Financing issues in proposed HIV/AIDS intervention of providing anti-retroviral drugs to selected regions in India

Ramesh Bhat Somen Saha



Indian Institute of Management Ahmedabad

May 2004

Financing issues in proposed HIV/AIDS intervention of providing anti-retroviral drugs to selected regions in India

Abstract

The development of antiretroviral therapy has given a new hope for people living with acquired immuno deficiency syndrome. In the face of increased disease burden due to HIV the global and political commitment towards controlling the pandemic has received renewed thrust in recent times. The Government of India has initiated antiretroviral treatment as a part of national public health programme in the six high-prevalence states. The aim of the paper is to provide the programme planners and other stakeholders, information about the impact of initiating antiretroviral therapy programme in the country. The paper discusses the global commitment towards fighting the disease in the light of the development in affordability and accessibility of antiretroviral drugs therapy. The paper highlights the importance of infrastructure and logistic requirement for developing a comprehensive treatment programme for the affected population in India. Finally, the paper has drawn broad financial implications of the antiretroviral therapy under different treatment scenarios. The estimated financial requirement for treatment vary from Rs. 92 crores per annum if focusing on 400,000 HIV/AIDs cases to identify patients requiring ARV Therapy to 1008 crores per annum if all 4 million patients are screened for coverage. Against this NACO has allocated total of Rs. 113 crores for treatment part of the proposed intervention. Even under the most conservative estimate achieving the treatment target in India with the proposed programme budget will be a challenging task.

Financing issues in proposed HIV/AIDS intervention of providing anti-retroviral drugs to selected regions in India

1. Introduction

The allocation of resources assumes greater complexity in health sector interventions because of lack of cost-effectiveness measures. Also, the allocation experiences are constrained by several complexities arising out of ethical, legal and human rights issues. The HIV/AIDS programme, in particular, is confronted with these issues in serious way. To spend on prevention or treatment or research – is a dilemma which the programme planners are facing while developing financial plans for AIDS control programme. Given the limited financial resources the question of cost-effectiveness of prevention and treatment interventions are important. How much funds can be utilised for treatment by diverting resources from prevention activities without adversely affecting the prevalence, particularly when there is no cure or vaccine and "prevention is still the only cure for HIV/AIDS".

Some of these questions have been discussed at different forums, but it has assumed particular attention because of recent round of negotiation on anti-retroviral (ARV) drugs, making it around 10 times cheaper to earlier drug prices. The trade-offs on cost front has eased significantly. In view of these developments and declaring non-availability of drugs to the AIDS affected cases as a global emergency, World Health Organisation recently came out with a strategy to reach out to 3 million people by 2005, mostly in the severely affected African countries with ARV drugs. The Government of India too has already initiated programme intervention to make available treatment with High Active Antiretroviral Therapy (HAART) to the 6 severely affected states of India.

The drug price is not the only component in cost of treatment interventions. Regular laboratory and clinical check-up for the patient, need to continue the drugs for life-time, side-effects of the drugs, resistance to drugs and ensuring continual treatment of the patient are some of the key issues in HIV treatment for which there is a requirement for massive mobilisation of health infrastructure, human skills and overall a coherent strategy.

The objective of this paper is to address financing issue in the proposed HIV/AIDS intervention of providing anti-retroviral drugs to selected regions in India. The paper will briefly discuss the epidemiology of HIV/AIDS in India and how India has geared itself to respond to the challenge. A brief review of pros and cons of prevention and treatment is presented. In reviewing the data, the paper draws from examples of how the world has geared itself to deal with the problem. Towards the end of the paper we make an attempt to analyse the financial implications of the strategy of the National AIDS Control Organisation (NACO) to initiate antiretroviral therapy programme in India. The last section of this paper attempts to estimate the cost of implementing antiretroviral therapy programme in India.

2. HIV/AIDS status in India

There is a global rise in political commitment to combat the pandemic. The Global Fund to fight AIDS, TB and Malaria has approved a total of US \$2 billion over two years to 224 programmes in 121 countries with disbursement currently amounting to US \$245 million (Global Fund 2004). The World Bank is one of the largest sources of financing in the United Nations system for HIV/AIDS programmes. In the last five years, the Bank has committed US \$1.5 billion through grants, loans and credits to programmes to fight HIV/AIDS. This also includes support to local authorities and nongovernmental organisations. Besides, several bilateral and multi-lateral agencies are contributing resources to this sector. Recently WHO has initiated a programme to treat 3 million people affected by AIDS by 2005. UNAIDS has estimated that the world will need about \$10 billion per annum to mount an effective and comprehensive response in low and middle income countries. Currently the total amount of fund that is available to fight the problem is only to the tune of \$4.7 billion including resources from Global Fund to Fight AIDS, TB and Malaria and the World Bank.

