Treating HIV/AIDS patients in India with antiretroviral therapy: a management challenge

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Abstract

India stands at a critical junction of HIV pandemic. Controlling spread of HIV is critical. Ignoring this will lead millions of Indians in grip of this pandemic. Ever since HIV/AIDS was acknowledged as a problem, the strategies to address the issue have focused on prevention, treatment and research. This paper discusses the treatment aspect. With currently available antiretroviral agents, eradication of HIV infection is not likely. The aim of treatment is thus to prolong and improve the quality of life by maintaining maximal suppression of virus replication for as long as possible. Brazil has shown how to implement antiretroviral therapy programme. India has embarked upon an ambitious programme to introduce antiretroviral therapy in six high prevalent states and the national capital. The paper discusses the technical, management and financing challenge in implementing this intervention.

Key words: HIV/AIDS, Antiretroviral therapy, NACO, State AIDS Control Societies

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1. Introduction

The Government of India on November 30, 2003 announced a plan to place 100,000 AIDS cases in India on structured anti-retroviral therapy by the end of 2005 and 15 to 20 per cent additional AIDS cases each year, thereafter, for a period of five years. The first quarter of the free AIDS-drugs initiatives was started from April 2004. The supply of antiretroviral drugs to support the first quarter of this initiative is sourced through the World Health Organisation (WHO) procurement mechanism, and is expected that from the subsequent period, government will enter into a pact for delivery of the medicines with the pharmaceutical companies. Initially the programme will be restricted to six high prevalent states of India with a funding commitment of Rs. 2 billion ($44 million) for the infrastructure needed to implement this programme. Of this amount, Rs. 1.13 billion ($25 million) is meant for medicines and Rs. 0.87 billion ($19 million) for providing infrastructure to screen people for HIV/AIDS infection (NACO 2003). National AIDS Control Organisation (NACO), the nodal agency for implementing HIV/AIDS prevention and control programme in India has drafted "Programme Implementation Guidelines for a phased scale up of access to Antiretroviral Therapy" which deals with detail plan of implementation of antiretroviral drugs to people living with HIV/AIDS.

We observe a degree of ambiguity in the Programme Guideline towards the introduction of antiretroviral therapy as a part of community based or clinic based programme in India. We feel there is considerable management challenge in implementing the proposed programme guidelines. We have made an attempt to present in this paper an analysis of management challenge in implementation of the programme and literature scan on some of the key aspect of introducing antiretroviral therapy in India. We build up our study in the light of three major challenges in

implementation of the programme: technical challenge, financial challenge and management challenge. In doing so, we attempt to address the existing infrastructure of Indian HIV control programme, implication of work flow, management structure and experience of Brazil in implementing antiretroviral therapy as a part of national public health programme. In conclusion we attempt to build up a discussion in the light of the above issues and challenges.

2. Technical issues on initiating antiretroviral therapy

In this section, we discuss issues regarding when to start antiretroviral therapy in HIV positive patients, impact of such therapy on mortality and incidence of opportunistic infections (OI). We build up this section based on various published studies and guidelines available through literature scan. The vital issues we attempt to address here are the period between HIV infections to development of full blown AIDS, the risk of opportunistic infections and time to initiate antiretroviral therapy.

Natural history of the disease

Up to three months of HIV infection, there is often an asymptomatic viraemia (spread of virus in blood stream), during which period although patients are infective, ELISA test for HIV antibodies are negative. Progression to symptomatic disease i.e., the amount of time it takes from HIV infection to become full blown AIDS depends on the general health and nutritional status before and during the time of HIV infection. According to WHO, the average time for an adult is approximately ten years. The median survival for a person with full-blown AIDS and without antiretroviral therapy is 2 years (WHO 2002).

Most of the information regarding natural history of HIV infection is available for developed countries only. Sometimes using these indicators can be problematic in case of developing countries where the local condition and nutrition diet status are likely to be different. Epidemiologists and health planners use the cumulative number of AIDS

cases as the reference point. The criterion used in defining the HIV/AIDS case has implications for who should be included and has need for antiretroviral therapy. There is, however, some agreement on that the criterion based on CD4 cell count may be an effective way to identify the cases that need ARV treatment and should be covered. Figure 1 present graphically the natural history of disease progression corresponding to the number of T-helper lymphocytes per cubic millimeter of blood, known as CD4 cell count.

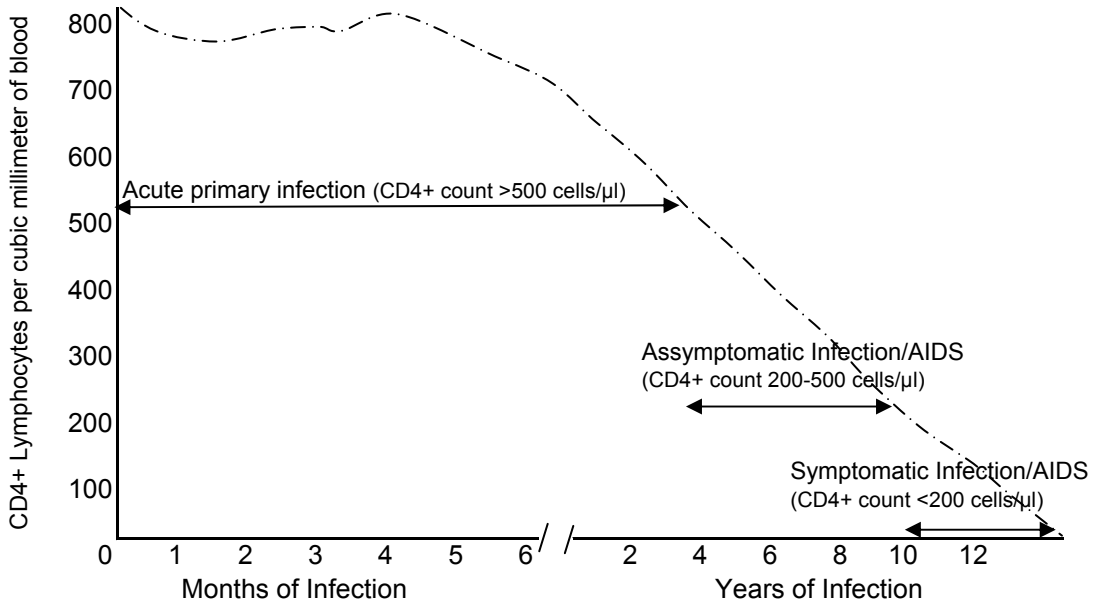

Figure 1: HIV disease progression as compared to the CD4 cell count

Initiating antiretroviral therapy

The Department of Health and Human Services (DHHS), United States, recommends offering treatment to asymptomatic patients with CD4 cell counts of fewer than 200 cells/µL (DHHS 2004). WHO has devised a clinical staging system for HIV infection and disease in adults and adolescents. Details of the WHO clinical staging of HIV/AIDS is given in Appendix 3. WHO recommends that in resource-limited settings persons with symptomatic disease (AIDS, WHO adult stage IV and advanced stage III disease) should receive ARV treatment irrespective of the CD4 cell or total lymphocyte count (WHO

