A REVIEW OF THE IMPACT OF AVAILABILITY OF ANTIRETROVIRAL [ARV] DRUGS ON THE QUALITY OF CARE RECEIVED BY PEOPLE LIVING WITH HIV/AIDS

By ALEXANDER ANABA

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A REVIEW OF THE IMPACT OF AVAILABILITY OF ANTIRETROVIRAL [ARV] DRUGS ON THE QUALITY OF CARE RECEIVED BY PEOPLE LIVING WITH HIV/AIDS [PLHA] IN DEVELOPING COUNTRIES.

BY

ALEXANDER ANABA

A THESIS SUBMITTED TO DEPARTMENT OF GENERAL PRACTICE AND PRIMARY HEALTH CARE, FACULTY OF MEDICINE, UNIVERSITY OF HELSINKI: IN PARTIAL FULFILMENT FOR THE AWARD OF A MASTER OF HEALTH CARE QUALITY IMPROVEMENT AND LEADERSHIP DEVELOPMENT [MQI].

NOVEMBER 2008
ABSTRACT

Objective: To investigate the availability of ARV drugs for PLHA in developing countries, factors that affect it and how this affects the quality of health care this group of people receive.

Data Sources: This review consists of literature from Medline, Pubmed and Google scholar. The following key words were used: Health service Accessibility, Anti-HIV Agents, HIV infection, Anti-retroviral Agents, Quality of Health care, Health policy, and Developing countries.

Study Selection: The articles were selected based on their validity and relevance. This meant that only articles which presented data based on research [empirical] was included. Articles were also chosen to cover a good spread of the entire developing countries. Abstracts, personal opinions, propaganda papers, and News/editorials were excluded.

Results: The articles reviewed were in concordance with the objectives of the review, and showed conclusive data to make deductions with respect to the general objective of the review.

Conclusion: The data in the review showed some evidence that availability of antiretroviral drugs had significant impact on the quality of life of people living with HIV/AIDS
Acknowledgements

My gratitude goes to my family for all their love, support: both financial and psychological, that has seen me through this program. I commend all their effort at enduring my absence.

I wish to also extend my gratitude to my Professors: Pertti Kekki and Marjia Shirvonen, for their pain staking effort at ensuring that I get this knowledge.

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But above all my most profound gratitude goes to GOD ALMIGHTY for this achievement.
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DEFINITION OF ABBREVIATIONS

PLHA---People living with HIV/AIDS
NGO---- Non governmental organisations
ARV---- Antiretroviral
ART---- Antiretroviral therapy
HIV----- Human Immunodeficiency Virus
AIDS--- Acquired Immunodeficiency Virus
UNAIDS—United Nations AIDS
WHO---- World Health Organisation
CRN---- Cost related medication non-adherence
HAART---- Highly active antiretroviral therapy
EAP--- Expanded Antiretroviral Program
CHAPTER I

BACKGROUND

HIV infection in humans is now pandemic, a joint United Nations programme on HIV/AIDS [UNAIDS] and the World Health Organization [WHO] estimates that AIDS has killed more than 25 million people since it was first recognised on December 1, 1981, making it one of the most destructive pandemics in recorded history [2]. According to current estimates, HIV is set to infect 90 million people in Africa [3].

Today, the average life expectancy in sub-Saharan Africa is 47 years; without AIDS, it would be 62. If widespread treatment of opportunistic infections (particularly tuberculosis), and antiretroviral drugs are not made available. Zimbabwe will lose 19% of its adult population, Botswana will lose 17%, South Africa 11%, Tanzania 9%, and the Ivory Coast 8%.

Prevention of HIV infection is often promoted as the only feasible option in resource poor settings despite the existence of drugs to treat it. As recently as 2002, experts argued that prevention should take priority over treatment for AIDS in Africa based on cost effectiveness. However, cost effectiveness analyses fail to take into account the most important reason for implementing widespread HIV treatment—treating sick people. Prevention strategies do nothing to improve the quality or length of life of the millions of people living with HIV. Moreover, the unchecked spread of HIV is resulting in indirect costs, ranging from orphanning to famine and from stigma to professional burnout, that are damaging already heavily burdened societies. [22]
The development of new generations of antiretroviral drugs, including protease inhibitors and non-nucleoside reverse transcriptase inhibitors: combination drug therapies: and improved techniques for monitoring disease progression and therapeutic effectiveness have radically altered how the HIV disease is perceived. Despite their promise to prolong survival and improve the quality of life of persons with HIV, the new therapeutic regimens are also much costly than their predecessors. Moreover, as people live longer, they consume greater health care resources, driving the over all health care cost associated with HIV infection even higher. Resources to fund HIV prevention programmes are limited and must be used wisely to maximise their prevention potential.

Antiretroviral treatment reduces both the mortality and the morbidity of HIV infection, but routine access to antiretroviral medication is not available in all countries, and to all the PLHA in these countries. This is mostly true of the hardest hit African continent.

The quality of care of PLHA in these countries and hence their level of mortality and morbidity depends to a large extent on the availability and subsequent accessibility to this ARV drugs by this group of PLHA.

The AIDS medicines and diagnostic service [AMDS] is a team in the WHO HIV/AIDS department responsible for the supply, management, of HIV commodities, and brokers cooperation between technical partners, funding agencies, manufacturing companies, and other organisations [4]. This is the body charged with the responsibility of the logistics of ensuring the coordination and availability of ARV drugs. The report of this body on Nigeria, one of the leading nations of Africa on the situation of ARV therapy, usage, and the care received by PLHA, indicated that
availability of these drugs were grossly inadequate and this was due to several factors, which includes drug management problems and logistics [5].

The principles and success of treatment in the Third World may differ considerably in developing and developed countries. In the Third World, medical manpower is scarce, and HIV is managed essentially by very few resources, without specialised investigations. The principles of drug therapy may not be understood by patients, and the supply of drugs is often erratic; and these are major reasons for poor compliance with treatment. World Health Organisation (WHO) initiatives have stressed the extensive use of an essential drugs list, but this emphasis may be misdirected, and in practice neither proposal has achieved much success.

