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Brief Communication: Economic Comparison of Opportunistic Infection Management With Antiretroviral Treatment in People Living With HIV/AIDS Presenting at an NGO Clinic in Bangalore, India

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Abstract

Context: Highly active antiretroviral treatment (HAART) usage in India is escalating. With the government of India launching the free HAART rollout as part of the "3 by 5" initiative, many people living with HIV/AIDS (PLHA) have been able to gain access to HAART medications. Currently, the national HAART centers are located in a few district hospitals (in the high- and medium-prevalence states) and have very stringent criteria for enrolling PLHA. Patients who do not fit these criteria or patients who are too ill to undergo the prolonged wait at the government hospitals avail themselves of nongovernment organization (NGO) services in order to take HAART medications. In addition, the government program has not yet started providing second-line HAART (protease inhibitors). Hence, even with the free HAART rollout, NGOs with the expertise to provide HAART continue to look for funding opportunities and other innovative ways of making HAART available to PLHA. Currently, no study from Indian NGOs has compared the direct and indirect costs of solely managing opportunistic infections (OIs) vs HAART.

Objective: Compare direct medical costs (DMC) and nonmedical costs (NMC) with 2005 values accrued by the NGO and PLHA, respectively, for either HAART or exclusive OI management.

Study design: Retrospective case study comparison.

Setting: Low-cost community care and support center Freedom Foundation (NGO, Bangalore, south India).

Patients: Retrospective analysis data on PLHA accessing treatment at Freedom Foundation between January 1, 2003 and January 1, 2005. The HAART arm included case records of PLHA who initiated HAART at the center, had frequent follow-up, and were between 18 and 55 years of age. The OI arm included records of PLHA who were also frequently followed up, who were in the same age range, who had CD4+ cell counts < 200/microliter (mcL) or an AIDS-defining illness, and who were not on HAART (solely for socioeconomic reasons). A total of 50 records were analyzed. Expenditures on medication, hospitalization, diagnostics, and NMC (such as food and travel for a caregiver) were calculated for each group.

Results: At 2005 costs, the median DMC plus NMC in the OI group was 21,335 Indian rupees (Rs) (mean Rs 24,277/-) per patient per year (pppy) (US \$474). In the HAART group, the median DMC plus NMC was Rs 18,976/- (mean Rs 21,416/-) pppy (US \$421). Median DMC plus NMC pppy in the OI arm was Rs 13623.7/- paid by NGO and Rs 1155/- paid by PLHA. Median DMC and NMC pppy in the HAART arm were Rs 1425/- paid by NGO and Rs 17,606/- paid by PLHA.

Conclusion: Good health at no increased expenditure justifies providing PLHA with HAART even in NGO settings.

Introduction

With over 5 million people living with HIV/AIDS (PLHA), India has the world's second highest number of HIV-positive cases.[1] With their average income majority, PLHA find it difficult to procure highly active antiretroviral treatment (HAART), despite the presence of generic drugs. Until a few years ago, financial constraints led to focusing on opportunistic infections (OI). This affects the mortality and morbidity due to OIs, but the need for HAART remains inevitable.[2-7]

The national free HAART program, which began in 2004 as part of the "3 by 5" initiative, targets a goal of reaching 100,000 eligible PLHA over 5 years.[8] In 2004/2005, a total of 25 HAART centers were functioning in India (17 in the 6 high-prevalence states, 2 in the national capital, and the remainder in the medium-prevalence states). The program goal was to initiate HAART in 25,000 PLHA in that time period. The national estimate for AIDS cases in India for August 2006 was 124,995.[9,10]

Currently, many nongovernment organizations (NGOs) send PLHA to the government centers to obtain HAART. Very few NGOs provide HAART to PLHA and have the expertise to do so. Many NGOs do not take on the responsibility of initiating free HAART therapy for PLHA because lack of adequate funds could affect sustainability. The national rollout is currently located in a few district hospitals and is undergoing a scale-up with more government centers due to open in the course of 2006. The government HAART centers' criteria for enrolling PLHA are CD4+ cell counts of ≤ 200 cells/microliter (mCL) and/or clinical stage III or IV according to the World Health Organization and National AIDS Control Organization (NACO) guidelines.[11] The government HAART centers request the presence of a family member to take responsibility of ensuring that the PLHA maintain follow-up. There are patients who are unable to avail themselves of the government's free HAART program, including those with CD4+ cell counts between 200 and 250/mCL whose quality of life has been affected due to recurrent illness and patients who are too ill to undergo the prolonged wait at the government hospitals. In addition, the government program has not yet started providing second-line HAART, which in India means protease inhibitors.

