

# **Masters Programme in International Health**

## **MASTERS THESIS 2006**

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**THESIS TITLE:** “ARV medication price and its influence on ART coverage in post conflict situations- An analysis”

**KEY WORDS:** HIV/AIDS, HAART, Refugees, IDP's, Forced displacement, post emergency situations

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## ***Acknowledgement***

HIV/AIDS is not only an important issue in the field of International Health but has also been of special interest to me since my medical school days. The havoc this diminutive Lentivirus has created is immense and the implications of its transmission and infection are profound let it be the epidemiology or the prevention strategies or the treatment protocols or the socio-cultural issues related to it. Much research has been done and many programs have been undertaken to control and treat the infection, yet we continue to observe vulnerable populations being affected. My thesis focuses on HIV treatment for a vulnerable population – people in post conflict regions. If this study could do even the least in eliciting interest on HIV therapy for populations in such situations, my study would have achieved its purpose.

In this context I would like to thank both of my supervisors Dr.Tania Draebel and Prof. IB Bygbjerg of the International Health Department, Copenhagen University for being immensely kind and helpful with me in the process of preparation of my thesis. It was indeed a pleasure working with Dr.Draebel, an expert on complex emergency situations and Prof.Bygbjerg an expert on HIV and international health. I would also like to thank staff from Institute of International Health and Development, Edinburgh namely Oonagh O Brein , and Suzanne Fustukian, for providing me material and assistance towards the completion of my thesis, Dr. Christa Hook and Dr.Tom Ellman of MSF for directing me to relevant sources of information, the staff at Institute of Child Health, London for teaching me the fundamentals of International Health, Bernadette Peterhans of Swiss Tropical Institute for providing me relevant advice and Marianne Dithmer and the staff of International Health Department, Copenhagen University for their enormous patience and kindness. I must also not fail to mention my gratitude to the European Commission, and the TROPED consortium for providing me the honor and the experience of being an Erasmus Mundus Scholar.

### **Sandeep Reddy**

Student, Erasmus Mundus Master in International Health,  
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## **Abbreviations:**

**AIDS** – Acquired Immunodeficiency Syndrome

**ARV**- Anti Retro Viral drugs

**ART** – Anti Retroviral Therapy

**DOTS**- Directly Observed Therapy Short course

**HAART** – Highly Active Anti Retroviral Therapy

**HIV** – Human Immunodeficiency Syndrome

**MOH**- Ministry of Health

**MSF** – Medicins Sans Frontieres

**MTCT** – Mother to Child Transmission

**NNRTI** – Nucleoside Reverse Transcriptase Inhibitor

**NRTI** – Non Nucleoside Reverse Transcriptase Inhibitor

**NGO** – Non Governmental Organization

**PEPFAR** – Presidents Emergency Plan for AIDS Relief

**PLWHA**- People Living With HIV/AIDS

**STI** – Sexually Transmitted Infection

**TB** – Tuberculosis

**TRIPS**- Trade Related aspects of Intellectual Property Rights

**UN** – United Nations

**UNAIDS** – United Nations Programme for AIDS

**UNHCR** – United Nation High Commission for Refugees

**VCT** – Voluntary Counseling and Testing

**WHO** – World Health Organization

**WTO**- World Trade Organization



**Abstract:**

**Problem Statement:** Post conflict nations face various problems in terms of delivering health services. Anti Retroviral Treatment (ART) programs in such regions also face numerous hurdles in accomplishing their set goals. One of the important barriers to increase ART coverage is the financial price of ARV medications. It would be important for the national authorities or other agencies to work towards reducing or subsidizing the prices of ARV drugs to increase access to such programs. Post conflict nations like Uganda, Mozambique, and Haiti have seen activities undertaken by local governments and other organizations in this direction. It is necessary to learn of these activities and their effect on ART coverage. Also, it would be important to learn if factors, other than ARV medication prices, are also responsible for influencing ART coverage in these countries. This essay attempts to review ART programs in terms of the above mentioned intentions.

**Research Objective:** *“To analyze the influence of financial price of drugs on ART coverage in post conflict regions-utilizing the examples of Uganda, Mozambique and Haiti”*

**Methods:** The study is a desk study on available material – both peer reviewed and grey literature on the topic of “activities of national authorities and other organisations to increase ART coverage in Uganda, Mozambique, and Haiti”.

**Findings:** When analyzing the influence of financial price on ART coverage, it has been found that indeed the national authorities in all of the 3 countries –Uganda, Mozambique, and Haiti have shown political commitment and taken up activities to reduce the price of ARV medication and increase coverage. They have also been supported by UN agencies like WHO and UNAIDS, bilateral agencies like PEPFAR, and various NGOs in their implementation of ART programs. However, ART is still out of reach for most of the HIV patients in these countries. This is mainly because the ARV medication price ,which inspite of great reductions, is still very high for both the governments of these resource poor nations to procure and for the HIV patients of these nations to buy. Also there are other barriers which influence ART programs like dependence on external funding to maintain the functioning of these programs, political instability in some countries, inadequate health infrastructure to deliver ART, security issues, and social factors.

**Discussion:** ART programs in Uganda, Mozambique, and Haiti have made a beginning and as noted in the findings there are factors other than ART price which also have an influence on ART coverage. Problems such as these abound, considering the poverty of resources and shortage of health workers in these nations. We have noted the differing ART coverage among individual post conflict countries but we also have noted that successful examples of delivering ART in resource poor settings have been demonstrated earlier. To further tackle these issues, there is a requirement of strong and decisive government support and also increased funding from international donor. In this regard, it is necessary to r examine these issues ;and the role of financial price and other factors on ART coverage in individual post conflict countries through field studies to obtain more clear opinions and answers.



## **PART 1 Introduction:**

It is estimated that more than 200 million people live in countries which are affected by complex emergencies [Connolly et al, 2004]. Many of these countries also have populations affected by HIV/AIDS. People of conflict affected regions have been through trauma –both psychological and physical, which increases the risk of contracting HIV. This vulnerability and other factors have contributed to HIV infection prevalence in post conflict nations. Anti Retroviral Treatment (ART) programs relating to HIV care and treatment for the affected people are a requirement in such situations. In this regard, this study analyses the role of financial price of ARV medication as well as the role of other factors that influence ART coverage in such situations.

### **1.1] *COMPLEX EMERGENCIES AND HIV:***

Complex emergencies<sup>1</sup> could be said to occur in phases, namely – I] Pre-conflict, II] Conflict, III] Stabilization phase, and IV] Return and Post-conflict phase [WHO, 2000]. Pre-conflict is the period occurring before the outbreak of conflict and is marked by increasing instability and general worsening of economic and social conditions. Though the conflict phase is self explanatory, it may not be uniform and could go through alternating stages of stability and fighting. This phase is also when forced displacement because of the ongoing conflict leads to Internally Displaced People's (IDP's) or refugees.

After the passing of the initial emergency phase, the stabilization phase occurs. During this phase, reorganization of people into families and communities takes place and provisions for basic health care needs are made. Following this phase the displaced population returns to their area of origin either through unplanned or planned means leading to the post conflict phase, when there are opportunities for reintegration of displaced people and reconstruction of infrastructure.

Planning and implementation of health programs in post conflict situations is necessary to alleviate the suffering of a conflict affected population, to consolidate the

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<sup>1</sup> **Complex emergency is defined as “a situation that affects large civilian populations and usually involves a combination of war or civil strife, food shortages and population displacement resulting in significant excess mortality [Burkholder BT and Toole MJ, 1995].**



peace process, and to obtain long term returns of a healthy population. Many of the difficulties post conflict regions face, in terms of health services, are similar to what resource poor regions face, as conflict causes lasting socio-economic consequences [Mock NB et al, 2004]. Hence discussion of health services problems in post conflict relate to problems encountered in resource poor settings.

One of the many health issues populations in such situations face is HIV/AIDS. It is stated that one in four African countries which are currently affected by conflict are also facing high prevalence of HIV [Ellman et al, 2005]. Violent conflicts and related complex emergencies, joined with HIV/AIDS have set development in Africa back and negated most of the gains achieved over the past 50 years [ Tulane University , 2001]. More than 25 million people live with HIV/AIDS in this background.

There have been various opinions on transmission of HIV during conflict situations while some studies relate that conflict increases transmission [ Population Reports,1996 ; Lowicki-Zucca M et al ,2005] , while others argue of low prevalence of HIV during conflicts because of isolation and lack of factors that support HIV transmission– mainly mobility [Spiegel, 2004]. If we consider the argument of low prevalence of HIV during conflict , it would also be necessary to note that the end of conflict would result in return of peace and economic growth, and enable factors ( mobility) that increase transmission of HIV among these vulnerable population – as what happened in Mozambique [Barreto et al, 1996; Ellman et al, 2005].

Reports and programmes on the strategies for the treatment of acute illnesses and control and prevention of the spread of HIV/AIDS in complex emergencies have been published. But there are limited studies relating to the treatment strategies and programs for the care of HIV/AIDS patients in these situations.

This could be partly due to the fact that treating acute and manageable illnesses like Diarrhea, Respiratory illnesses, Malaria and Measles would take priority both in emergency and post emergency situations [ Connolly MA, 2004 ; Redmond AD, 2005], instead of chronic illnesses like HIV/AIDS which need long term management and compliance on part of the patients. Also, some experts in the past have argued



That HIV prevention should take priority over treatment based on cost effectiveness [Marseille et al, 2002; Creese et al, 2002]

Though it is commendable to implement prevention and control strategies for HIV/AIDS, it would be negligent not to take into consideration the treatment and care of existing HIV/AIDS patients who are vulnerable to transmission of HIV among post conflict populations. Prevention strategies do nothing to improve the lives of HIV patients [Mukherjee JS et al, 2003]. Non treatment of AIDS cases results in indirect costs because of loss of workforce. Moreover, experiences with other infectious diseases like Tuberculosis and Syphilis have shown that successful control of disease requires a combination of prevention, education and treatment.

**Scientific / Study perspective:** This study is mainly based on a public health perspective and Schneider defines public health as “a multidisciplinary field whose goal is to promote the health of the population through organized community efforts” [Schneider, 2006]. The health of a community is protected or improved by various measures which involve disciplines ranging from Preventive Medicine to Health Economics. Similarly in an Anti Retroviral Treatment (ART) program, various disciplines like Preventive Medicine (Counselling), HIV treatment (Prevention of AIDS), Health Economics (drug costs), Sociology (Human Rights) are involved in the implementation. As the objective of the study is to analyse the influence of financial price of ARV medication on ART coverage, there is emphasis on Health economics and at the same moment the study utilises information from other areas of public health to analyse factors other than ARV medication price.

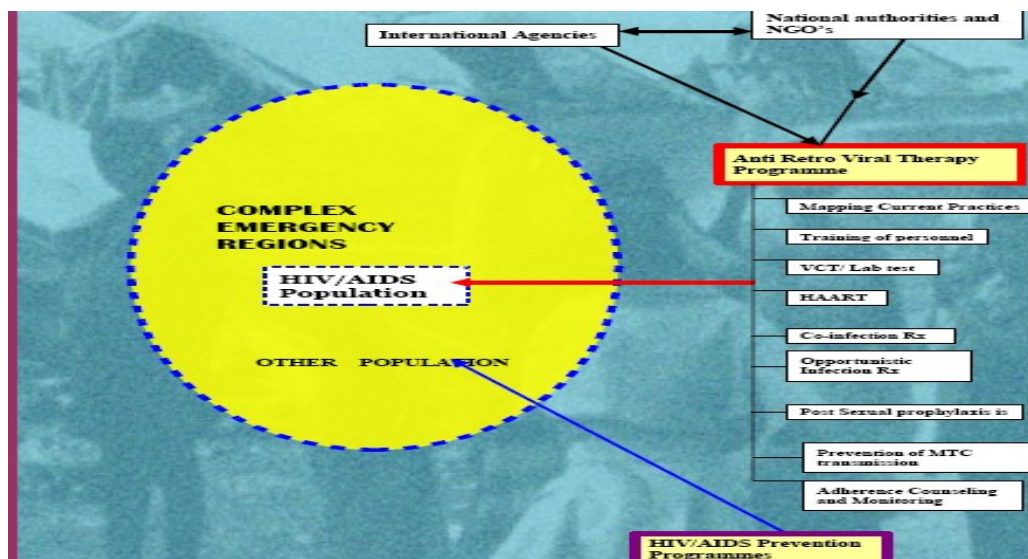


Fig I. ART Program Chart Prepared by author using IASC, 2003; Grant and De Cock, 2002; Kitahata MM et al, 2002; as source]





The different steps of an ART program in complex emergencies like training of personnel, establishing laboratory testing, procurement and provision of ARV medication, opportunistic and co-infection treatment, Prevention of Mother to Child Transmission (PMTCT) and others have been charted above. Antiretroviral Treatment programs in these situations have many risks and challenges. These are the complicated case management of ART, patient adherence, drug resistance, regular requirement of laboratory testing facilities, high prices of ARV drugs and in post conflict countries –inadequate medical infrastructure and human resources shortage [MOH Uganda, 2003].

Affordability of ARV medications provided by ART programs is an important indicator for access to ART. The price of first line Anti Retro Viral treatment, with fixed dose combination prescriptions, has continued to decrease [WHO, 2006]. Between 2003 and 2005, the price of first –line medication decreased between 37% and 53%, depending on the regimen. The fall in the prices has been because of competition among a growing number of WHO-prequalified products and negotiations between foundations (William J. Clinton foundation) and generic manufacturers. In 2005, patients in low income countries paid for WHO-prequalified first line treatment from US \$ 148 (for the most widely used combination of stavudine + Lamivudine+ nevirapine) to US \$ 549 per person per year. The average price comes to US \$ 268 per person per year.