Qualitative data showed that some socio-economic factors, logistic and drug-related problems and people's poor knowledge and perceived benefits of treatment played a role in a proportion of the population not receiving or taking the ARV drug.

Developing countries are plagued with many problems, of which poverty and poor economic status of the countries are the most important. This translates to the earning power of the people or the ability of the governments to provide this ARV drugs freely to PLHA.

Hence considering the economic powers of these countries, the will or willingness of the governments to provide ARV drugs, and the state of poverty of its people, and the extent to which these factors affect availability and utilisation of these ARV drugs it is therefore imperative that the degree of availability of ARV drugs for PLHA is understood.

This will to a large extent give a clear picture of the progress made in the control of the pandemic of HIV/AIDS and the quality of care received by PLHA.
DEFINITION OF KEY WORDS

- Anti retroviral drugs
- Quality of care
- HIV/Aids
- People living with HIV/Aids [PLHA]
- Availability

ANTIRETROVIRAL DRUGS

These are medications for the treatment of infections by retroviruses which are primarily HIV that result to AIDS. They are broadly classified by the phase of the retrovirus life circle that the drug inhibits as follows;

- Nucleoside and Nucleoside reverse transcriptase inhibitors [NRTI]
- Non-nucleoside reverse transcriptase inhibitors [nNRTI]
- Protease inhibitors
- Integrase inhibitors
- Entry inhibitors
- Maturation inhibitors[under investigation]

HIV/AIDS
HIV stands for human immunodeficiency virus. This is the virus that causes AIDS. HIV is different from most other viruses because it attacks the immune system of humans. HIV finds and destroys the white blood cells [T cells or CD4 cells] that the immune system must have to fight diseases.

AIDS stands for acquired immunodeficiency syndrome; this is the final stage of HIV infection. Reaching this stage can take years even without treatment. Having AIDS means the viruses weakens the immune system to the point at which the body has difficulty fighting infections.

PEOPLE LIVING WITH HIV/AIDS [PLHA]

This is the group of people that have been infected with HIV, are at various stages of the disease, and are living with it. This includes those with full blown AIDS.

AVAILABILITY

This literally implies the presence of goods or services in measurable quantity, in this case antiretroviral drugs. This means the existence of this antiretroviral drugs. However there are many perspectives to the definition of the word availability. The English dictionary defines availability as;

- Present and ready for use, at hand, accessible
- Capable of being gotten, obtainable
- Qualified and willing to be of service or assistance
- The quality of being at hand when needed.
QUALITY OF CARE

Works in the area of improving quality of care started as far back as in the days of the Crimean war [1853-1856] by Florence Nightingale, to decrease the spread of infection in military hospitals. There is no consensus on the definition of quality, a lot of theories have been proposed for quality, like the one proposed by Donabedian’ that argued that “quality is a property of and a judgement upon some definable unit of care”, and that care is divisible into at least two parts; technical and interpersonal. Quality of medical care in summary can be said to be the management that is expected to achieve the best balance of the risk ; benefit ratio of health. This can be affected by the following factors;

- Access to care
- Use of service
- Quality of service
- System for delivery care
- Monetary cost
- Individual expectations

RESEARCH PROBLEM AND OBJECTIVE OF STUDIES

The UN aids 2006 report on aids gives an estimated 38.6 million [33.4-46.0 million] people world wide were living with HIV in 2005. An estimated 4.1 million [3.4-6.2 million] become newly infected with HIV. [1]

The greater percentage of this figures occur in developing countries. As this figure continues to increase with an increase in population the economy of this countries
continues to decline, hence bringing down with it the standard of living of the people in this regions. These declines in living standards also affect the quality of health care received by PLHA.

Medicines play a very important role in the improvement of the quality of health care in any society, hence the importance of ARV drugs in the treatment of PLHA. A lot of publicity has been made about aids in the form of drugs [ARV] being sent to developing countries by NGO’s, the G-8, and other developed countries.

There is therefore the need to really review the availability of these drugs for PLHA in the context of the following;

- Source of the drug supply
- Availability location
- Diagnosis and prescription
- Sufficiency and adequacy of the drugs
- Monetary costs
- Government policies

These will be able to give us an understanding of the extent to which the ARV drugs are available to the end users, the PLHA in developing countries. This to a large extent determines the progress made by these organisations in these countries in terms of trying to achieve the goal of controlling the disease and improving the quality of care received by PLHA and ultimately improving their quality of life.

OBJECTIVES

GENERAL OBJECTIVE
The general objective of this work is to investigate the availability of ARV drugs for PLHA in developing countries, factors that affect it and how this affects the quality of health care this group of people receive.

**SPECIFIC OBJECTIVES**

1. To find out if the source, distribution, logistics, supply chain, accessibility, equity, funds, economy, and socio-cultural issues in any way affect the availability of ARV drugs in developing countries.

2. To investigate if there is enough ARV drugs available in developing countries to take care of the needs of PLHA.

3. To look at the possible reasons for the non availability of the ARV drugs were they exist.

4. To ascertain if this availability affects the quality of health care received by PLHA in this regions of the world.

5. To further ascertain in what ways it affects the quality of care and to what extent.

**CHAPTER II**

**DATA AND METHODS**
2.1-SEARCH STRATEGY

This review consists of literature from Medline and Pubmed. Due to the difficulty in finding relevant empirical articles from this source, the number of articles used in this review was somewhat limited in number and some materials were taken from Google scholar.

The under listed search words were used in searching for the articles:

- Health service Accessibility
- Anti-HIV Agents
- HIV infection
- Anti-retroviral Agents
- Quality of Health care
- Health policy
- Developing countries
- Primary Health care

Using search words from the first three as search I, and those from the fourth to the last as search II, two searches were done with both limited to full text materials and English language. Then the two searches were combined using the word “AND” this produced over 4354 articles out of which 20 were found to be relevant and selected.

The articles from WHO sites and its allied organisation [UNAIDS] were sourced from Google scholar.