In the NGO sector, HAART depends on the PLHA's socioeconomic condition or available funding. Hence, NGOs with the expertise to provide HAART continue to raise funds and look at innovative ways of making HAART medications available to those PLHA who are unable to access the government services. In addition, there are many PLHA who would prefer to pay for their medications and go to the private/NGO sector for various reasons, such as confidentiality, convenience, less time-consuming, and more personalized attention. Some of

the NGOs that have strong HAART programs are able to obtain concessions on bulk purchase of HAART drugs, and these concessions are in turn passed on to the PLHA.

A pertinent question for NGOs in such settings would be in regard to costs incurred by the organization and the PLHA for HAART/OI management vis-a-vis overall benefit to the patient. High-income countries with well-functioning public health systems indicate that providing HAART is not a burden on the economy.[12-14] However, lessons from countries, such as Nigeria, show that a weak public health system can retard the HAART program.[15] This study compares the costs incurred for OI management with the cost of providing HAART by this NGO and by PLHA.

Materials and methods

Setting

Freedom Foundation is an Indian NGO with many centers that provide care and support for PLHA. This study was conducted in Bangalore, India (capital of Karnataka state and one of the high-prevalence states), where their head office is located.

The NGO includes a 60-bed inpatient (IP) facility of which 25 beds are for children. An outpatient (OP) clinic functions 5 days a week. The personnel include a project coordinator, 1 medical officer, 6 nurses (1 on night shift), 1 lab technician, 4 counselors, and 12 members in other supportive capacities. At the time of this study, the laboratory was equipped to handle HIV rapid spot tests, Venereal Disease Research Laboratory test (VDRL), hepatitis B surface antigen (HBsAg) rapid test, sputum microscopy, and basic biochemistry tests, such as liver and renal function tests, hemoglobin, and total and differential white blood cell counts. At the time of this study, advanced tests, such as CD4+ T lymphocyte counts and x-rays, were referred out. Between April 2003 and April 2004, there were 629 (IP + OP) new registrations, 407 readmissions, and 2350 OP follow-up visits.[16] Among the new registrations that year, 398 (63.3%) were men; 196 (31.1%) were women; 33 (5.2%) were children; and 2 (0.4%) were eunuchs. Ninety deaths were recorded at the center. Five hundred seventy-two (91%) new registrations were infected via unprotected heterosexual intercourse.

The majority of PLHA accessing care at the Freedom Foundation NGO at Bangalore are from lower socioeconomic strata. Among new registrations in 2003/2004, 151 (24%) were daily wage workers; 75 (12%) were agricultural laborers; 122 (19.4%) were housewives; and remaining people had other occupations. Most can't afford prolonged medical care. The NGO receives an annual government grant that includes the cost of certain categories of essential drugs that play a supportive role in the management of OIs. Some of the antibiotics provided included tetracy-

cline, tinidazole, metronidazole, and cotrimoxazole. Other more specific antibiotics/antiviral drugs that are used to treat or prevent other OIs were not included.[17] The NGO has been provided with tuberculosis (TB) medication by the Revised National TB Control Program (RNTCP). Other government support includes (1) food for IPs, (2) one-time infrastructure support, (3) ongoing support for remuneration for the staff of the NGO, and (4) an allowance for rent, water, and electricity. With the government grant, about 750 patients can get IP care at our NGO (assuming that a patient gets admitted for 1015 days), and this accounts for about 25% of the total number of PLHA who received medical care in 2003/2004. Donor funding provides treatment for the remaining patients (approximately 2500 individuals). Separate funds are raised by our NGO in order to provide free HAART to a few PLHA, especially all eligible children, widowed mothers, and destitute people. Nearly 1 in 5 of the adults on HAART (17.6%; 23 patients among 131) at the center during the study period were supported through these donations. Between 2003 and 2004, 31 PLHA were started on HAART at the center. Government grants do not support HAART at this NGO, and patients who enroll under NGO HAART programs (for the reasons stated above) have to either pay for their own HAART (medicines and laboratory monitoring) or receive continued support from the NGO.