But not all low income countries have adopted these regimens and ART still remains out of reach of many HIV affected population of low income countries. In 2003, globally only 5 % of affected had access to life saving Anti Retroviral Therapy [Stabinski et al 2003] and less than 2% of HIV positive Africans received antiretroviral therapy [Mukherjee J S et al, 2003]. Moreover, second line treatment, a regimen of tenofovir + Abacavir + Lopinavir, is much more expensive ranging from US\$ 888 per person per year (low income countries) to US\$ 4126 (middle income countries) [WHO, 2006].

HIV patients in low income countries suffer from the consequences of AIDS due to difficulty in access to drugs mainly because of these high prices [Mukherjee JS et al, 2003; Berwick D, BMJ, 2002]. It has been estimated that average life expectancy in



Sub-Saharan Africa is 47 years and without AIDS it would be 62 years [Mukherjee JS et al, 2003]. Without availability of antiretroviral and opportunistic infection treatment in the coming years, HIV affected countries would lose significant numbers of their population, especially the skilled workforce. For example, a report from Ivory Coast, a post conflict nation, indicated that in 1996-97, more than 50% of deaths among elementary school teachers who lacked access to ART were from AIDS.

### **1.3] RELEVANCE OF STUDY:**

We have already noted that post conflict countries have a vulnerable population in relation to HIV and it would be important to have an antiretroviral treatment program serving those affected by HIV infection in these countries. While there has been material and focus on prevention of HIV/AIDS in these settings, treatment and care of HIV/AIDS affected people seemed to garner less interest. This elicited queries on what could be the reasons behind such inattention? Was it negligence or was it because of the supposedly impractical nature of Anti Retroviral Treatment (ART) program in such situations? These questions set the author out to study ART programs in such settings. National governments of such countries along with International agencies have been trying to improve availability of ART to HIV affected population [AfDB, 2005; UNAIDS, 2001].

In this regard, it would be important to learn what specific actions or strategies the authorities or agencies of these nations have adopted to make ARV medication affordable to patients affected by HIV in these countries, as it has been increasingly suggested that drug prices are a significant barrier for access to ART programs [Mugenyi, UNAIDS 2001; Berwick D, BMJ, 2002]. It would also be necessary to learn the effect of these activities on ART coverage and to know if factors, other than drug price, are affecting ART coverage in post conflict regions. Based on these intentions the essay has chosen ART programs in three post conflict nations- Uganda, Mozambique and Haiti for review.

### **1.4] MAIN OBJECTIVE:**

The main objective of this thesis is:

*“To analyze the influence of financial price of drugs on ART coverage in post conflict regions-utilizing the examples of Uganda, Mozambique and Haiti*



### **1.5] SPECIFIC OBJECTIVES:**

- *To describe the activities in relation to costs, those are carried out by national authorities and agencies to increase coverage of ART programs in Uganda, Mozambique and Haiti.*
  - *To describe factors, other than price of antiretroviral medication, which influence ART coverage in Uganda, Mozambique and Haiti.*
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## **PART 2**

### **Methods:**

#### **2.1] STUDY AREA:**

Study of HIV infection and its implication is a broad area which involves several disciplines like Medicine, Sociology, and Health Economics among others. Also HIV infection and transmission is related to the surrounding environment. In this regard, this study researches HIV/AIDS in a post conflict environment and also utilises public health disciplines like health economics and others to study the influence of ARV medication price and other factors on ART programs. Conflict and HIV have each by itself huge amount of studies conducted on them. In this regard it was interesting to learn of the issues that develop when these two phenomenon occur together-i.e. "HIV/AIDS in Complex emergencies". To be mindful of the time available and also to be practical, a particular focus area within this broad topic had to be chosen.

.Knowing that the course of antiretroviral medication intake is a chronic process meant that stability (or relative stability) would be a major consideration in implementation of ART programs. Therefore the essay further narrowed its focus to post conflict situation where there would be a certain degree of stability. In this setting, the essay set out to study ART programs in general and in particular the influence of ARV medication prices and other factors affecting ART coverage. While exploring for and identifying material to be utilised for the study, it was found that there were limited studies based on the topic and this area of study was just beginning to open up for research. Research of previous studies raised questions, like issues of



prevention of HIV v/s treatment of HIV, practicality of ART programs in post conflict settings, extent of government and donor support for ART programs in such settings, would reduction of financial price of ARV drugs by itself have a major influence on ART coverage. So to make a start, post conflict countries with known ART programs were selected to study issues raised from previous research.

Three countries which were in the post conflict phase and which also had problems relating to HIV/AIDS were selected - namely Uganda, Mozambique and Haiti. A brief review of conflict in these countries is provided in the annexe. Here, it must be mentioned that the selection is not because of overwhelming commonalities of these nations but rather on the basis of availability of literature relating to ART programs in such situations. Therefore it will be important to appreciate that when comparing programs across these nations, even though these nations share common problems of history of conflict, HIV, and limited resources for health provision, these are also countries with unique features as in their geography, culture, political systems and else.

## **2.2] *STUDY DESIGN:***

The study is primarily a desk study which is exploratory and qualitative in nature. Since the study is attempting to explore an area in which research has just begun, it is exploratory in nature; and since the research method conducted is not subject to formulaic analysis and outside a quantitative framework, the study is also qualitative in nature.

## **2.3] *SOURCES OF DATA AND METHODS OF COLLECTION:***

The method of research was a desk study with a review of current literature pertaining to ART therapy and interventions in emergency situations. Literature looked for was in the English language. Databases like Pub-Med and Athens were utilised to identify relevant articles. Journals like Lancet, BMJ, HIV Medicine and others yielded further information for the essay<sup>2</sup>. Publications from international organisations like UNAIDS, UNHCR, and WHO further provided pertinent material. Also, search engines like Google and Google Scholar were used to identify organisations involved in humanitarian and HIV programs in emergency situations

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<sup>2</sup> For full list of journals used for research please note the Reference list.



and also to locate grey literature. Hand/manual search of research material was also conducted in the libraries of QMUC Edinburgh and Copenhagen University. Private correspondence, both personal and by e-mail, was also carried with academics and humanitarian aid workers in the early parts of the study to acquire information on matters such as principles behind implementation of such programs, to obtain advice on identifying sources of information and also to discuss the direction in which the study had to proceed.

#### **2.4] STRATEGY FOR DATA ANALYSIS:**

Key words like ART, Complex emergencies, post conflict, ARV medication and ARV medication prices were utilised to identify relevant details among the collected material. Within this collected data, search was further narrowed to ART programs in complex emergencies. Since the objective of the study was to analyse the influence of financial price on ART coverage in post conflict nations, material pertaining mainly to ART programs in post conflict countries was kept aside for review. Upon studying this material, it was found that 3 countries –Uganda, Haiti and Mozambique would provide suitable data for performing a desk study on the above mentioned objective. Identified studies on ART programs in these countries were analysed for the role of ARV drug prices in ART programs, while at the same moment noting if any other factors impacted ART coverage.

**2.5] PERIOD OF STUDY:** The study was mainly conducted over a period of 4 months i.e. From May to August 2006.

**2.6] REFLECTION ON STUDY METHODS:** The study chose an option of desk study. The advantage of a desk study was that this research could be planned and conducted over a short period -3 months, whereas a field study on ART programs in 3 post conflict countries would not be practical in such a short period. Though, this was an area in which research was still developing recently; and considerable efforts were required to identify sources within this time. Large amount of the material available on this topic either comes from national authorities or international agencies. This could lead to a possibility of bias on the way the results /functioning of ART programs are portrayed. Therefore material from independent sources was actively sought after and where possible views from both sides were presented in order to



minimise information bias. Other limitations that this study could have is that the study material (obtained from the literature ) was not verified at the field level and also literature utilised for review was entirely from the English Language. This study knowledgeable of its inherent limitations is not purporting to provide answers for all questions but it rather seeks to provoke interest on the topic to necessitate further studies.

## **PART 3**

### **Findings:**

Transitions from conflict to peace are brought about by events like peace agreements or complete military victory of one side over the other [HLF, 2005]. Though in some cases like Somalia or Democratic Republic of Congo, the process is slower and erratic, and the real features of a post conflict situation emerge much later. Post conflict situations present both challenges and opportunities for the Health sector. The challenges that a recovering health sector may face include lack of funding, weak donor support, insufficient capacity, and different priorities among stakeholders.

Similarly, ART program implementation in post conflict situations faces these problems. Though, it will be necessary to consider that there are some unique issues which are associated with ART programs in these settings. Before we begin to review these issues, we need briefly further examine some of the basic elements of ART programs. For treatment of HIV, there would be a requirement for a stable environment, population residing for at least 6 months, and sufficient funds [Spiegel PB, 2004]. ART therapy is in a way distinct from other chronic infectious disease programs (like DOTS) because of the complicated diagnosis and follow up, life long treatment and need of much more funds. The goal of any ART should be “to prolong the life the patient’s life while maintaining the best possible quality of health and life” [Hoffmann C et al, 2005]. The treatment mainly suppresses the viral load and postpones the advent of AIDS. The effectiveness of ART has improved greatly with the biological rationale for maintaining a clinical response having been established [Weller IVD and Williams IG, 2001]. ART inhibits viral replication which results in partial reconstitution of the immune system in most patients, reducing the risk of clinical disease progression and death. Though, ART cannot completely eliminate the



HIV virus as it lies dormant in infected resting T Lymphocytes and other long lived cell populations.

Even with early and proper initiation of ART, there may be treatment failure because of drug resistance, non adherence of drug regimen and sub optimal pharmacological profile [Back DJ et al, 2000]. Non compliance leads to drug resistance, necessitating a change to a second line regimen, a much more complex and costlier regimen. Studies in stable situations looking at ART adherence rates have shown a high adherence rate ranging from 70% to 90% [Chesney MA et al, 2000].

Prices of ARV medication are an important issue in resource poor settings such as post conflict countries and this study examines this factor further. The high prices of branded antiretroviral drugs are due to the high costs involved in Research and Development (R&D) of these medications by pharmaceutical companies [ Moatti et al, UNAIDS 2001].

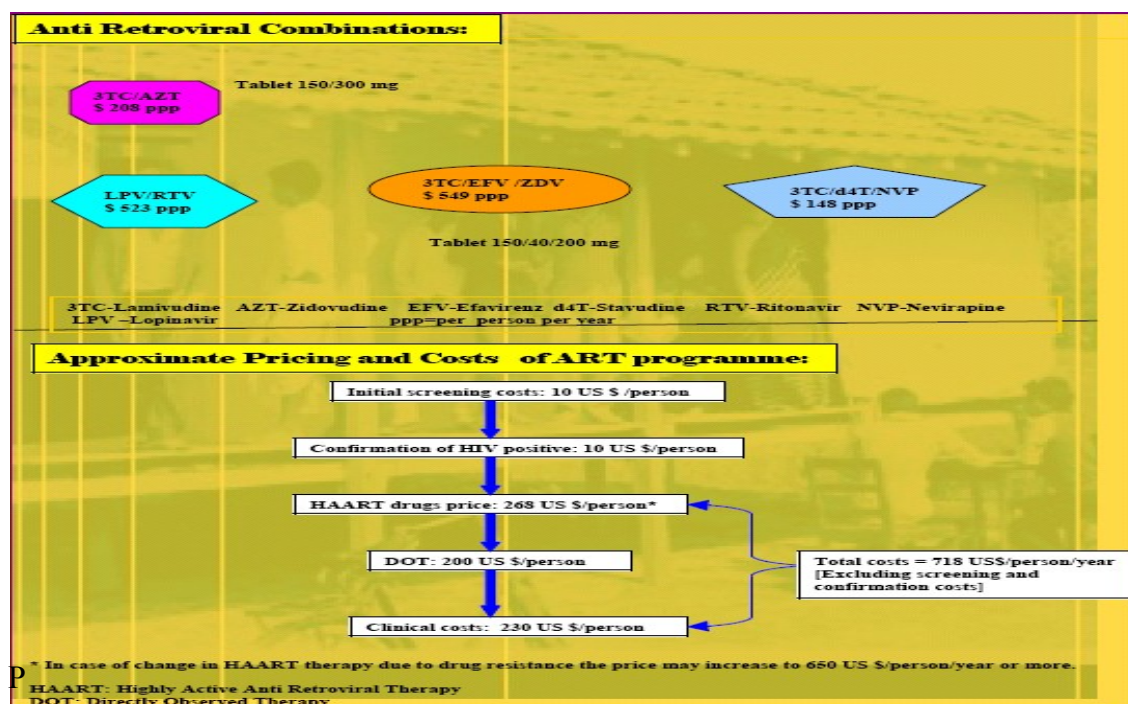


Fig II. Approximate pricing and costs chart of ART program [prepared by author using WHO, 2006 and Harvard Consensus statement, 2001]

Patents exist to protect the pharmaceutical companies' rights to manufacture these drugs. But once the validity of these patents expires, the right to manufacture enters the public domain and are taken by generic drug manufacturers. Since the marginal production cost (the cost required to produce another drug unit) for the generic manufacturer is low and also because they either do not pay the patent fees or they



manufacture molecules already in public domain; they are capable of offering medications for very low prices.

