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CHARACTERISTICS OF HIV INFECTED PATIENTS CARED FOR AT "ACADEMIC MODEL FOR THE PREVENTION AND TREATMENT OF HIV/AIDS" CLINICS IN WESTERN KENYA
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ABSTRACT

Background: **With the new initiatives to treat large numbers of HIV infected individuals in sub-Saharan Africa, policy makers require accurate estimates of the numbers and characteristics of patients likely to seek treatment in these countries.**

Objective: **To describe characteristics of adults receiving care in two Kenyan public HIV clinics.**

Design: **Cross-sectional cohort analysis of data extracted from an electronic medical records system.**

Setting: **Academic Model for the Prevention and Treatment of HIV/AIDS (AMPATH) HIV clinics in Kenya's second national referral (urban) hospital and a nearby rural health center.**

Subjects: **Adult patients presenting for care at HIV clinics.**

Main outcome measures: **Gender and inter-clinic stratified comparisons of demographic, clinical, and treatment data.**

Results: **In the first nineteen months, 790 adults visited the urban clinic and 294 the rural clinic. Mean age was 36±9 (SD) years. Two-thirds were women; a quarter had spouses who had died of acquired immune deficiency syndrome (AIDS). HIV/AIDS behavioural risk factors (multiple sexual partners, rare condom use) and constitutional symptoms (fatigue, weight loss, cough, fever, chills) were common. Rural patients had more symptoms and less prior and current tuberculosis. Men more commonly presented with symptoms than women. The cohort CD4 count was low (223 ± 197mm^3), with men having significantly lower CD4 count than women (185 ±175 vs 242 ± 205 p = 0.0007). Eighteen percent had an infiltrate on chest radiograph. Five percent (most often men) had received prior antiretroviral drug therapy, (7% in urban and 1% in rural patients, p = 0.0006). Overall, 393 (36%) received antiretroviral drugs, 89% the combination of lamivudine, stavudine, and nevirapine. Half received prophylaxis for tuberculosis and *Pneumocystis jirovecii*. Men were sicker and more often received antiretroviral drugs.**

Conclusions: **Patients presenting to two Kenyan HIV clinics were predominantly female, ill and naïve to retroviral therapy with substantial differences by clinic site and gender. Behavioural risk factors for HIV/AIDS were common. A thorough understanding of clinical and behavioural characteristics can help target prevention and treatment strategies.**

INTRODUCTION

The HIV/AIDS epidemic has reached devastating proportions in Kenya, which has the fourth highest prevalence of HIV infection (6.7%) and contains 10% of all Africans with HIV (1,2). There are approximately 180,000 deaths due to HIV/AIDS every year in Kenya, and life expectancy has fallen from 54 to 48 years over the last five years (1,2). The annual number of AIDS deaths increased by over 60% between 1998 and 2003, however the estimated number of new infections has dropped by two thirds since its peak in 1993 (3). Effective approaches to stemming the HIV/AIDS epidemic in Kenya will require coordinating the activities of government and international health agencies to generate effective treatment and prevention initiatives. Because the epidemiology of HIV/AIDS in Africa is fundamentally different than other areas of the world, (4) locally specific data are needed to delineate the scope of the problem and design locally appropriate intervention strategies.

With the new initiatives to treat large numbers of HIV infected individuals in sub-Saharan Africa, policy makers require accurate estimates of the numbers and characteristics of patients likely to seek treatment in these countries. Understanding socio demographic differences among patients seeking HIV care will assist in developing culturally specific HIV/AIDS care programmes. This will ensure uniform standards and access to care.

In 2001, the Moi University College of Health Sciences, Indiana University School of Medicine and Moi Teaching and Referral Hospital in a joint initiative created the Academic Model for the Prevention and Treatment of HIV/AIDS (AMPATH) (5,6). Brought about by a longstanding collaboration between the Moi University College of Health Sciences and Indiana University School of Medicine (7,8). The patient care being provided in AMPATH clinics include; management of opportunistic infections, prevention of mother to child transmission of HIV, provision of highly active antiretroviral therapy, economic, nutrition and psychological support. The AMPATH programme has established HIV care system that serves the needs of both urban and rural clinics. The first two adult HIV/AIDS clinics were opened in November 2001 in western Kenya, one in Kenya's second national referral hospital and one in an affiliated rural health centre. These clinics now contain Kenya's largest public HIV/AIDS treatment programme. In this paper, we describe the demographic, clinical, social, and behavioural characteristics of the first 1000 adult patients seen during these clinics' first 19 months of operation, along with the treatments initiated in this resource-poor setting.

MATERIALS AND METHODS

Approval of the study was granted by both the Indiana University School of Medicine Institutional Review Board and the Moi University College of Health Sciences Institutional Research and Ethics Committee.