2002). Therapy is also recommended for people with earlier symptomatic (WHO adult stages II and III) and asymptomatic (WHO adult stage I) disease when the CD4 cell count nears or falls below 200 cells/μL or when the CD4 percentage is below 15 per cent. When CD4 cell monitoring is unavailable, treatment is recommended for symptomatic persons (WHO adult stages II and III) with total lymphocyte count (TLC) below 1200/mm^3. Based on the recommendations of panel on clinical practices for treatment of HIV infection convened by the Department of Health and Human Services, an algorithm of the treatment recommendation for HIV patients is presented in Appendix 2 (DHHS 2004).

Positive externalities of antiretroviral therapy

The introduction and widespread use of highly active antiretroviral therapy (HAART) for HIV-infected persons in San Francisco in the late 1990s reduced their risks of infecting partners by 60 percent (Corinna 2003). According to a review of the immunological data (Guislaine, Taisheng and Brigitte 1999), combined drug regimens induce a major and durable viral load reduction and bring about a stable CD4 count increase in infected person. The authors concluded that HAART, at whatever the stage of the disease it is initiated, allows immune restoration and protection against opportunistic pathogens.

Monitoring of patients on antiretroviral therapy

WHO has recommended minimum laboratory tests for monitoring of patients on antiretroviral therapy. This includes HIV antibody test, and hemoglobin or hematocrit level. Highly desirable tests are white blood cell count and differential, CD4 count, serum alanine, aspartate aminotransferase level, serum creatinine, blood urea nitrogen, serum glucose, bilirubin, amylase and serum lipids, and pregnancy tests for women. Ideally CD4 cell count for a patient on HAART should be monitored quarterly. Toxicity should be monitored clinically based on patient reports and physical examination, supplemented by a limited number of laboratory tests depending on the symptoms that arise and the specific combination regimen that is used. According to a

study by YRG care, Chennai, India, total lymphocyte count, hemoglobin (Hg), and weight changes may be able to predict CD4 count change in patients on HAART. The cost of a single CD4 count in resource limited setting in India is approximately $28 and the same for total lymphocyte count is $2.40 per test (Kumarasamy, et.al. 2004).

3. Experience of Brazil in implementing antiretroviral therapy

Brazil is the first developing country to have implemented a large-scale universal antiretroviral distribution programme. There is huge potential for countries like India to learn from the success and challenges of the Brazilian programme in providing free antiretroviral therapy as a part of public health programme. We present a brief literature scan of the financial and logistic management of the Brazilian programme in this section.

The Brazilian response is made possible through a concerted government response and a strong social and political commitment towards the problem. The programme of introducing antiretroviral treatment therapy was adequately supplemented by prevention efforts to control spread of new infections. In 1988, the Brazilian public-health system began to distribute drugs to treat opportunistic infections, and in 1991, began to offer Zidovudine (brand name of AZT, the first antiviral treatment to be approved for use against HIV). In 1996, the government of Brazil initiated a programme of free distribution of drugs to people living with HIV/AIDS. Brazilian government produced domestic generic drugs to contain the drug cost.

Management structure and logistic systems

The programme created a network of more than 1,000 public alternative care and HIV testing services to provide the necessary infrastructure to support this policy. Four hundred twenty four sites, known as AIDS Drugs Dispensing Units (ADDU) were created around Brazil to function as the treatment centres (Jane 2002). The programme implemented a computerised system for control of drug logistics system known as the Sistema de Controle Logístico de Medicamentos (SICLOM), which

registers distribution of antiretroviral, helping to maintain needed stocks of drugs at ADDUs and to track prescriptions. A network of 138 public laboratories was established to test CD4 cell count and viral load of patients. In the year 2001, 138 such laboratories conducted 400,000 tests at a total cost of around US$ 18 million. Another computer system - Sistema de Controle de Exames Laboratoriais (SISCEL) tracks test results and changes of CD4 and viral load for use by clinicians.

Financial implications of the programme

Government's spending on antiretrovirals was: US$ 34 million in 1996; $224 million in 1997; $305 million in 1998; $336 million in 1999; $303 million in 2000; and $ 235 million by 2001. On an average Brazil spend 2 per cent of total health budget on antiretroviral therapy programme.

Average cost of ARV drugs per patient		Government spending on ARV drugs			
Year	Cost (USD)	Year	Cost (Million USD)	Avg. # of patients	% of health dept budget
1996	$ 3,810	1997	224	35,900	1.2
1997	$ 4,860	1998	305	55,600	1.8
1998	$ 4,540	1999	336	73,000	3.2
1999	$ 4,240	2000	303	87,500	2.9
2000	$ 3,320	2001	235	105,150	1.6
2001	$ 2,530	2002	167	125,000	1.8
Source: Brazilian Ministry of Health					

Scale and scope of the programme

The $300 million annual expenditure on antiretroviral therapy in Brazil has proved to be cost effective, because it outweighs what would otherwise have to be spent on hospitalisation, on drugs for opportunistic infections, and on coping with large numbers of people unable to work. An evaluation of the results of the Brazilian AIDS policy shows a striking reduction in mortality (40-70 per cent), morbidity (60-80 per cent) and hospitalisation rates of HIV+ patients, with more than 90,000 avoided deaths and 60,000 AIDS cases prevented. During the period more than 358,000 AIDS-related hospital admissions were avoided. This resulted in savings to the Government of more than US$1.1 billion from 1997 to 2001. However, when an additional US$1.2 billion saved on ambulatory care, including drugs for opportunistic infections, were taken into consideration, the total amount rises to approximately US$2 billion (Chequer, Hearst and Hudes 1992; Marins 2002).