Patients

Purposive sampling[18] of PLHA treated at the center between January 1, 2003 and January 1, 2005 was done in order to identify patient records in the HAART arm. Purposive sampling was used to select records of patients who were on HAART and being followed up at regular intervals because the main aim was to compare costs of sustaining HAART with the cost of providing OI treatment. The HAART arm included case records of clients who initiated HAART at the center, regularly followed up for more than 1 year, for whom complete documentation of records was available, between 18 and 55 years age and still alive. These were matched with cases in the OI arm; matching criteria included age and sex, for whom complete documentation of records was available. Overall, patients in the OI arm were of a similar age group, had CD4+ cell counts < 200 cells/mcL or an AIDS-defining illness, and were not on HAART solely for socioeconomic reasons. All PLHA in the OI arm had at least 1 hospital admission. A total of 50 records were analyzed. Costs for medication, hospitalization, laboratory investigations, and nonmedical costs (NMC; caregiver expenses and travel) were considered. Twenty-five case records were selected for each arm. The HAART arm included 3 cases with pre-HAART CD4+ cell counts above 200 cells/mcL. Treatment of those patients was started when the protocol for initiating HAART was a CD4+ cell count < 500 cells/mcL. Exclusion

criteria in both groups were age, not eligible for HAART as per NACO guidelines, or poor follow-up.

Analysis

Analysis of economic resource utilization in both arms was based on case record assessment. Treatment expenditure was divided into direct medical costs (DMC) and NMC.[19] Variables considered for DMC were medicines, laboratory and other diagnostic tests, service providers' fees (although no fee is charged to the PLHA it has been included in the calculations in order to have more clarity in the results), costs for hospitalization (totally borne by the NGO), and food. (The patients' food is provided free, whereas the caregivers' food may be paid for either by the NGO or by PLHA). NMC included travel for PLHA and food and travel for a caregiver. The cost was calculated for 1 year in all arms.

The data analysis was done with SPSS software.

Patients consented to the use of data in their records.

Results

Baseline Data

A total of 50 patient files were selected, 25 in the HAART arm and 25 in the OI arm. Table 1 provides baseline details of those included in the study, and Table 2 provides clinical features of PLHA in the OI and HAART arms. There were socioeconomic differences between the groups, which are discussed subsequently.

Occupation and income

Prior to entering the treatment program at the Freedom Foundation community care and support facility, PLHA in the OI arm had the following occupations: Ten (40%) were laborers; 5 (20%) were drivers, 4 (16%) were unemployed; and the remaining people had other professions. In the male HAART arm, before starting HAART, 8 (32%) of the male patients were self-employed; 5 (20%) were unemployed, and the remaining men had other occupations. After a year on HAART, 5 (20%) men were self-employed; 3 (12%) were unemployed; and the rest of the men had other occupations. In the female HAART group, 4 (50%) were housewives before initiating treatment; 12.5% were daily wage laborers; and 25% had other forms of employment. About 12.5% of women were in very small businesses that generated very little income; the person involved usually owns a small shop where he/she would sell things, such as cigarettes and chocolates. possibly even small-time fruit vendors and roadside flower sellers. in India, women string together jasmine, marigold, and other such flowers, which are then sold. After HAART 3 (37.5%) continued as housewives; 3 (37.5%) had other occupations; and 2 (25%) were daily wage laborers.

Table 1: Baseline Demographic Characteristics of Persons Living With HIV/AIDS

Parameter	Characteristic	OI Arm	HAART Arm
Age, median		31 years	34 years
Sex	Woman	7 (32%)	7 (32%)
	Man	18 (68%)	18 (68%)
Marital status	Single	6 (24%)	6 (24%)
	Married	16 (64%)	14 (56%)
	Widowed	3 (12%)	5 (20%)
Geographic location	In Bangalore	10 (40%)	16 (64%)
	Outside Bangalore	15 (60%)	9 (36%)
Months enrolled in study, mean		12 ± 1.6	12 ± 0.0
Income per day prior to OI treatment/HAART, median		Rs. 33/day*	Rs 133/day

*US \$1 = approximately Rs 45 during the study period in 2005

Rs = rupees; OI = opportunistic infection management only; HAART = highly active antiretroviral therapy

Drug regimens

In the HAART arm, 16 (64%) were on either zidovudine or stavudine plus lamivudine and nevirapine, and the remaining people were on other regimens. HAART was started at the NGO itself. Regimens varied depending on affordability, drug reaction, and the presence of tuberculosis. Cotrimoxazole prophylaxis for *Pneumocystis carinii* pneumonia was used for all patients in both arms.

Clinical Outcomes

Twenty-two PLHA (88%) in the OI arm and 9 (36%) in the HAART arm had multiple OIs and/or concomitant infections, which merited admission to the Freedom Foundation care and support facility during the study period. Table 3 lists each infection once regardless of the

number of episodes. PLHA in the OI arm had a median IP stay of 52 days of admission and 9 episodes of OP (mean, 9.2 ± 4.2) follow-up. There were no admissions in PLHA in the HAART arm, and there were 12 episodes of follow-up (mean, 10.96 ± 2.92).