This phenomenon happens even in the case of ARV medications, with notable generic manufacturers like Cipla, Ranbaxy offering first line regimens at very low prices [Rosen et al, 2005]. Also, the Trade-Related Aspects of Intellectual Property Rights (TRIPs) made in 1994 allowed for compulsory licensing which authorised signatories to allow for manufacture a patented product without the authorization of the title holder in case of a national emergency or when the state wants to have public use on non commercial grounds [Shantaram,2005]. Apart from ARV medication, it is also necessary to note other ART program costs (see chart above) arising from Lab equipment/testing and opportunistic/co-infection treatment

3.1] ART PROGRAMS IN UGANDA, MOZAMBIQUE AND HAITI:

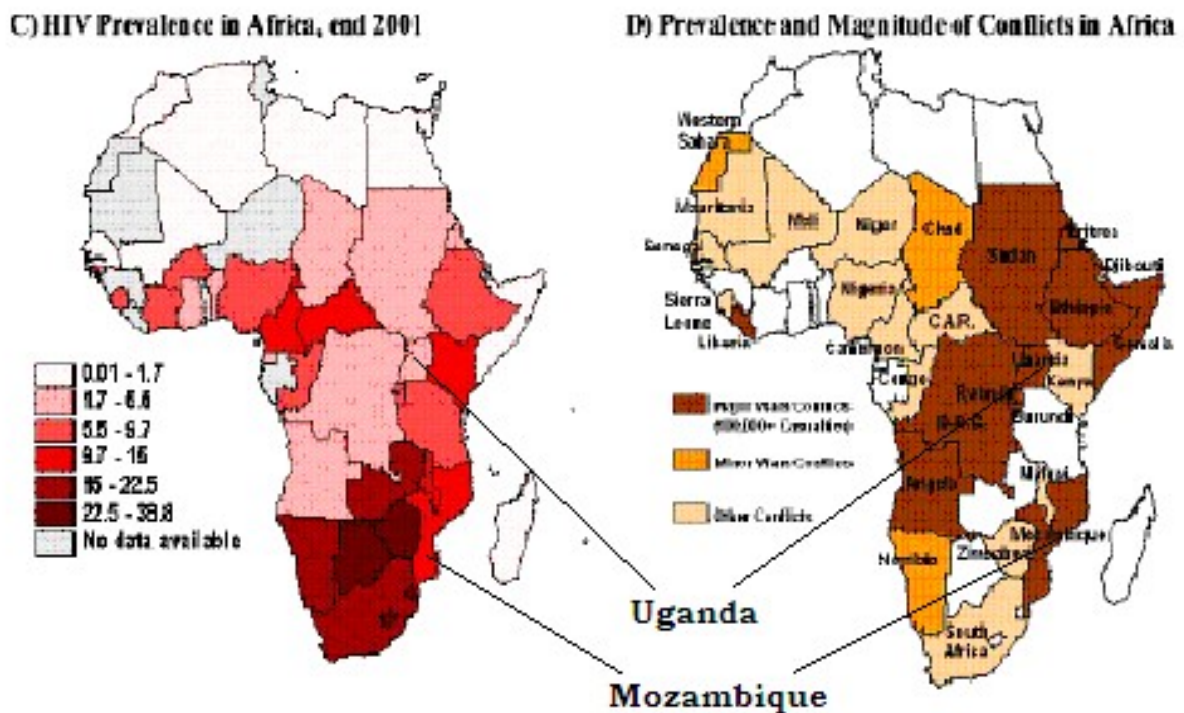


Fig III. Relation between conflict and HIV in Africa [Source: Mock NB et al, 2004]

As mentioned previously this essay chooses 3 post conflict nations –Uganda and Mozambique from Sub Saharan Africa and Haiti from the Caribbean to review ARV medication prices and ART coverage in post conflict circumstances.



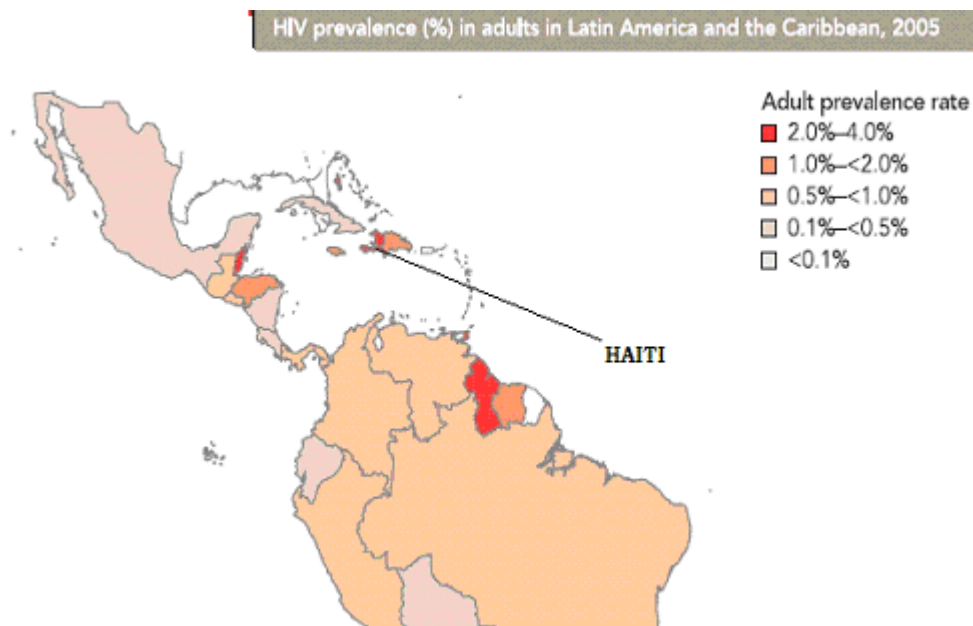


Fig IV. HIV prevalence in Haiti [Source: UNAIDS, 2006]

In this review of ART programs of these nations, the findings are divided into 2 parts for, namely:-

1] Activities (undertaken by national authorities and other agencies to decrease ARV medication prices and increase access to ART programs)

And

2] Factors (factors other than ARV medication prices, influencing ART coverage)

### **3.1.1] ACTIVITIES:**

The main entities involved in the health sector in a post conflict situation are the Government/national authorities, Funding agencies ( formal and informal), Rebels (if any), UN agencies, NGOs( International and local), and private for profit entrepreneurs [ HLF, 2005 ]. Accordingly, this part will review the activities of these entities in relation to ART programs in general and ARV medication prices in specific in Uganda, Mozambique and Haiti from available literature.

#### **A] National Authorities:**

The impact of conflict on the health situation of a country varies depending on the nature of the conflict and the prior state of the health infrastructure [Ugalde et al, 1999]. National authorities play an important role in these situations by setting priorities, negotiating funding from the international community and implementing



health programs [Anderlini and El-Bushra, 2004]. It would mean setting up systems that are mindful of the availability of resources and addressing needs of a vulnerable population. These principles hold the same in implementation of Anti Retroviral Treatment programs and there has been varying involvement in such programs by the national authorities in Uganda, Mozambique and Haiti.

### **Uganda:**

The first case of AIDS in Uganda was diagnosed in 1982 [Luboobi and Mugisha, 2005]. There was little understanding of what HIV was in Uganda or any strategies to control spread, which led to a very high prevalence [Nakiyemba et al, 2004]. Since then political support for strategies to reduce HIV incidence has led to fall in prevalence from 30% in 1990s to 6% at end of 2004 [Asamoah-Odei et al, 2004]. In 2003, it was estimated that 100,000 people in Uganda lived with AIDS requiring Anti-Retroviral Treatment [MOH Uganda, 2003] and the total number of adults and children living with HIV/AIDS was estimated to be between 350000 and 880000 [WHO country profile: Uganda, 2005]

Though ART has been available in Uganda since 1998, it was not available to the wider public through the public systems. Treatment was mainly available from NGOs, commercial providers or research projects. Most of the 10,000 or so people in Uganda benefiting from ART lived in urban areas and were paying from their own pockets or sharing costs with employers.

ARV medication was first introduced in 1992 in Uganda by the Joint Clinical Research Center (JCRC) (a private research organisation in Kampala supported by the Government of Uganda and other international agencies) when it initiated a trial of Zidovudine [MOH Uganda, 2003]. Eventually, more medications were added as they became available.

In 1998, the Ministry of Health (MOH) launched the Drugs Access Initiative (DAI) project. The aim of the initiative was to increase access to ART in the context of a resource constrained setting as in Uganda. Through this initiative a total number of approximately 1700 were treated at JCRC. The MOH further set up an advisory board and a non profit company, Medical Access Uganda Limited to achieve its objectives.



Initially five centers in Uganda achieved accreditation to provide ARVs. These centers were JCRC, Nsambya hospital, Mildmay center, Mengo hospital and Mulago hospital. Later ART became operational in over twenty health facilities including regional hospitals of Mbdara, Mbale, Soroti, Kabale, Arua, Masaka, Fort Portal and Gulu; private facilities like CASE medical center, Victoria medical center, and KADIC; and finally other hospitals like Kampala international, Tororo and Kiw oko (Luwero) hospitals.

Also, the Government in its effort to address issues relating to HIV/AIDS has developed the “National Strategic Framework for Expansion of HIV/AIDS Care and Support in Uganda”. This framework aims to reduce morbidity and mortality due to HIV/AIDS and to improve the qualities of lives of HIV infected people [MOH Uganda, 2003]. This would be achieved by building capacity for provision of care, provide essential drugs and promote research on HIV/AIDS along with other objectives.

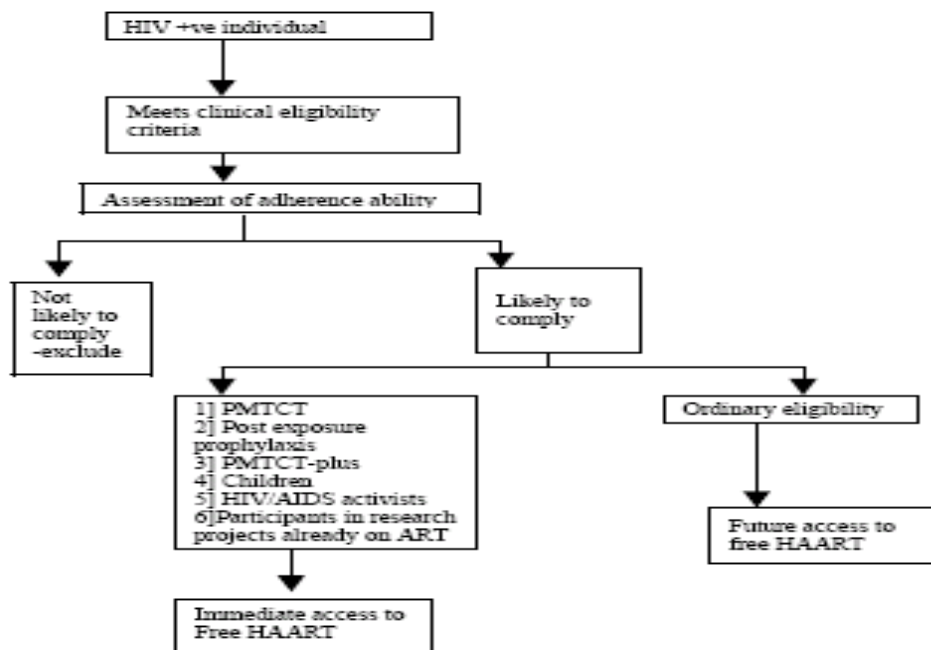
The Ministry Of Health [MOH] is the implementing unit of the ART program. The MOH is further responsible for the monitoring and evaluation the ART program in terms of its impact on health, financing and the socio-economic composition of those benefiting from ART in the public and private sectors to ensure equity is attained. The government of Uganda has tried to achieve price reductions of ARVs through various efforts as in negotiation, competition and tax exemption. It has contracted the National Medical Stores (NMS) as its primary procurement agency for antiretroviral medications [MOH Uganda, 2003]. It has also developed a long term procurement plan as a mechanism to coordinate forecasting, procurement, and shipments from multiple donors. A limited selection of ARV drugs is used in the public sector to allow benefit from lower prices that come from larger volume purchases, simplify the treatment protocols to be followed in public ART facilities and facilitate the distribution and storage of those high value inputs. Importation of generic ARV drugs for the first time in 2000 resulted in a reduction of prices of most commonly used tri therapies by 20% to 45% [UNAIDS, 2001].

Selection of suppliers is based on criteria that manufacturers are currently registered with the National Drug Authority (NDA) and manufacturers prequalified by WHO or



other internationally recognized bodies like MSF. Uganda has also tried to address Trade Related aspects of Intellectual Property Rights (TRIP) related issues of drugs by developing an “Industry Property Bill 2002” to create a legal means to import generic drugs, which are much cheaper than branded drugs.

Priority for access to free ARV drugs in Uganda has been made available for the following categories through a free ART plan [MOH Uganda, 2003]: *For prevention purposes*: In case of Prevention of Mother to Child Transmission (MTCT) and post exposure prophylaxis (accidental exposure in health worker or in rape victims) ; *For treatment purposes*: In case of treatment of HIV infected mothers identified in PMTCT programs and their HIV infected family members (PMTCT plus); in treating children and infants infected by HIV through MTCT, blood transmission, blood transfusion, or infected needles; in treating HIV patients already enrolled in care and support activities; and finally HIV patients involved in health research projects for HIV/AIDS whose access to ARV drugs is interrupted after end of the research.



**Fig V. Selection criteria for free access to Highly Active Anti Retroviral Treatment in Uganda [adapted from Bennett and Chanfreu, 2005]**

In 2004, 2700 People Living with HIV/AIDS (PLWHA) had access to ART through the government free programme [Nakiyemba et al, 2004]. As a result of decentralisation, many of the rural poor also now had access to ART. At the end of



June 2005, a total of 63 896 patients received ART of which 10 600 received free treatment through the MOH. In 2002, the end user price for one months treatment using a generic three drug combination of Stavudine, Lamivudine and Nevirapine (Triomune) was 56 520 Ugandan Shillings ( US \$ 31) [ Stewart R et al, 2004]. In July 2004, the average cost of the first line regimen was US\$ 180 per person per year, including the cost of drugs, laboratory tests and training [WHO country profile: Uganda, 2005].