Achievement of the programme

Initiated in the early 1990s with the distribution of AZT, Brazil now provides free antiretroviral medication to about 125,000 patients, which reflects coverage of virtually all people living with HIV/AIDS. By March 2002, close to 240,000 AIDS cases (Table 1) reported to the Ministry of Health (MOH) and an estimated 35,900 individuals received these drugs in 1997; 55,600 in 1998; 73,000 in 1999; 87,500 in 2000; and 105,000 in 2001 (Jane 2002). During 2002, about 125,000 patients received ARV freely in Brazil which

means more than a third of the estimated total number of ARV treated patients in the entire developing world at the end of 2002 live in Brazil (Teixeria, Vitoria and Barcarolo 2003). In the mid-nineties, the World Bank estimated 1.2 million Brazilians would be infected with HIV by the year 2000. Today, the number of those estimated to be infected with the virus is half that amount.

4. Management issues in initiating antiretroviral therapy

The Brazilian experience shows that the delivery of antiretroviral drugs to large number of persons living with HIV/AIDS (PLWHAS) is a challenging task owing to physical infrastructure requirements and coordination among care providers at different levels. Managers of the programme have to successfully overcome challenges in service delivery and challenges related to roles and responsibility of people in the health sector. Managers have to worry about organisational behaviour of healthcare professional and its related structural rigidities owing to high people interface in health service sector. To examine the roles and responsibility and other organisational issues, we present a brief review of the NACO programme guidelines, organisation of healthcare system in India and organisation of HIV/AIDS programme.

NACO Programme Guidelines

HIV/AIDS prevention, care and treatment programme is implemented in India through National AIDS Control Organisation (NACO) as the nodal organisation. It is estimated that about 4.2 million people live with HIV infection in India and 600,000 cases urgently need treatment (WHO 2004). According to the draft policy document for scaling up of antiretroviral therapy in India, the first phase of the NACO programme will be focussed on antiretroviral drug distribution among HIV-positive mothers who have participated in the national prevention of parent-to-child transmission programme (PPTCT), HIV-positive children, and people with AIDS who seek treatment in government hospitals (NACO 2003). Costing an estimated US$100 million a year, the programme will initially cover 15 centres in six states where HIV prevalence

exceeds 1 per cent of women attending antenatal clinics. The second phase of the programme will extend the antiretroviral drug distribution to government hospitals with medical colleges, and the third phase will include all district hospitals in these states. NACO programme also plans to strengthen 540 Voluntary Counselling and Testing Centres (VCTC) existing in the country. The programme envisages community involvement for tracking of people living with HIV/AIDS with the help of trained paramedical personnel, community workers and people living with HIV/AIDS. The programme will be implemented within the existing structure of healthcare sector in India.

Healthcare structure in India

Health is State subject and therefore States are primarily responsible for the healthcare system. The Ministry of Health and Family Welfare at the centre is responsible for planning and coordination of national health programmes implemented through State level infrastructure.

The departments of health in the States are implementing agencies of national health programmes and central sponsored programmes. The state level agencies are also responsible for providing inputs in formulating the key polices to strengthen the national health programmes. These departments are mostly headed by an officer of the rank of Principal Secretary (PS). The PS is subordinated by a Secretary (Family Welfare) and a Commissioner/Director (Health). The Commissonerate or Directorate are the technical wings of the health and family welfare department. At the operational level, the Directorate of Medical, Public Health and Family Welfare Services is responsible for program planning, implementation and monitoring. The directorate works under the supervision and guidance of the respective Secretaries. Additional Directors, Joint Directors and Deputy Directors assist the Directors in various programmes and activities.

Two officers, i.e., the Civil Surgeon-cum-Hospital Superintendent and the Chief Medical & Health Officer (CMHO) mainly look after the district level health administration. The Civil Surgeon-cum-Hospital Superintendent is mainly responsible for management of district hospital (DH). The CMHO is mainly responsible for management of health care set up in rural areas of the district, which includes Community Health Centres (CHCs), Primary Health Centres (PHCs), and Sub-centres (SCs), and also the Civil Hospitals (CHs). The CMHO heads the district management team and supported by officers for various programmes.

Along with the above Public Health System, there exists a complex array of medical systems consisting of several traditional text-based medical systems, modem allopathic medicine, Ayurveda, Unani, Homeopathy, Naturopathy, Traditional Faith Healers and large number of Private Providers both qualified and non qualified in India. In India the private sector provides eighty percent of healthcare through not-for-profit, organised, and informal sectors. While the not-for-profit and organised health sectors are largely concentrated in urban areas, rural areas support a wide range of private health care providers, from allopathic and traditional medical practitioners to faith healers.

HIV/AIDS programme structure and its linkage with healthcare structure

At the central level, National AIDS Control Organisation (NACO) is responsible for planning and implementation of HIV/AIDS control programme in India. NACO is created as a semi-autonomous body within the Ministry of Health and Family Welfare. In order to strengthen programme management at the state level, State AIDS Control Societies (SACS) were organised in every state of India. SACS is responsible for the programme implementation and coordination of AIDS control activities and fund disbursement among NGO partners. SACS are headed by Programme Directors. Besides, several states also have set up a Project Support Units (PSU), which are responsible for project implementation in the state in coordination with NGOs.

The broad responsibilities of SACS are

- Budget allocation and fund release for different HIV/AIDS interventions
- Management of programme on HIV intervention
- Carrying out sentinel and ANC clinic surveillance and report estimated HIV cases in the state
- Carrying out HIV prevention activities

The broad responsibilities of PSU are

- Implementing HIV/AIDS project for SACS
- Implementing Targeted intervention through NGOs
- Carrying out Need Assessment Survey

The HIV/AIDS control programme in India is implemented through the government health infrastructure and public-private partnerships. Treatment and curative centres at the district level are part of the district hospital and tertiary hospitals structure in states. The preventive and promotive programmes are implemented through Chief Medical & Health Officers (CMHO) of every district. Besides this the Project Support Unit is responsible for implementing the projects through NGOs working at the community level.

Service delivery model for the antiretroviral therapy programme

The model for delivery of antiretroviral therapy adopted by NACO is a centralised institutional model supported by NGOs and CBOs. However, the widespread utilisation of traditional practitioners in the country suggests that they are trusted, accessible, and affordable practitioners among a section of population. Moreover, for a problem like STD, HIV/AIDS, lot of taboo/stigma is attached if a person approaches an institution, specially set up for this purpose. People carry negative perception of government healthcare centres for reasons such as improper behaviour of health staff, staff shortages, a lack of supplies and drugs, and long waiting times to see a doctor (Bhat and Maheshwari, 2004). The availability of female doctors, nurses, and midwives

affects choice of health services. This coupled with lack of transport facilities resulted in most of the deliveries in India, non-institutional. According to NFHS 2 survey over eighty percent of deliveries occur at home in rural areas. Traditional Birth Attendants (TBA), popularly known as dais in the community attends 48 percent of the deliveries, another 40 per cent are attended by relatives or others and only 11 percent are attended by a doctor or nurse-midwife at home. This poor rate of institutional delivery raises serious doubt about control and treatment of AIDS among sero-positive mothers and children below the age of 15 years as envisaged in the programme documents.

