances are one of the main barriers to reaching universal access to ART.

One way that the obstacle of cost can be addressed is to raise awareness. This can

be done through a variety of means such as publications to the general public, news reports on television, and using influential people as spokespersons. Both the cost of providing ART and the current funding available need to be announced. It is also important that funding is coordinated well. There are currently many programs and organizations raising money for the HIV/AIDS crisis. They need to be overseen and organized so that the resources are mobilized to where the need is.

#### *Lack of Healthcare Facilities and Skilled Healthcare Workers*

In order to effectively provide antiretroviral therapy, there must be a large base of healthcare facilities and workers that are willing to participate. Healthcare providers are the connection between the public and current medicine and technology. Unfortunately, there is a lack of healthcare providers in Sub-Saharan Africa. This results in understaffing of hospitals and clinics. In addition, since there are not sufficient numbers of healthcare workers, new hospitals and clinics cannot be started. As a result, there are many people in rural villages and towns that cannot receive medical care because there is not a healthcare facility close enough to their home. In order to increase the number of healthcare facilities dispersed in low-income countries, money must be raised and workers must be recruited.

Compared to the rest of the world, Sub-Saharan Africa is lagging behind in their workforce. Even though Africa has 14% of the world's population and 25% of the disease burden, they only have 1.3% of the health workers. On average, there are 0.8 health workers per 1000 people. The world's average is more than quadruple this statistic (4.2 per 1000 people). The WHO regional director for Africa stated that "Africa is literally engaged in a war against diseases and health challenges of all descriptions—old,

neglected, emerging, and re-emerging. This war cannot be fought without soldiers!”  
(Sambo, 2007, p. 5).

There are multiple reasons why the health workforce is struggling. First of all, the human resource departments in countries of Sub-Saharan Africa are lacking in structure and organization. They often lack policies, are poor at planning, and have weak management. In addition, they usually have inadequate incentive systems. It is a struggle for these departments to recruit and retain workers for the healthcare field (Lusamba-Dikassa, 2007).

Secondly, they often do not have the resources to adequately train and pay health workers. Healthcare providers in Sub-Saharan Africa have very low salaries compared to those in other countries. Therefore, recruiting for this region is difficult. Not only are there insufficient funds for paying workers, but there are also not enough funds to cover the cost of training. This can jeopardize the quality of training. The easiest place to train healthcare workers is in the hospitals. Unfortunately, healthcare students who only receive training in hospitals do not learn much about disease prevention and health promotion. Instead, all of their training is based upon diagnoses and treatment. Therefore, there is often a lack of holistic care. This affects the healthcare workers' ability to educate patients about HIV prevention. With more investment in healthcare training, institutions could be evaluated and improved (Lusamba-Dikassa, 2007).

Thirdly, it is hard to recruit people to the health field, and even harder to keep them there. Since there are few healthcare providers, the workload is high, especially in the hospitals. This puts a large burden on the staff because they must provide care for so many patients that they become overworked. A study in Tanzania showed that 82% of

healthcare workers in Tanzania felt like they were overworked (Hardon, Akurut, Comoro, Ekelzie, Irunde, Gerrits, et al., 2007). Being a healthcare professional can be very frustrating and stressful. The combination of physical, emotional and mental stress often leads to fatigue and burn-out. Therefore, this makes medical professions less attractive. In Sub-Saharan Africa this leads to a high migration rate. Many healthcare workers leave this region to work in countries where there is a better established healthcare system. This is often attractive because workload is usually less, pay is better, and there are more benefits and incentives (Marchal, De Brouwere, Kegels, 2005). Rates of migration in African countries can be as high as 60% (Lusamba-Dikassa, 2007). According to the South African Medical Association, more than 4000 doctors left the public health system between 2000 and 2004. They either went abroad or started a private practice. This roughly equaled the number of doctors trained within that time (Kapp, 2004).

Finally, HIV has a direct effect on the health workforce. Besides claiming the lives of many healthcare workers, it also affects the morale and attitude of current healthcare workers. The percent of HIV positive patients in the hospitals is on the rise, which makes it worse. Currently about 46% of patients admitted into hospitals in South Africa are HIV positive. Research has shown that AIDS patients stay almost twice as long as patients without AIDS. In one study, AIDS patients stayed in the hospital an average of 13.7 days. Non-AIDS patients were admitted in hospital for an average of 8.2 days. Therefore, this shows that this disease dramatically increases the need for medical care. This leads to a high workload, stress, and fatigue. In addition, most patients with HIV/AIDS are brought to the hospital in advanced stages of the disease. High death rates among these patients lead to a sense of helplessness among healthcare workers (Marchal,

De Brouwere, Kegels, 2005).

Fear of being exposed to HIV is an additional reason why it is hard to recruit and maintain healthcare workers. Even though the actual risk of HIV transmission after percutaneous exposure is only about 0.3%, the perceived risk is much higher. Often there are inadequate supplies (such as gloves, gowns and disinfectant) for healthcare providers to use to protect themselves. This instills fear in current healthcare workers, which then affects the quality of care that HIV patients receive. It also deters potential healthcare workers (Marchal, De Brouwere, Kegels, 2005).

Even if health workers do maintain their positions, the heavy workload and high stress effects the care that they are able to give to their patients. The morale of current health workers is often very low and it is hard to provide motivation. As a result, patients often do not receive quality care. Quality care is no longer amongst the healthcare workers' main concerns. This is especially true for patients with HIV who are sometimes neglected as a result of the healthcare worker's fear of exposure. The low morale also leads to a high rate of absenteeism (Marchal, De Brouwere, Kegels, 2005).

