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Research Article

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Equity in HIV/AIDS management and prophylaxis: How free is the free ART program in India?

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ABSTRACT

The concern for most public health policies and decision-makers is the equitable distribution of the nation's healthcare resources. Also, in the public health care system, the primary aim is assuaging the burden of the disease. This study captures and evaluates some important health equity aspects with its relevance with the ART (Antiretroviral Therapy) program in India. The study is an exploratory and descriptive study based on secondary data. The sources of secondary data are published official reports from NACO (National AIDS Control Organization), United Nations AIDS Program (UNAIDS), World Health Organization (WHO) etc. The roll-out of the ART program in 2004 by the Govt. of India made a paradigm shift in the HIV/AIDS scenario in the country. "The adult HIV prevalence at the national level has continued its steady decline from an estimated level of 0.41% in 2001 through 0.35% in 2006 to 0.27% in 2011". Equity in plain words means fairness. In the sense of health policy and HIV/AIDS studies, the reduction in prevalence rate equates to positive health equity. The enervation of HIV infection by taking ART drugs had helped in curbing the prevalence and the fact that it is provided free of cost has proven this program to be the epitome of distributive justice in public health.

KEYWORDS: Health equity, People living with HIV/AIDS, Antiretroviral Therapy (ART)

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INTRODUCTION

The ART (Antiretroviral Therapy) program provides ARV drugs to PLHIV (People living with HIV/AIDS) for free. The model for the delivery of antiretroviral therapy adopted by the National AIDS Control Organization is a centralized one. This public health policy was initiated in 2004 by the Ministry of Health and Family Welfare, Government of India lauded as game-changing in the fight against the HIV epidemic. On 1st April 2004, the Government of India launched free ART under the second phase of the National AIDS Control Program at 8 centres. As of 2016, there are 528 ART centres operating in the country; these centres promote the delivery of medicines (ARV drugs) and provide counselling to patients from time to time. But, why is it important that this one policy is considered the very best?

In this study, we will try to understand the credibility of the former question posed and not just the rhetoric. In health economics and policy-making, one key assumption is that it should be efficient and equitable. To elucidate this point in the context of HIV/AIDS is that; when a person gets infected by HIV, he/she shall get the adequate treatment required without any discrimination whatsoever. The launching of the "Test and Treat" model on 28th April 2017 by the Government of India to put People Living with HIV (PLHIV) on ART as soon as they are detected HIV positive, irrespective of their CD4 count. The main objective here is to improve the survival rate and quality of life of HIV patients at the individual level.

Programs on making antiretroviral drugs available to the HIV-patients 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. The attempt is to describe the process involved in each of the issues along with the probable providers for the services.

Case Identification: Testing and Pre-ART

In an event of possible HIV infection, the route of transmission of the disease is traced. The routes of transmission are sharing of syringes amongst intravenous drug users, having unprotected intercourse with an infected person, vertical transmission i.e. from infected mother to child and unsafe blood transfusion. Since, the main carrier of the pathogen is bodily fluids like blood, semen, lactation etc. Some miscellaneous cases also occur, for

example, syringe accidents in medical profession where a doctor or nurse dealing with an HIV infected patient gets injured by a used needle. Also, in recent years Pre-exposure prophylaxis (PrEP) for HIV is advocated for people who are at significant risk for contracting HIV. In this, the person takes a daily dose of HIV medications (further breakdown will be given in later sections) to prevent them from getting the infection. Research has shown that PrEP has been effective in reducing the risk of HIV infection in people who inject drugs (Centers for Disease Control and Prevention, 2018a).

An individual can get tested for HIV in any private or public health care centre where the facility is available. It can be by one's own choice or as a part of a prescribed procedure by a medical practitioner. The procedure basically involves taking the blood sample of the patient and checking the viral load. CD4 count is a major indicator in deciding which course of action that should be taken towards treatment in case of positive patients.

Treatment and Drug Distribution: Enrollment in ART Program

Once it is known that an individual is HIV- positive, necessary steps to be taken involve checking the patient for co-morbidities, CD4 count and counseling. It is strongly recommended that all pregnant and breastfeeding women and patients with TB co-morbidities be initiated on ART regardless of clinical eligibility.

Clinical eligibility hinges on two main factors: CD4 count and viral load. As mentioned in the previous section, CD4 count and viral load are diagnostic tests that patients have to take regularly. CD4 counts, a component of white blood cells, demonstrate the robustness of the immune system and a healthy immune system normally has a CD4 count ranging from 500 - 1,600 cells per cubic millimeter of blood (cells/mm^3). An HIV viral load test measures the number of HIV particles, also known as "copies" in a milliliter (mL) of blood. The test is very crucial in assessing the progression of HIV in the body. The measure of viral load is useful in seeing how well a person's HIV therapy is managing the virus in their body.