The articles were selected based on their validity and relevance. This meant that only articles which presented data based on research [empirical] was included. Articles were also chosen to cover a good spread of the entire developing countries. Abstracts, personal opinions, propaganda papers, and News/editorials were excluded.
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- accessibility
- agents
- anti-hiv
- anti-retroviral
2.2-DESCRIPTION OF THE DATA FOUND

Hogan et al [2005] {6} analysed data from biological and behavioural parameters, from clinical and observational studies, population based survey, and the WHO-CHOICE data base. This analysis was undertaken for two regions classified using the WHO epidemiological grouping- AFR-E, countries in the sub-Saharan Africa with very high adult and child mortality, and SEAR-D, countries in south east Asia with high adult and child mortality. They used base line prevalence projections from the joint United Nations program on HIV/AIDS and the WHO to calibrate key parametric values for AFR-E and SEAR-D.

The objective was to assess the costs and health effects of a range of interventions for preventing the spread of HIV, of which drug therapy was one. This was done in the context of the millennium development goals for combating HIV/AIDS.

They found out that antiretroviral therapy is as cost effective in reducing HIV transmission and improving population health as most of the other preventive interventions.
Cowburn et al [2007]{7}, looked at results from a prospective observational study conducted in a paediatric teaching hospital in cape town in south Africa. Data from sixty eight of the ninety six HIV infected children, of median age 3 months, over a 16 month period commencing February 2003.

They aimed to describe the short-term outcome of critically ill HIV- infected children with access to highly active antiretroviral therapy in a developing country.

They studied the data collected from routine hospital and laboratory records, and included duration of hospital admission, clinical diagnosis during admission, centre for disease control and prevention clinical [A,B,C] and immunological categories [I,II,III], base line cd4 lymphocyte count, predicted mortality by paediatric index of mortality and hospital outcome.

They concluded that although few critically ill HIV-infected children survived to become established on the HAART, the long-term outcome of children on HAART is encouraging and warrants further investigation.

Galarrag et al [2007] {8}, tried to estimate the number of individuals receiving antiretroviral drugs to 2008. They calculated the volume of active pharmaceutical ingredients needed to meet these needs. Using treatment data gathered from 30 low and middle income countries used as the bases for estimating antiretroviral global demand. The future load was forecasted using a linear regression prediction, based on the last three observations available
This project was compared with the total need estimates in the UNAIDS project to the end of 2008.

They aimed to use a normative approach modelling implementation of country specific guidelines and a empirical model to project current trends in drug use as estimated by a survey of country HIV programmes. They used data from patients estimated to reach 3.38 million by the end of 2008. The estimates were based on first line and second line treatment drugs.

They concluded from a comparism of the results from the normative and empirical demand quantities that some countries were using less of some of the drugs than required by the treatment guidelines and more of some others, hence recommending adjustments in the usage of these drugs.

Renaud-thery et al [2007] {9}, carried out a multi-country survey under the umbrella of AIDS medicines and diagnostics service of the WHO in 2006. This was to address the information gap on current use of antiretroviral drugs in developing countries.

Questionnaires covering both first and second line regimens were issued out to countries, with 23 countries [96%] returning the questionnaires. They calculated weighted percentages of use of ART across the cohort adults and children and the results correlated with 2006 WHO guidelines.
They found out that only 25% of those receiving second line treatments were on regimens consistent with those preferred by WHO.

In conclusion they found out that the survey has provided valuable information on the uptake of ARTs in developing countries and will help forecast future demand.

Beck et al [2006] {10} investigated the existence of national adult ART guideline in 43 WHO focus countries, and compare their content with 2003 WHO ART guidelines.

This investigation was carried out in 2006 using questionnaires out of which 39 countries returned their questionnaires. These countries were identified by WHO as requiring special attention for developing HIV therapeutic and preventive health service. Both English and French questionnaires were developed and sent to WHO staff in the respective countries. They first established whether or not countries had developed national adult ART guidelines or not. They only completed the questionnaires if they had. It consisted of 25 structured and open ended questions.

Results showed that of the 39 countries 3 did not complete the questionnaires and were excluded, of the 36, three had developed national ART guideline but had not developed and published a comprehensive national HIV treatment and care plan.
They concluded that most countries had developed national ART guideline as part of a comprehensive national HIV programme. Concordance with WHO recommendations was strong on starting first line ART regimens and routine monitoring but lower for second line recommendations.


They used eleven public sector hospitals providing detailed patient chart data. Monthly observations by calendar months, this varied by extent of prescription refill, adherence levels, and compliance with national treatment guidelines. The study focused on the patterns of utilization of services and on the costs associated with the introduction of HAART. Data were collected from 902 patients records, the number of patients selected from each site was proportional to the total number of HIV/AIDS patients in the site.

Their results showed that antiretroviral therapy prescription practices were largely inconsistent with guidelines. Modelling of the economic impact of treatment practices showed that it would have been possible to effectively treat the same number of patients at the same or lower cost per patient.
They concluded that in addition to dispensing drugs, countries scaling up ART must find ways to ensure consistent drug supply, appropriate prescription practices and effective levels of adherence.

Wolft et al [2005] {12}, tried to describe the Chilean expanded access program [EAP] to antiretroviral therapy and the model for evaluating its impact.

The Chilean AIDS cohort program began in 2001 an expanded AIDS program to antiretroviral therapy by providing ART monitoring, and funding for management of associated complications in 32 points of care. It enrolled 98% of these patients and was created for standardised treatment and impact evaluation.

They obtained basic epidemiological data from epidemiology bulletins published by the national commission on AIDS. A patient was considered to be a member of the cohort and reported after having a treatment request approved by the central office and initiating treatment under the EAP. All patients from the cohort with complete baseline data by July 2004 were included for analysis. They used the following descriptive statistics, bio-demographic, immunologic, and clinical data.

They found out that there is still no free or subsidized ART for about 15% of the HIV-infected non indigent population cared for by other systems or without any coverage.
They concluded that an EAP in middle income countries with only local resources or some minor foreign aid is possible, and clinical results are more than encouraging.

Coetzee et al [2004] {13}, found out that ART can be provided in resource limited settings with good patient retention, clinical outcome, and with responsible implementation.

They did this by analysing data on a cohort of patients with symptomatic HIV disease and a CD4 count less than $200 \times 10^6$ cells /L. Two hundred and eighty seven [287] adults naïve to prior ART who started ART treatment between may 2001 and Dec 2002 were followed for a median duration of 13.9 months, and included in the analysis. This study was carried out in Khayelitsha, South Africa.