Study cohort: Patients comprising the study cohort came from two HIV/AIDS clinics opened in November 2001 at the Moi Teaching and Referral Hospital and the Mosoriot Rural Health Centre (located twenty five kilometres from Moi Hospital), both located in the north Rift Valley Province. Closely affiliated with Moi University College of Health Sciences, Moi hospital is Kenya's second national referral hospital, located in Eldoret, Kenya's fifth largest city with a population between 400,000 and 500,000. Moi hospital serves a catchment area of approximately thirteen million people representing more than ten tribes. The Mosoriot Rural Health Centre serves approximately 40,000 people in surrounding communities, predominantly of the Nandi tribe that consists primarily of subsistence farmers with limited access to electricity, potable water, and other essential services.

Both HIV clinics offer comprehensive HIV/AIDS care, including antiretroviral therapy, funded primarily by philanthropic donations, the Kenya

Ministry of Health through National AIDS and Sexually Transmitted Diseases Control Program (NASCOP) and the Maternal-To-Child-Transmission (MTCT)-Plus program (9), while a small number of patients purchase antiretroviral drugs with their own funds. Since 2004, major funding has been provided by the United States Presidential Emergency Plan for AIDS Relief (PEPFAR). Patients with a total lymphocyte count less than 1000, a CD4 count less than 200, or a plasma viral load greater than 100,000 are eligible for antiretroviral therapy. Patients with poor adherence to previously prescribed drugs or clinic visits, severe non-HIV comorbidity, or non-treatable HIV-related comorbidity (e.g., extensive HIV-related malignancy) are ineligible for antiretroviral treatment. This study includes all patients with at least one visit to either HIV clinic between November 2001 through June 2003. Data were recorded on paper encounter forms and stored in an electronic medical record system.

Clinical evaluation and statistical analyses: All patients seen at the HIV/AIDS clinics receive a thorough initial evaluation, with standard demographic, historical, psychosocial, physical, and laboratory data stored in an existing electronic medical record system (10-14). Follow-up evaluations are also standardised and guided by clinical necessity and international guidelines. Categorical descriptive data are presented as frequency distributions while continuous data are presented as means ± standard deviations. We used chi-square tests to compare categorical data between groups and Student's t-tests to compare continuous variables. P-values of <0.05 are considered statistically significant.

RESULTS

Between November 2001 through June 2003, 1084 patients were enrolled in the HIV clinics, 790 (73%) at Moi Teaching and Referral Hospital and 294 (27%) at Mosoriot (Table 1). Patients were predominantly young women (65% at MTRH and 73% at Mosoriot). The majority were married and in monogamous relationships with approximately four children. The divorce rate was low, and nearly one third had deceased spouses. Women were significantly younger and more often divorced or had deceased spouses, the majority from AIDS (25% of women had spouses who had died of AIDS). While still, less women than men visited the urban hospital clinic than the rural Mosoriot clinic. Men were more often married and from families with more than one wife. More patients visiting the Mosoriot rural clinic had dead spouses, the majority from AIDS.

Full historical and symptom information was collected on 1005 (93%) of all patients. HIV/AIDS behavioural risk factors were common among men and women presenting at both clinics (Table 1). One out of every four patients at both sites admitted to engaging in extramarital sex. Men more often admitted to having extramarital sex (38% of men), but reported sexual encounters in the prior six months were more common among women. 40% of women more often suspected their husbands of having extramarital sex. Regular condom use, uncommon in both sexes, was more common among men. Additionally, nearly a third of the women and a sixth of the men at both sites reported their spouse being deceased. Despite the prevalence of deceased spouses, less than a third of patients knew the HIV status of their spouse. Men and urban clinic patients more often knew the HIV status of their spouse.

Fatigue, weight loss, cough, fever, and chills were the most commonly reported symptoms at both clinics (Table 2). The symptom burden was generally greater in men than in women and among patients treated at the rural clinic. Conversely, a history of prior tuberculosis and active treatment for tuberculosis was much more common among urban clinic patients. Prior antiretroviral therapy was rare but significantly more prevalent among urban than rural clinic patients (7% vs 1%, $p = 0.0006$). Women were significantly less likely to have had prior antiretroviral therapy than men (4% vs 8%, $p = 0.01$).

Contrary to the high prevalence of abnormalities in symptoms and prior history, abnormal findings on physical examination were less common, the most prevalent being a rash and oral candidiasis (Table 3). There were no consistent differences between urban and rural clinic patients in the prevalence of abnormalities on physical examination. Comparing genders, men more often had lower oxygen saturations, oral candidiasis, abnormal breath sounds, and temporal muscle wasting. A small proportion of both men (4%) and women (3%) presented with Kaposi's sarcoma.