According to WHO, there are several combinations of drugs used for the treatment of HIV/AIDS known commonly as Antiretrovirals (ARVs). ARVs are a mix of two or more combinations of drugs given to HIV infected patients to inhibit further replication of the virus. In the NACO Technical AIDS report, the detailed grouping of ARVs is given. Broadly, categorized under Nucleoside Reverse Transcriptor Inhibitor (NRTI), Non-Nucleoside Reverse Transcriptor Inhibitor (NNRTI), and Protease Inhibitor. In the first line of ART, two types of ARVs are mostly recommended. They are:

1. Nucleoside Reverse Transcriptor Inhibitor (NRTI)
    a. Zidovudine
    b. Lamivudine*
    c. Tenofovir
    d. Stavudine
    e. Abacavir**
2. Non-Nucleoside Reverse Transcriptor Inhibitor (NNRTI)
    a. Nevirapine
    b. Efaviranz

Here, it should be noted that a drug with a single asterisk (*) is most commonly used; while drugs with a double asterisk (**) are prescribed in cases where the patient is suffering from renal damage.

Essentially, in the course of action taken to remedy, there are multiple combination of prescription drugs to be taken by the patient. From time to time routine check-ups and investigations have to be carried out. In the following sections, a brief cost breakdown is given to elucidate the expenditure on treatment.

Once enrolled the CD4 count and viral load that time decides which course of action to be taken.

Monitoring the Progress: Adherence to the Program

After registering in an ART centre, the patient is expected to adhere to the program. Adherence should be assessed and routinely reinforced by the respective HIV care team which includes treating physicians (senior medical officers/medical officers), counsellors, nurses, pharmacists, peer educators, care coordinator, CSC staff and others at each of the patient's visits to the ART centre. The patient has to come and collect his/her dosages routinely on the specified day of each month. For proper monitoring of the advancement/arrest of the disease, CD4 count and viral load test are conducted via blood test once every three months and six months respectively.

A high degree of adherence to the ART program is necessary for the overall well-being of the patient. Consistent usage of ARV drugs is crucial for optimal virological suppression. Studies indicate that > 95% of adherence is required for optimal viral load suppression. Negligence or lesser degrees of adherence are often associated with virological failure.

Common reasons associated with poor adherence include a poor patient-clinician relationship, high pill burden, lack of caregiver, the distance of the ART centre from home, financial problems, home or job work responsibilities, recurrent travel plans, negligence, mental illness, psycho-sociological factors, lack of patient education, the inability of patients to identify their medications, substance abuse, drug toxicity, cultural factors (e.g. fasting for religious purpose), beliefs about treatment, faith in traditional faith healers, false perception of good health and the impression of being too ill for treatment (NACO, 2018).

Here, the cost incurred by the patient is both tangible and intangible. The table below reflects the market price of some of the mandatory diagnostic tests a patient has to undergo at the initial stage of registering to the ART program. After which, CD4 count test and X-ray are routinely required to keep track of healthy immune function and co-morbidity.

Post-exposure prophylaxis (PEP) for HIV is when people take antiretroviral medicines to prevent becoming infected after being potentially exposed to HIV. According to the Centre of Disease Control, PEP should be used within 72 hours after a recent possible exposure and only be used in emergency situations. These situations arise when an individual is exposed to HIV during sex, through sharing needles, or sexual assault (Centers for Disease Control and Prevention, 2018b).

Managing Opportunistic Infections and Side Effects Due to the Drugs

Besides the expected cost, mentioned in Tables 1 & 2, HIV patients are at higher risk of getting infected by infectious diseases; commonly, tuberculosis (TB), Hepatitis, fungal infections, diarrhea etc. The point of caution is that due to their compromised immune system these common ailments can easily turn fatal. Since 2010, the World Health Organization has recommended that ART be started in all TB patients living with HIV, regardless of CD4 cell count, as soon as possible within the first 8 weeks of TB treatment.

Table 1: Cost break-down of prescription ART drugs

Sl. No.	Combination of drugs prescribed	Dosage (per 4 weeks)	Cost in rupees
1	Tenolam E (Lamivudine+Tenofovir+Efaviranz)	Once daily (OD)	1500
2	Tenolam (Lamivudine+Tenofovir)	Twice daily (BD)	1200
3	Virocom N (Zidovudine+Lamivudine+Nepirapine)	Twice daily (BD)	1000
4	Virocom (Zidovudin+Lamivudine)	Once daily (OD)	1300

Table 2: Cost of investigations for diagnosis

Sl.no	Name of test/investigation	Cost in rupees
1	ELISA double test	500
2	Western Blot test (not used nowadays)	-----
3	CD4 count	5000 to 6000
4	X-ray Chest	150

Table 3: Cost of investigations for regulation of treatment

Sl. No.	Name of infection and regulative test	Cost in rupees
1	Tuberculosis (TB)	
a.	X-Ray Chest	150
b.	FNAC of lymph node	300
c.	Sputum examination	100
d.	Mantoux test	50
2	Hepatitis antibodies	
a.	Hepatitis B	150
b.	Hepatitis C	150
3	General investigative tests	
a.	Complete hemogram	300
b.	Liver function test (LFT)	500
c.	Kidney function test (KFT)	500
d.	Blood Sugar	150
e.	VDRL (Venereal Disease Research Laboratory) test	300
f.	CD4 Count	5000

According to guidelines, investigations for regulation of treatment are adviced to the patients for follow-up every six months wherein the individual has to go through the list of investigative tests. Table 3 gives the highlights of the main procedural examination.