According to estimates around 4.6 million individuals, (slightly less than 1 percent of the adult population) are infected with HIV. According to official estimates by NACO, cumulative AIDS cases in India till March 2004 are 68809. The number of people living with the virus is fast approaching 5 million. These figures, although questioned to be gross under-estimation at different forums is enough to press the alarm bell as we are now having the second largest number of people living with the HIV/AIDS, after South Africa.

Given India's large population, HIV/AIDS can assume threatening proportions. For example, by a mere 0.1 percent increase in the prevalence rate, the number of adults living with HIV/AIDS will increase by over half a million persons. According to World Bank estimates the epidemic has already advanced into the generalised state (with an adult population of more than 1 percent) in six states and India accounts for 10 per cent of global HIV burden and 65 per cent of that in South and South East Asia (World Bank 2003). The major route of transmission is through sexual contact. Another risk group is injecting drug users in the early years. There are threats that this disease is gradually spreading from the high-risk groups to the general population through the "bridge population". The spread to the general population is borne out by rising number of cases among pregnant women and their infants. The growing prevalence of HIV/AIDS poses serious social and economic threats and need effective policy response.

In response to the growing prevalence of HIV/AIDS cases, the Government of India in 1987 established national AIDS control programme with the primary objective of monitoring HIV infection rates among risk population in a few major cities. The first funding commitment of \$99.6 million to the Indian National AIDS Control Project Phase-I (1992-1997) was finalised in 1992. The project was funded by an \$84 million International Development Association (IDA) credit of World Bank and supplemented by WHO/GPA co-financing of \$1.5 million and a planned government contribution of \$14.1 million. The project objective was to contain the spread of HIV by initiating a major effort to prevent HIV transmission. National AIDS Control Organisation (NACO) was established as a semi-autonomous body under the MOHFW and Sate AIDS control cell were established in all states.

The second phase of the project with total financial commitment of \$229.8 million (Rs. 1155 crore) got finalised in 1998. The World Bank contributed \$191 million and the rest coming from Government of India. At the same time the government of India also initiated two other projects with the support of US assisted AVERT in Maharashtra for Rs.166 crores and DFID in Andhra Pradesh, Orissa, Kerala and Gujarat for Rs.104 crores. These funding commitments marked the Phase II of the National AIDS Control Programme (1999-204) as a 100 per cent Centrally Sponsored Schemes. The approved year-wise phasing of the budget and expenditure incurred in the programme is given below:

Allocation and Expenditure (Rupees in crores)							
Year							
	World Bank, GoI	USAID	DFID	Total	Expenditure*		
1999-2000	154.5	43.6	12.63	201.73	135.25		
2000-2001	270.1	28.5	18.69	317.29	179.64		
2001-2002	257.9	28.5	22.22	308.62	228.49		
2002-2003	193.1	28.5	22.14	243.74	240.00		
2003-2004	198.0	25.1	28.31	251.42	NA		
2004-2005	81.40	11.80		93.20	NA		
Total	1155.0	166.0	104.0	1425.00	783.38		

^{*}Source: Lok Sabha unstarred question no. 3275, dated 04.02.2004(India Stat)

The component- wise allocation of this amount is as follows:

Component Allocation of WB & GOI funding (in crores of rupees)	
Targeted interventions for groups at high risk	265.6
Preventive interventions for the general community	389.1
Low cost AIDS care	163.3
Institutional strengthening	286.5
Inter-sectoral collaboration	50.5
Total (1999-2005)	1155.0

Source: NACO website

The programme implementation was through the various AIDS control societies specially constituted for the implementation of this programme. The Planning Commission of India had also approved an outlay of Rs. 1270 crores for implementation of the HIV/AIDS Control Programme during the 10th Five Year Plan Period as against a total budgetary outlay of Rs. 9253 cores for the Ministry of Health and Family Welfare (Planning Commission). Besides several bilateral and multi-lateral agencies like Bill & Melinda Gates Foundation and Global fund to fight AIDS, TB and Malaria has also ensured support HIV/AIDS intervention in India.

3. Anti-retroviral Drugs and HIV

With no vaccines for HIV round the corner, antiretroviral therapy is considered to be the only option available to contain the disease progression once it affects the human body. The drugs are generally of four classes based on the enzymes the virus requires in order to replicate - Protease Inhibitors (PIs), Nucleoside Reverse Transcriptase Inhibitors (NRTIs), Non-

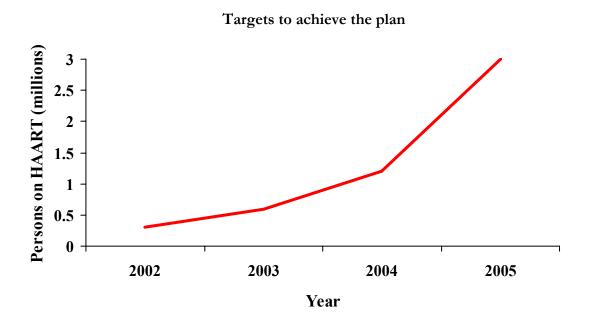
Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) and fusion inhibitors (Laurence and Coffey 2003). WHO has approved the use of the first three drugs. The drugs do not cure the disease but helps in prolonging the life span and has to be taken throughout the life. Default in taking the medicine results in relapse of the disease and efforts on structured intervention will result into limited success.