The life long treatment required for HIV/AIDS and priority access for free HAART to certain groups' only, means that ARV medication prices are still way above many HIV patients in Uganda<sup>3</sup> [Nakiyemba et al, 2004]. Also, the continuing conflict in northern Uganda means that the extension of HIV/AIDS services to this region has been made difficult, leading to continued high prevalence of HIV in this region in spite of overall decline in the rest of Uganda [Luboobi and Mugisha, 2005].

### **Mozambique:**

Mozambique is among the lowest ranking countries on all components of the human development index among southern African countries [Mock NB et al, 2004]. Against this background, there were an estimated 1.5 million people living with HIV/AIDS in 2003, causing it to be one of the most HIV affected countries in the world [CHG, 2003].

There is a high prevalence of HIV/AIDS in the central region which has been attributed to a number of factors, including return of an estimated 2 million refugees after the peace agreement in 1992 from neighbouring countries such as Malawi and Zambia where HIV prevalence is high; and also the mobility of the population along the transport corridors that link Mozambique and the port of Beria to Zimbabwe and Malawi is another factor [CHG, 2003]. In the southern regions, the highest adult prevalence rates are in Gaza where there is a large portion of adult men who earn their income as migrant workers in the mines of South Africa.

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<sup>3</sup> Per capita income in Uganda in 2002 was less than US\$250 per annum and an estimated 35% of people in Uganda live on less than US\$1/day [Stewart R et al, 2004]



The government considering this situation has in its Plan of Action for the Reduction of Absolute Poverty (PARPA) committed itself to respond to HIV/AIDS through health related activities [CHG, 2003]. Also, the government has endorsed the Declaration of Commitment on HIV/AIDS adopted by the UN General Assembly in 2001 and the UN Millennium Development Goal to halt and reverse the spread of HIV by 2015.

The Ministry of Health (MOH) set up the National Program to Combat AIDS in 1998, and in 2000 this program was superseded by the National AIDS Council (NAC) [CHG, 2003]. Its tasks included co-ordinating, monitoring and evaluating all HIV/AIDS related activities in the country as well as to mobilise resources for a comprehensive and multisectoral response to HIV/AIDS. The board of NAC is composed of members of government as well as of civil society representatives.

The Medical Care Unit within the National Health Department of the MOH co-ordinates procurement and supply-chain management of ART [WHO country profile: Mozambique, 2005]. It is supported in this regard by the National Centre for Medications and Medical Supplies and the parastatal procurement agency MEDIMOC.

Further in 2000, the National Strategic Plan to Combat HIV and STD (NSP) was developed utilising extensive consultation [WHO country profile: Mozambique, 2005]. Provincial HIV/AIDS co-ordinators were appointed and provincial plans were also developed to enable implementation of the strategy. The NSP among others has prioritised improved coverage of voluntary counselling and testing, as well as care and treatment; and reduce impact of HIV/AIDS in People Living With HIV/AIDS (PLWHA) through support and care.

While budgetary allocations were made for the implementation of the NSP, in practice it remained unfunded and planned activities were not undertaken. The number of patients who were presumed to be in need of ART in 2003 was 54,000 and less than 2000 received treatment that year.



This led to a rethink on the NSP and a revision of strategies. Funding was invited from international donors to support the implementation of plans and improve the Pharmaceutical Departments storing capacity for ARV medication. A more comprehensive list of services was to be implemented which included Voluntary Counselling and Testing centres (VCT), Laboratories for CD4 and viral load measurement, PMTCT, and home based care. The MOH established treatment criteria in line with WHO recommendations and guidelines on antiretroviral therapy have been reviewed to incorporate changes according to international standards [WHO country profile: Mozambique, 2005].

By March 2004, an estimated 240 doctors had been trained to deliver antiretroviral therapy. A new national drug management and logistics system is being developed to anticipate any scale up of ART coverage and under this system, drugs instead of being sent to Maputo, the capital, will be sent directly to the five provincial hospitals at Maputo, Belra, Nampula, Zambezia and Manika.

Delivery of ART in Mozambique is facility based and initiated by the physician [WHO country profile: Mozambique, 2005]. An integrated network of day hospitals and clinics provide ART, Voluntary Counselling and Testing centers, PMTCT, home based care services. To increase coverage the MOH is intent on putting into 129 integrated health networks across the country. In 2005, an estimated 24 sites were offering ART in the public sector through collaboration between the government and NGOs. In 2005, the first line drug regimen Lamivudine+ Stavudine+ Nevirapine was procured at a price of US\$140 per person per year. When last estimated in 2004, there were still an estimated number of 188343 people requiring antiretroviral treatment.

### ***Haiti:***

Haiti, just 90 minutes by plane from USA is one of the poorest countries in the world [Partners in Health, 2005]. It also faces the worst AIDS epidemic outside Africa and the greatest burden of HIV in the western hemisphere [WHO country profile: Haiti, 2005]. The HIV epidemic in Haiti is fuelled by endemic poverty, illiteracy, inadequate health and social services which have been weakened by chronic political instability, high internal migration rates and a high prevalence of Sexually Transmitted Infections (STI). It has been estimated that 280 000 adults and children



were living with HIV/AIDS at the end of 2003 and 24000 adults and children died from AIDS in the same year.

Haiti's government has been attempting to halt the spread of HIV and also support care and treatment to HIV patients [Partners in Health, 2002]. The National Commission to Fight HIV/AIDS, a joint public-private organisation was established in 1989 under the leadership of the Ministry of Public Health and Population to coordinate response to the HIV epidemic [WHO country profile: Haiti, 2005]. This was reorganised in 2001 under the leadership of the first lady and an interim HIV/AIDS strategic plan for 2001-2002 was developed in 2000. Further in 2002, a National Strategic Plan for 2002-2006 was developed. The HIV/AIDS National Strategic Plan for 2002-2006 emphasised care and treatment as well as rapidly scaling up voluntary counselling and testing centers to comprehensively manage the epidemic.

Haiti is also a member of the Pan-Caribbean Partnership against HIV/AIDS launched in 2001 to strengthen collaboration among countries in the region and to consolidate resources under the leadership of the Caribbean Community Secretariat [WHO country profile: Haiti, 2005]. This partnership has been actively engaged in negotiating affordable prices for anti retroviral drugs in the Caribbean.

The Ministry of Public Health takes leadership in delivery of ART [WHO country profile: Haiti, 2005]. It is supported in this by many International agencies and NGOs- both local and international. In 200, it was estimated that 40,000 people in Haiti needed ART. In Haiti, ART has been delivered mainly through private initiatives (this will be reviewed later in this section). There are clinics for HIV testing and treatment in the capital of each of Haiti's nine departments and two in the national capital, Port-au-Prince [Partners in Health, 2002].

In 2003, HIV patients in Haiti requiring ART numbered 40,000 and by end of 2004, the number had risen to 42,500 people [WHO country profile: Haiti, 2005]. Various first line regimens are currently being used. It has been estimated that first line regimens like Zidovudine+Lamivudine+Efavirenz (or nevirapine) and Stavudine+Lamivudine+Nevirapine cost about US\$ 720 per person per year and





second line regimens range from US\$ 900 to US\$ 1920 per person per year. Generic drugs are available but access to drugs has been limited by weakness in the national supply management system.

Though in Haiti, political commitment to tackle the HIV/AIDS epidemic and support care to HIV patient exists, political and economic instability in recent years have stalled efforts and worsened the inadequacy of health sector response and capacity.

### **B) International Agencies, NGO's and the private sector:**

Apart from national authorities, various other important entities would be involved in providing support to the health sector in post conflict nations. These would be the funding agencies, UN bodies, NGOs and the private sector.

Funding agencies, both bilateral and multilateral donors, are one those most important actors in supporting post conflict health provision. Initially in the post conflict phase they may act indirectly through UN agencies and the NGOs, but later on may assume greater visibility and direct influence [HLF, 2005]. UN agencies often enjoy several comparative advantages as in a long term presence in the country, a technical mandate and a relative distance from geopolitical and economic interests. However, they may also struggle to fulfil their potential because of under-funding and related fund raising. NGOs represent a precious asset with a wealth of unstructured knowledge and experience. Though some times local NGOs are dependant on national authorities, the NGOs could develop autonomy by allying with funders willing to engage in the health field. Private entrepreneurs have an important contribution to the delivery of health in post conflict states. These entrepreneurs include formal and informal health businesses (health care facilities, laboratories, training outlets) and suppliers of medicines. Despite their influence on political decisions and on field operations, the private sector is rarely included in the formal debate about service delivery.

### **Uganda:**

As any resource poor country planning to implement ART programs, Uganda has had to rely on the support of international donors and UN agencies. UN agencies like WHO and UNAIDS are involved in several stages of implementation of ART programs in Uganda [WHO Country Profile: Uganda, 2005]. WHO and UNAIDS provide support to the National AIDS Program of the MOH of Uganda in planning



and co-ordination of ART programs. WHO supports the Joint Medical stores in procuring ARV medication and supply chain management. Further, WHO supports the MOH in undertaking operational research on scaling up ART in resource constrained settings and it also provides technical assistance in setting up monitoring and evaluation systems for ART programs. UNAIDS supported the MOH in establishing the first large scale ART program in Africa, the Drug Access Initiative (DAI) in 1998 [Stewart et al, 2004]

Uganda has submitted a successful Round 1 proposal to the Global Fund to Fight AIDS, TB, and Malaria seeking support for ART programs along with other HIV programs [ WHO Country Profile: Uganda, 2005]. The total funding request was for US\$51.8 million and a 2 year approved funding of US\$ 36.3 million Also, Uganda has submitted a Round 3 proposal to the Global fund with a total funding request for US \$ 118.5 million and two year approved funding of US\$ 70.3 million for scaling up ART for orphans and vulnerable children. The country is also receiving an estimated US \$ 2 million from multilateral agencies to support ART programs.

Agencies and institutions like US Center for Disease Control (CDC), the Elizabeth Glaser Pediatrics AIDS Foundation, the German Gesellschaft fur Technische Zusammenarbeit (GTZ), Medecins Sans Frontieres (MSF) and Plan International; are involved in supporting PMTCT programs [ WHO Country Profile: Uganda, 2005].

President George Bush of the United States announced the President's Emergency Plan for AIDS Relief (PEPFAR) in his State of the Union Address on January 28, 2003 [Brainard L (Ed).2006]. The President promised resources for HIV/AIDS upto US\$15 billion over five years. This amount was more than any international organization or donor had been able to congregate. The plan being implemented by the United States Global Office for HIV/AIDS (USG) would cover 15 focus countries<sup>4</sup> which included many post conflict countries like Uganda. At least 55% of the PEPFAR appropriations through the fiscal year 2006 -2008 are earmarked for ART and related cares to 2 million persons in these focus countries. Under this plan, Uganda has received more than US \$ 90.7 million in fiscal year 2004 for HIV/AIDS

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<sup>4</sup> [Uganda](#), [Mozambique](#), [Haiti](#), [Botswana](#), [Ethiopia](#), [Guyana](#), [Ivory Coast](#), [Vietnam](#), [Kenya](#), [Namibia](#), [Nigeria](#), [Rwanda](#), [South Africa](#), [Tanzania](#), and [Zambia](#).



programs [US Global AIDS office-Uganda, 2005]. The USG supported nine partners in Uganda to provide ART in 2005. These partners served a total of 39,538 clients in 27 districts, meaning that about 78 % of all patients on ART in Uganda were supported by PEPFAR. During the first 18 months of PEPFAR funding, the Joint Clinical Research Center (JCRC) was able to expand its provision of ARV medication to over 19000 clientele and expand nationally to more than 30 clinics [Bass E, 2005]. Also, around 2000 orphans and pregnant women receive free medications from PEPFAR funding in many clinics.

The private sector is playing a significant role in the provision of ART in Uganda, with even the Government of Uganda and International agencies recognising this fact [MOH Uganda, 2003 and Bass E, 2005]. The Government of Uganda has listed the Private Not for Profit (PNFP) facility based and non facility based private health practitioners, and traditional and complementary medicine practitioners as all under the designation of private health sector [MOH Uganda, 2003].

These private providers include Reach out Mbuya, Uganda Cares Program in Masaka, Kamwokya Christian Caring Community [WHO Country Profile: Uganda, 2005]. Reach out Mbuya is a NGO situated on the outskirts of Kampala involved in provision of ART, Uganda cares is a community based ART center, and Kamwokya Christian Caring Community is a faith based organization planning to provide ART upto 500 people with funding support from PEPFAR. The AIDS Service Organisation (TASO) is another major NGO involved in ART is also being supported by PEPFAR [Bass E, 2005]. In its first 18 months, TASO started providing ART to approximately 2500 individuals. These individuals would attend a series of adherence counselling sessions before they went on ARV medications. Medications were then provided fees, but patients could be asked for a user fee ranging from \$0-30. The Uganda Network of AIDS Service Organizations co-ordinates the activities of the key NGOs involved in ART and other HIV programs [WHO Country Profile: Uganda, 2005].

In the corporate sector, the Bank of Uganda in 2000 began to subsidise ART for its employees [Stewart et al, 2004]. The employees would pay for 25% of drug costs and the remaining drug and lab costs would be borne by the Bank of Uganda. Also, Coca Cola announced in 2003 that 40 of its bottlers had committed to provide ARV



medication to its employees. In this initiative, Coca Cola would cover 50% of the treatment costs, the bottler 40% and employees the remaining 10% of costs.