Economic Comparisons

DMC

DMC included drugs, hospital costs, and tests used in diagnosis and monitoring. Table 4 shows the total DMC incurred by the NGO and PLHA, respectively, for both arms.

The median cost of drugs for OI management and supportive treatment in the OI arm was Rs 4016/per person

Table 2: Baseline Clinical Features

	OI Arm (n = 25)	HAART Arm (n = 25)
HIV disease stage, number (%)		
Asymptomatic*	0 (0%)	4 (16%)
Stage III	4 (16%)	7 (28%)
Stage IV	21 (84%)	14 (56%)
CD4+ cell counts, median cells/mcL (SD)	74 (57.56)	135 (101.47)
Mean period since HIV detection, months	22.8	33.9

*Asymptomatic with CD4+ cells < 200 cells/microliter (mcL)

OI = opportunistic infection management only; HAART = highly active antiretroviral therapy

Table 3: Opportunistic Infections and Concomitant Diseases

Infection, Number (%)	OI Arm	HAART Arm
Tuberculosis	22 (88%)	11 (44%)
Oral Candida	17 (68%)	6 (24%)
Recurrent diarrhea	8 (32%)	6 (24%)
Cryptococcal meningitis	5 (20%)	2 (8%)
Other: Herpes zoster, toxoplasmosis, <i>Pneumocystis carinii</i> pneumonia, Cytomegalovirus	7 (28%)	4 (16%)

OI = opportunistic infection management only; HAART = highly active antiretroviral therapy

per year (pppy); this was completely borne by the NGO with no PLHA contribution. The median PLHA-borne expenditure on HAART was Rs 15,768/pppy. Median cost incurred by the NGO to provide free HAART to 5 PLHA was Rs 10,585/pppy. Within the HAART arm, the median expenditure for supportive drugs was Rs 556/pppy for the NGO and Rs 438/pppy for the PLHA.

Hospital costs included food, laundry, consultants' fees, and overhead. PLHA in both arms were admitted for OIs, drug reactions, and palliative care and didn't contribute toward the expense of hospitalization. The median NGO-borne costs for hospitalization were Rs 6105/pppy for the OI arm and Rs 300/pppy for the HAART arm.

Laboratory and other diagnostic or monitoring tests included sputum for acid-fast bacilli, x-ray, CD4+ cell

counts, liver function tests, hemoglobin, and other investigations as required. CD4+ cell count was available to all patients at subsidized rates and was done every 36 months. The median investigation cost in the OI arm was Rs 1160/pppy, of which the NGO-borne median cost was Rs 755/pppy. In the HAART arm, the median cost of investigations was 1400/pppy, of which NGO-borne median cost was Rs 713/pppy.

Indirect NMC

NMC included travel for patients and caregivers, food for patients and caregivers during travel, and caregivers' food during hospitalization.

In both arms, often the caregivers' food was provided by the NGO. Median NMC in the OI arm was Rs 7370/pppy, of which the median Rs 3640/pppy was NGO-borne. In

Table 4: Total Direct Medical Costs Incurred by the Nongovernment Organization (OI Arm, n = 25) and Persons Living With AIDS (HAART Arm, n = 25)

Type of Direct Cost	OI Arm Total NGO-Borne Costs, Rs (% of Total Study-Arm Cost)	OI Arm Total PLHA-Borne Costs, Rs (% of Total Study-Arm Cost)	Total Cost in OI Arm, Rs (% of Total Study-Arm Cost)	HAART Arm Total NGO-Borne Costs, Rs (% of Total Study-Arm Cost)	HAART Arm Total PLHA-Borne Costs, Rs (% of Total Study-Arm Cost)	Total Cost in HAART Arm, Rs (% of Total Study-Arm Cost)
Drugs	119,008 (19.6%)	3028 (0.49%)	122,036 (20.11%)	*69,040 (12.9%)	380,241 (71.01%)	449,282 (83.91%)
Hospital care	226,460 (37.3%)	0 (0%)	226,460 (37.3%)	23,525 (4.39%)	0 (0%)	23,525 (4.39%)
Investigations	21,860 (3.6%)	19,365 (3.2%)	41,225 (7%)	665 (1.24%)	27,205 (5.08%)	33,870 (6.33%)
Total cost	367,328 (60.52%)	22,393 (3.69%)	389,721 (64.21%)	99,230 (18.53%)	407,446 (76.09%)	506,677 (94.63%)
Mean	14,693	896	15,588.8	3969	16,298	20,267
Median	10,495	100	13,448	1425	17,366	18,646

the HAART arm, the median NMC pppy was Rs 240/-, of which the median Rs 200/- was PLHA-borne. Table 5 shows total DMC and NMC in both arms. Total costs for 1 year were similar: median Rs 20,040/- (mean, Rs 23,402/-) pppy in the OI arm and median Rs 18,976/- (mean, Rs 21,416/-) in the HAART arm.