Their results showed that in many of those countries worst affected by the HIV pandemic, scarcity of resources and capacity will mean that not every one with the potential to benefit from ART will be able to access it. That the difference in survival in the Khayelitsha cohort between those starting treatment with CD4 counts of $50 \times 10^6$ cells /L or more compared to the group with counts below this level, suggest that one of the major challenges in contexts such as this is to ensure a fair balance between providing access to ART for those presenting very late, whilst preserving the opportunity for a better prognosis for those who have presented earlier.
Desclaux et al [2003] {14}, described and analysed the antiretroviral drug access initiative of the Senegalese government launched in 1998. They looked at the design of the project, evaluating the feasibility, efficacy, and acceptability of the project.

The project enrolled 400 adults, 19 children, and 17 pregnant women in a small number of sites.

Persons qualified for ARV therapy were selected on the basis of immunological and clinical criteria.

They found out that not all patients for whom antiretroviral treatment was medically indicated had access to the programmes, due to availability of health services in a low income country. They also found out that drug costs alone are not a valid reason for withholding antiretroviral treatment in a poor country.

They concluded that the social, health and economic situation that prevails in most sub Saharan countries is not an insurmountable obstacle to the creation of a sound and effective programme of anti retroviral therapy. The creation of national antiretroviral programme is not only the affair of African policy makers; it must also be based on an international strategic response proportional to the world AIDS crisis.

Diomerde et al [2003] {15}, using empirical data from the drug access initiative in Cote d ivore, which enrolled 2138 HIV positive and ART naïve
adults between July 1998 to July 2000 tried to describe the cost and outcomes associated with the use of CD4 cell count and viral load tests as part of screening strategies to identify persons eligible for subsidized antiretroviral therapy in Cote d’Ivoire.

After dully analysing their data they concluded that viral load testing should not be included as a mandatory part of eligibility screening as it is not an effective use of scarce public health resources. They also concluded that health personnel should be trained to identify and refer clinically symptomatic persons for HIV care with ART.

Msellati et al [2003] {16}, aimed to compare the socio-economic and health characteristics of HIV infected patients in Cote d’Ivoire. Whether or not, they had access to antiretroviral drug treatment. To do this they did a cross-sectional survey of 711 patients, using medical files, blood sampling for CD4 cell counts and face to face interviews, and by carrying out a multivariate analysis using multiple logistic regression using generalized estimating equation. The data was over a six week period in five referral centres and three other centres in charge of HIV care in Abidjan and Boukake, from Dec.1999 to Feb. 2000

They concluded among other things after their analysis that at the individual patient’s level, affordability of drugs remains a major barrier between HIV infected individuals and access to ARV treatment in Africa. They also found
that in spite of public subsidies for ARVs, patients from the poorest social and economic background did not achieve access to ARVs.

Carmody et al [2003] {17}, conducted a retrospective study to refine data collected instruments, determine best method for data analysis and to gain a grounded on site understanding of HIV care in 2001.

They collected data using a standard abstraction form from available medical records for all patients listed in the clinic registration book that were not documented as deceased or archived. The data were collected on patient demographics, clinical characteristics, and ARV medication use. The data were from 67 patients.

They found out that nearly one-fourth of patients did not refill medication in a timely manner. That lack of stock of ARV drugs occurred, due to delays in obtaining drugs from the health department in Rio, transportation obstacles or receiving fewer bottles than needed.

Their study was limited by small sample size and one health post. One of their recommendations was to improve planning of drug transport to prevent local drug shortages.

They concluded that given the challenges they saw, resource-poor nations can deliver successful HIV/AIDS treatment if ARV drugs are made available.
Green et al [2001] {18}, in their study explores the attitude of patients with HIV and the general public towards specific rationing strategies for ARV drugs. The method they used was a Likert-style, self administered questionnaire about rationing expensive HIV medication in the context of a budget shortfall.

This they administered to 100 patients with HIV and 101 shopping mall patrons in central Pennsylvania in 2000.

Respondents were asked to indicate how much they agreed or disagreed with the several HIV drug rationing policies.

Their results showed that a majority in both groups strongly or somewhat disagreed with six of the seven rationing policies described in the questionnaire.

The patients more strongly disagreed with the policies than the public.

They concluded that HIV drug rationing policies currently in use do not reflect the preferences of patients and the public.
Severe, et al [2005] {19}, studied the efficacy of antiretroviral therapy in the first 1004 consecutive patients with AIDS and without previous antiretroviral therapy who were treated beginning in March 2003 in Port au-prince Haiti.

They tried to establish the feasibility of antiretroviral therapy in a large number of patients in an impoverished country.

They found out that the challenges involved in providing antiretroviral therapy in developing countries include high rates of poverty, malnutrition, and tuberculosis. They also found that the single greatest logistic challenge was maintaining the supply of ARV drugs. Delays in delivery resulted in a change in therapy. Developing reliable manufacturing and distribution systems for ARV drugs is an urgent international priority.

They concluded that with proper infrastructural development, personnel training, mentorship, and international collaboration. Treatment outcomes equivalent to those achieved in developed countries could be achieved in developing countries.

Kidder et al [2007] {20}, sought to compare health status, health care use, HIV ARV medication use, and HIV ARV medication adherence among homeless and housed people with HIV/AIDS.

They derived data from a cross-sectional multi-site study that collected behavioural surveillance data from adults with HIV at 19 surveillance sites in
USA. Trained interviewers conducted individual interviews with 7925 individuals 18 years or older between May 2000-Dec. 2003.

They found that a lower percentage of homeless respondents reported having ever taken HIV ARV medication, and were also likely to currently be taking these medications. Among the respondents taking HIVARV medication, self reported adherence was significantly lower in the homeless group. A higher percentage of homeless respondents than housed respondents reported they had stopped taking prescribed HIV/AIDS medication.

They concluded that homeless people with HIV/AIDS are at increased risk of negative health outcomes and housing is a potentially important mechanism for improving the health of this vulnerable group.

Moore et al [1994] {21}, tried to determine whether socio-demographic characteristics of patients influence the receipt of drug therapy in practice.