In order to improve morale and patient care, it is imperative that the shortage of healthcare providers is addressed. Steps need to be taken to decrease the workload, reduce the risk of exposure (and the fear associated with it), and reduce the rate of migration of healthcare workers. In order to decrease the risk of exposure, universal precautions need to be maintained on a stricter level. Facilities need to make it a priority to provide all their staff with gloves, gowns, and goggles and to provide a safe way to dispose of used needles and contaminated items. It is also important to adopt safer nursing and medical techniques according to current research. Finally, post-exposure

prophylaxis should be provided to healthcare workers free of charge (Marchal, De Brouwere, Kegels, 2005). Adhering to these practices will help provide safety as well as reduce fear. An additional way to reduce fear among healthcare workers is to provide training about safe techniques as well as additional education about HIV. Since the perceived risk is often much higher than actual risk, more education would help to reduce the fear associated with exposure to HIV.

It is vital that these people work in the areas of greatest need. One way to improve the retention of healthcare workers in smaller rural towns and villages is to recruit people who live in particular towns or villages that are in need. These people can be trained in larger cities and then return to their original home. Since they would have family and friends in this area, it would be more likely that they would stay. Due to the fact that most people in these rural areas would not be able to afford medical training, funds need to be raised to provide scholarships and grants for their training.

It is also important that additional incentives are provided so that the medical field in Sub-Saharan Africa becomes more attractive to healthcare workers. This will reduce the rate of migration of healthcare workers out of Africa. One possible incentive is to provide medical or nursing education at a reduced cost if students agree to work a certain number of years in a particular location that needs healthcare workers.

In order to address the large workload, additional people need to be recruited to join the medical field. For this come to fruition, effort needs to be put into the human resource departments. Three of the main goals that HR departments should strive for are improved planning and formation of policies, enhanced management, and better training of staff. It is essential that progress is monitored and evaluated. Countries need to help



human resource departments achieve these by allocating money, showing their political commitment, and helping to raise awareness. Not only does each individual country need to take leadership over the issue, but they need to be willing work collectively with other countries and global organizations to discuss the most effective ways of enhancing human resource departments (Lusamba-Dikassa, 2007).

### *Lack of Organization*

Weiser said in his research study that it is important to “strengthen the health infrastructures for delivering care” (Weiser, et al., 2003). In resource-poor countries there is usually poor organization within the health field. As opposed to more developed countries such as the United States, countries in Sub-Saharan Africa do not have very well designed healthcare systems. Many do not have well planned programs, policies, and procedures. Countries usually have to rely on plans and procedures suggested by international organizations. They need to take it a step further by researching and determining what works best for their country. Then they need to outline and organize this information and amend policies and procedures as needed.

Poor organization often leads to poor communication. This has been an additional challenge in Sub-Saharan Africa. If communication between the different healthcare levels is lacking, reporting becomes more challenging. Therefore, it is difficult to put together databases and study the epidemiology. In addition, also makes it difficult to evaluate performance. Therefore, there is often a lack of accountability.

I have come across poor reporting and participation in research through my own data collection. As stated above, I sent out 10 surveys regarding ART use and common

obstacles encountered to healthcare professionals in different African countries. The response was very poor; only one survey was returned.

#### *Government Regulations Regarding ART*

The extent of government involvement in HIV treatment varies greatly from country to country. Government regulations can sometimes become obstacles to healthcare providers. For instance, in Benin, the government selects which hospitals that they will supply ART for. The remaining hospitals are unable to provide treatment for their HIV patients. The selected hospitals have rules that they are supposed to follow, regardless of if they are feasible or not. The nurse who completed my survey in Benin said the following:

They have certain rules for following up with labtests, which I cannot always do, since in our lab we cannot do the tests and they don't supply us with any money for travelling elsewhere. (CD 4 and viral charge). There is also a whole pile of paperwork to be done each month.

It was also mentioned that the government comes to check on their stock on a regular basis. However, they have run out on several occasions. Even though government resources are necessary for HIV treatment, it is important to evaluate the government's regulations. It is important for them to address impractical or outdated regulations and procedures.

#### Patient-Related Obstacles

Regardless of how efficient a country is at distributing ART, many patients face multiple obstacles of their own, which drastically affects HIV treatment. According to a study by Mshana, et al. in Tanzania, the top three areas of concern by potential ART

recipients were “financial constraints, reaching the regional hospital and sustaining treatment” (Mshana, Wamoyi, Busza, Zaba, Changalucha, Kaluvya, et al., 2006). Each of these factors affect how well the patients are able to adhere to their drug regimens.

#### *Patient Adherence to Drug Regimen*

Consistent adherence to the drug regimen is a vital factor in treating HIV/AIDS. Optimal adherence is greater than 95%. This means that a patient can only miss one dose in 10 days if he or she is on a twice-a-day regimen (Weiser, et al., 2003). If adherence is poor (<80%), the drugs are not maintained at high enough concentrations to stop HIV replication. This leads to detectable viremia, poor treatment outcomes, and even drug resistance. A study of 45 HIV-infected patients determined that 87% of patients with less than 80% adherence went into virologic failure (Chesney, 2000). Even nonadherence for as short of a time as a week can result in rapid rebound of the virus (Weiser, et al., 2003).