Antiretroviral therapy costs remain an important barrier to treatment. The prohibitive cost of the drugs so far hindered many people from taking the medicine or continuing treatment. According to estimates, of the 6 million people who currently urgently need antiretroviral therapy in developing countries, fewer than 8 per cent are receiving it (WHO 2003). While the initial price for an antiretroviral three-drug regimen was about US\$ 10,000 per patient per year, high-quality generic drug regimens are now available for as less as US\$ 140 per person per year.

Some developing countries have shown good success in their response to HIV/AIDS, particularly when it comes to preventing new infections among young people and treatment of AIDS cases with antiretroviral therapy. In Thailand, government determination to enforce 100 per cent condom use in brothels and to ensure wide access to HIV prevention campaigns through schools, mass media, and workplace have been key factors in lowering HIV infection rates. The broad-based campaign has led to an increase in condom use, a reduction in visits to sex workers, and a dramatic reduction in HIV infection rates (WHO 2000a). The Mwanza Trial is an example of effectiveness of improved treatment service for sexually transmitted infection (STIs) in preventing HIV infection (Grosskurth, Mosha and Todd 1995). The administration of antiretroviral drugs during pregnancy time around delivery has proved to be effective in significantly reducing the risk of MTCT (mother to child transmission), mainly among nonbreastfeeding population. A study in Uganda (WHO 2000b) demonstrated a 47 percent reduction in MTCT following the administration of a single dose of nevirapine to the mother at the onset of labour and to the baby within 72 hours after birth. The Brazilian experience of providing free Anti-retroviral drug therapy to HIV/AIDS patients has resulted in more than 60,000 AIDS cases, 90,000 deaths and 358,000 AIDS related hospital admission averted from 1996 to 2002. This resulted in a cost savings of more than US\$1.1 billion from 1997 to 2001. This compounded with savings from ambulatory care and drugs for opportunistic infection rises to approximately US\$2 billion (Teixeira, Vitória, and Barcarolo 2003).

4. WHO initiative of treating 3 million by 2005

The lack of antiretroviral treatment has been recognised as a global health emergency. There is significant need to deliver antiretroviral treatment to the millions who need it. In 2003 UNAIDS along with Global Fund to fight AIDS, TB and Malaria partnered with WHO to develop a strategy of providing treatment to 3 million people of developing countries with High Affective Anti-retroviral Treatment (HAART) by 2005. The reports (WHO/UNAIDS 2003, WHO 2002) has estimated that under optimal condition, 3 million people living in developing countries could be provided antiretroviral therapy and access to medical services by the end of 2005. The total estimated fund needs for the programme is estimated at minimum of \$5.5 billion by end 2005.



5. Prevention vs. treatment: cost-effectiveness analysis

The question has posed a wide range of debate among programme planners, particularly considering the high cost of the drugs and the fact that a person on HAART needs to continue it throughout his life time. A study by Marseille 2002, on the cost-effectiveness of HIV prevention in sub-Saharan Africa and on highly active antiretroviral therapy (HAART) indicates that prevention is at least 28 times more cost effective than HAART. Further the study pointed that spending \$200 million on treatment of AIDS will generate the same amount of Disability

Adjusted Life Year (DALY) as would \$55 million spend on prevention. On the other hand, it is estimated that a higher percent of 1.5 million people living with HIV in high-income countries will lead a productive life as a result of receiving highly active ARV therapy. In the USA, the introduction of triple combination ARV therapy in 1996 led to a decline of 70 per cent in deaths because of HIV/AIDS (WHO 2002). In developing countries with access to ARV therapy the same profound effects have been documented. For example in Brazil, AIDS deaths have decreased by 73 per cent since the introduction of highly active ARV therapy (Teixeira, Vitória and Barcarolo2003). According to a recent study by researchers from the San Francisco Department of Public Health (Porco, Martin and Shafer 2004), the introduction and widespread use of high active antiretroviral therapy (HAART) for HIV-infected persons in San Francisco in the late 1990s reduced their risks of infecting partners by 60 per cent. However, a concurrent increase in risk behaviour has been noticed among the study population. Therefore the programme managers have been suggesting an effective strategy which also focused on better counselling and various preventive measures along with ARV therapy to reduce the spread of virus from the infected person and thus lower the incidence of the disease among the community. Using this argument, the pharmaceutical companies also argue for the strategy of both prevention and treatment.