They analysed the use of antiretroviral therapy among 838 patients enrolled. All patients presenting for the first time to the HIV clinic from March 1990-Dec 1992 were enrolled. Data on socio-demographic and clinical variables and on drug use were collected at the time of presentation and after six months at the john Hopkins hospital AIDS service, Baltimore, USA.
They found out that in a logistic regression analysis, race was the feature most strongly associated with the receipt of drug therapy.

They concluded that among patients infected with HIV, blacks were significantly less likely than whites to have received ARV therapy when they were first referred to an HIV clinic. This disparity suggests a need for culturally specific interventions, to ensure uniform access to care, including drug therapy and uniform standards of care.

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<tr>
<td>6</td>
<td>Hogan et al</td>
<td>British medical journal</td>
<td>Afr-E and Sear-D</td>
<td>Qualitative data from WHO data base to</td>
<td>Analysis of data from biological and behavioural parameters from clinical and observational studies and population based survey</td>
</tr>
<tr>
<td></td>
<td>December 2005</td>
<td></td>
<td>Countries</td>
<td>access the costs and health effects of a range of interventions for preventing the spread of HIV</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Cowburn et al</td>
<td>British Medical Journal</td>
<td>Cape Town</td>
<td>Data collected from a prospective observational study to describe the short term outcome of critically ill HIV infected children with access to highly active antiretroviral therapy in a developing country</td>
<td>The routine hospital and laboratory records were used to predict mortality by paediatric index of mortality 1, and hospital outcome of sixty eight HIV positive children of median age 3 months over a 16 month period</td>
</tr>
<tr>
<td>8</td>
<td>Galarrag et al</td>
<td>Journal of International AID</td>
<td>30 low and middle income countries</td>
<td>Treatment data used as basis for estimating antiretroviral global demand.</td>
<td>Data of estimated 3.38 million patients using linear regression prediction models to project current trends in drug use as estimated by a survey of country HIV program.</td>
</tr>
<tr>
<td>9</td>
<td>Renaud-Thery Et al</td>
<td>Journal of International AID</td>
<td>23 developing countries</td>
<td>Qualitative data collected in 2006 to address the informed gap on current</td>
<td>Questionnaires were issued to countries, weighted percentages of</td>
</tr>
<tr>
<td>No.</td>
<td>Authors</td>
<td>Journal</td>
<td>Country/Region</td>
<td>Data Collection &amp; Results</td>
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<tr>
<td>10</td>
<td>Beck et al</td>
<td>Journal of International AID</td>
<td>43 WHO focus countries</td>
<td>Data collected in 2006 investigating adult national ART guideline. Questionnaires were issued to countries that were structured and open ended</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Bautista-Arredondo et al</td>
<td>Journal of International AID</td>
<td>Mexico</td>
<td>Collection of data used to estimate the associated economic costs of scaling up of antiretroviral treatment. Data collection from 902 patients records focusing on the pattern of utilization of services, on the costs associated. This was carried out at 11 public sector hospitals.</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Wolff et al</td>
<td>Journal of acquired immune deficiency syndrome</td>
<td>Chile</td>
<td>A cohort study that obtained epidemiological data to describe the expanded access program to ARV therapy and the model for evaluating its impact. Patients enrolled at 32 points of care using descriptive statistics, bio demographic, immunological and clinical data obtained tried to describe access to subsidised ART</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Coetzee et al</td>
<td>Journal of International AID</td>
<td>Khayelitsha South Africa</td>
<td>A cohort study of patients with symptomatic HIV disease, to ascertain access to ARV therapy 287 adult patients data collected and analysed with respect to symptomatic HIV disease and CD4 counts, and</td>
<td></td>
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<tr>
<td></td>
<td>Authors</td>
<td>Journal</td>
<td>Country</td>
<td>Study Description</td>
<td>Participants</td>
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<tr>
<td>14</td>
<td>Desclaux et al</td>
<td>Journal of International AID</td>
<td>Senegal</td>
<td>Data from antiretroviral drug access initiative study, evaluated for feasibility, efficacy, and acceptability in 1998.</td>
<td>Enrolled 400 patients that were qualified for ARV therapy selected on the basis of immunological and clinical criteria.</td>
</tr>
<tr>
<td>15</td>
<td>Diomande et al</td>
<td>Journal of International AID</td>
<td>Cote d'ivoire</td>
<td>Empirical data from drug access initiative from 1998-2000, used to describe the cost and outcomes associated with screening strategies to identify persons eligible for subsidies on ARV therapy.</td>
<td>Enrolled 2138 HIV positive and ART naïve adults. Analysed data from the use of CD4 cell count and viral load tests as part of screening strategies.</td>
</tr>
<tr>
<td>16</td>
<td>Msellati et al</td>
<td>Journal of International AID</td>
<td>Abidjan and Bouake Cote d'ivoire</td>
<td>A cross-sectional study to compare the socio-economic and health characteristics of HIV infected patients.</td>
<td>Data from 711 patients, using medical files, blood sampling for CD4 cell counts and face to face interviews was analysed using multiple logistic regression.</td>
</tr>
<tr>
<td>17</td>
<td>Carmody et al</td>
<td>Journal of tropical Medicine and international health</td>
<td>Rio de Janeiro Brazil</td>
<td>A retrospective study to refine data collection instruments, determine best methods for data analysis.</td>
<td>Data was collected from 67 patients using standard abstraction forms from available medical records</td>
</tr>
<tr>
<td>18</td>
<td>Green et al</td>
<td>Journal of acquired immune deficiency syndrome</td>
<td>Pennsylvania USA</td>
<td>A Likert-style self-administered questionnaire was used to gather data about rationing.</td>
<td>Questionnaires were administered to 100 patients with HIV and 101 shopping mall patrons,</td>
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<tr>
<td>19</td>
<td>Severe et al</td>
<td>December 2005</td>
<td>The new England journal of medicine</td>
<td>Data collected from patient records, studied to establish the feasibility of ARV therapy in a large number of patients in an impoverished country. 1004 consecutive patients with AIDS and without previous ARV therapy were studied.</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Kidder et al</td>
<td>December 2007</td>
<td>American journal of Public health</td>
<td>Data was collected from 7925 adults enrolled at 19 surveillance sites to compare health status, health care use and HIV ARV medication use</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Moore et al</td>
<td>March 1994</td>
<td>The new England journal of medicine</td>
<td>Data collected on whether the socio-demographic characteristic of patients influences the receipt of drug therapy in practice. ARV drug use among 838 patients were analysed with all patients presenting for the first time to the clinic. Data on socio-demographic And clinical variables were analysed using logistic regression.</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER III

SUMMARY OF FINDINGS

Looking at the results of all the studies included in this review, references 6-10 showed that antiretroviral therapy was an important factor in the management of HIV/AIDS, and also availability and accessibility of this ARV drugs to PLHA was vital to achieving control.