***Mozambique:***

International agencies like WHO have assisted the MOH in Mozambique to establish guidelines on Antiretroviral Therapy [WHO Country profile: Mozambique, 2005]. WHO also provides support to the MOH in expanding services of VCT and PMTCT. It has also as part of the WHO/OPEC fund Multi-country initiative on HIV/AIDS and WHO/Italian initiative on HIV/AIDS in Sub-Saharan Africa provided support to PMTCT services and clinical management of HIV, including ART.

Mozambique is expecting an estimated US\$6.3 million from the Global Fund to Fight HIV/AIDS, TB, and Malaria to scale up ART [WHO Country profile: Mozambique, 2005]. In April 2004, Mozambique submitted a successful proposal to the World Bank and the proposal, of US\$1 million, included components on ART, VCT, PMTCT, MCT-plus and home based care among others. In May 2006, the African Development Bank (AfDB) approved a grant of approximately US\$29.42 million to fight communicable diseases ( HIV/AIDS, TB....) to 8 Southern African Development Community ( SADC) which included Mozambique [ AfDB, 2006]

Other organisations/agencies involved in supporting ART in Mozambique include PEPFAR , the Canadian International Development Agency (CIDA), the French Cooperation , the Belgian cooperation, and the William.J.Clinton foundation [WHO Country profile: Mozambique, 2005]. Under the PEPFAR plan, Mozambique received approximately US\$ 37.4 million in 2004 to implement HIV/AIDS programs including ART [US Global AIDS office-Mozambique, 2005]. In 2005, the US Global AIDS office provided second line and Pediatric formulation ARV medication, and also supported measures to improve supply chain and logistics to allow for uninterrupted supply and availability of ARV medication.

Also in Mozambique are involved in implementing or supporting ART programs. Through collaboration with the government, NGOs like Community of Sant'Egidio and Medicins Sans Frontieres (MSF) are offering ART at 24 sites [WHO Country profile: Mozambique, 2005]. Health Alliance International, a US NGO, is providing



support for PMTCT services, and the Instituto Emilio de Infectiologia Ribas of Brazil and Columbia University of New York are providing support for training health workers in ART.

***Haiti:***

In Haiti ART has been mainly provided through private projects like the Haitian Study Group on Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) and Partners in Health in collaboration with Zanmi Lasante clinic [WHO Country profile: Haiti, 2005] . These two NGOs have provided ART free of charge since the late 1990's in collaboration with the Ministry of Public Health and Population. GHESKIO has been serving the population of Port-au-Prince, the capital of Haiti, with free HIV counselling, testing for HIV infection, prevention against HIV infection services, as well as HIV care and treatment [Severe P et al, 2005].

In 1998 against the prevailing trend, Partners in Health launched the HIV Equity Initiative to provide free ART to a couple of AIDS patients in a squatter settlement in Cange, in Haiti's Central Plateau [Partners in Health, 2005]. It utilised a community based model to train and employ local people to administer ARV medications daily and also provide societal support to the patients. The services offered by Partners in Health with local collaborators in addition to provision of free ARV medication included access to free VCT, the provision of AZT ( Zidovudine) for PMTCT and aggressive diagnosis and treatment of opportunistic infections [ Farmer P et al, 2000]. The ARV treatment was made available to AIDS patients in whom the disease no longer responded to opportunistic infection treatment [Harvard Consensus Statement, 2001]. A protocol (Harvard-Haiti) was established to bypass expensive lab tests like CD4 testing and viral load testing to initiate treatment in these AIDS patients.

Since then Partners in Health with its sister organisation in Haiti-Zanmi Lasante in addition to operating a full service medical center in Cange have expanded to 7 other sites across central Haiti [Partners in Health, 2005]. By 2005, 912,000 patient encounters had been recorded across Zanmi Lasante's clinical sites and mobile clinics, 48000 people had been tested for HIV each year and ART was being provided to 1,687 patients with advanced AIDS.



In addition to the above mentioned NGOs, other agencies and organisations have also been involved in supporting ART programs in Haiti. WHO has been providing assistance to the government of Haiti in developing the HIV/AIDS National Strategic Plan for 2002-2006 and in developing guidelines for PMTCT [ WHO Country Profile: Haiti, 2005]. An approximate of US \$ 4 million for scaling up ART is expected from the Global Fund to Fight AIDS. The PEPFAR plan has committed US\$ 9.1 million for scaling up ART during 200-2005. In December 2004, the Immaculate Conception Hospital in Cayes became the first public hospital to deliver ART. It was supported in this initiative by PEPFAR, Family Health International and the French Cooperation. Family Health International is also providing to 4 other public sites to provide ART.

### **3.1.2] FACTORS:**

Whilst studying implementation of ART programs in conflict affected countries, a range of important issues come up as those affecting coverage of such programs-these include effectiveness and price of medications, strength of Health systems (Infrastructure, Personnel, delivery system...), societal attitudes, legal issues, poverty ...etc [Piot P, 2000]. Also we have previously noted in the introduction the various components of ART programs of which importantly are the Voluntary Counselling and Testing (VCT), ART (*administration of ARV medication, now called as Highly Active Antiretroviral Treatment (HAART).*), Prevention of Mother to Child Transmission (PMTCT), Opportunistic and Co-infection treatment [ Grant and De Cock , 2001; Kitahata MM et al, 2002; IASC, 2003 ]. So this would mean even if ARV medication prices are a major factor in the implementation of ART programs , there are other factors that also influence ART program costs and ART coverage [ Egger et al, 2005 ; Attaran and Gillespie-White , 2001 ; Luboobi and Mugisha , 2005].

Based on review of available literature, these factors have been grouped under the following headings: ***Economic, Political, Security, Health services, Legal/Regulatory, Other ART costs, Drug related issues, and Social factors.*** Examples of Uganda, Mozambique and Haiti relating to these factors are mentioned based on their suitability and availability.



**Economic:**

International funding agencies play a major role by financing the rebuilding of the health sector or implementation of health programs in post conflict situations [HLF, 2005]. For example in 1996, 2 years after end of the conflict, the Mozambican ministries depended on external donors for more than 75% of their budget [Barreto et al, 1996]. In the post conflict phase perhaps programs that emphasize issues like demobilization, reinsertion, reintegration and development could gain more importance in funding than HIV/AIDS programs [Mock NB et al, 2004]. Even if HIV programs received funding, it could be that priority is granted to HIV prevention programs than treatment programs [Mukherjee et al 2003; Stewart et al, 2004].

Though now, experts and funding agencies are recognizing that prevention and treatment need to go together for successful implementation of HIV programs [UNAIDS, 2001; GTZ, 2002]. Also, funding for ART programs has been increasing in post conflict countries in the past few years [WHO Country profiles: Uganda, and Mozambique 2005; US Global AIDS office-Uganda and Haiti 2005].

Yet it stands that there is still a major requirement of funding for large scale implementation of ART programs, for example to reach the WHO “3 by 5” treatment target , Uganda needed something between US\$ 69.2 million and US\$ 131.7 million ( for a target of 55000 people), Mozambique needed something between US\$ 92.7 million and US\$ 98.7 million , and Haiti needed between US\$27.9 million and US\$28.3 million to reach a target of 20,000 people [ WHO Country Profiles: Uganda, Mozambique and Haiti, 2005]. It would be important for the funding agencies to continue support for ART programs in these countries to ensure continuous provision of ART and also to extend coverage of ART programs [WHO Country Profiles: Uganda, Mozambique and Haiti, 2005; US Global AIDS office-Uganda and Haiti 2005; Bass E, 2005].

**Political:**

It is vital for any national authority to be (politically) committed to control HIV/AIDS within a country for these programs to be successful. HIV/AIDS related needs should be accorded priority in national policy and health budgets in HIV affected countries [UNAIDS, 2001]. Though in post conflict countries, apparent leadership may not



come from newly installed or insecure governments [HLF, 2005]. Also people who return from exile and take up senior positions in the government may have lost touch with ground realities and local authorities may not exactly pursue the policies of the central government.

In spite of all these hindrances, it has been noted that there has been a strong political commitment from the National authorities in Uganda, Mozambique, and Haiti for ART programs [WHO Country Profiles: Uganda, Mozambique, and HAITI, 2005; CHG, 2003]. In Uganda for example, strong political commitment and direct approaches has resulted in a great reduction in HIV sero prevalence [Ammann AJ, 2002]. Also, the Ugandan government has shown clear support for increasing ARV medication access and reducing prices of the ARV drugs [US Global AIDS office, Country Profile: Uganda, 2005; MOH Uganda, 2003]. Similarly the governments in Mozambique and Haiti have also shown political commitment for HIV/AIDS programs [CHG, 2003; WHO Country Profile: Haiti, 2005]. Though strong political commitment has been demonstrated in these post conflict nations, they face other problems like political instability (Haiti), and dependency on external funds for scaling up access to ART (Mozambique).

### **Security:**

In countries affected by complex emergencies, though the post conflict phase is marked by relative stability it may be interspersed with episodes of conflict or it may be that some areas of the countries are still held by forces not amenable to the national authorities [ WHO 2000; HLF, 2005; Luboobi and Mugisha, 2005]. There may be questions of the feasibility of ART programs in such settings during outbreaks of violence.

In June 2003, a Prevention of Mother to Child Transmission (PMTCT) program was introduced in the Central Plateau of Haiti by MARCH, a community based organisation [Murphy H and Berggren R, 2004]. MARCH provided Voluntary Counselling and Testing (VCT), Directly observed therapy with antiretroviral (DOT-ARV) intervention with either Zidovudine or highly active antiretroviral therapy (HAART). The services were available for a nominal fee and services were subsidised for those who could not pay. In 2004, political conflict broke out in this region and





other regions. This meant that number of women who had HIV were diagnosed late (making it too late for Zidovudine therapy to be effective) or were not screened at all. This happened because of the ongoing conflict. MARCH had to think of methods to reach to their patients in the rural areas and utilised mobile clinics to do so. In spite of the initial difficulties arising out of the conflict, once peace keeping troops arrived, resumption of services happened. It was noted in spite of the conflict, there was no shortage of infant formula or ARV medications during this time. These had been stored in an ARV warehouse in Cange, therefore allowing continuing supply of ARV medications.

In Uganda, even though there has been a continued improvement and scaling up of ART services in most of the country, the 18 year old conflict in northern Uganda has made implementation of ART programs and provision of ARV medication very difficult in this part of Uganda [Luboobi and Mugisha, 2005].

These examples from Haiti and Uganda show that conflict and security (or lack of it) does have a certain impact on access to ART programs/ ART coverage.

**Legal/ Regulatory:**

It has been noted earlier in the essay about the high price of branded drugs, the policy of patents protecting the manufacturing rights of pharmaceutical companies, and the cheaper ARV medications manufactured by generic companies. It was also mentioned that the Doha declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) allowed for public health needs to be placed before commercial interests [Stewart et al, 2004]. In reviewing ART programs in post conflict countries it would be necessary to note how these policies are affecting ART coverage.

A study conducted on the patent statuses of 15 ARV medications in 53 African countries including Uganda and Mozambique has (in its results) suggested that patents and patent laws are not a major barrier for ART access in these countries [Attaran A and Gillespie-White L, 2001]. It found that most African countries in its study have offered patent protection for pharmaceuticals. The study states that other factors like ARV medication prices, national regulatory requirements for medicines, tariffs and sales tax and, above all, inadequate funding from international donors



among others are more responsible for acting as barriers to ART coverage, rather than patents.

In the study results, Uganda had patent coverage for most of the important ARV medications though Mozambique had none. The authors suggest that it could be because of the pharmaceutical agencies as a common practice name a large number of countries on international applications but do not follow them through because of patent fees or other reasons, and hence leading to a few number of patents in force in Africa.

In Uganda, the national authorities have adopted a neutral position on the issue of branded v/s generic drugs. It is importing both branded and generic drugs, ascertaining that the generic drugs match that of to the WHO recommendations for ARV medications [MOH, 2003]. Also the government is addressing issues that may arise from the World Trade Organisation (WTO) and TRIPS through an “Industry Property Bill”.

**Health services and infrastructure:**

For effective and safe delivery of ARV medication; and also to support other components of ART programs like VCT and PMTCT, there is a need for an adequately functioning and affordable health service in resource poor settings [Kitahata MM et al, 2002]. To effectively run this health service, there would also be a requirement for trained health personnel. In post conflict situations, health services suffer from inadequate capacities, weak infrastructure and lack of skilled personnel [HLF, 2005]. Health needs beseech for priority among many non-health agendas and further strengthening of health services in these regions would require attention.

In Mozambique, the public sector health care system has faced many challenges to provide care and treatment to PLWHA [CHG, 2003]. The public health network in Mozambique is composed of 1000 units with most of these being health posts with limited provision of services. Heavily populated regions like Nampula and Zambezia In northern Mozambique have the fewest beds per 1000 people and also face a huge number of HIV patients requiring hospitalisation. The laboratory in many hospitals and health centers lack equipment for HIV testing and if available are prioritised for blood donors. Also Mozambique faces a huge shortage of doctors and other skilled



health personnel. In 2003, less than 50 percent of the districts in Mozambique had a doctor. Among these doctors, few are credited to prescribe ART. Similarly Mozambique faces shortage in pharmacists and VCT counsellors.

Similarly Uganda also faces shortage of doctors in the public health sector and this has been compounded by factors like low salaries and lack of incentives [WHO Country Profile: Uganda, 2005]. The availability of ART services is inadequate at the district and sub district levels. The Ugandan government is hoping to address these issues through the national delivery plan which anticipates that in the long term, tasks relating to ART usually performed by doctors will have to be shared and involve other health providers such as nurses who are in large numbers [Stewart et al, 2004]. Also Uganda has undertaken a countrywide program to make sure that staff providing ART were well equipped. The program focused on ART, opportunistic infection treatment, drugs logistics, stock management and other clinical issues.