There have been multiple studies that investigated adherence rates of countries in Sub-Saharan Africa. A study conducted by Hardon, et al. in Botswana, Tanzania, and Uganda in 2007 estimated that 77% of African patients adhere to the drug regimen (Hardon, et al., 2007). However, according to a study by Weiser, et al., the levels of adherence in Botswana were significantly lower. Using questionnaires and interviews they collected data from 109 HIV patients and 60 healthcare providers in Botswana. According to patients' self-report, 54% of patients were adherent, 17% were non-adherent and 29% had gaps in treatment. Healthcare providers estimated that 56% of their patients were adherent and 44% were non-adherent (Weiser, et al., 2003).

In developed countries such as the United States, poor adherence usually stems from substance abuse, dietary restrictions, the “pill burden,” and side effects. However,

research has shown that economic factors predominate poor adherence in resource-poor settings (Chesney, 2000). It is actually rare that lack of motivation leads to poor adherence. In fact, studies show that Africans are actually highly motivated to take their medications as prescribed. However, there are many other constraints that limit their ability to do so (Hardon, et al., 2007).

Many of the barriers to ART adherence were documented the study mentioned above by Weiser, et al. They chose Botswana to collect their research because of the high prevalence of HIV—the highest in the world. In fact, 60% of their hospital beds are occupied by AIDS patients (Weiser, et al., 2003). The top reasons they listed for non-adherence are included in Table 5.

Table 5. *Reasons Stated by Patients for Non-adherence* (Weiser, et al., 2003)

Reason	Percent of Patients	Reason	Percent of Patients
Finances	48%	Hard to follow instructions	5%
Forgetting	29%	Too sick	4%
Ran out of medicine	17%	Misunderstanding doctor	3%
Travel	13%	Pharmacy closed	3%
Side effects	12%	Stigma	3%
Too busy	12%	Alcohol	1%
Doctor's orders	8%	Felt better	1%
Distance from clinic	5%	Stresses at home/work	1%

It is also interesting to note that gaps in treatment were more common than day-to-day non-adherence. This shows that patients are motivated to take their medication on a regular basis. It is more common that barriers (such as cost or transportation) prevent them from receiving their next supply of medication (Weiser, et al., 2003).

Concerning the adherence of HIV patients in Benin, the nurse who filled out my survey stated the following:

Most people are very keen to start treatment when they are very sick, but we have seen some non-adherence by some of them when they were better. We have decided not to put people on treatment anymore, unless we know where they live and they have to sign an agreement before we start treatment with one other member of their family or a friend present. This makes it easier to check up on them when they don't show up for appointments.

Poor adherence in this hospital in Benin predominantly stemmed from the following obstacles: lack of funds, geographic proximity to healthcare facility, and social/cultural issues. Since they had only been distributing ART for two years, there was little data about resistance. In addition, they had no way to test for resistance.

Although the major obstacles to optimal adherence will vary from country to country, it is still important to analyze each one. The remainder of this thesis will provide current research about the following obstacles: cost, transportation, proximity to healthcare facilities, side effects and hunger, hospital-related factors, cultural beliefs, social stigma, pill burden, lack of adequate counseling, and lastly, drug resistance.

### *Cost*

The most widely mentioned barrier is cost. Many people with HIV will not seek out treatment at all because they assume it will be too expensive. Even if they do seek out treatment, many patients in rural towns and villages of Sub-Saharan Africa are unable to pay. A patient interviewed in Mshana's study said the following: "If you go to Bugando without money, they will completely not care about you...there are good services if you have money, but if you don't have money, the services are not good" (Mshana, et al., 2006, p. 653).

As a result of the increasing awareness regarding HIV/AIDS in Sub-Saharan Africa, funding is being increased to assist patients paying for ART. In fact, many governments and organizations are beginning to provide ART free of charge. However, this is not the case in all areas. In 2003, when Weiser et al. completed their study in Botswana, patients were only receiving about one third of the cost of optimal ART. Medical aid programs supplied up to 1,000 pula each month. However, the cost of a 3-drug regimen ranged from 2,000 to 4,000 pula per month. If patients were able to afford therapy at all, many of them had to resort to sub-optimal therapy, which was usually a regimen of only one or two drugs. It was estimated that if cost was eliminated as an obstacle for the patients in this study, good adherence would increase from 54-56% to 74% of the patients (Weiser, et al., 2003).

Even if the government or a nonprofit organization pays for the cost of ART, there are still additional expenses that make it difficult for patients to afford their HIV treatment. Many clinics and hospitals charge a registration fee or visit fees each time they come to pick up the medication. In addition, often there are laboratory fees. These can be difficult for patients with low incomes to pay. For instance, in one of the facilities in Tanzania that participated in Hardon's study, there was a visit fee up to US\$3 and a US\$15 lab fee (Hardon, et al., 2007). However, the average daily wage in this country is only about US\$1.40 per day (Wikipedia, 2007 & *Currency Converter*, 2007). This would cost approximately 13 days wages! In addition, these patients often lose an entire day's wages on the day that they visit the clinic or hospital (Hardon, et al., 2007).

Even if patients have enough money to cover these expenses, they may choose not to continue with their drug regimen because they have other unrelated expenses that they

would not be able to cover. It is important that these patients have enough remaining money to care for their families—providing them with food, clothing and shelter. These obligations are of more importance to them than their HIV treatment (Weiser, et al., 2003). It is important that additional funds are raised to help patients pay for some of these additional expenses. This will improve patient adherence overall. One way to do this on an individual basis is through sponsorship programs. Families throughout the world can sponsor an HIV patient, supplying extra money so that the patient can pay for transportation, hospital fees, food, and additional costs.