After the end of the study period of 1 year in the OI arm, 7 (28%) were started on HAART. After the end of the study period, 8 (32%) expired from OIs; 5 (20%) were still alive; and 5 (20%) were lost to follow-up. All PLHA in the HAART arm were followed after the study period. All patients were alive during the study period (both arms).

Discussion and Conclusion

The study population was small. Sampling of records on the basis of selected adds bias. Those on HAART were originally from a higher income bracket and hence could sustain their medications. Better socioeconomic conditions indicated by the ability to bear these costs would imply better access to healthcare, monitoring of CD4+ cell counts, appropriate initiation of HAART, and better follow-up. The pretreatment CD4+ cell counts in the HAART arm were greater than those in the OI arm. Baseline health status is bound to affect all subsequent costs hospitalization, drugs, etc. The description of costs applies to this NGO only. Costs may vary in other settings depending on drug costs and administrative policies. The cost of protease inhibitor-based regimens was not considered because PLHA who were accessing care at the center were still on treatment with nucleosides and nonnucleoside reverse transcriptase inhibitors.

Although this study lacks sufficient numbers for significant conclusions, the similarity between costs for exclu-

sive OI treatment and HAART is apparent regardless of who pays NGO or patient. Our observations concur with findings from other international studies. African studies indicated that unaffordability prevents PLHA from taking HAART.[20] (Although Indian generics are available in foreign countries for \$140 pppy, in India it costs nearly \$148 pppy.) Studies from Tanzania have shown that PLHA who pay for their HAART medication have a higher risk of nonadherence.[21] Studies from Brazil indicated that supporting PLHA with domestically produced HAART results in a 48% cost reduction per patient. Brazilian and African studies showed that HAART reduces the average number of annual hospitalizations and hence result in considerable cost savings.[22-24]

In our study, the NGO contribution to DMC and NMC was 83% in the OI arm and 24% for the HAART arm. Hospitalization costs for PLHA could be double than for HIV-uninfected people.[25,26] Studies in Italy showed that 74% of medical costs for PLHA were for HAART;[27] our study indicated 80%.

It is known that AIDS results in loss of activity and decreased productivity. HAART, however, helps sustain economic productivity and reduces absenteeism.[28-30] Increased longevity has other implications, such as reduction in number of orphans, thereby reducing financial strain on the government. These factors were, however, not considered in this study because it was a case record analysis based on purposive sampling, and the patients in the OI arm were not available for ascertaining information.

Observations from Nigeria indicated that a weak public health sector weighed down by high drug costs, inade-

Table 5: Direct Medical and Nonmedical Costs Incurred by the NGO and PLHA in 1 year (OI Arm, n = 25; HAART Arm, n = 25)

Cost	OI Arm NGO-Borne Rs (% of Total Study-Arm Cost)	OI Arm Patient-Borne Rs (% of Total Study-Arm Cost)	Total Costs OI Arm Rs (% of Total Study-Arm Cost)	HAART Arm NGO-Borne Rs (% of Total Study-Arm Cost)	HAART Arm Patient-Borne Rs (% of Total Study-Arm Cost)	Total Costs HAART Arm Rs (% of Total Study-Arm Cost)
Direct medical costs	367328 60.52%	22,393 3.69%	389721 64.21%	99,230 18.53%	407,446 76.09%	506,677 (94.63%)
Nonmedical costs	134,330 (22.1%)	82,870 (13.65%)	217,200 (35.7%)	4130 (0.77%)	24,610 (4.6%)	28,740 (5.37%)
Total	501,658 (82.7%)	105,263 (17.34%)	606,921	103,360 (23.92%)	432,056 (80.70%)	535,417
Mean	20,066.34	4211	24,277	4134	17,282	21,416
Median	13,623.7	1155	21,335	1425	17,606	18,976

NGO = nongovernment organization; PLHA = persons living with AIDS; OI = opportunistic infection management only; HAART = highly active antiretroviral therapy; Rs = rupees

quate and/or intermittent drug supplies, lack of trained healthcare providers, inadequate patient monitoring, and inconsistent selection criteria can weaken HAART programs.[31,32]

In conclusion, although the situation in India merits scaling up HAART, resource constraints make it imperative for the government and NGO sector to unite and explore more sustainable programs.

Authors and Disclosures

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