Notwithstanding all arguments that treatment is far more expensive than prevention, given the positive externalities, governments do have a moral responsibility towards providing treatment to people living with HIV/AIDS. This becomes all the more important for number of reasons because the anti-retroviral drugs are still not affordable to an average person. Since the drug has to be administered throughout the life, achieving good compliance rates is problematic if the costs of treatment are borne by the patient. The default rates may be high because of financing burden. It is also expected that the availability of therapy will be a good incentive for more and more people to disclose their HIV status and come forward for screening and treatment. Last but not the least, those on regular HAART will be carrying lower viral load in their blood stream and hence less prone to transmit the virus to others. Over and above the various gains of providing treatment with HAART will be in terms of: delayed clinical progression of the disease, improvement in quality of life, reduction in the number of orphans in the population, reduction in the people being hospitalisation because of HIV/AIDS, reduction in HIV transmission,

reduction in opportunistic infection (OI) and return in productive life by people as a result of the above.

6. Are we adequately prepared for the task?

Last year the government of India announced a plan to cover 100,000 AIDS cases in India and provide treatment on structured anti-retroviral therapy. The target to achieve this goal is 2005. In addition to this the programme envisages to provide treatment to additional of 15 to 20 per cent of AIDS cases each year, thereafter, for a period of five years. Initially the programme will be implemented in six high prevalent states with a funding commitment of Rs. 200 crores for the infrastructure needed to implement this programme. Of this amount Rs. 113 crores is meant for medicines and Rs. 87 crores for providing infrastructure to screen people for HIV/AIDS infection (NACO 2003). Regarding the provision of drugs, the programme aims to focus on three categories of patients viz., (i) sero-positive mothers who have participated in the PPTCT programme; (ii) seropositive children below the age of 15 years; and (iii) people with AIDS who seek treatment in government hospitals (NACO 2003). According to the plan, patients will be provided a cocktail of three drugs - Lamivudine and Nevirapin with either Stavudine, Zidovudine or Efavirenz - to be taken twice daily. This task would involve addressing the following key elements.

Need to find the number of people requiring HAART: One of the important tasks in implementing the programme is to identify the cases that would be covered by HAART. For this purpose epidemiologists and health planners use the cumulative number of AIDS cases as the reference point. However, it is quite evident that the definitions of AIDS cases and those who should be covered by HAART vary from country to country. The criteria for defining the number of cases has implications for who should necessarily or directly be having need for antiretroviral therapy. There is, however, some agreement on that the definition based on CD4 cell count (i.e., number of viral copies) may be an effective way to define the need for ARV treatment than the number of cases (cumulative) or total estimate of HIV infected individuals. It is important to have better estimates of the total number of individuals who actually need antiretroviral therapy in order to plan the budgets to provide treatment through anti-retroviral therapy. The official figure of NACO on estimated HIV

infected cases and actual number of people with full blown AIDS is questioned at various levels as under-reported. However, there is no reliable estimate by any agencies/organisation about the exact number of AIDS cases on the basis of CD4 cell count who actually need to initiate antiretroviral therapy in order to live a productive life.

Monitoring the risk: For effective implementation of ARV therapy it is important to monitor risk. For this purpose there is a need to establish adequate chain of laboratories to monitor CD4 cell count and viral load every 3-6 months in people under clinical care for HIV infection. In Brazil, for example, where anti-retroviral therapy is provided free as a part of national health programme to 1 lakh of its population, the government has created a chain of laboratories in order to screen 4 lakh people living with HIV/AIDS for their viral load count. The draft policy document of NACO does not specify any mechanism to create laboratory chain to screen the people living with HIV/AIDS. The programme document also does not talk about any formal supervisory mechanism for implementation of the programme.

Although the programme guidelines have made an attempt to justify that due to higher frequency of administration of the drug therapy, it might not be possible to imitate DOTS type strategy in HIV treatment, however, some degree of supervision is essential for implementation of such programme which has a higher risk of side-effects and non-compliance resulting in negative notion towards the programme. Another aspect to look at the scheme of providing ART to AIDS patients is supply-chain management. The importance of supply chain management can best be explained from the experience of pre and post Revised National Tuberculosis programme (RNTCP) in India. Proper and timely accessibility of the multiple drugs for Tuberculosis has led to treatment adherence in post RNTCP era, while failure to do so in the pre-RNTCP period lead to lot of treatment non-compliance (Sahu, Reuben and Chauhan 2003). The point of reference is sited here because anti-retroviral therapy also involves a cocktail of multiple drug regimens. The NACO programme document states that the overwhelming short term priority is for first-line regimens which will facilitate the scaling up of treatment. Second-line treatment is not a priority in the short-term.