### *Transportation*

Transportation costs can also be a burden on patients. Some patients fail to make it to follow-up visits where they would have received a refill on their medication. Most Africans do not own a vehicle, therefore they must pay for a bus or taxi. For long distances in Uganda, transportation can cost 30,000 shillings (US\$17) round trip (Hardon, et al., 2007). The average Ugandan only makes 42,000 shillings (US\$24) per month (Stoker, 2005). Therefore, this is huge cost! In addition to the cost of transportation, the inconsistency and unreliability of transportation can make patients late. This means that they may run out of pills before they are able to get back to the clinic or hospital. Overall, cost and transportation are two of the main causes of sub-optimal adherence (Hardon, et al., 2007).

If it is possible to raise additional funds, some of the money raised can be used to help patients reach the healthcare facilities. However, since money is also one of the largest obstacles this will probably not be an option for most countries. Another idea is to buy a large van or other vehicle to pick up patients and provide transportation for follow-

up visits. This will work best in towns where there is a large need and the distance between patients' homes is not very far.

#### *Geographic Proximity to Treatment Facility*

Another hindrance for people who need ART is that there is often not a healthcare facility close enough for them to go to. As discussed above, this problem stems from the fact that most countries are lacking in resources and in their number of healthcare professionals. Some patients from Weiser et al.'s study said that they had to travel 800-1000 km in order to reach the clinic or hospital. It was very difficult for them to do this on a monthly basis (Weiser, et al., 2003). Even if there are closer hospitals and clinics, many do not have the ability to test and treat HIV. There are many villages dispersed throughout the Africa countries. Many are 100 km or more from cities where ART is provided. Therefore, even if an HIV patient can make it to a healthcare facility once, it will be difficult for him or her to go for follow-up visits every month to pick of more medication. This leads to poor adherence. It is important that countries as a whole assess their need for additional healthcare facilities based upon the need in various locations. (Hardon, et al., 2007).

#### *Side Effects and Hunger*

Sometimes side effects that the patients experience can lead to poor adherence to the drug regimen. Usually the side effects dissipate with time; however, some patients do not know this. The most common side effects include headache, nausea, vomiting, diarrhea, increased heart rate, rash, and swollen legs. If the effects are bad enough, some patients will begin skipping doses, or quit altogether. Some patients will only take their pill once a day instead of twice a day in order to alleviate some of the symptoms. In



addition, sometimes the symptoms (such as sweating) are embarrassing, so patients will not want to take the medication when they are out in public. This is another reason why some patients skip doses (Hardon, et al., 2007).

Nearly every patient will experience side effects; however, they will be more extreme in some patients than in others. Healthcare providers need to monitor their patients for side effects. The patients who experience very mild side effects may be able to live with the side effects. However, for the patients with severe side effects, healthcare providers should look into other regimens. Adherence will improve if the symptoms with the new regimen are less severe. It is also important that healthcare providers inform their patients that some side effects will gradually dissipate over time. This will encourage patients to remain adherent at the beginning of their regimens. If major side effects do not wear off, they should notify their healthcare provider so that other regimens can be explored.

Many patients on ART also complain of hunger during the initial stages of treatment. As the body is regaining its weight and strength, it requires extra food (Hardon, et al., 2007). It is also recommended that these patients eat a well-balanced meal, which usually means they have to buy more expensive food. Patients in rural towns and villages do not have the resources to buy supplemental food, or an increased quantity of food. Often they will have a limited food supply at home and are unable to satisfy their appetites. The hunger can become so bad that patients don't want to take their medication. A male participant in Mshana's study can be quoted as follows: "you take those medicines, they can overpower you, so you find it is just better to leave them, due to lack of that food you need" (Mshana, et al., 2006, p. 653). This demonstrates how

hunger can affect adherence to the drug regimen. Some healthcare facilities try to meet this need by supplying their patients with supplemental nutrient and protein-rich flour and foods.

### *Pill Burden*

Some patients may get tired of going to the hospital and taking pills on a regular basis. They may decide to take a break from it all. A Tanzanian who was interviewed commented on the discouragement some HIV patients on ART experience: "...one who can take them after some time gives up hope, [saying], 'I have been taking these drugs for many days now and I think it is enough...if I am to be cured I will be cured and if not, then I don't care even if I die, let me stop taking those drugs'" (Mshana, et al., 2006, p. 653). In addition, this is especially common in patients who are "feeling better." They may not see a need to continue their medication (Mshana, et al., 2006). Education is needed in this situation.

### *Hospital-Related Factors*

Sometimes patients are unwilling to begin or continue ART because they do not trust hospitals. They might be hesitant to go to hospitals because of the hospital's reputation or because they have had a bad experience there in the past. For instance, information gained through interviews in one study revealed that some staff at medical facilities would demand bribes for access to healthcare. This deterred patients from returning (Mshana, et al., 2006).