Here, it has to be noted that the mentioned costs are only for diagnostic tests i.e. to check the basic information of whether the patient tests negative or positive. For example, in the above table it is mentioned that for Hepatitis B & C, the hepatitis antibodies test will provide the patient with the diagnosis of whether the individual has Hepatitis B or C. In case of positive results, the additional cost of medicine for treatment will be incurred. This shall be discussed in later sections.

Opportunistic infection

1. Fungal infection – fluconazole – Rs. 200/-; Co-trimoxazole – Rs. 100/-
2. Diarrhoea – Nitazoxanide Rs. 300/-
3. Fever – Paracetamol Rs. 100/-
4. TB – Isoniazid, ripampicin, pyrizinamide, ethambutol – Rs. 3000/- (free of cost under national tuberculosis control program)

Hepatitis C Treatment Cost

Names of drugs used

a. Sofosbuvir 400 mg X 12 weeks: Rs. 4000 to 5000/-
b. Ledipasvir 90 mg X 12 weeks: Rs. 5000 to 6000/-
c. Combination of a and b: Rs. 10000 to 12000/-
d. Daclatasvir 60 mg X 12 weeks: Rs. 5000 to 6000/-
e. Rebavirin 200 mg X 12 weeks: Rs. 700/-

Treatment Plan According to Genotype of Hep C Virus

1. For types: I, II, IV, V, VI
   a. Standard – a + b for 12 weeks
   b. With previous treatment/cirrhosis/fibrosis – a + b + d X 24 weeks
2. For type III
   a. Standard – a + c for 12 weeks
   b. With previous treatment/fibrosis/cirrhosis – a + c + d X 24 weeks

Cost of monitoring investigations

1. Rapid Viral Response (RVR)
   a. Viral load – Rs. 12000 to 14000/-
   b. Liver function test (LFT) – Rs. 500 to 600/-
   c. Fibroscan of liver – Rs. 1500/-
2. End of Treatment (ETR)
   a. Viral load
3. Sustained Viral Response (SVR) or Clinical Cure
   a. Viral load – 3 months after completion of AVR therapy

METHODOLOGY AND DATA SOURCES

For this study, secondary data sources published by government sources are used. In India, National AIDS Control Organization (NACO) is an apex body in HIV related research and surveys. Their state branch, State AIDS Control Society (SACS) also releases annual reports on the prevailing HIV/AIDS situation in respective states. International bodies like World Health Organization (WHO) are the most consistent source of secondary data. HIV Estimations are periodic exercises undertaken by the National AIDS Control Program (NACP).

According to India HIV Estimation 2019 report, the estimated adult (15-49 years) HIV prevalence trend is declining in India since the epidemic's peak in the year 2000. The estimate for this indicator was 0.22% (0.17-0.29%) in 2019 (Figure 1).

As reported by HIV Estimations 2019, India maintains a low prevalence rate with an estimated adult (age, 15-49 years) HIV prevalence of 0.22% (0.17-0.29 %) and 23.49 lakh (17.98 - 30.98 lakh) People Living with HIV (PLHIV) in 2019. Of the total PLHIV, 79,000 are Children Living with HIV (CLHIV) accounting for 3.4%. "There were around 69.22 thousand (37.03 – 121.50 thousand) new HIV infections (HIV incidence per 1,000 uninfected population at 0.05 [0.03 – 0.09]) and 58.96 thousand (33.61 -102.16 thousand) AIDS-related deaths in the year 2019". There has been a decline in adult prevalence as noticed in Annual New HIV Infections (ANI), which have declined by 86% since attaining a peak in 1997 and by 37% since 2010. New HIV infections have declined by 23% and AIDS-related mortality declined by 39% between 2010 and 2019, globally (UNAIDS, 2020).