**Other ART costs:**

We have already learnt that ART program is made of several components like VCT, PMTCT and opportunistic infection/co-infection treatment. Implementation and running of each component entails costs of its own. Apart from ARV medication and opportunistic infection medication prices, the costs of diagnostic and monitoring tests have acted as constraints for ART coverage in resource poor settings [Mukherjee et al, 2003; Mugenyi P, 2001]. Lab tests are not only required for detection of HIV in patients but also to monitor the response to ARV medication [Grant DA and De Cock KM,]. Monitoring for ARV medication response requires tests for CD4 count and viral load. These monitoring tests which are used to initiate ART in HIV patients are more expensive than HIV detection tests [UNAIDS, 2001].

The WHO in 2002 put forward recommendations for initiating ART in adults in resource poor settings [WHO, 2002]. These recommendations (see annexe) stated that people who are HIV positive and have clinical AIDS are eligible for treatment, irrespective of CD4 count. Basically this meant lab testing for CD4 was not required to initiate ART in HIV patients who satisfied the criteria set in the recommendations.



In Haiti, Zanmi Lasante in its Clinique Bon Sauveur employed these criteria to initiate HAART<sup>5</sup> to HIV patients [Mukherjee J et al, WHO, 2003]. But, on a later review found that a subset of patients who appeared well (and not presenting with clinical AIDS and thus not receiving HAART) had died within 2 years of diagnosis with HIV, probably as a result of sub clinical immune suppression leading to virulent opportunistic infections. Later the clinic acquired a flow cytometer and could measure CD4 on site. While very sick patients are still initiated with HAART based on the WHO recommendations, patients without clear AIDS defining illnesses (see annexe) are screened to determine if they meet immune criteria ( CD4 count < 350 cells/mm<sup>3</sup>) for initiating HAART. To monitor the response to therapy, the clinic mostly utilises clinical monitoring, like the patients weight (see annexe for a case history) which is closely followed. CD4 counts are used only if the patient starts to lose a lot of weight and develop new opportunistic infections. Clinical monitoring of the treatment is done at the periods of one week, one month, 3 months and every 3 months thereafter.

The WHO recommendations for initiating HAART and clinically oriented monitoring and evaluation of ART provision is also being utilised in Uganda [ MOH Uganda, 2003]. The “Monitoring and Evaluation Plan for the Expanded National Response on HIV/AIDS in Uganda” provides recommendations in this direction and focuses on clinical responsiveness of the ARVs in viral control in those receiving ART and monitoring drug resistance along with other recommendations.

In another study done over 2003-2004 in Haiti on 1004 HIV patients receiving HAART , it was found that Laboratory monitoring came to US \$ 300 per person per year (pppy) , medications other than ARV drugs – US \$ 75 pppy , data monitoring – US \$ 75 pppy, personnel – US\$ 450 pppy , and miscellaneous other costs –US\$ 100 pppy [ Severe et al, 2005]. The ARV medication costs itself ranged from US\$ 550 pppy for generic medication to US\$ 750 pppy for branded drugs.

### **Drug related issues:**

Adherence to HAART is an important issue because of the implications arising out of non adherence. Drug adherence/compliance is defined as “as the extent to which

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<sup>5</sup> HAART involves a more complex regimen than the normal ART. For full list of HAART regimens refer to the annex



patients take medications as prescribed by their health care providers” [Osterberg L and Blaschke T, 2005]. In treatment of HIV / AIDS, it is expected to achieve a very high adherence to HAART among patients for viral suppression and to avoid drug resistance. This (adherence) is challenging both for health providers and the patients as the regimen includes multiple medications, complex dosing schedules and have side effects. Serious toxicities because of the ARV medication include hyperlipidemia, insulin resistance, lactic acidosis, pancreatitis among others [Kitahata MM et al, 2002]. Also, ART for specific subpopulations is convoluted by drug interactions among HIV patients with TB and who are taking antituberculosis drugs and there is a risk of hepatic toxicity among people infected with both HIV and Hepatitis viruses who are taking ART.

These and other issues are often cited to raise concern regarding the ability of health systems in resource poor settings to ensure HAART adherence among HIV patients [Stewart et al, 2004]. But surveys carried out in Uganda and other countries in Africa have shown on average a 90% adherence rate, higher than that of adherence rates in USA. In Uganda, the NGO –TASO would require HIV patients to attend a series of adherence counselling sessions ending with a signed contract before they started on ART [Bass E, 2005]. In Mozambique, some public sector pilot ART projects required patients to have a family member or friend who would provide support to them in adhering to the treatment [CHG, 2003].

The HIV Equity Initiative in Haiti has been a pioneer in administering ART in resource poor settings and based on previous experience from TB programmes , it set up the Directly Observed Therapy-HAART (DOT-HAART ) model [ Mukherjee J et al, 2003]. Each person eligible for ART in the program was followed by an *accompagnateur*. The *accompagnateur* would in their daily visits observe the patient take one dose of HAART and visits for observing intake of the second dose would be voluntary. The *accompagnateur* were also trained to assess for common side effects of the medications and signs of HIV related illness. New patients along with clinical assessment also underwent social assessment to identify barriers to adherence to HAART.



These examples illustrate that adherence to HAART could be maintained with implementation of suitable measures in resource poor settings. However challenges remain with these adherence criteria and programs not being employed throughout the public health sector (Mozambique) [ CHG,2003] and drug resistance circulating among patients because of non monitored use of black market ARV medications , as in Uganda [ Nakiyemba et al , 2004].

Perhaps, large scale implementation of adherence programs based on the Haiti HIV Equity Initiative model, greater access to affordable ARV medications and the current availability of a 3-in-1 ART pill for poor countries (see annexe) would enable adherence among HIV patients in these countries.

***Social Factors:***

Social factors like education, belief and knowledge, social support and stigma have been considered important for uptake of VCT and adherence to ART [Stewart et al, 2004; Nakiyemba et al, 2004]. Lower levels of education, lack of interest in HIV knowledge, and negative beliefs of the affects of HAART all have effects on adherence to HAART. Also living alone and social isolation are negative predictors of adherence to HAART. Stigma directed against HIV patients has been considered to be a major barrier to treatment and has contributed to the growth of the HIV epidemic as HIV infected people feel reluctant to get tested and involve in unsafe and risky behaviour. Stigma also works against adherence to ART as the patient needs to keep his intake of ARV medication private and hidden. This leads to lack of social support.

In Mozambique , even when counselling sessions were being provided and ART was provided for free , some patients would not show up for treatment due to stigma and lack of awareness [ Hog E,2006]. The patients would fear that they would be discovered to have HIV by acquaintances or others while receiving ART at the hospital or would postpone treatment reasoning they were not sick and turn up for treatment only at the last moment ( severe AIDS ).

Similarly in Haiti, knowledge of HIV and its prevention is limited and PLWHA face stigma [WHO Country Profile: Haiti, 2005]. But following introduction of ART in central Haiti by Partners in Health, attitudes towards PLWHA changed [Mukherjee J



et al, WHO, 2003]. Before the introduction of ART, HIV infection meant a “death sentence”. Improvement of the health status of HIV patients on HAART meant hope and a change in the attitude of people towards PLWHA. Decrease in stigma led to a general improvement of quality of life of those PLWHA and a willingness to get tested and discussion of HIV related issues more openly.

In Uganda to address stigma and discrimination, the National AIDS Control Program (ACP) involved religious leaders and faith based organisation, as these entities were involved with large populations [Luboobi and Mugisha, 2005]. Also Uganda introduced confidential VCT to address stigma and privacy issues. AIDS Information Centers were opened which provided same day results and also post test clubs were set up to provide long term support for behaviour change to the tested, irrespective of their sero-status.

A society of openness and culture of acceptance is necessary for ART to be truly successful. Continued support for and implementation of HIV Information and Education campaigns, and sensitisation of societies to the needs of PLWHA are necessary to enable expansion of ART coverage.

**Influence of these factors on ART programs:**

We have learnt that ARV medication prices are indeed a major factor affecting ART coverage in post conflict nations, but there are other factors, apart from prices, which also have an influence on access to ART programs and its coverage. Therefore, authorities and agencies have to take into consideration all these factors together in their planning and implementation of ART programs.



**3.2] Comparison of important issues relating to Anti Retroviral Treatment across Uganda, Mozambique and Haiti:**

<b>ISSUES/FACTORS</b>	<b><i>Uganda</i></b>	<b><i>Mozambique</i></b>	<b><i>Haiti</i></b>
<b>Political</b>	Strong Political Commitment	Government politically committed to HIV/AIDS programs	National Authorities politically committed but country marked by political instability
<b>Security</b>	Northern parts of Uganda affected by conflict affecting implementation of ART programs	Relative peace and stability since the end of civil war	Frequent flare ups of political and civilian conflicts
	Per capita income in 2002-US \$ 250	Per capita in 2004 US \$ 270	Per capita in 2003 US \$ 400
<b>Per capita expenditure on health ( US\$) in 2002</b>	18	11	29
<b>Number of people needing ART in 2004</b>	114 000	199000	42500
<b>Number of people receiving ART in 2004</b>	40 000-50 000	6500-8000	3919
<b>Important agencies /NGOs involved in provision of ART</b>	WHO, UNAIDS, Global fund ,PEPFAR, JCRC, Mildmay Uganda Center and others	WHO, UNAIDS, PEPFAR, Global fund, World Bank, William.J.Clinton Foundation, San't Egidio community...	WHO, UNAIDS, PEPFAR, Partners in Health-Zanmi Lasante, GHESKIO, MARCH...
<b>ARV medication price</b>	First line regimen in July 2004 cost US \$ 180 per person per year.	US \$ 140 per person per year for first line regimen.	US \$ 720 per person per year for first line regimen.
<b>ART Coverage (%) in 2004</b>	40	4	9

[Sources: Egger et al, 2005, WHO country profiles, Uganda, Mozambique and Haiti, 2005; Luboobi and Mugisha, 2005; Murphy H and Berggren R, 2004; MOH Uganda, 2003; CHG, 2003; US Department of State, 2006; World Bank, 2006]





## **PART 4 Discussion:**

We have noted that are complexities and difficulties associated with Anti Retroviral Treatment , but experts and agencies are stating that ART programs are not impossible to implement in resource poor settings [ Mukherjee J S et al , 2003; UNAIDS, 2001; GTZ, 2002]. In fact, the debate has moved from the introduction of ART programs in such situations to the delivery and effectiveness of ART programs in such settings [Egger M et al, 2005]. Post conflict nations face many problems that resource poor nations face in implementing ART programs such as the high prices of ARV medication. Along with the high prices, post conflict nations face some unique concerns like security among others. As reviewed in 3.1.1, activities are being undertaken in post conflict nations to decrease prices and increase ART coverage. However, it was also noted that factors other prices have an influence on ART coverage in these countries. Therefore it is essential to consider not only possibilities of further reduction of ARV medication prices, but also means of overcoming barriers other than ARV medication costs to allow for further access to existing ART programs.

### **4.1] Discussing political Support, ARV price reduction, Drug Adherence, Security and other issues:**

We have observed in 3.1.1 –A that there has been political commitment from all 3 national authorities in Uganda, Mozambique and Haiti to implement or support ART programs. However in 3.2, we note that in terms of ART coverage Uganda leads the group. Agreeing that the other 2 countries face some unique issues like political instability in Haiti and a huge inadequacy of the health sector in Mozambique [See Annexe I], it must also be considered that Uganda as a resource poor nation more or less shares many problems the others face in implementation of ART programs. What seems to be perhaps tipping the scale in favour of Uganda is the extent of support from national authorities in Uganda to HIV/AIDS programs. This and other factors have seemed to make a clear impact on the ART coverage in Uganda.

We also have other instances where a government's strong commitment and support have made a difference in the fight against HIV. Success stories come from countries like Thailand and Brazil where strong support to ART programs from national



authorities has made a noticeable difference [Ammann A J and Nogueira S, 2002]. The MOH in Thailand has a policy whereby all pregnant women are provided VCT services and those who are detected as HIV positive are offered PMTCT. In Brazil also, the public sector hospitals provide free HAART to HIV positive patients and PMTCT to HIV positive pregnant women. Brazil has challenged the international patent laws and utilised the “public health emergency” amendment in the TRIPS agreement to allow local pharmaceutical companies to manufacture patented ARV drugs. The political support from these countries could be contrasted to the South African government which facing one of the highest rates of HIV infection in the world in 2002 cut down on support to PMTCT programs and later spent money on procuring military equipment.

Even with strong political support, these post conflict nations still would face the problem of high prices of ARV medication, which constitute a major barrier to ART coverage especially in these resource poor settings. Mugenyi of Uganda states that to further lower costs of ARV medications in these countries , methods like *“advocacy and activism for drug cost reduction, International policies to amend TRIPS to make it address the needs of the poor and of national health, encouragement of competition among pharmaceuticals , elimination of taxes on life saving drugs, improvement in logistics for drug purchases , storage and distribution, consideration of bulk purchases to achieve lower individual costs and setting up of national/regional non-profit-distribution centers to minimize overhead costs”* are to be adopted. [Mugenyi P, UNAIDS, 2001].