Hospitals in Africa occasionally have the reputation of being "unfriendly and confusing." The hospital experience can often be intimidating to people from smaller rural villages. Technology, large medical facilities, and doctors may be completely new

to villagers, which can be very daunting. Plus, less time can be spent on hospitality and patient education since there is a lack of healthcare providers. Therefore, patients may see doctors and nurses as being impersonal and/or ruthless. Yet, even if they are treated kindly, some patients may leave confused about their disease and the use of ART. Whether a patient has personally had negative experiences such as these, or heard about one from someone else, the hospital setting may deter him from going to the hospital to receive ART and maintain follow up appointments.

In order to rectify some of the misconceptions, hospitals need to educate their staff about the potential problems and train them to treat their patients with kindness, dignity and respect. They should also receive additional training on patient education. The better patients understand the medical procedures and policies, the more comfortable they will be in healthcare facilities. Therefore, they will be more likely to return for follow-up visits and adherence will improve.

An additional factor that affects patient adherence is the long waiting time at the healthcare facilities. On average, patients will wait for 4 to 6 hours. In Hardon's study, some patients had to wait as long as 10-12 hours. This can be very exhausting for patients, especially for those who traveled long distances to reach the facilities. Some patients leave without being seen due to discouragement and obligations at home (Hardon, et al., 2007). A patient in Tanzania commented on this saying, "You may go there and be kicked like a ball. Maybe you arrive there and you give him/her your referral slip, you will wait a long time without being attended" (Mshana, et al., 2006). Healthcare facilities need to address this issue to the best of their abilities. They need to evaluate

their appointment procedures. If a long waiting time is inevitable, they should warn their patients of this, and provide food and drinks at a low cost.

### *Cultural Beliefs*

Although most patients will not list cultural beliefs as one of their barriers to adherence, this is still a possibility in rural villages. Many beliefs regarding health and disease are passed down through the generations. Often this is not accurate medical information. Despite patient education in the hospitals or clinics, patients may still hold to traditional beliefs. This can distort their beliefs regarding the cause of HIV and the best way to treat it. In fact, 62% of medical providers included in Weiser et al.'s study in Botswana alleged that treatment adherence was often impeded by traditional etiologic explanation (Weiser, et al., 2003).

Although Western medical practices are becoming more prevalent in Sub-Saharan Africa, many rural villages still use their traditional healer. In a study in Botswana, 21% of HIV patients expected that they would go to a traditional healer for HIV treatment in the future (Weiser, et al., 2003). Despite the fact that a patient may be receiving ART, he may consult his or her traditional healer as well. He might even feel pressure from the community to do so. The traditional healer will often give different recommendations than trained medical providers. Superstition is often a major component of traditional healer's medical practices. Unfortunately, the patient might be advised to stop using ART, revise the regimen or use a traditional treatment instead. Therefore, this can become an obstacle to adherence. Patient education and community awareness are key in this situation.

*Social Stigma*

Social stigma may affect patient adherence as well. In fact, in his study, Mshana suggested that “pervasive stigma remains the most formidable barrier” to distribution of ART and that it is “the backdrop to all difficulties in achieving a successful ARV programme” (Mshana, et al., 2006, p. 649, 653). Being HIV positive is viewed as very dishonorable and is often an immense disgrace on the family. Patients often feel guilty and ashamed. They may be afraid of disappointing family and friends. It is also possible that they will be blamed for passing on the virus to a partner, or for being unfaithful to a spouse (Mshana, et al., 2006). Sometimes employment is denied for these patients. In addition, these patients will often be abused, neglected, or rejected. (Kohi, Makoae, Chirwa, Holzemer, Phetlhu, Uys, et al., 2006). For example, in Hardon’s study, some patients in Botswana were treated badly by their spouse or even abandoned. In Uganda, some patients were isolated by members of the community (Hardon, et al., 2007). In addition, one of the participants in Mshana’s study died due to neglect from her family and food deprivation (Mshana, et al., 2006).

The fear that the social stigma instigates in Africans can often discourage people from being tested for HIV. Often people will not want to know because they are afraid that they would be positive for HIV. Instead of being properly tested, some people will weigh themselves on scales that line the streets. They will watch their weight to see if they are losing weight. This will give the person an idea if he is HIV positive without letting anyone else know.

If a person knows that he is HIV positive, he may chose not to receive ART because of social stigma. In some cases, the person may be concerned about

confidentiality issues (Weiser, et al., 2003). In other situations, patients may decline ART because they do not feel they can comply with the treatment program's regulations. For instance, in a study in Tanzania, the treatment program being studied required that patients have a "treatment buddy." This treatment buddy would remind the patient to take his medication on a regular basis. Some patients refused treatment because they refused to disclose their diagnosis to anyone. They were afraid to choose a treatment buddy because of the social stigma (Mshana, et al., 2006).

Even if patients agree to take ART, they may fear the negative outcomes from disclosing this information to the extent that they avoid telling anyone. In Weiser, et al.'s study, 94% of their patients kept their diagnosis of HIV a secret from their community. Furthermore, 69% of them kept their HIV status a secret from their family. This can greatly affect adherence to drug regimens (Weiser, et al., 2003).

Since many patients do not disclose this information to anyone, it means that they will have to take their medication in secret. It can be difficult to find a time and place to be alone; therefore, it leads to inconsistency in taking their medication. In addition, these patients will not receive support and encouragement from their family to take their medication. If the patient's family knows about their HIV status, there is a chance that they will be proactive and help them find transportation to the clinic or hospital and remind them to take their medication. However, due to the social stigma, some families will provide little to no support concerning their therapy; they may even ostracize them (Hardon, et al., 2007). In some cases, when children have HIV, the family may send them to school without their medications because they want to hide the fact that their child has HIV. This would also lead to poor adherence (Chesney, 2000).