They also showed that there was need to be in concordance with WHO recommendations by, complying with its guidelines on treatment regimens.

Hogan et al [6] found in their studies that it is as cost effective to use drug therapy as preventive interventions in reducing HIV transmission. Therefore making these drugs available will be as important as any other preventive measures that may be put in place to control the disease.

Gallarrag et al [8] concluded from their work that some countries were using less of some of the drugs than required by the WHO treatment guidelines and more of some others. Hence the need for adjustment in the use of these drugs: towards following the guideline.

References 11-21 showed that the cost and economic situation goes a long way in determining how PLHA access ARV drugs. They also showed that despite the
negative beliefs, it was possible to achieve standards in treatment outcomes equivalent to those in developed countries, in developing countries. Though not totally, without the efforts or contributions of the international community.

Bautsista-Arredondo et al [11] showed in their work that finding ways to ensure consistent drug supply, appropriate prescription practices and effective levels of adherence, was necessary for developing countries to achieve the same number of patients treatments at lower costs.

Coetzee et al [13], found that scarcity of resources and capacity was a very important factor in the availability of drug therapy for PLHA, as this means that not every one with the need to benefit from ART will be able to access it.

Msellati et al [16], showed that poor economic situations of the people, which translates into the ability to afford the drugs, remains a major barrier between PLHA and access to ARV treatment in developing countries. Therefore more effort should be put in on the part of the governments to subsidise ARV drugs to improve accessibility.

Carmody et al [17] saw that negligence on the part of the patients and lack of stock of ARV drugs caused by delays in logistics and supply affects a successful HIV/AIDS treatment plan.

Severe et al [19], found in their work that it is possible to achieve a treatment outcomes equivalent to those achieved in developed countries, with proper
infrastructure, development, personnel training, mentorship, and international collaboration.

Moore et al [21] found out that socio-cultural factors played very significant roles in the ease of receipt of ARV therapy by patients. Therefore recommends the need for culturally specific intervention to ensure uniform access to care.

They also showed the need to balance the little resources, in terms of delivering HIV therapy and making ARV drugs available.

RELIABILITY AND VALIDITY

Reliability is the consistency of your measurement, or the degree to which an instrument measures the same way each time it is used under the same condition with the same subjects. In short, it is the repeatability of your measurement. A measure is considered reliable if a person's score on the same test given twice is similar. It is important to remember that reliability is not measured, it is estimated.

Validity is the strength of our conclusions, inferences or propositions. More formally, Cook and Campbell (1979) define it as the "best available approximation to the truth or falsity of a given inference, proposition or conclusion." In short, were we right?

Looking at the above definitions, the next paragraph will try to discuss the validity and reliability of the articles considered in this review.

The research work in these articles can be considered to be reliable in the context of the areas or locations where they were carried out. But on a general scale their
reliability could be questioned, because the samples used and the sample size of the population in the studies can not be said to be universal.

But in the context of this review the validity of the articles were assessed based on the methodology used in the researches, the results obtained and if the inferences drawn from these results were conclusive of the results obtained. The generalizability and repeatability of the data collection methods used in the researches were also considered towards assessing their validity.

Table two below illustrates the key findings of all the articles that presented data for this research paper.