Given that about 57 per cent of hospitals and 32 per cent of hospital beds are in the private sector (Bhat 1999) and 80 per cent of 390,000 qualified allopathic doctors registered with medical councils of India are working in the private sector (Jesani 1989; Bhat 1996), antiretroviral drug distribution among HIV-positive mothers who have participated in the national prevention of parent-to-child transmission programme (PPTCT) will account for a small fraction of the problem.

The NACO programme document envisages bringing to centre-stage the HIV-TB co-infection through linkages with the TB control programme for free treatment of TB among people living with HIV/AIDS. According to a report 50 per cent of the tuberculosis patients approach private providers first for relief (Narayanan, Santha and Paul 2003). Their relative advantages include easy access, convenient timings, better communication, greater confidentiality and perception of better quality of care. Study on government service delivery mechanism shows that often doctors are available at the health facility only for 3-4 hours on a working day. Employees at health centres are not available on holidays and vacations, which are nearly 40 per cent of days in a year in India in government services (Mavalankar 1999b). Hence, to build up an effective service delivery model for antiretroviral therapy drug distribution through government facilities would be grossly inadequate. There is a need for an effective mix of public private partnership and greater involvement of private providers in the

system. Rather than a centralised institutional model, a community-based model would be more appropriate for drug administration and follow up of PLWHAS. The community based model would essentially require re-examination of roles and responsibilities at different levels.

Programme on making antiretroviral drugs available to the needy people involve the following process: (a) case identification, (b) treatment and drug distribution, (c) monitoring the progress, and (d) managing opportunistic infections and side effects due to the drugs. We attempt to describe the process involved in each of the issues along with the probable providers for the services.

Case identification: It is the first step for drug therapy of PLWHAS. WHO recommends initiating antiretroviral therapy for persons with symptomatic disease irrespective of the CD4 cell count and for persons with asymptomatic stage antiretroviral therapy should be initiated when CD4 cell count nears or falls below 200 cells/μL (WHO 2002). Implementation of this recommendation essentially leads to two challenges. The soft challenge is regarding the availability and behaviour of service providers and the hard challenge relates to the physical infrastructure.

Given, the difficult reach to the healthcare centres in many areas, lack of transport facilities and inadequate service providers, private providers, NGOs, CBOs, PLWHAs and health workers - ANMs and MPWs have a greater role in primary screening of patient through motivating patients to undertake testing for CD4 cell count and thereby enrol for treatment of antiretroviral drugs therapy. A proper symptom checklist and training of the health workers and private providers may suffice the need. However, this should be supplemented by adequate infrastructure for service delivery and laboratories for clinical examination and testing of the patients for their treatment requirements.

Treatment and drug distribution: Antiretroviral therapy regimens available in the market involve a cocktail of three drugs to be taken twice daily. Hence, the primary point of concern for building up a successful response with antiretroviral therapy is timely supply of drugs to the patients on treatment. It has been one of the key reasons for success of Revised National Tuberculosis Control Programme (Narayanan, Santha and Paul 2003). Although treatment initiation and supervision is to be done at the secondary health facilities for example district hospitals and above; primary health centres, ANMs, MPWs, NGOs, CBOs can be empowered for drug delivery and monitoring of the patient progress. Private providers can play a key role with proper monitoring at the local level.

Monitoring the progress: Proper monitoring of patients on treatment is a vital element for treatment adherence and performance of the drugs. Patient has to be monitored for their viral load count in the blood. The YRG Care study shows that total lymphocyte count, haemoglobin (Hg), and weight changes are cost effective and able predictors of CD4 count changes in patients. The facility for total lymphocyte (type of white blood cell involved in human body immune system) counts is available in majority of the primary health centres in India. The toxicity of drugs could be monitored clinically based on patient reports and physical examination, supplemented by a limited number of laboratory tests depending on the symptoms that arise and the specific combination regimen that is used. This becomes important as drug toxicity is often identified as symptoms of AIDS leading to treatment failure among the patients. Hence the patient, family/community members need to be properly sensitised about the different aspects of treatment adherence. Moreover efforts to de-stigmatise the community about the disease will help in a long way to deal with the problem. Primary healthcare system, private providers and NGOs can play a vital role in the monitoring process. With proper facilitation and supervision from the healthcare system, an effective monitoring system can be developed.

Managing opportunistic infections (OIs) and side-effects due to the drugs: HIV infected patients die due to the opportunistic infections owing to reduced immune system of the body. Simultaneously the antiretroviral drugs, as mentioned above, often cause high toxicity leading to treatment failure. Hence, the management risk of opportunistic infections and drug side effects is crucial for this sector. These twin issues have to be effectively dealt with on two fronts – treatment and sensitisation. Until patients are well sensitised about the issues, proper treatment adherence is difficult to achieve. The sensitisation of the patient and community members could be done at the community level with the involvement of ANMs, MPWs, NGOs, CBOs, and private providers. The sensitisation has to be on a wide range of issues, like preventive aspects, risk of transmission during the treatment period etc.

Based on the data and information available, we attempt to map the different HIV/AIDS services into different service delivery settings. Table 1 proposes an optimal level of service delivery in terms of provision of services in various settings. As emphasised in the above table, it is expected that grass root bodies like government sub-centres, primary health centres and different community based organisations and private clinics will play a wider role in the area of promotional activities, preliminary screening of patients requiring antiretroviral therapy, counselling and care of patients, case identification and monitoring the progress of patients at community level. However, there are several challenges in expecting the services of grass root public delivery organisations and involving private providers in implementation of antiretroviral therapy. Some of the challenges are mentioned below:

Non availability of staff: Employees at health centres are not available on holidays and vacations, which are nearly 40 per cent of days in a year in India in government services (Mavalankar, 1999a). In the absence staff, there is none at primary health centres and Community health centres to provide care. It is estimated that only 52 percent of staff of PHCs, located in villages, stay at the place of their postings (Mavalankar, 1999a). Rest of them prefer to stay in nearby towns from where they

commute daily. There are evidences to show that staff members are irregular to health facilities on working days. The doctors and staff are found reluctant to work in rural areas owing to not only physical hardships but also owing to lack of professional growth opportunities. Further, often doctors are available at the health facility only for 3-4 hours on a working day (Mavalankar, 1999a).