Adherence is also affected by disclosure (or nondisclosure) of HIV status to patients' employers. Patients take a risk when disclosing this information at their workplace. Some patients may lose their job or face other kinds of discrimination if their employers find out. Each patient has to decide whether or not to tell his employer that he is HIV positive. If the employer does not know, the patient may not be able to get time off of work to go to the clinic or hospital for his follow-up visits and ART refills. However, if the patient tells his employer, he may lose his job, or the employer may not support his need for treatment and care. Therefore, the patient may not be able to adhere to his drug regimen because he cannot get time off to go to a healthcare facility (Hardon, et al., 2007). Social stigma needs to be targeted in a similar way to that of cultural issues—through education. First, healthcare providers need to assess the affects of social stigma in their communities. A possible assessment tool to use is provided in Appendix B (Hozemer, Uys, Chirwa, Greeff, Makoae, Kohi, et al., 2007). Then whole communities need to be taught about HIV/AIDS and the importance of treatment. It is also important for the community's leaders and influential people advocate for HIV testing and treatment.

#### *Poor Quality Counseling*

In order for patients to be able to adhere well to their ART drug regimen, they need to receive counseling and education. Without it, patients may not comprehend the importance of taking medication. Patients with insufficient counseling and education will be much less likely to continue taking their medication when they encounter side-effects and other barriers. They will also be more likely to quit taking the medication when they begin to feel well. In addition, they may not understand the drug regimen itself. For

instance, they may take their medication too often or too seldom. This results in poor adherence, increased viral load, and a higher risk of drug resistance. Many healthcare workers in clinics and hospitals of Sub-Saharan Africa do not have proper training in counseling. In a study that reviewed exit interviews, only 21% of patients on ART received counseling (Hardon, et al., 2007). Therefore, this is a major need in these healthcare facilities.

Stenson, et al. devised a tool to assess patients' need for counseling during their study in South Africa. Healthcare providers should use something similar to this tool routinely during their ART visits. This tool is included in Appendix C (Stenson, Charalambous, Dwadwa, Pemba, Du Toit, Baggaley, et al., 2005). HIV patients need to be taught about HIV itself, when to take the pill, how often to take the pill, and side effects of the medication. This helps the patient understand the situation and become more organized. They should also be counseled about the importance of adhering to the regimen, how to talk to family and friends about it, how to deal with the social stigma, and any other concerns that the patient may have. It may also be helpful to tailor the drug regimen to suit the patient's life. One way to do this is to link particular daily activities with taking their medication (Chesney, 2000).

### *Resistance to Drugs*

Despite the fact that antiretroviral therapy has been improving the lives of millions of HIV patients, a high concern for these patients is that they might become resistant to the medications. Drug resistance can become a major problem when patients do not adhere to their drug regimen. A study conducted by Laurent determined that approximately 12.5% of patients became resistant to at least one drug (Akileswaran,



Lurie, Flanigan, & Mayer, 2005). This problem is significant because when resistance develops, the patient has to be switched to a different drug regimen—second line treatments. This often costs about 10 times as much as the first line treatment (Hardon, et al., 2007). This makes it hard for the healthcare facilities in Sub-Saharan Africa to access and provide the necessary drugs.

To address this concern, a program called the Global HIV Drug Surveillance Network is currently being developed to monitor global resistance and provide strategies to minimize resistance. The World Health Organization is collaborating with the International AIDS Society for this program (WHO, 2006). Research on resistance in sub-Saharan Africa is limited. However, data collected thus far has paralleled data from more developed countries such as the U.S. Multiple drug resistance has increased from 1.1% of patients to 13.2% of patients in the United States between 1999 and 2001 (Vella & Palmisano, 2005). In order to prevent future cases of resistance, it is important to understand how resistance develops, determine which classes of ART patients most likely to become resistant to, and track and prevent resistance.

There are multiple reasons why resistance develops. First of all, HIV has a very high turnover rate. In a chronic infection, half of the virions in the body are lost every 6 hours. In order to make up for this loss, between 1 and 10 billion virions are produced on a daily basis. Secondly, there is a high likelihood of mutation. It is estimated that 10 incorrect base pairs are incorporated into viral DNA every replication (Lehne, 2007). The high probability of error is due to the fact that HIV reverse transcriptase does not have a proofreading mechanism. Once a viron has mutated, it is harder for a drug to stop its replication. For instance, mutation can lead to a structural change in gp41 (the

glycoprotein on HIV's envelope). This can prevent a fusion inhibitor from binding to it, making the drug ineffective. Or if a mutation causes HIV reverse transcriptase to change shape, the administration of NRTIs and NNRTIs will be useless. As a result of varying mutations, many genetically different strains of HIV can be found within the same patient (Vella & Palmisano, 2005 & Lehne, 2007).

If a patient has never been on antiretroviral therapy, drug-sensitive virions will greatly outnumber resistant virions. This is because the replication of "normal" virions is unopposed. Once ART is initiated, the drug prevents numerous viruses from replicating; the only surviving viruses are the less susceptible (or resistant) strains. These are the only ones that are able to continue replicating. This is similar to the idea of the "survival of the fittest." Therefore, when a patient begins treatment, it is possible for him or her to quickly become drug-resistant. If resistance occurs, there is typically cross resistance with drugs within the same class (Vella & Palmisano, 2005).