Managing HIV co-infection: The programme needs to have strategies to cope with HIV co-infections among patients undergoing anti-retroviral therapy. Although, the programme

document has mentioned about management of HIV co-infections, it is not explicitly mentioned whether the same will be provided as free to patients undergoing antiretroviral therapy.

Financial planning: In order to assess the total funds requirements to implement programme and ensure that drugs supply is maintained, the programme will require developing a good financial system to forecast funds requirements over the period. As discussed in previous sections that the treatment has to life-long and need sound system of forecasting the requirements to implement the programme effectively. This becomes all the more important because, cost for the programme does not only involve cost for the drugs, but also cost for routine diagnosis of the patients, cost of mobilising human resources and health system machinery and cost of opportunistic infections averted and cost of benefits gained by each HIV infections averted. With a proper financial system it would be easy to establish cost-effectiveness of the programme. It can assess the risk better and can evaluate the momentum to enhance capacities of the public health systems for rational management of the HIV infected in a sustainable manner.

Treatment effort has to be adequately complemented by prevention activities because of the risk of clients discontinuing condom use and ignoring various preventive approaches.

7. Factors determining financial requirements

For calculating the cost of the programme, we need to understand the natural history of the disease progression, life time risk of patient to contract the disease, incidence of Opportunistic Infections relative to CD4 cell count in the patient and survival analysis thereof. The median interval from HIV infection to the development of severe immune deficiency appears to be similar in all populations (i.e., in developed and developing countries) and is estimated to be about 7-8 years. However, there is a consensus that the survival period from the development of severe immune deficiency to death is much shorter in most developing countries compared with developed countries, where the advent of HAART therapy has significantly increased survival of patients with moderate immune deficiency related to their HIV infection. A recent review of cohort studies in Uganda, Thailand and Haiti indicates that the median interval from HIV infection to death is 9 years (UNAIDS 2003). It has been found that the survival time after

onset of AIDS related illnesses is also variable. Prior to the development of effective ARV therapy, average survival time was about 2 to 4 years in most developed countries and about 6 months or less in developing countries. The proportion of HIV infected persons who, in the absence of ARV treatment, will ultimately develop AIDS has been estimated to be over 90 per cent. In the absence of effective ARV treatment, the AIDS case-fatality rate is very high. Most (80-90 per cent) patients in developed countries die within 2-4 years after the diagnosis of AIDS is made. It should be noted that most of the information on effects are from developed country context. It is well known that the risks and its effects vary from country to country. In India the relation between CD4 cell count and risk of developing Opportunistic Infections and median time of survival thereof has been investigated by YRG Care, an NGO working in southern India. Based on their studies we have drawn the risks of HIV at various CD4 counts.

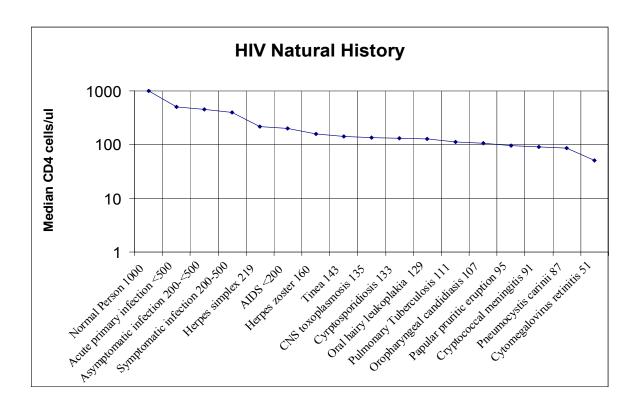


Figure 1: HIV natural history (based on YRG Care study)

Figure 1 depicts the natural history of HIV/AIDS in terms of the number of T-helper lymphocytes per cubic millimetre of blood, known as CD4 cell count. The figure depicts the transition of an HIV infected person from the period of transition to the period of developing full blown symptoms of AIDS defining illness corresponding to their CD4 cell count. The

AIDS defining opportunistic infections listed here are the common opportunistic infections found in the Indian sub-continent. However, the figure has to be interpreted with much care. The median CD4 cell count depicted in the figure cannot be taken as standardised. For example the pulmonary tuberculosis which was reported at median CD4 cell count of 111 cells/µL (from the cohort study of 594 cases in YRG Care, India) is reported at median CD4 cell count of 6 cells/µL in a similar study in a cohort study at Switzerland (Bruno et.al.1999). The difference may be attributed to the differential disease pattern based on geographical and epidemiological variation, however the details for the reason is not discussed here. We have referred the Indian study data, since our major objective is to assess the cost of treatment intervention in India. The YRG Care study has tried to find out through univariate analysis, the median duration of survival for patients who presented with or developed opportunistic infections as compared to those who did not. The study result showed that various OIs (such as pulmonary tuberculosis, oropharyngeal candidiasis, P. carinii pneumonia, cryptococcal meningitis and CNS toxoplasmosis) were associated with increased risk of death in a patient. Further the study found that person who had more than one opportunistic infection were 2.6 times more likely to die than were those who did not.