OBSERVATION AND DISCUSSION

With new advances in research and development, the progress in HIV treatment will also change. The rapid change in treatment regimes coupled with stronger and more effective drugs is the resultant product of incessant work both in medical and pharmaceutical research. The benefits of which can be harness in the improved health status of HIV infected individuals. The rationale for equity in ART programs in India is evidenced by the rapid decline in the prevalence rate. The effectiveness issue is covered by the decrease in death rate and the fact that HIV infection is now a chronic but manageable ailment. Also,

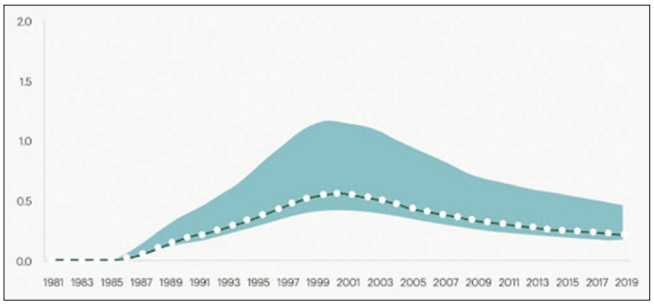

Figure 1: Adult HIV Prevalence in India, 1981-2019 (NACO & ICMR, 2020)

the wide range of services that an ART centre provides to the patients is exemplary of distributive justice.

The goal of ART centres, roughly categorizingas clinical, virological, therapeutic and preventive are holistic in approach in combating the HIV epidemic. The clinical and virological goals aim for better well-being and sustained reduction in viral load, respectively. Achieving these goals benefits the patients' health directly as continued viral suppression over time increase CD4 count, which in turn leads to a reduction in opportunistic infections as well as reduced morbidity and mortality. The therapeutic goal seeks for facilitating future treatment options, limiting toxicity induced by drugs and maintaining adherence to the ART program.

Now, coming to the crux of the study: How free is free ART? By policy and policy implementation, it is provided for free and at no charge at all to whomever it is required. As re-iterated before it is evidently followed in most ART centres. However, if we observe it closely, the cost is acquired in its implementation. Firstly, the cost of travelling to the ART centre is frequent i.e. if a person has to be on 100% adherence he/she has to pay a visit to the centre every month. In theory, once every month may not sound too inconvenient where health and well-being is a concern but if this has to be done lifelong, which is a reality for HIV patients, then the nuisance value is apparent. Yet another factor is that because of the stigma attached to HIV a lot of people who are HIV infected or a caregiver (in case of HIV infected minors) choose to attend ART centres which are further from their dwelling place just to avoid social derision and maintain anonymity. This invariably escalates travel fare and cost of travel by additional cost of food and accommodation, if the person registered in the ART centre in the city or another district.

Secondly, strict guidelines are to be followed in the monitoring of CD4 count and viral load tests. These high-priced tests have to done by the patients repeatedly every 3 months and 6 months. In many cases, ART centres which provide the ARVs are not equipped to carry out these mandatory tests thereby compelling the patients to get it performed elsewhere. Even in instances, where the patient is attending an ART centre attached to huge and well-functioning government medical institutions, the patients' have to foot the bill as there is an overlap and a long waiting list to get the investigative test. Here, the problem is, the test which could be carried out at a much cheaper price in government hospitals is unable to take in the time which is to be presented in the next ART visit. In conditions like these, patients are forced to render services from private hospitals or independent diagnostic centres wherein the cost of each test is understandably steep. This same issue is also true for the other compulsory routine tests of X-ray, Liver function test (LFT) and Kidney function test (KFT).

Thirdly, the issue of absenteeism from work is not because of HIV related illness but to go to an ART centre. It is mainly difficult for patients who are in the informal sector and daily wage earners. The leading issue is the loss of income for the day; by an already economically deprived section of society.

Mostly, in a single ART visit, the collection itself takes very less time which is the time where the concerned pharmacist hands over the required doses of ARVs. Still, even while excluding the wait time, patients have to present the record that the centre maintains for them with their personal records and reports of routine diagnostic tests. This apart, the patient has to meet with a counselor and in times where they have missed the previous visit, has to give an explanation before they are finally allowed to meet the pharmacist. The sensibility behind this procedure is quite straightforward yet it is counter-intuitive in the outcome. Considering the fact that HIV is a chronic disease most patients after a point of time gets too acquainted with the various people (medical officers, counselors and pharmacists) and processes of the ART system. Subsequently, all the processes become repetitive and redundant, resulting in incoherent attendance and worst dropping off from the program altogether.

CONCLUSION

Quoting Noble laureates Banerjee and Duflo (2011), "*--- large-scale waste and policy failure often happen not because of any deep structural problem but because of lazy thinking at the stage of policy design*". The execution of the ART program includes the target population i.e. people who are at risk of getting infected and people who are living with HIV. The decline in the prevalence rate is an indicator of the positive result of the ART program.

In health economics, the perception of health equity is best captured in two concepts: efficaciousness (Can it work?) and effectiveness (Does it work?). Both are examines from the viewpoint of health providers, health consumers and societal perspectives. In the present study, the current ART program touches all the requirements of an effective and efficacious health policy.

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