Two other major causes of resistance include poor patient adherence or a drug regimen with too low of a potency. These problems make it impossible to suppress the virus and allow the virus to replicate itself (Lehne, 2007). It is also important to note that HIV-2 (found in West Africa) is more resistant to medications. Therefore, treatment might be more difficult (Mullins, et al., 2004).

The reason that physicians prescribe multiple medications for HIV is to prevent resistance. It is rare that a mutation in HIV could cause resistance to three or four different drugs at the same time. Each drug has a different target area which would require a mutation in order for the HIV strain to become drug resistant. On the other hand, it would be very easy for a patient to become resistant to a single drug used alone (Lehne,

2007).

Once resistance itself is understood, statistics regarding resistance to specific drugs need to be analyzed. Concerning individual classes of antiretroviral therapy, research shows that patients are most likely to develop resistance to NRTIs. The CATCH study in Europe compared resistance to each class of drug in treatment-naive patients (those who had never received ART beforehand). There results were as follows: NRTIs- 6.9% of patients, NNRTIs: 2.6%, protease inhibitors: 2.2%, and using a combination of at least two classes: 1.7% of patients (Vella & Palmisano, 2005). This showed which drugs patients are most likely to become resistant. In addition, it confirmed the idea that using a combination of drugs decreases the risk of resistance. Data collected by Laurent in Africa suggested the same order of resistance when comparing classes of drugs (Akileswaran et al., 2005).

Next, steps need to be taken to prevent drug resistance. Currently, most healthcare facilities in Sub-Saharan Africa do not have the resources and equipment necessary to test for resistance. Developing cheaper methods of testing for HIV resistance would be beneficial. In addition, there are a variety of other methods of preventing resistance that should be implemented. First of all, global research about the epidemic needs to be increased. As this information becomes organized, worldwide surveillance programs need to be in place so that the epidemic and treatment can be tracked. Secondly, patients need to be encouraged to adhere to their regimen—especially when on resistant-prone classes of drugs. Furthermore, it is important for patients to discontinue their ineffective drugs. Thirdly, since beginning drug therapy increases the risk of resistance, it is important to weigh the pros and cons on an individual basis before beginning a patient on

a particular regimen. Lastly, education about HIV and transmission should be continued. This is important because once a patient is drug-resistant, these are the strains of HIV that he or she can transmit to another person (Vella & Palmisano, 2005).

A main factor that reduces a patient's chance of becoming resistance is maintaining optimal patient adherence. Possible suggestions were listed above and included ideas such as additional fundraising for patient expenses and providing transportation to healthcare facilities. In addition, patients should be provided with supplemental food, monitored for severe side-effects and be switched to a different regimen if needed. Finally, education of patients, providers and communities are necessities. Even though these suggestions will not eliminate all obstacles, they will make distribution and maintenance of ART regimens more feasible.

Despite the multitude of possible obstacles, the use of ART in Sub-Saharan Africa is well worth the risk. Even though a complete cure may not be possible, putting more patients on ART will improve quality of life and increase life expectancy. Access to HIV can be improved by determining where the unmet need is and targeting the obstacles of providing treatment. Taking a proactive stance to do this will help to fight the devastating HIV epidemic that has been sweeping the globe.

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## Appendix A

## Antiretroviral Therapy Survey

Please answer the following questions and return to Elizabeth Paquette at [ejpaquette@liberty.edu](mailto:ejpaquette@liberty.edu).

Thank you!

*(Press **Tab** key to advance to next data entry field)*

- 1) What is your name/title?
- 2) What country/city do you serve in?
- 3) What is the name of your medical facility?
- 4) Are you able to provide antiretroviral therapy for HIV/AIDS patients?
  - yes       no
  - If no, why not?
  - If yes, continue please continue to answer questions 5-14.
- 5) Approximately how many HIV/AIDS patients do you provide antiretroviral therapy for each year?
- 6) Approximately what percent of HIV patients seeking treatment are you able to help?
- 7) Who provides the funding for your facility?
  - Government
  - NGO
  - SIM Projects
  - Private grants
  - Other (please specify)
- 8) Are you able to provide antiretroviral therapy free of charge?  yes       no  
If not, what is the approximate cost for each patient?
- 9) Which classes of drugs are available to you? (check all that apply)
  - NRTIs
  - NNRTIs
  - Protease Inhibitors
  - Fusion Inhibitors
- 10) Which drug regimen do you use most frequently?
- 11) Does your facility have the capability of testing for resistance to drugs?  yes  
 no

If not, please skip to question 14.

12) Approximately what percent of the patients in your facility have become resistant to 1 or more drug?

13) Which is the most common class of drug that your patients have become resistant to?

- NRTIs
- NNRTIs
- Protease Inhibitors
- Fusion Inhibitors

14) What major regulations does the government place on you in providing antiretroviral therapy?

15) Have you seen social stigma effect adherence to drug regimens?  yes  no

If so, in what ways?

16) What major obstacles have you encountered while trying to provide treatment?

(check all that apply)

- Lack of funds
- Lack of staff
- Lack of facility
- Antiretroviral drug availability
- Government regulations
- Geographic proximity to treatment facility
- Patient adherence to drug regimen
- Resistance to drugs
- Social stigma and cultural issues
- Other (please specify)

Comments:

## Appendix B

## HIV/AIDS and Stigma Tool

I'm going to read a list of events that may have happened to you during the past three months. After I read each item, please tell me how often it happened to you because of your HIV status:

In the past 3 months, how often did the following events happen because of your HIV status?