Table 1: Mapping of service provision

Service Provider / Intervention	Government						Private		
	SC	PHC	CHC	DH/VCTC	TH/VCTC	BB	Clinic	PH	NGOs
Prevention									
Blood Safety			**	****	****	****		****	
PPTCT			***	****	****			***	
STI Clinic		***	****	****	****			***	
Targeted Intervention	***						**	****	****
Promotion									
Condom Promotion	****	****	**	**	*	***	***	****	****
IEC	****	****	**	**	*	***	***	****	****
Family Health Awareness Campaign	****	****	**	**	*	***	***	****	****
Screening of patients									
Preliminary Screening	****	***					****		****
Clinical Screening		**	**	****	****			***	
Counselling and Care	*	**	**	****	****	***	**	****	****
Treatment for OIs									
High Complexity		*	***	****	****		*	***	
Medium Complexity		**	**	***	***		**	****	
Lower Complexity		***	****	**	**		***	***	
Treatment with ARV	*	**	***	****	****		**	****	**

This table uses asterisks to indicate desirability of services in various settings. Four asterisks to no asterisk indicate: high presence, medium presence, moderate presence, low presence and no presence. The definition of other terms used in the table is as follows: SC: sub-centre, PHC: primary health centre, CHC: community health centre, DH: district hospital, TH: teaching hospital, VCTC: voluntary counselling and testing centre, BB: blood bank, Clinic: private clinic, PH: private hospital, NGO: non-government organisation, PPTCT: prevention of parent to child transmission, STI: sexually transmitted infection, IEC: information, education and communication, OI: opportunistic infection, ARV: antiretroviral therapy

Competency of physicians: The supply of trained and competent physicians who can prescribe ARV is a major concern for success of the programme. With a greater number of doctors willing and able to treat HIV positive patients as per recommended guidelines, there will be greater willingness on the part of individuals to access such treatment. According to a research study (Gupta and Sankar 2003), unless the doctors seeing the patients explain or mention about ARV, there is no easy way for patients to even consider antiretroviral therapy.

Capacity issues and regulatory concerns: An estimated one million illegal practitioners are said to be managing 50-70 per cent of primary consultations, mostly for minor illnesses and form the de facto primary curative healthcare system of rural India. According to a rough estimate, the number of voluntary organisations working in healthcare areas in India is more than 7000 (Mishra 2000). These NGOs have the potential to improve access, quality and equity of services, either through direct provision or through advocacy and other action. The challenge is to devise innovative mechanisms that address distortions and malpractices, yet do not stifle private initiatives particularly in backward states and remote areas, and to ensure systems that will keep such participation accountable and transparent. The specific areas identified in which private practitioners and NGOs could make a significant contribution in treatment with antiretroviral therapy programme are: advocacy; case management; counselling and health education; improving case notifications, and liaising with other stakeholders such as business and industry for increased commitment to national control efforts and resource mobilisation.

Solution to these challenges requires interventions in the structure and policies of the health sector, HR policies and practices and monitoring mechanisms. Treating a patient requires different tasks to be carried out by variety of experts who possess different skills and who need to cooperate with each other (Lee 2001). Effectiveness of health system is dependent upon availability of adequately skilled personnel who

exhibit spontaneous intrinsic cooperative response towards other stakeholders in the system.

Challenge in roles and responsibility in health sector: In order to address the challenge in service delivery model and greater involvement of community in the delivery of antiretroviral drugs, the roles and responsibilities of health professionals needs to be redefined. This requires addressing the issues of roles, responsibilities and structural rigidities. Currently health professionals at district level perform three distinct activities. These are regulating and monitoring, provision of health care services and facilitating and coordinating the provision of services. These are summarised in the following table adopted from Bhat and Maheshwari (2004)

Table 2: Roles and responsibilities in health sector

Activities	Regulation	Service delivery	Facilitating the services
Goals and objectives	Implementing the laws and standards to protect the health of people like laws related to adulteration of food articles.	Caring the patient	Coordinating between personnel responsible for different health schemes
Expected behaviour	Authority driven Top-down communication Paternalistic Bureaucratic behaviour	Influence driven Bottom-up communication Benevolent leadership Pro-social behaviour	Coordinating abilities Both-way communication Customer sensitive
Supportive structure	Centralised decision-making High power distance between different levels Long hierarchy	Empowerment at lower levels Low power distance between different levels Short hierarchy	Democratic decision-making Equitable power distribution Medium hierarchy
Assumptions behind the structural design	Do not trust people unless proved worthy of that Do not leave things to chance	Trust people unless proved unworthy of that	Neither trust them not mistrust them, be open to examination every time.

The three different roles of district health officials require three different patterns of behaviour. In order to perform these roles effectively, the health systems lack enabling structures and communication process. The existing structure, with serious inherent rigidities is inadequate to manage these roles effectively. The structural rigidities of health system are explained by Bhat and Maheshwari (2004) as:

- **Operating islands** characterised by very little coordination and communication between centre, state, district, sub-division, blocks, sectors and villages with highly unpredictable resource flows, high variability in performance and inconsistent practices.

- **Fragmented sector** characterised by very little coordination across Health, Family Welfare and Indian System of Medicine (ISM) and

- **Broken hierarchy** characterised by little influence to steer the programme and lack of clarity on linkages and resource flows, inadequate role in strategic planning and policy and considerable gaps in capacities.

The structural rigidities and discontinuities have instigated mechanistic system of decision-making in the health sector. Over the years many of these rigidities have been reinforced and have to a large extent been institutionalised by centralising decision-making powers at the state and central level. This centralised decision-making over a period of time has seriously affected the creativity and commitment among the healthcare providers in the system.

Further, the HR systems are not performance-driven. They are seniority driven, instead. Consequently the performance focus in the state is found to be low. The healthcare personnel primarily concentrate on meeting the documented targets relating to different national programmes than to quality of care to patients visiting the health facilities. Without addressing this issue, it will be difficult to implement a

decentralised HIV/AIDS programme. The treatment process as envisaged for effective implementation of HIV/AIDS programme would essentially require a network of sustained relationships between care providers at different levels. It may essentially happen through informal channels of communication and networking.

HIV/AIDS sector requires extremely high sensitivity of the care providers owing to associated stigma issues. This sensitivity could be ensured through pro-social behavior (Table 2). This behaviour essentially requires high organisational and occupational commitment of health professionals and professional competency development of healthcare providers. The current structures, processes and systems that prevail in most of the state do not instill confidence that such behaviour could be achieved in near future. NACO would be able to implement the programme better by enhancing the professional commitment of healthcare providers. The professional commitment could be enhanced by investment in professional competencies of doctors and other technical staff and intense socialisation on technical issues through conferences, debates and discussions. The application of technology could be effectively utilised for technical discussions.