**TABLE 3**

**SUMMARY OF FINDINGS AND ASSESSMENT.**

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>FINDING</th>
<th>CONCLUSION</th>
<th>ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hogan et al December 2005</td>
<td>Antiretroviral therapy is as cost effective in reducing HIV transmission and improving population health.</td>
<td>Drug therapy is as cost effective as other preventive intervention in reducing HIV transmission.</td>
<td>VALID</td>
</tr>
<tr>
<td>Cowburn et al March 2007</td>
<td>The long-term outcome of children on HAART is encouraging and warrants further investigation.</td>
<td>Therefore more efforts should be put into investigating children on HAART in a long term.</td>
<td>VALID</td>
</tr>
<tr>
<td>Galarrag et al July 2007</td>
<td>Some countries were using less of some of the drugs than required by the treatment guidelines and more of some others.</td>
<td>There should be adjustments in the usage of these drugs to follow the guideline.</td>
<td>VALID</td>
</tr>
<tr>
<td>Renaud-Thery Et al July 2007</td>
<td>Only 25% of those receiving second line treatments were on</td>
<td>Adjustments should be made in second line regimen treatments towards meeting the WHO recommendations.</td>
<td>VALID</td>
</tr>
<tr>
<td>Study Authors and Year</td>
<td>Summary</td>
<td>Comments</td>
<td></td>
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<tr>
<td>------------------------</td>
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<tr>
<td>Beck et al July 2006</td>
<td>Concordance with WHO recommendations was strong on starting first line ART regimens and routine monitoring but lower for second line recommendations.</td>
<td>There should be more concordance with the WHO recommendations for second line regimens to improve the quality of health of those on second line regimens. <strong>VALID</strong></td>
<td></td>
</tr>
<tr>
<td>Bautista-Arredondo Et al January 2006</td>
<td>Modelling of the economic impact of treatment practices showed that it would have been possible to effectively treat the same number of patients at the same or lower cost per patient.</td>
<td>Finding ways to ensure consistent drug supply, appropriate prescription practices and effective levels of adherence was necessary for countries scaling up on ART. <strong>VALID</strong></td>
<td></td>
</tr>
<tr>
<td>Wolff et al December 2005</td>
<td>An EAP in middle income countries with only local resources or some minor foreign aid is possible, and clinical results are more than encouraging.</td>
<td>EAP was believed not to be possible in middle income countries, but has been shown to be achievable. <strong>VALID</strong></td>
<td></td>
</tr>
<tr>
<td>Coetzee et al April 2004</td>
<td>In many of those countries worst affected by the HIV pandemic, scarcity of resources and capacity will mean that not every one with the potential to benefit from ART will be able to access it.</td>
<td>Ensuring a fair balance between providing access to ART for those presenting very late, whilst preserving the opportunity for a better prognosis for those who have <strong>VALID</strong></td>
<td></td>
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<tr>
<td>Author(s)</td>
<td>Date</td>
<td>Key Points</td>
<td>Validity</td>
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<tr>
<td>Desclaux et al</td>
<td>July 2003</td>
<td>It is not an impossible task to have a sound and effective programme of</td>
<td>VALID</td>
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<td></td>
<td></td>
<td>anti retroviral therapy in sub-Saharan Africa</td>
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<td></td>
<td></td>
<td>International Aid is need to improve the antiretroviral therapy programme in</td>
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<td></td>
<td>Africa</td>
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<tr>
<td>Diomande et al</td>
<td>July 2003</td>
<td>Viral load testing should not be included as a mandatory part of eligibility</td>
<td>VALID</td>
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<tr>
<td></td>
<td></td>
<td>screening.</td>
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<tr>
<td>Msellati et al</td>
<td>July 2003</td>
<td>Affordability of drugs remains a major barrier between HIV infected</td>
<td>VALID</td>
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<tr>
<td></td>
<td></td>
<td>individuals and access to ARV treatment in Africa.</td>
<td></td>
</tr>
<tr>
<td>Carmody et al</td>
<td>May 2003</td>
<td>Nearly one-fourth of patients did not refill medication in a timely manner.</td>
<td>VALID</td>
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<tr>
<td></td>
<td></td>
<td>That lack of stock of ARV drugs occurred, due to delays in obtaining drugs</td>
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<td></td>
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<td>from the health department in Rio, transportation obstacles or receiving</td>
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<tr>
<td></td>
<td></td>
<td>fewer bottles than needed.</td>
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<tr>
<td>Green et al</td>
<td>January 2001</td>
<td>HIV drug rationing policies currently in use</td>
<td>VALID</td>
</tr>
<tr>
<td></td>
<td></td>
<td>There is the need to remove rationing policies on the accessibility of ARV</td>
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<td></td>
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<td>drugs for PLHA, to improve the</td>
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</tr>
<tr>
<td>Author(s)</td>
<td>Year</td>
<td>Summary</td>
<td>Recommendation</td>
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</tr>
<tr>
<td>Severe et al</td>
<td>December 2005</td>
<td>That with proper infrastructural development, personnel training, mentorship, and international collaboration, treatment outcomes equivalent to those achieved in developed countries could be achieved in developing countries.</td>
<td>There should be a coordinated effort with both local and international authorities to achieve desired treatment outcomes in developing countries.</td>
</tr>
<tr>
<td>Kidder et al</td>
<td>December 2007</td>
<td>Homeless people with HIV/AIDS are at increased risk of negative health outcomes and housing is a potentially important mechanism for improving the health of this vulnerable group.</td>
<td>There should be an improvement in the housing of people especially those with HIV/AIDS.</td>
</tr>
<tr>
<td>Moore et al</td>
<td>March 1994</td>
<td>Among patients infected with HIV, blacks were significantly less likely than whites to have received ARV therapy when they were first referred to an HIV clinic.</td>
<td>There is a need for culturally specific interventions, to ensure uniform access to care, including drug therapy.</td>
</tr>
</tbody>
</table>
CHAPTER IV

DISCUSSION

This review set out to investigate the availability of ARV drugs for PLHA in developing countries, factors that affect it and how this affects the quality of health care this group of people receive.

The review specifically aimed to find out the following:

[1] FACTORS AFFECTING AVAILABILITY

If the following factors source, distribution, logistics, supplies chain accessibility, equity, funds, economy, and socio-cultural issues in any way affect the availability of ARV drugs in developing countries.

[2] SUFFICIENCY IN THE QUANTITY OF ARV DRUGS

To investigate if there is enough ARV drugs available in developing countries to take care of the needs of PLHA.

[3] NON-AVAILABILITY OF ARV DRUGS

To look at the possible reasons for the non-availability of ARV drugs were they exist.

[4] IMPACT OF AVAILABILITY OF ARV DRUGS ON QUALITY OF CARE

To ascertain if, this availability affects the quality of healthcare received by PLHA in this regions of the world.
[5] EFFECTS OF AVAILABILITY OF ARV DRUGS

Then finally to further ascertain in what ways it affects the quality of care and to what extent.

Hogan et al [2005], concluded that drug therapy is as cost effective as other preventive measures in reducing HIV transmission. This conclusion is important when considering the quality of care of PLHA who are in their millions and are the major sources of the spread of the virus. So putting more resources to improve therapy for this group and hence their quality of life will be worth while.

Bautista-Arredondo et al [2006], found out that, finding ways to ensure consistent drug supply, appropriate prescription practices and High levels of adherence, are necessary if PLHA are to benefit from ARV drug therapy. These are some of the most important factors that should be addressed if ARV drug are to be made available for PLHA, as epileptic drug supply and inappropriate prescription patterns has plagued developing countries for years.

Coetzee et al [2004], inferred that scarcity of resources and capacity will mean that not every one will be able to access it. But that does not mean that clinical outcomes as good as those in developed countries can not be achieved for majority of the PLHA with proper care and will to be committed on the part of the governments of these developing countries.

Looking at the economic situation of these developing countries: if most or all of the PLHA are to benefit from ART at very subsidised rate, then the efforts of these governments must be complimented by a well coordinated intervention contributions or aid to improve the ART programme in most developing countries [Descleux et al 2003].
But most importantly if these drugs are to be made available and accessible for PLHA, then they must be made affordable for people in developing countries plagued with poor economic situation [Msellati et al 2003]. This could be achieved by improving international trade relations among these countries and the developed countries. Secondly by encouraging the production or supply of generic drugs and the removal of patent laws on HIV drugs in these developing countries to encourage the production of newer and better HIV drugs and subsequently reduction on prices of ARV drugs in developing countries.