Financial requirements for antiretroviral therapy

According to NACO statistics the cumulative reported number of AIDS cases in India as on March 2004 is 68809. The ARV therapy programme has proposed to include 100,000 persons on antiretroviral drugs by 2005. There are questions regarding these numbers as well as whether we have provided adequate funding for this intervention. Since, we do not have accurate data on the exact number of cases we base our projections of financial requirements based on two scenarios.

Scenario 1

We assume that the cost will be incurred in screening the entire estimated HIV affected cases and then identifying and placing 100,000 population with CD4 cell count less than 200 cells/ μ L or symptomatic patients urgently requiring treatment under HAART regimen. This scenario is further divided into two cases: (i) where screening is done in the six high-prevalence states of India and the policy proposes to implement the treatment programme and (ii) if screening is done throughout the country to assess the actual number of cases requiring treatment. The

second option of Scenario 1 is more appropriate one, but there would be many practical difficulties in implementing this intervention. This is because the sentinel surveillance data of estimating the HIV cases gives the crude estimate of HIV affected cases and not the absolute identification of the infected cases.

Scenario 2

WHO has estimated that about 10 per cent of HIV cases estimated may need ARV therapy (WHO 2002). The antiretroviral therapy programme of Brazil has a network of 138 laboratories which screened about 400,000 risk cases and then focused on those needing ARV therapy. We develop second scenario based on this point. We also assume that facilities will be set up for screening of 400,000 high-risk cases per year and then placing 100,000 cases who have progressed to sever symptomatic phase or asymptomatic cases with CD4 cell count less than 200 cells/µL on the therapy.

In making our financial projections under both the scenarios we make the following assumptions:

- The patients will continue treatment effectively under first line therapy throughout their life span. The cost of first line therapy is taken as the Clinton Foundation agreed price \$140¹ and in rupee terms as Rs. 6790 per person per annum.
- · For calculating the cost of CD4 cell count we use two price scenarios: one, the current market price at Rs. 1200 per test and second, Clinton Foundation agreed price \$5 (in rupee terms Rs. 243). This information is taken from Wall Street Journal (January 14, 2004).
- As per recommended guidelines the HIV infected person CD4 cell count test will be repeated twice every year in order to monitor the progress and for the patients under treatment the test will be repeated quarterly to monitor the progress of treatment.
- The estimated HIV infected cases in Scenario 1 for the six high-prevalence states and for Scenario 2 all Indian states combined is taken from the official NACO estimate for 2002.

¹ Exchange rate used in the paper is \$1 = Rs. 48.50

Estimates

Figure 2 gives the summarised financial requirements under two different scenarios. The details of these calculations are given in Table 1. Scenario 1 (six high-prevalence states), the annual combined cost of screening, cost of anti-retroviral therapy and monitoring the progress of patients come to approximately Rs. 714 crore per annum under assumption of CD4 cell count test at Rs. 1200 per test and Rs. 198 crore under assumption of CD4 cell count test at Rs. 243 per test. The corresponding projections, if the entire Indian HIV population are screened would be Rs. 1008 crore and Rs. 258 crore.

Scenario 2 assumes that there would be adequate facilities and infrastructure by way of chain of laboratories for screening of 400,000 HIV infected case and identifying 100,000 cases under structure antiretroviral therapy. The annual cost will come to Rs. 187 crore under the presumption of CD4 cell count test at Rs. 1200 per test and Rs. 92 crore under the presumption that CD4 cell count test will be available at Rs. 1200 per test. Table 1 provides the details of these computations under each scenario and component-wise under two price scenarios. Figure 2 provides summary of these financial requirements.

Scenario	Scena	Scenario 2	
Price (assumption)	Six high-prevalent states	All-India	Screening of 400,000 high-risk cases
Market Price of CD4 cell count (Rs. 1200 per test)	7141	10081	1879
Clinton Foundation agreed price of CD4 cell count (Rs. 243 per test)	1988	2583	922

Figure 2: Per annum cost (in millions of rupees) of treating 100,000 population

In above calculations we have not included the cost of treating Opportunistic Infection. However, as plotted in Figure 1, the median CD4 cell count for various Opportunistic Infections, it is evident that a person with CD4 cell count less than 200 cells/ μ L, is at a high risk of contracting Opportunistic Infections. Moreover, potent antiretroviral therapy is known to reduce the incidence of opportunistic infection by about 85 per cent.