5. Financial challenge for initiating and up scaling antiretroviral therapy

The task of providing antiretroviral therapy to HIV infected people requires substantial financial commitment. The tenth five-year plan of India 2002-2007 provides an outlay to the tune of 14 per cent of total central health budget for implementation of HIV/AIDS control programme (Rs. 1270 crores for implementation of the HIV/AIDS Control Programme as against a total budgetary outlay of Rs. 9253 cores for the Ministry of Health & Family Welfare). But the entire amount is primarily meant for prevention and promotion approach. The details of allocation and expenditure for the Indian National AIDS Control Organisation are discussed in detail in Bhat and Saha (2004). Recently, India and the Global Fund to Fight AIDS, Tuberculosis and Malaria signed two grant agreements that will allow the disbursement of $33 million over the

next two years and a total of $129 million over five years (Times of India). The grants, which were approved on 30th January 2003, during the Global Fund's second round of grant proposals, will be used to expand the country's national HIV/AIDS and TB prevention and control programme. In its third round of grants, the fund approved another $15 million for Indian HIV/AIDS and TB prevention and treatment programmes. Overall, the Global Fund has committed to India $153 million over five years (Times of India). Most of the money from the Global Fund will go toward the provision and administration of antiretroviral drugs to HIV-positive people (Global Fund 2004). Responding to the problem effectively, however, requires significant financial commitment. The success story of Thailand is probably of greatest relevance to India. According to reports, Thailand spends roughly 55 cents per person on prevention and treatment, Uganda $ 1.85, but India only about 17 cents. In 2000 (the latest year for which comparative figures exist), India spend only $17 per person on health, of which four-fifths was in the private sector; indeed, on one measure government health spending was only $4 per person. India is one of only eight countries whose public-health budget is less than 1 per cent of GDP.

The cheapest triple combination antiretroviral therapy available as of now is of the Indian pharmaceutical companies agreeing with Clinton Foundation at prices close to Rs. 17 per day per patient ($140 or about Rs. 6,078 for a year). The Clinton Foundation has secured a deal with five manufacturers of CD4 and viral load tests, the cost of a CD4 cell count will fall from $11 - $12 to between $3 - $5, with no up front payment for machines. Under the agreement, the cost of a viral load test is confidential, but is thought to have been reduced to around $20 a test. The machines for carrying out the tests will be maintained and serviced by the manufacturers, and they will also provide training in how to carry out the tests. (Wall Street Journal 14th January 2004).

The Government of India has estimated that the total fund required for placing 100,000 patients on antiretroviral therapy by 2005 will be Rs. 2 billion ($44 million).

However, the programme documents are silent on quantifying the system up-gradation required to meet the challenge of providing and monitoring antiretroviral therapy to the patients. 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. According to a study (Bhat and Saha 2004) under conservative estimate, the annual combined cost of screening, cost of anti-retroviral therapy and monitoring the progress of patients in India, the annual cost of the programme will be Rs. 1.87 billion ($427 per patient) under the presumption of CD4 cell count test at Rs. 1200 per test and Rs. 0.92 billion ($210 per patient) under the presumption that CD4 cell count test will be available at Rs. 243 per test. The study presumed that 400000 HIV infected case would be placed under screening and 100000 cases will be placed under structure antiretroviral therapy annually. However, the study does not include cost of additional infrastructure needed to upscale the programme and costs related to human resource mobilisation. Quantification, procurement, and supply chain management of HIV test kits and other commodities are a major challenge as well for the programme managers. The summarised study result is given in Table 3.

Table 3: Per annum cost (in millions of rupees) of treating 100,000 population

Price (assumption)	Scenario 1		Scenario 2
	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

Source: Bhat and Saha (2004)

6. Conclusion

India stands at a critical junction of HIV pandemic. If the rate of HIV infection were to rise by just a few percentage points, millions more Indians will be affected by the virus. Ever since HIV/AIDS was acknowledged as a problem, the strategies to address the issue have focused on it as a disease. Little has been done to address the root causes of vulnerability to infection. The strategies in this area have focused on prevention, treatment and research. This paper discussed the treatment aspect. With currently available antiretroviral agents, eradication of HIV infection is not likely. The aim of treatment is thus to prolong and improve the quality of life by maintaining maximal suppression of virus replication for as long as possible (WHO 2002). Brazil has shown how to achieve success with antiretroviral therapy programme. In Brazil, for example introduction of antiretroviral therapy has increased the survival time from less than 6 months to close to 5 years. In a study in India by YRG care, the median duration of survival for subjects who initiated antiretroviral therapy when their CD4 lymphocyte counts were less than 200 cells/mL was 45 months; for those with comparable CD4 lymphocyte counts who did not receive antiretroviral therapy, the median duration of survival was only 33 months. On the other hand effort to stop treatment in patients on HAART has met with limited success so far. A critical question for any government considering initiation of ARV is how long the patient will have to continue on these drugs. Studies have produced a varying result on the same and the general remark is that patient may have to continue to receive ARVs for the rest of life.

India has embarked upon an ambitious programme to introduce antiretroviral therapy in six high prevalent states and the national capital. However, there seems to be several missing links in the programme. A programme of this scale needs better counselling in order to ensure that persons who are diagnosed and who don't need ARV's immediately should learn how to manage their immune function without the medicine, similarly they need to be counselled for their nutritional requirement which are crucial for patients infected with HIV. Supply chain management is probably the

key issue in the programme. To start them and then find that there are insufficient resources to continue the supply, such as what is now happening in Nigeria may be counterproductive. A report compiled by Kaiser Family Foundation, the National Association of State and Territorial AIDS Directors and the AIDS treatment data network shows that United States itself is struggling to provide antiretroviral therapy to poor patients and in many cases are forced to limit the drugs in order to cut down cost. The high costs of drugs has forced 1,263 patients in nine states to be on waiting lists as of April 2004, in spite of a 9 per cent increase in overall budget to provide the antiretroviral drugs to the poor patients.

A research study (Gupta and Sankar 2003) conducted in Delhi, Mumbai and Chennai among people living with HIV/AIDS and undertaking treatment in several hospitals of the states found that as many as 29 per cent of respondents ever been on ART reported non-adherence and 72 per cent of them sited economic factors as the reason for non-adherence. This figure will only go to the higher side if taken at national level. Hence, we suggest a high degree of advocacy is needed in order to disseminate information regarding recent development in drugs and monitoring front of delivering antiretroviral therapy. This paper is aimed to be a step in this direction.