Competition among pharmaceuticals may allow for decline of prices of ARV medications. We have earlier observed in 3.1.1 –A that this happened in Uganda . There are examples from other countries like Cote d’ Ivoire ( another post conflict nation). In 1996 , the wholesale drug distributor for the public health sector in Cote d’ Ivoire - the Pharmacie de Sante Publique ( PSP) invited pharmaceutical companies in its tender to supply ARV medication [ Moatti JP et al, UNAIDS 2001]. The competition between the branded and generic manufacturers, effective purchase of generics, and the stable economic situation all together resulted in a decline in the average prices of ARV medication. Over the periods of 1997-2000, the average prices of nucleoside inhibitors, Protease Inhibitors, and nucleoside inhibitors declined



by 12%,13%, and 40% respectively. However, it was observed that the price reductions were not sufficient enough to allow for greater access to ART programs, as there was limited reduction of prices of monthly treatments and tritherapies.

Pharmaceutical companies have showed some interest in reducing prices of ARV medications for poor countries. In 2000, a number of leading pharmaceutical companies reached an agreement with UNAIDS to provide poor countries with branded ARV medication at reduced prices [Harvard Consensus Statement, 2001]. This initiative termed “Accelerating Access Initiative” has led to agreement on price reductions in poor countries including Uganda. In return for the discounted ARV medication, countries had to respect patent rights and make sure that these drugs would not reach the black market. Soon after this other many other specialist pharmaceutical companies also offered discounts on ARV drugs not only to governments but also to NGOs involved in ART programs. However, even with reduced prices there has been little improvement in scaling up ART programs in these countries. This was because of the poor countries inability to even buy the heavily discounted drugs or to provide medical services required for delivery of ART programs.

As pharmaceutical companies more or less do not gain any profit from sales of their ARV medication in these poor nations , Berwick in 2002 called for these companies to offer their drugs for free to these nations and make history and acquire immense good will [ Berwick D, 2002]. Though this has not happened, we certainly have observed major reduction of ARV medication prices during the past few years [WHO, 2006] However, what is really important is continued support to ART programs from donors and scaling up of assistance to strengthen health infrastructure in post conflict nations, as these nations not only have to deal with the high ARV medication prices but also have inadequate health infrastructure. It is also imperative for these funding agencies not just to fund ART programs but also to ensure sustainability of these programs [Bass E, 2005].

It would be further necessary for both national governments and donors to post conflict nations to consider the role of private medical sector of these countries in provision of ART, as it has been noted that in poor countries the main care providers



of HIV disease are in the private medical sector. [Brugha R, 2003]. HIV patients seek medical care from these private providers because of fears of being recognised with HIV while seeking care in the public sector. In many poor countries, the private sector is unregulated and drugs are dispensed illegally. This improper use of ARV medication can lead to drug resistance. In Uganda it has been noted that there is now emergence of drug resistance to some first line regimens because of use of non monitored ARV drug regimens from the private sector [Nakiyemba et al, 2004]. Also, it was found in a survey of 21 Ugandan private medical facilities there was no proper monitoring of drug adherence because of delayed or non availability of CD4 and viral load results; and many facilities had run out of drug stocks [Brugha R, 2003]. Some patients even sought ARV medication from relatives from abroad for treatment. These examples not only illustrate the importance of recognising the role of these private providers in provision of ART by donor agencies and governments and also the need to plan strategies for working with these private providers in provision of ART.

Authorities of post conflict nations face problems like HIV and inadequate resources; and hence have to be decisive in their approach and think of new strategies to gain financial support for their ART programs, like developing a public private partnership program. An example of a public private partnership in Sub – Saharan Africa is the African Comprehensive HIV/AIDS Partnership (ACHAP), a joint initiative of the government of Botswana, the Bill and Melinda Gates Foundation and the Merck Pharmaceutical Company [ Clark PA and O’ Brein K , 2003]. ACHAP was launched in 2000 in Botswana as a pilot project for 5 years. During that period, the Gate Foundation and Merck Company would not only donate \$50 million but also Merck would donate ARV medication for appropriate treatment programs developed by the national authorities. Because this program not only provided support to ART, but also addressed other social and medical issues of HIV/AIDS through its other strategies, it has been considered a successful model of combating HIV in resource poor settings through a public- private partnership. However it is important to consider that ACHAP in selecting a pilot country for implementation of its plan chose Botswana not only for its high rates of HIV but also for its stable climate. This leads us to our next issue-Security.



We observed in 3.1.2, that insecure conditions do affect the functioning of ART programs. But we also noted how the PMTCT program conducted by MARCH in Haiti was able to resume its activities by adopting mobile clinics and further we noted that the stocks of ART remained safe even during the peak period of conflict [Murphy H and Berggren R, 2004]. In Uganda, HIV programs and ART coverage in Northern Uganda have been affected by the conflict in this region [Luboobi and Mugisha, 2005].

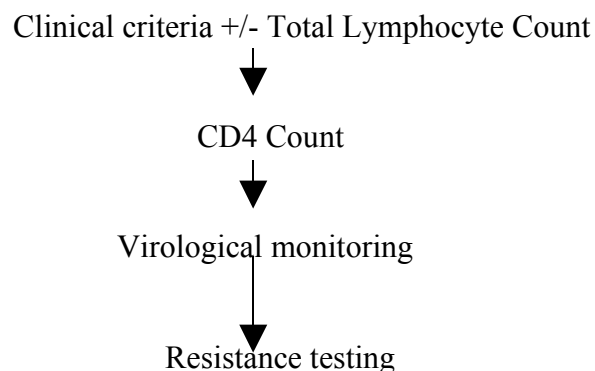
To gain a complete idea on the impact of security on ART programs, we also need to look at other examples of chronic disease treatment in conflict situations. A DOT – based TB treatment programs was initiated in 1998 in Churachandpur district, Manipur State in India [Rodger AJ et al, 2002]. This area had been affected by conflict following a clash between 2 ethnic groups in 1997, and health services in this region had also been affected by the conflict. In 1998, a ceasefire was brought about by a church. The region is also noted for high prevalence of HIV mainly due to Intravenous transmission while using drugs. Against this background, the program utilising WHO guidelines initiated TB treatment. Of the 178 patients diagnosed with TB and given DOTS, a successful outcome of 91% cure was recorded. The proponents of this program state that by utilising outreach workers of both ethnic groups, limiting distance travelled by patients for treatment, reducing direct observation of treatment to thrice a week instead of daily and strong community support; treatment and control of chronic diseases was possible in a conflict setting. In Bukavu in Democratic Republic of Congo, a region ravaged by conflict, MSF is providing ART since 2003 [Ellman et al, 2005]. MSF in its implementation of the ART program drew lessons from previous TB treatment program in conflict settings. Attention was paid to involvement of patients in assessments relating to care and treatment. In the course of the ART program, there was an outbreak of conflict in 2004. Many people in the region were displaced and health staff was temporarily evacuated. However some dedicated local staff that had remained continued a minimum program and announced on radio that ART was still available to its patients. Adherence to HAART was maintained by the patients during the period of conflict and following return of stability, the treatment continued without disruption. Analysing these examples, it would indicate that even though security is indeed important for an ART programs, it would not be totally impossible for ART programs



to function in conflict affected settings by adapting the program to the circumstances and using innovative methods.

Adherence issues relating to HAART in these post conflict nations had been mentioned earlier in 3.1.2. We have observed through the DOTS-HAART model in Haiti [Mukherjee J et al, 2003] and by study results indicating high adherence among HAART users in Africa [Mugenyi P, 2004] that adherence to HAART is possible in resource poor settings /post conflict nations. But it is also vital to enforce successful models (as that of in Haiti and JCRC and TASO in Uganda) more widely and vigorously; and monitor drug supplies to ensure that drugs do not reach the black market. Complacency on part of health authorities would lead to widespread drug resistance to available first line regimens, and considering the high costs of salvage regimens or second line treatments, ART programs and ART coverage in such situations could falter.

Another obstacle to ART programs in post conflict nations is the inadequacy of the health infrastructure and shortage of health workers. But this should not discourage authorities from planning or initiating ART programs. Community based infrastructure which have been utilised by DOTS programs for TB previously in resource poor settings, could similarly be used for ART programs [ Mukherjee JS et al, 2003] A step wise strategy of incorporating all components of ART program like VCT, PMTCT , and preventive strategies into a bigger comprehensive care program should be employed [Mugenyi P, 2004]. Problems with limited laboratory infrastructure should be addressed by scaling up services in a step wise manner, as seen below [adapted from Mukherjee JS et al, 2003].





Staff shortages could be partly compensated by training and involving PLWHA and community based organisations to support and help the existing ART programs. Also funding from international donors should be utilised for providing decent salaries to recruit and retain skilled health personnel [Mugenyi P, 2004; Mukherjee JS et al, 2003].

#### 4.2. “Everyone has AIDS” –A sense of identification.

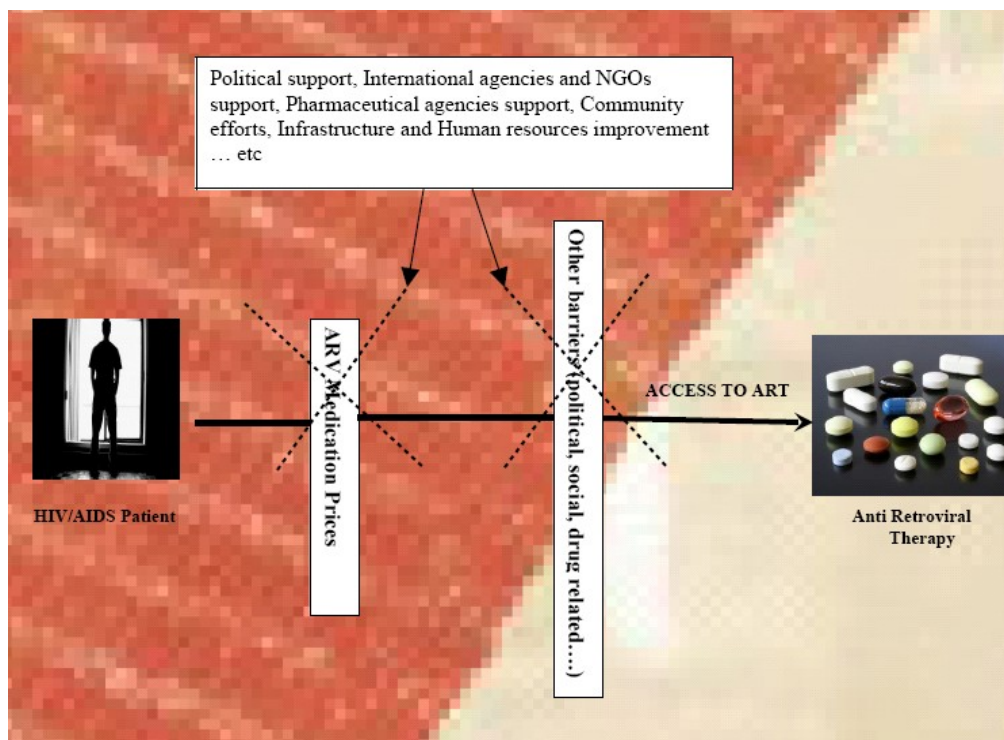


Fig VI. Breaking down barriers to access Anti Retroviral Treatment. [Prepared by author]

Thus by far we have learnt issues like ARV medication prices and other factors have created barriers to access to ART in post conflict nations. We have noted the various activities taken by national authorities, agencies, donors and NGOs in their attempts to break these barriers. We also have noted that there is still much to be done to completely overcome these barriers. HIV/AIDS is a clear and present problem which these nations or international agencies cannot wish away. Neither can the large number of HIV patients not receiving ART because of these barriers be ignored.

It has already been seen through programs like the HIV Equity Initiative in Haiti or the provision of ART through JCRC in Uganda, that ART programs are possible in these settings. At the same moment ART programs in post conflict nations face



difficulties like ARV medication prices and further requirement of funds. Many HIV patients in these nations die because of lack of ART, while HIV patients in developed nations have been able to lead long lives with provision of ART. What is required is motivation on the part of donors, pharmaceutical companies and international agencies to support and scale up ART programs in poor nations and for this there has to be a sense of identification with those suffering from HIV and lack of ART. Berwick relates in his article that when Jewish people in Denmark during world war II were ordered by the Nazi occupation forces to wear a yellow star in order to identify themselves, the then king Christian X threatened that if the Jews had to wear them, he would also wear it., thus not only identifying himself with the Jews but also rallying his nation to identify with the Jewish people and saving them from the Nazis [Berwick D, 2002]. Similarly it is now necessary for international agencies, national authorities, and pharmaceutical companies to identify with PLWHA in poor nations and say “Everyone has AIDS”. Perhaps then HIV/AIDS would become everybody’s problem and provision of ART to these people would become an immediate priority.

## **PART 5**

### **Conclusion:**

Post conflict nations are in a vulnerable position in relation to HIV because of the socio-economic consequences of conflict. It has also been seen that post conflict situations, depending on the context and the country, have had influence on HIV prevalence. Governments of such nations are poorly placed to provide ART to their HIV affected population due to many factors. One of the main factors is the high prices of ARV medication.

#### **Financial price, the only factor influencing ART coverage?**

We have observed in recent years the decline of ARV medication prices because of advocacy of International agencies and International Health experts, Competition among generics and specialist pharmaceutical companies, and because of voluntary initiatives by the pharmaceutical companies themselves. Authorities of post conflict nations, such as Uganda, Haiti and Mozambique, have utilised these developments to increase ART coverage in their countries. Yet, we have observed in our findings that





there is still a huge shortfall in reaching adequate ART coverage in post conflict /resource poor nations indicating that factors apart from financial prices of ARV drugs may be influencing ART coverage.