In addition to these costs, following items need to be included to develop a comprehensive cost calculation:

- · Establishment and up-gradation cost of existing facilities.
- · Additional human resources and supervisory cost required for the purpose
- Alternative therapy in case of drug failure or drug resistance and cost of treatment for opportunistic infection.

Cost of various other tests for example, Elisa and Western Blot test are done for screening of the HIV infected tests and viral load count (optional) for monitoring of patients under treatment. There are several other tests to find out drug compliance and tests for opportunistic infections during the treatment period. These tests were not included in this cost calculation.

The cost calculation presented here are only for one year. Additional cost of the therapy is not included in the calculation. This cost arises because new cases may get included in the treatment category. Ideally the cost calculation should consists of cost per person year lived after adjusting for mortality rates and because of which some cases will get excluded from treatment. In order to do these calculations we would need information on median life survived by a patient on antiretroviral therapy as adjusted against his/her viral load. The YRG Care study shows the median duration of survival for subjects who initiated antiretroviral therapy when their CD4 lymphocyte counts were <200 cells/µL was 45 months, as against those with comparable CD4 lymphocyte counts who did not receive antiretroviral therapy, the median duration of survival was only 33 months. This figure was different (22 months) in the study of Skiest and Crosby (2003). There is significant variation in the results and geographic region and development index seem to influence these results obtained by these studies. We have not done this adjustment in our estimates here.

8. Conclusion

Under most conservative estimates, the annual requirement of funds for ARV intervention works out to be Rs. 92 crores per annum. This is based on assumption that infrastructure (including testing facilities) would be available to screen at least 400,000 HIV infected cases per year and these tests would be done at the cost agreed upon by international companies with the Clinton Foundation. This estimate does not include many other costs associated with treatment and human resource mobilisation as mentioned above. This raises questions on the financial feasibility of government's programme as it has been proposed to allocate total of Rs. 113 crore

towards treatment of 100,000 AIDS cases on structured anti-retroviral therapy by the end of 2005. Beside financial cost, there are several other management and implementation issues pertaining to technical aspect, capacity aspect and public-private partnership issues particularly involving NGOs in managing the programme which needs to be addressed in greater detail.

The financial requirements as estimated are highly sensitive to price assumptions. In case we do not get favourable price the requirements go as high as Rs. 714 crores in six high-prevalence states. The programme implementation strategies need to consider these scenarios. There is also need to learn from our previous experiences. For example, the financial requirements turned out to be significantly different than what was planned in pre DOTS strategy on treating Tuberculosis. Along with the funds requirements for HAART intervention, the programme will require funds for preventive interventions as well. WHO in their cost estimation for reaching the target of 3 million with access to antiretroviral therapy by 2005 has indicated that their cost estimation includes only those preventive activities required to support the programme directly. They do not include scaling up other interventions and health infrastructure given the short time frame until 2005. There is need to carry out detailed exercise on developing proper financial plan keeping in view all the budgetary constraints and objectives of the programme. Various scaling-up issues can also be addressed through this exercise. The implementation of programmes will also need high political commitment and support. The financial planning framework should also address the question of spending on prevention and treatment and should consider treatment strategy as complementary to prevention strategy. We also need to initiate pilots and develop some understanding of the risks involved in these choices. In the absence of this framework, the programme implementation and policy formulation will remain ad-hoc and would be subject to high implementation risk.

Table1
Scenario 1: Screening the entire HIV estimated case and putting 100000 case with CD4 cell count less than 200 on treatment

	Six high prevalent state	All Indian state		
HIV estimate in 2002	2592498	3817656		
Screening cost				
Cost of CD4 cell count at Rs. 1200	6221995200	9162374400		
per test @ 2 test per year				
Cost of CD4 cell count at	1259954028	1855380816		
\$5~Rs. 243 @ 2 test per year				
Treatment cost				
Cost of giving first line ARV @ \$ 140~Rs. 6790	679000000	679000000		
per person per year for 100000 person				
Additional Cost of CD4 cell count for the 100000	240000000	240000000		
patients for 2 extra test per year at Rs. 1200 per test				
Additional Cost of CD4 cell count for the 100000	48600000	48600000		
patients for 2 extra test per year at \$5~Rs. 243 per test				
Total cost				
Cost of screening, providing drugs and monitoring at pres	sent CD4 cell testin	g cost (Rs. 1200)		
In six high prevalent states =Rs. 714,09,95,200				
Cost of screening, providing drugs and monitoring at present CD4 cell testing cost (Rs. 1200)				
in all over India = Rs. 1008,13,74,400				
Cost of screening and providing drugs and monitoring at agreed CD4 cell testing cost (Rs.				
243) in six high prevalent states = Rs. 198,75,54,028				
Cost of screening and providing drugs and monitoring at agreed CD4 cell testing cost (Rs.				
243) in all over India = Rs. 258,29,80,816				