The findings from this review can be presented as follows:

[1] FACTORS AFFECTING AVAILABILITY
A look at the factors that affect the availability of ARV drugs in developing countries after reviewing the articles showed that cost of providing the drugs, poor economy, funds, socio-cultural issues, and equity played major roles with respect to availability of these drugs for PLHA. Finding ways to ensure consistent drug supply, appropriate prescription practices and effective levels of adherence [11] played important roles in the availability and access to ARV drugs by PLHA.
Poor economic conditions of developing countries and the impact of poverty on the patients have made affordability of these ARV drugs a major issue and a barrier between PLHA and access to ARV [16].
A summary of the implications of the impact of these factors would mean that a large percentage of the PLHA in these areas of the developing countries would not have access to ARV drugs, or if they do it would be for a short period and would not be
sustained. This translates to a poor quality of care for this group of PLHA in developing countries. There is therefore urgent need for the governments of these countries to develop more will power to devote more resources to the sustenance of the provision of ARV drugs for PLHA.

Developing countries having to make hard decisions on how and where to spend scarce economic resources available to them, makes it an important issue as funds made available for the provision or subsidization of ARV drugs are limited [13]. This brings about the design and implementation of rationing policies on who receives these drugs [18]. In this case factors like cost of these drugs, funds available and socio-cultural issues play very important roles.

Factors like logistics also play similar roles in the availability of ARV drugs as infrastructure, delivery systems, the will to act by the governments, storage facilities and distribution networks all go a long way to determine if these drugs are available or not.

International influence and guidelines also should not be overlooked as they are needed when determining how much of these ARV drugs are available and used by PLHA.

[2] SUFFICIENCY IN THE QUANTITY OF ARV DRUGS

Looking at the sufficiency in the quantity of ARV drugs available for PLHA, it can be said that most of the developing countries could not meet the ARV drug demands of its PLHA, leading to rationing policies for these drugs. [17][18].

[3] NON-AVAILABILITY OF ARV DRUGS

The review found out that most of the developing countries had certain amount of ARV drugs available and the issue of non-availability was not observed.
It is obvious looking at the various articles that the issues of availability of ARV drugs is of paramount importance with respect to the quality of care received by PLHA. Most countries could not meet the demand for ARV drugs, putting that group of PLHA that could not get access to the ARV drugs to very poor quality of care. The work by Hogan et al [2005] showed that ARV therapy plays a very positive role in reducing HIV transmission and improving population health. Showing that, these drugs play important roles in controlling the HIV virus. This in turn improves the quality of health of PLHA and decreases the mortality rate for PLHA. This implies therefore that the quality of health care received by PLHA will be sub-standard. This calls for a boost in the resources channelled to the provision of more ARV drugs to improve the quality of care received by PLHA.

[4] IMPACT OF AVAILABILITY OF ARV DRUGS ON QUALITY OF CARE

It has been shown that ART plays a very important role in the quality of care received by PLHA [6]. Therefore it is imperative that making ARV drugs available will go a long way to improve the quality of life of PLHA. There is therefore need to improve the present level of availability of ARV drugs, if the quality of health care received by PLHA is to be improved.

[5] EFFECTS OF AVAILABILITY OF ARV DRUGS

It has been shown that better treatment outcomes has been achieved with available and consistent ARV drug therapy [17][19], and that it is also possible to achieve these outcomes in developing countries amidst poor economic conditions, with more will power and commitment on the part of the governments [14] and more support from international community [12].
It is therefore imperative that to achieve a better availability of ARV drugs for PLHA and in turn a better quality of care, these factors have to be taken into consideration.

**RELIABILITY AND VALIDITY**

My study had some limitations that are worth noting when interpreting the results and conclusion. Most of the limitation is related to the data base used to retrieve articles as this was restricted to English language articles, therefore possibly contributing to a selection bias due to language, as most of the developing countries speak languages other than English.

Journals used in this review do not represent all scientific journals published on this issue: as a result of the limitation to English language journals only.

Most of the studies included were on a country by country basis, limiting there generalizability to other developing countries.

It was also not possible to access more articles limiting the review to a small size or number of articles.

Despite these short comings, the findings from this study are still valid and important because the methods employed in this review are standard methods that can be repeated using any set of data from any research, hence, the review can be said to be reliable. Sample sizes in the individual studies are large and methods employed are of generally accepted types. Though the review can not be said to be generalizable as a result of the limitations outlined above, but is still of significance and important.
CHAPTER V

CONCLUSION AND IMPLICATION

CONCLUSION

The most important findings of this review were:

[1] Poor economic states of the developing countries play a significant role in the availability of ARV drugs.

[2] Costs associated with the provision of the ARV drugs is an important factor in its availability

[3] The will to act on the part of the individual governments of the countries, determine to a large extent how available these drugs are.

[4] The ARV drugs play a very paramount role in the quality of care/health of PLHA.

[5] International collaboration is essential in achieving standards of quality of care as those in developed countries. The efforts should not be left to the individual governments of the countries alone.

[6] Socio-cultural factors play significant roles in the accessibility of ARV drugs for PLHA.
IMPLICATION

The implication of these findings is that ARV drugs are very essential in the improvement of the quality of care of PLHA and in turn decreasing their mortality. Therefore to achieve the increased availability of ARV drugs for PLHA it is imperative that the individual governments should be more committed to the course of HIV prevention and management and improving the quality of care of PLHA. This can only be achieved if the governments devote more resources and ensure that what is devoted is properly managed.

The availability of ARV drugs in developing countries though an important responsibility of the individual governments, can not be achieved by those governments alone, considering their economic status and cost of these drugs. Therefore international efforts in the form of financial aids and logistics must be provided as aids to these countries if the ARV drugs must be made available for PLHA in the developing countries of the world.
CHAPTER VI

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pages s97-s103


[16] Msellati et al, Socio-economic and health characteristics of HIV-infected patients seeking care in relation to access to the drug access initiative and antiretroviral treatment in cote d ivoire, Official Journal of International AID, vol 17 suppl 3, July 2003, pg s63-s68


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