	Never	Once or twice	Several times	Most of the time
1. I was told to use my own eating utensils.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I was asked not to touch someone's child.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I was made to drink last from the cup.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Someone mocked me when I passed by.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I stopped eating with other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I was asked to leave because I was coughing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Someone stopped being my friend.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. A friend would not chat with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I was called bad names.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. People sang offensive songs when I passed by.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I was told that I have no future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Someone scolded me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I was told that God is punishing me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I was made to eat alone.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Someone insulted me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. People avoided me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. People cut down visiting me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. People ended their relationships with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I was blamed for my HIV status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Someone tried to get me fired from my job.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. My employer denied me opportunities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The next set of questions is about your experiences in the hospital or clinic. In the past 3 months, how often did the following events happen because of your HIV status?

	Never	Once or twice	Several times	Most of the time
22. I was denied health care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I was refused treatment because I was told I was going to die anyway.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I was discharged from the hospital while still needing care.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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- |   |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 25. I was shuttled around instead of being helped by a nurse. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 26. At the hospital/clinic, I was made to wait until last     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 27. At the hospital, I was left in a soiled bed.              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 28. In the hospital or clinic, my pain was ignored.           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

These questions are about some of your thoughts or feelings. How often have you thought or felt this way during the past 3 months because of your HIV status?

- |  | Never                    | Once<br>or twice         | Several<br>times         | Most of<br>the time      |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 29. I felt that I did not deserve to live. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 30. I felt ashamed of having this disease. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

(Hozemer, Uys, Chirwa, Greeff, Makoae, Kohi, et al., 2007)

## Appendix C

## Counseling Resource



## Guidelines for ART Counselling

### Step 1 Counselling Protocol

<b>Name of Counsellor</b>	
<b>Place of counselling</b>	
<b>Date</b>	
<b>Patient</b>	
<b>Industry number</b>	
<b>Mine / Place of work</b>	

	Tick Here
1. Identify yourself and introduce the topic. Give assurance of confidentiality	<input type="checkbox"/>
2. Assessment of patient's knowledge and suitability for treatment:	
- Assess knowledge of HIV/AIDS	<input type="checkbox"/>
- Assess acceptance of HIV positive status	<input type="checkbox"/>
- Assess attitude of patient towards AIDS and treatment	<input type="checkbox"/>
- Assess alcohol and drug use	<input type="checkbox"/>
- Assess mental status	<input type="checkbox"/>
- Assess support systems	<input type="checkbox"/>
- Assess whether family and/or colleagues are aware of his/her status	<input type="checkbox"/>
- Assess whether he/she would take treatment in front of them	<input type="checkbox"/>
3. Discuss the implications of ART treatment:	
- Explain how the medication works	<input type="checkbox"/>
- Discuss the importance of adherence and the consequences of non-adherence	<input type="checkbox"/>
- Discuss the possibility of side effects	<input type="checkbox"/>
- Discuss the regular monitoring and the blood tests as part of ART	<input type="checkbox"/>
- Discuss the importance and implications of lifelong treatment	<input type="checkbox"/>
- Discuss the importance of safe sexual practices	<input type="checkbox"/>
4. Ask the patient if he /she has any questions or needs any further explanations	<input type="checkbox"/>
5. Tell the patient to go and think carefully about ART and to return with a decision in 1 week/ 2 weeks.	<input type="checkbox"/>



**Guidelines for ART Counselling**

**Step 2 Counselling Protocol**

<b>Name of Counsellor</b>	
<b>Place of counselling</b>	
<b>Date</b>	
<b>Patient</b>	
<b>Industry number</b>	
<b>Mine / Place of work</b>	

**Tick Here**

- 6. Assess patient's knowledge, memory and understanding of the Step 1 counselling:
  - Ask what happens if a person frequently fails to take their HIV treatment
  - Ask why almost everybody finds it difficult to take any treatment everyday for the rest of their lives
  - Ask what are the situations most likely for patients to miss a dose. Discuss being on leave, shift work etc.
  - Ask what effect unsafe sexual practices will have on treatment
  - Ask whether it will be possible to take treatment in front of family/ colleagues.
  - Ask what consequences would there be if patients sells or shares the tablets.
- 7. Discuss the consent form and get the patient to sign.
- 8. Rehearse tablet recognition and dosing
- 9. Explain procedure to obtain tablets
- 10. Explain and demonstrate the self report card/diary
- 11. Explain procedure for medical monitoring and blood tests
- 12. Stress the importance of adherence again and explain the procedure to follow if there are any problems with ART.



**Guidelines for ART Counselling**

**Step 3 Counselling / Monitoring**

<b>Name of Counsellor</b>	
<b>Place of counselling</b>	
<b>Date</b>	
<b>Patient</b>	
<b>Industry number</b>	
<b>Mine / Place of work</b>	

	Tick Here
13. Assess adherence	<input type="checkbox"/>
14. Assess progress and problems	<input type="checkbox"/>
15. Remind patient of next clinic appointment	<input type="checkbox"/>
16. Refer to the clinic in the event of major problems	<input type="checkbox"/>
17. Motivate patient with regard to continued adherence	<input type="checkbox"/>
18. Report back to ART counsellor	<input type="checkbox"/>

(Stenson, Charalambous, Dwadwa, Pemba, Du Toit, Baggaley, et al., 2005)