Scenario 2: Screening of 400000 HIV cases through a chain of testing centres for CD4 cell count and putting 100000 case with CD4 cell count less than 200 on treatment

Screening cost		
Cost of CD4 cell count at Rs. 1200 per test @ 2 test per annum for 400000	960000000	
HIV+ve cases		
Cost of CD4 cell count at \$5~Rs. 243 per test @ 2 test per annum for	194400000	
400000 HIV+ve cases		
Treatment cost		
Cost of giving first line ARV @ \$ 140~Rs. 6790 per person per year for	679000000	
100000 person		
Additional Cost of CD4 cell count for the 100000 patients for 2 extra test per	240000000	
year at Rs. 1200 per test		
Additional Cost of CD4 cell count for the 100000 patients for 2 extra test per	48600000	
year at \$5~Rs. 243 per test		
Total cost		
Cost of screening and providing drugs and monitoring at present CD4 cell testing cost		
(Rs. 1200) = Rs. 187,90,00,000		
Cost of screening and providing drugs and monitoring at present CD4 cell testing cost		
(Rs. 243) = Rs. 92,20,00,000		

References

- Bruno L, et. al. (1999). AIDS-Related Opportunistic Illnesses occurring after Initiation of Potent Antiretroviral Therapy. The Swiss HIV Cohort Study JAMA, Vol. 282, No. 23; American Medical Association.
- 2. Department of Health and Human Services (2004). Guidelines for using antiretroviral agents among HIV-1-infected adults and adolescents. Developed by the panel on clinical practices for treatment of HIV Infection.
- 3. Grosskurth H, Mosha F, Todd J (1995). Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial. Lancet 346: pp. 530-6.
- 4. Global Fund to fight AIDS, Tuberculosis and Malaria, Progress Report, February 2004.
- 5. Kumarswamy N, Solomon S, Flanigan TP, Hemalathan R, Thyagarajan SP (2003). Natural History of Human Immonodeficiency Virus Disease in Southern India. Clinical Infectious Diseases 36:79-85.
- 6. Laurence P, Coffey S (2003). Overview of Antiretroviral Drugs. University of California San Francisco.
- 7. Marseille E, Hofmann PB, Kahn JG (2002). HIV prevention before HAART in sub-Saharan Africa. Lancet 5; 359(9320):1851-6.
- 8. NACO (National AIDS Control Organisation) (2003). Programme Implementation Guidelines for a phased Scale up of access to Antiretroviral Therapy for People Living with HIV/AIDS.
- 9. NACO, Ministry of Health & Family Welfare, Government of India. Programme Financing.
- 10. Planning Commission, Government of India, Tenth Five Year Plan.
- 11. Porco TC, Martin JN, Shafer K (2004). Decline in HIV infectivity following the introduction of highly active antiretroviral therapy, *AIDS* 18(1):81-88.
- 12. Skiest DJ, Crosby C (2003). Survival is prolonged by highly active antiretroviral therapy in AIDS patients with primary central nervous system lymphoma, AIDS. Volume 17(12) pp 1787-1793
- 13. Solomon S (2004). AIDS Current Status and Year Ahead. Expertspeak, WebHealthCentre.com
- 14. Sahu S, Reuben G, Chauhan LS (2003). Role of WHO Recruited Consultants in Successful Implementation and Expansion of the DOTS Programme in India. Journal of the Indian Medical Association.
- 15. Teixeira PR, Vitória MA, Barcarolo J (2003). The Brazilian Experience in Providing Universal Access to Antiretroviral Therapy; International AIDS Economics Network; Economics of AIDS and access to HIV/AIDS Care in Developing Countries, Issues and Challenges, Chapter 2.
- 16. UNAIDS (2003). AIDS Epidemic Update.

- 17. WHO (2000a). Health a key to prosperity: success stories in developing countries Thailand achieves sustained reduction in HIV infection rates.
- 18. WHO (2000b). New Data on the Prevention of Mother-to-Child Transmission of HIV and their Policy Implications. Inter-agency task team on Mother-to-Child transmission of HIV.
- 19. WHO (2002). Scaling Up Antiretroviral Therapy in Resource Limited Settings: Guidelines for a Public, Health Approach.
- 20. WHO/UNAIDS (2003). Estimated cost to reach the target of 3 million with access to antiretroviral therapy by 2005 ("3 by 5").
- 21. World Bank (2003). AIDS Regional Update.
- 22. World Bank Operations Evaluation Department (2003). Project Performance Assessment Report; India National AIDS Control Project.