### **Political and Community Support:**

In post conflict nations like Uganda, Mozambique and Haiti, National authorities and NGO's have tried to undertake activities to ensure affordable ARV medication for HIV patients. We have also observed that inspite of these activities, a large number of HIV patients are still not obtaining ART. However in the case of Uganda, ART coverage seems to be increasing at a better rate compared to the other 2 nations? This has been mainly because of the strong support and dedication to HIV programs from the political leadership. Also in Haiti, we have observed pioneer and successful models of providing HAART in resource poor settings. These ART programs in Haiti were community based and utilised the support of community to ensure drug adherence. Post conflict nations in implementing ART programs face problems from factors other than high ARV medication prices and these include inadequate health infrastructure, shortage of health workers, and security issues. Laboratory inadequacies in these settings could be addressed through utilisation of WHO clinical criteria to initiate HAART until and when more sophisticated lab services are available. Health personnel shortage could also be addressed through training and utilisation of the services of community based organisations. In some cases, security has made an impact on the functioning of ART programs, but innovation and dedication to provide ART would ensure that these programs are not completely disbanded in such settings

### **Need for further studies:**

To examine the role of ARV medication prices on ART program in complex emergency or post conflict situations through a literature review we need findings on this topic and these are hard to come by because of limited peer reviewed studies on this topic and one has also to rely much on grey literature, from official agencies or national authorities or NGOs, for information on these programs. Therefore, one cannot be emphatic in his opinion on the extent of influence of drug prices, alone, on ART coverage in post conflict situations. However, based on the findings from this study it is observed that there are other factors, apart from drug prices, that have a role



on ART coverage in Uganda, Haiti and Mozambique. That means we cannot compartmentalise drug prices and other factors by themselves separately while examining ART coverage in post conflict nations. There is interplay between all these factors and therefore future studies should consider this fact while analysing ART programs in such nations. In this regard, there is definitely a need for further field studies to examine the influence of drug prices and other factors on ART coverage in individual post conflict countries. Studies in these individual post conflict countries would yield further information on the role of these factors and hence provide more clear opinions. These studies will not only be helpful in providing these answers but also may provide lessons for future implementation or scaling up of ART programs in post conflict nations.

**THE END**

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## Annexe:

### I] Conflict histories of Uganda, Mozambique and Haiti in a nut shell

[Adapted from US Department of State Background notes, 2006]:

#### Uganda:

The December 1980 elections after a long period of political turmoil returned Milton Obote to power. Obote's government tried to stamp out the insurgency led by Yoweri Museveni's National Resistance Army (NRA) which had arisen because of the regime's human rights abuse. In 1985, a military government was proclaimed and Obote went into exile. The new government was still in conflict with NRA and in 1985, the NRA seized power of the country. A new government was established with Museveni as president. The new government has largely performed well, even though allegations of political dictatorship have been heard.

In the northern part of Uganda, a vicious rebel group called Lord's Resistance Army continues to cause violence and kidnappings. Though it has not affected the political stability of the country, it has continued to create a humanitarian crisis with 1.4 million people being displaced.

#### Mozambique:

After independence in 1975, two parties vied for power- the FRELIMO party, which had established forcefully a one party state, and the rebel group RENAMO. Civil war raged as a consequence of this struggle for power. An estimated 1 million Mozambicans died and more than 2 million were forcefully displaced because of this civil war. Later in 1992, after peace negotiations the civil war ended with the Rome General Peace Accords. By mid 1995 more than 1.7 million Mozambican refugees returned home from neighbouring countries.

#### Haiti:

The democratically elected government of Jean Bertrand Aristide was overthrown in 1991 by a violent coup led by dis-satisfied elements of the army. Aristide went into exile and large number of Haitians fled Haiti by boat. It is said that thousands may have been killed by the military regime. Following failure of a long period of negotiations by the UN to have democracy restored in Haiti, the UN called in July 1994 for its member states to depose the defacto military regime. The US took the lead in forming a Multi National Force (MNF) to accomplish this task. By October 1994, the military regime was completely deposed and Aristide returned to Haiti. Later in the 1995 elections, Aristide was elected as president. Though, following this the country has been racked by political instability with both Aristide and Rene Preval, a former Aristide political ally, along with parties and supporters contending for power. This contention for power has been marked by violence and disruptions of daily lives in many parts of the country. In Feb 2006, Rene Preval was elected as president while Aristide is in exile in South Africa. UN peace keepers continue to remain in the country.





## **II] Summary of CDC 1992 classification for HIV disease:**

[Source: Mindel A and Tanant Flowers M,]

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**Group I** –Primary HIV

**Group II**- Asymptomatic Infection

**Group III**- Persistent generalised Lymphadenopathy

**Group IV**-Symptomatic Infection

**Group IVA**- HIV wasting syndrome [AIDS] and constitutional disease

**Group IVB**- HIV encephalopathy [AIDS] and neurological disease

**Group IVC1**- Major Opportunistic infection specified as AIDS defining

**Group IVC2**-Minor opportunistic infections

**Group IVD**- Cancers specified as AIDS defining

**Group IVE**-Other conditions

## **III] Indicator diseases of AIDS without laboratory evidence of HIV**

[Source: Adler 2001].

### **AIDS indicator diseases**

*x Diseases diagnosed definitely*

*x Candidiasis: oesophagus, trachea, bronchi, or lungs*

*x Cryptococcosis: extra pulmonary*

*x Cryptosporidiosis with diarrhoea persisting > 1 month*

*x Cytomegalovirus disease other than in liver, spleen, nodes*

*x Herpes simplex virus (HSV) infection*

*Mucocutaneous ulceration lasting > 1 month*

*Pulmonary, oesophageal involvement*

*x Kaposi's sarcoma in patient < 60 years of age*

*x Primary cerebral lymphoma in patient < 60 years of age*

*x Lymphoid interstitial pneumonia in child < 13 years of age*

*x Mycobacterium avium: disseminated*

*x Mycobacterium kansasii: disseminated*

*x Pneumocystis carinii pneumonia*

*x Progressive multifocal leucoencephalopathy*

*x Cerebral toxoplasmosis*



**IV] Anti Retro Viral drugs approved by FDA for use in HIV Infections [Source: Chang, 2004]**

Nucleoside reverse transcriptase inhibitors	Nucleotide reverse transcriptase inhibitors	Non-nucleoside reverse transcriptase inhibitors	Protease inhibitors	Fusion inhibitors
<i>Zidovudine (Retrovir)</i>	<i>Tenofovir (Viread)</i>	<i>Nevirapine (Viramune)</i>	<i>Saquinavir: hard gel (Invirase)</i>	<i>Enfuvirtide (Fuzeon)</i>
<i>Didanosine (Videx)</i>		<i>Delaviridine (Rescriptor)</i>	<i>Saquinavir: soft gel (Fortovase)</i>	
<i>Zalcitabine (Hivid)</i>		<i>Efavirenz (Sustiva)</i>	<i>Ritonavir (Norvir)</i>	
<i>Stavudine (Zerit)</i>			<i>Indinavir (Crixivan)</i>	
<i>Lamivudine (Epivir)</i>			<i>Nelfinavir (Viracept)</i>	
<i>Abacavir (Ziagen)</i>			<i>Amprenavir (Agenerase)</i>	
<i>Emtricitabine (Emtriva)</i>			<i>Fosamprenavir (Lexiva)</i>	
<i>Lamivudine + zidovudine (Combivir)</i>			<i>Atazanavir (Reyataz)</i>	
<i>Lamivudine + zidovudine + abacavir (Trizivir)</i>			<i>Lopinavir + ritonavir (Kaletra)</i>	

**IV] HAART Regimens [Source: Weller IVD and Williams G, 2001]**

I] 2 nucleoside reverse transcriptase inhibitors e.g.: Zidovudine or Stavudine + Lamivudine or Didanosine **PLUS EITHER**

1 non –nucleoside reverse transcriptase inhibitor –Nevirapine or Efavirenz

**OR**

1 protease inhibitor: Indinavir or Nelfinavir or Saquinavir soft gel

**OR**

2 protease inhibitors e.g.: Ritonavir + Saquinavir

II - 3 nucleoside reverse transcriptase inhibitors – Zidovudine + Lamivudine + Abacavir

**\*Choice will depend on efficacy, tolerability, adherence and resistance profile of regimen.**



VI] Toxicities associated with ART regimens [Source: Weller IVD 2001]:

Drug toxicities	
Drug	Toxicity
<i>Nucleoside reverse transcriptase inhibitors</i>	
Class associated	Lactic acidosis
	Hepatic steatosis
	Lipodystrophy (peripheral fat wasting)
Drug specific:	
Zidovudine	Bone marrow suppression, nausea, vomiting, myopathy
Stavudine	Peripheral neuropathy, hepatitis
Zalcitabine	Peripheral neuropathy, mouth ulcers
Didanosine	Pancreatitis, dry mouth, peripheral neuropathy
Lamivudine	Few side effects
Abacavir	Hypersensitivity reaction, nausea
<i>Non-nucleoside reverse transcriptase inhibitors</i>	
Nevirapine	Rash, hepatitis, Steven-Johnson syndrome
Efavirenz	Rash, dysphoria, mood changes, vivid dreams, hypercholesterolaemia
<i>Protease inhibitors</i>	
Class specific	Lipodystrophy (fat wasting or accumulation)
	Hyperlipidaemia, diabetes mellitus
Drug specific:	
Nelfinavir	Diarrhoea, rash
Saquinavir	Few side effects
Indinavir	Hyperbilirubinaemia, nephrolithiasis, nail changes, dry skin
Ritonavir	Perioral dysaesthesia, flushing, hepatitis, diarrhoea, nausea, vomiting
Amprenavir	Rash, nausea, diarrhoea
Lopinavir	Diarrhoea



**VII] Initiation of ART (Adapted from World Health Organization, Scaling up Antiretroviral Therapy in Resource-limited Setting, 2002):**

<p><b>. Recommendations for initiating antiretroviral therapy in adults and adolescents with documented HIV infection</b></p>	<p><b>Recommendations for initiating antiretroviral therapy in infants and children</b> <b>Infants under the Age of 18 months</b></p>
<ul style="list-style-type: none"> <li>• <b>Clinical presentation as per findings of the physical examinations</b> <ul style="list-style-type: none"> <li>○ WHO Stage IV of HIV disease (clinical AIDS), irrespective of CD4 cell count.</li> <li>○ Advanced WHO Stage III disease including recurrent or persistent oral thrush and recurrent invasive bacterial infections irrespective of CD4 cell or total lymphocyte count.</li> </ul> </li> <li>• <b>Absolute CD4 count, absolute CD8 count and CD4/CD8 ratio</b> <ul style="list-style-type: none"> <li>○ WHO Stage I, II or III of HIV disease, with CD4 cell counts equal or less than 200/mm<sup>3</sup>.</li> </ul> </li> <li>• <b>Total lymphocytes count (TLC)</b> <ul style="list-style-type: none"> <li>○ In case CD4 counts cannot be assessed, WHO Stage II or III of HIV disease with TLC below 1200/mm<sup>3</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• In settings where virologic confirmation (using either HIV PCR or immune complex dissociated HIVp24 antigen detection or HIV culture) of HIV infection for children under the age of 18 months is not available           <ul style="list-style-type: none"> <li>○ Infant HIV seropositive or born to known HIV-infected mother: WHO stage III of HIV disease and CD4 percentage less than 20%               <ul style="list-style-type: none"> <li>• In cases when infant under the age of 18 months has virologically proven infection using either HIV PCR or immune complex dissociated HIVp24 antigen detection or HIV culture</li> </ul> </li> <li>○ WHO Pediatric stage III HIV disease (clinical AIDS)</li> <li>○ WHO Pediatric Stages I and II disease and a CD4 percentage less than 20%</li> </ul> </li> <li><b>Children over the age of 18 months who are HIV antibody positive</b> <ul style="list-style-type: none"> <li>• Clinical presentation as per findings of the physical examinations. WHO stage III of HIV disease (clinical AIDS), regardless of CD4 percentage               <ul style="list-style-type: none"> <li>• CD4 percentage WHO stage I or II of HIV disease, if CD4 is less than 15%</li> </ul> </li> </ul> </li> </ul>
<p><b>Additional Considerations for ART initiation</b></p> <ul style="list-style-type: none"> <li>• Those found with active TB are treated for it before they may begin ART, because of possible conflicts between the TB drugs and the ARVs, unless there is a high risk of HIV disease progression and death during the period of TB treatment.</li> </ul>	



**VIII] A case of a HIV patient who had been provided ART in Haiti:**  
[Adapted from Mukherjee J et al, 2003.]



Fig. 1. Adeline before ARV therapy



Fig. 2. Adeline after ARV therapy was initiated

Adeline had contracted HIV when she was 18 years old and presented to the clinic years later with pneumonia. She was also found to have Herpes Zoster along with HIV. She was first put on opportunistic infection treatment for 10 years and when she was no longer responsive to the treatment and had lost a lot of weight to diarrhoea, HAART was started. Within weeks she has gained vigour and weight.

**IX] Announcement of a new 3 in 1 pill for use in PEPFAR sponsored ART programs** [Adapted from New York Times July 6, 2006]:

The Food and Drug Administration (FDA) has approved a 3 -in- 1 ARV pill (AZT + 3TC and NVP) manufactured by an Indian firm-Aurobindo Pharma for use as ART in programs sponsored by PEPFAR. The new pill also does not contain D4T, another common first line drug, but more toxic than others. Currently under PEPFAR, United States is the largest provider of ARV medication in the world and sponsors ART for 561,000 HIV patients in Asia, Africa, and the Caribbean.

The first 3-in-1 pill Triomune which won WHO approval in 2002 is manufactured by another Indian generic manufacturer –Cipla. This is being used by organisations like UNICEF, MSF and other donors to provide ART to 400,000 HIV patients.

AZT: Zidovudine  
3TC: Lamivudine  
NVP: Nevirapine  
D4T: Stavudine.