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Appendix 1

The information presented here are adopted from various sources

Seroconversion

Primary HIV infection occurs when HIV first enters the body, it encounters the immune system and begins to produce new virus (viral replication). Seroconversion is the development of detectable antibodies in the blood as a result of infection, or in other terms going from negative HIV status to positive HIV status. Antibodies are proteins produced in the body in response to a foreigner, like HIV. They contribute to the destruction of the virus at first, but the virus eventually takes over leaving the host extremely susceptible to other infections and diseases. It has been estimated that 95 – 99 per cent of individuals infected with HIV will seroconvert within 6-12 weeks of exposure although in some it may take longer. Two important factors in determining survival and progression to AIDS are age at seroconversion and time elapsed since seroconversion. The vast majority of people will develop AIDS within 20 years after seroconversion.

T-Cell (CD4) Counts

CD4 cell count correspondence to the number of T-helper lymphocytes per cubic millimeter of blood. T-helper lymphocytes help to organise body's defences against disease. Healthy adults and teenagers usually have a CD4 count of at least 800 cells per cubic millimeter of blood (a cubic millimeter is a very small amount, roughly one small drop). HIV attacks CD4 cells, and as time goes by people with HIV often see their CD4 counts drop. The lower the CD4 count, the greater is the chance of getting a number of very serious diseases. When your CD4 count is below 200, the risk of illness becomes severe.

Viral load

The viral load refers to the level or concentration of HIV in the blood. The level of the virus in the blood (viral load) indicates how fast the virus is multiplying and also how well or how poorly the virus is being controlled by the immune system. There are several tests that can be used to measure the viral load. These tests can measure any level from as low as 50 viruses per millilitre of blood (50 virus copies/ml) to as high as 10 million viruses per millilitre. The higher the viral load, the more rapidly the virus is multiplying and the more quickly a person will develop AIDS.

A rough guide:

- Viral load higher than 100,000 copies/ml: rapid disease progression
- Viral load between 10,000 and 100,000 copies/ml: average disease progression
- Viral load lower than 10,000 copies/ml: slow disease progression.

Candidiasis

Candidiasis is a fungal infection of the mucous membranes. This fungus appears not only on mucous membranes but on the skin so there is really no way to avoid exposure. Candidiasis usually occurs in the mouth and throat (oral candidiasis), the vagina (vaginal candidiasis) and the esophagus (esophageal candidiasis).

Cryptosporidiosis
Cryptosporidiosis is caused by the protozoan parasite Crypto sporidium parvum. When ingested it can be responsible for an extremely debilitating illness. The protozoan parasite infects cells lining in the digestive track - the small intestine, the airways and lung, bile duct and the colon and other gastrointestinal tract areas. This opportunistic protozoan is very contagious and causes diarrhoea of varying severity in immuno-compromised patients. Cryptosporidiosis is usually not an early opportunistic infection but normally appears in advanced stages of HIV disease.

Cryptococcoses
Cryptococcoses is the most common cause of meningitis in patients with advanced HIV disease and is caused by the yeast *Cryptococcoses neoformanf*--a harmless fungus that lives in soil, especially in soil fertilised by bird droppings. This fungus is found the world over and when inhaled by a normal host it is contained in the lungs, but when inhaled by an HIV-infected person it can cause infection in the pulmonary system, the retina, the central nervous system, the skin, bones, lymph nodes and other disseminated areas.

Cytomegalovirus Disease
Cytomegalovirus (CMV) is latent in most persons with HIV - in nearly 70 per cent of heterosexuals and 95 per cent of gay men. The virus typically reactivates in persons whose CD4 cell counts fall below 100 or, more frequently, below 50. It can affect virtually any organ however, and less frequently, though increasing in incidence, can cause neurological disease including encephalitis and very rarely pulmonary disease suggesting CMV dissemination.

Histoplasmosis
Histoplasmosis is a fungal infection that affects the lungs and respiratory system. A person can acquire histoplasmosis if they inhale air which contains the spores of the fungus Histoplasma capsulatum. In episodes of histoplasmosis where the infected person has a healthy immune system, there are often no symptoms. This is referred to as "acute self-limited histoplasmosis". If the person does develop symptoms, they are most often flu-like in nature, such as fever, cough, fatigue and chest pain. Symptoms usually appear ten days after exposure, and subside without treatment after a few weeks. When symptoms disappear, it is unusual for there to be long-term ill effects.

HIV-Related Malignancies: Kaposi's Sarcoma
Kaposi's sarcoma (KS) is a lesion-producing cancer of the lining of blood vessels that can be disfiguring and has a clinical course than can range from incidental or minimal

disease to a rapid, widespread tumour growth, depending on the individual. KS appears most frequently in those who acquire HIV sexually.

Mycobacterium Avium Complex

Mycobacterium avium complex or MAC disease is now regarded as one of the most common opportunistic infections in persons with AIDS and the most common bacterial infection. It is:

- usually one of the last opportunistic infections to be seen in persons with AIDS and is usually a sign of advanced HIV progression and significant immune suppression, most often appearing in those with a CD4 lymphocyte account below 50 cells per mm.
- is most often preceded by a prior HIV-related opportunistic infection
- does not occur in any specific HIV-infected group more than another -- occurring in all risk groups, races and ages who have advanced HIV disease.

It is believed that patients whose immune systems progressively worsen and reach CD4 lymphocyte counts as low as 10 cells per mm are at high risk for ultimately developing the disease.

Pneumocystis Carinii Pneumonia

Pneumocystis carinii is a microorganism. It does not respond to antifungal therapy, but shows pliancy to antiprotozoal therapy. *Pneumocystis carinii* pneumonia (PCP) is the most common opportunistic infection seen in patients with AIDS - and has been since the beginning of the HIV epidemic.

Toxoplasmosis

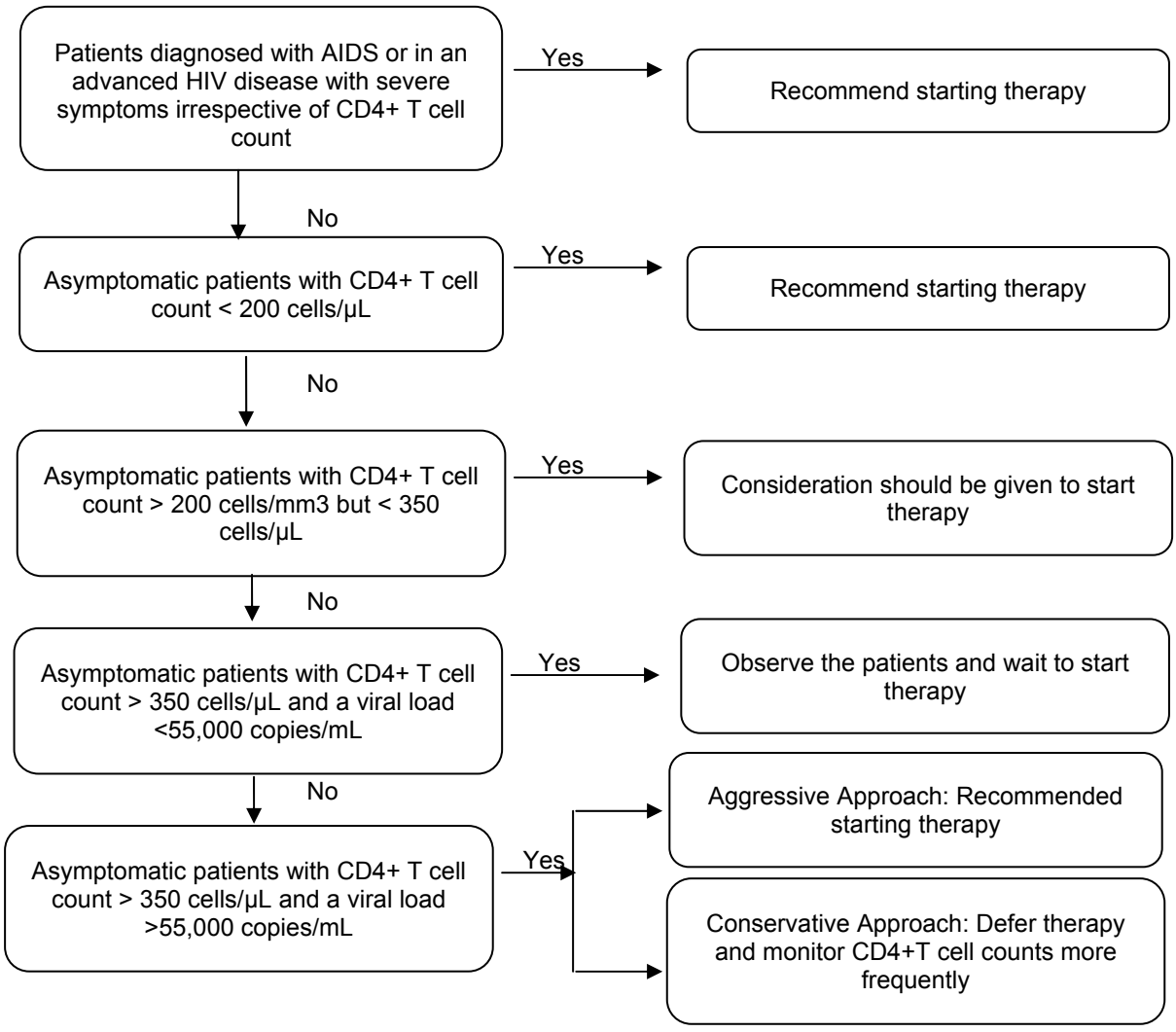
In patients with advanced HIV disease toxoplasmosis is a common infection of the central nervous system where it accounts for nearly 15 per cent of central nervous system infections and the disease in itself is an AIDS-defining diagnosis. *T. gondii* or *toxoplasma gondii* is an intracellular protozoan found in many birds and mammals as well as in humans who either ingest this protozoan parasite through the mouth or acquire it congenitally from a mother who was infected with the protozoan during pregnancy.

Tuberculosis

Tuberculosis occurs in 4 per cent of patients who have AIDS and in fact Mycobacterium tuberculosis located in any site in immunocompromised persons whose CD4 cells per microliter of blood are less than 200 is considered an AIDS-defining disease. TB is an infectious disease and can be transmitted by microscopic particles released in the air by the cough or sneeze of someone with active TB, though usually infection is the result of prolonged exposure to someone with TB.

Appendix 2

When to start Antiretroviral Therapy



Appendix 3

WHO staging system for HIV infection and disease in adults and adolescents

Clinical stage I (Performance scale 1: asymptomatic, normal activity)

1. Asymptomatic
2. Persistent generalised lymphadenopathy

Clinical stage II (and/or performance scale 2: symptomatic, normal activity)

3. Weight loss, < 10% of body weight
4. Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis)
5. Herpes zoster within the last five years
6. Recurrent upper respiratory tract infections (i.e. bacterial sinusitis)

Clinical stage III (and/or performance scale 3: bedridden < 50% of the day during the last month)

7. Weight loss, > 10% of body weight
8. Unexplained chronic diarrhoea, > 1 month
9. Unexplained prolonged fever (intermittent or constant), > 1 month
10. Oral candidiasis (thrush)
11. Oral hairy leukoplakia
12. Pulmonary tuberculosis within the past year
13. Severe bacterial infections (i.e. pneumonia, pyomyositis)

Clinical stage IV (and/or performance scale 4: bedridden > 50% of the day during the last month)

14. HIV wasting syndrome, as defined by the Centres for Disease Control and Prevention[a]
15. *Pneumocystis carinii* pneumonia
16. Toxoplasmosis of the brain
17. Cryptosporidiosis with diarrhoea > 1 month
18. Cryptococcosis, extrapulmonary
19. Cytomegalovirus disease of an organ other than liver, spleen or lymph nodes
20. Herpes simplex virus infection, mucocutaneous > 1 month, or visceral any duration
21. Progressive multifocal leukoencephalopathy
22. Any disseminated endemic mycosis (i.e. histoplasmosis, coccidioidomycosis)
23. Candidiasis of the oesophagus, trachea, bronchi or lungs
24. Atypical mycobacteriosis, disseminated
25. Non-typhoid *Salmonella* septicaemia
26. Extrapulmonary tuberculosis
27. Lymphoma
28. Kaposi's sarcoma
29. HIV encephalopathy, as defined by the Centres for Disease Control and Prevention.[b]

Note: both definitive and presumptive diagnoses are acceptable.

a. HIV wasting syndrome: weight loss of > 10% of body weight, plus either unexplained chronic diarrhoea (> 1 month) or chronic weakness and unexplained prolonged fever (> 1 month).
b. HIV encephalopathy: clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a

concurrent illness or condition other than HIV infection which could explain the findings.