Table 1

*Characteristics of the first 1084 adult patients during their initial visits to the Moi Teaching and Referral Hospital and Mosoriot Rural Health Centre HIV clinics**

	Clinic site			Gender*		
	Moi Teaching and Referral Hospital (n = 790)	Mosoriot Rural Health Centre (n = 294)	P-value	Men (n = 348)	Women (n = 725)	P-value
Age (years)	36 ± 9	36 ± 8	0.96	39 ± 9	34 ± 9	<0.0001
Sex = Female	65%	73%	0.01			
Married	82%	75%	0.01	94%	74%	<0.0001
Wives in family:						
(n) = 0	24%	40%		13%	35%	
1	60%	46%	<0.0001	74%	48%	<0.0001
2	13%	11%		12%	14%	
≥3	3%	3%		1%	4%	
Divorced or separated	8%	6%	0.23	3%	10%	<0.0001
Children (n)	3.4 ± 2.7	3.6 ± 2.3	0.28	3.9 ± 2.9	3.3 ± 2.4	0.001
Spouse deceased	21%	30%	0.003	13%	29%	<0.0001
Spouse died of AIDS	17%	25%	0.005	8%	25%	<0.0001
Patient aware of spouse's HIV status	25%	11%	<0.0001	32%	16%	<0.0001
Spouse aware of patient's HIV status	38%	20%	<0.0001	42%	27%	<0.0001
Spouse known to be HIV seropositive	6%	4%	0.18	4%	7%	0.09
Sexual encounter in the last six months	37%	33%	0.27	11%	40%	<0.0001
Admits to extramarital sexual relations	17%	19%	0.36	38%	8%	<0.0001
Suspects spouse of extramarital sex	30%	32%	0.46	11%	40%	<0.0001
Regularly uses a condom with intercourse	4%	3%	0.51	6%	3%	0.02

* Gender information was missing for 11 patients

Table 2

Symptoms and history among the first 1084 adult patients treated at the Moi Teaching and Referral Hospital and Mosoriot Rural Health Centre HIV Clinics

	Clinic site			Gender*		
	Moi Teaching and Referral Hospital (n = 790)	Mosoriot Rural Health Centre (n = 294)	P-value	Men (n = 348)	Women (n = 725)	P-value
Weight loss	56%	66%	0.003	69%	54%	<0.0001
Fatigue	53%	62%	0.009	60%	53%	0.04
Cough	37%	42%	0.13	47%	34%	<0.0001
Fever	36%	44%	0.01	37%	39%	0.61
Prior tuberculosis	31%	13%	<0.0001	35%	22%	<0.0001
Chills	29%	37%	0.01	31%	32%	0.79
Producing sputum	23%	23%	0.90	28%	20%	0.005
Prior pneumonia	23%	21%	0.60	21%	23%	0.61
Arthralgia	19%	25%	0.02	21%	20%	0.84
Chest pain	18%	18%	0.96	16%	19%	0.36
Weakness	15%	9%	0.36	19%	11%	0.001
Diarrhoea	14%	21%	0.006	21%	14%	0.01
Current tuberculosis therapy	19%	6%	<0.0001	22%	13%	0.0001
Exertional dyspnoea	11%	15%	0.11	15%	11%	0.11
Abdominal pain	10%	11%	0.60	9%	10%	0.44
Paresthesia	9%	10%	0.49	11%	8%	0.12
Dysphagia	9%	14%	0.01	12%	10%	0.19
Vomiting	8%	13%	0.02	9%	10%	0.64
Prior antiretroviral therapy	7%	1%	0.0006	8%	4%	0.01

* Gender information was missing for 11 patients

Table 3

*Physical examination findings among the first 1084 adult patients treated at the Moi Teaching and Referral Hospital and Mosoriot Rural Health Centre HIV Clinics**

	Clinic site			Gender†		
	Moi Teaching and Referral Hospital (n = 790)	Mosoriot Rural Health Centre (n = 294)	P-value	Men (n = 348)	Women (n = 725)	P-value
Systolic blood pressure (mmHg)	107 ± 14	110 ± 16	0.01	110 ± 15	107 ± 14	0.002
Diastolic Blood Pressure (mmHg)	67 ± 10	71 ± 10	<0.0001	69 ± 11	67 ± 10	0.01
Pulse (beats per minute)	99 ± 21	96 ± 21	0.05	94 ± 21	100 ± 21	<0.0001
Temperature (°C)	36.5 ± 0.7	36.3 ± 0.9	0.0001	36.4 ± 0.8	36.5 ± 0.7	0.03
Weight (kg)	57.7 ± 11	55.6 ± 13	0.02	60 ± 12	56 ± 11	<0.0001
O_2 Saturation (%)	96 ± 3	96 ± 4	0.10	94 ± 5	96 ± 3	<0.0001
Rash	19%	11%	0.002	19%	17%	0.44
Oral candida albicans	13%	14%	0.46	16%	11%	0.04
Abnormal breath sounds	12%	6%	0.005	16%	8%	<0.0001
Temporal muscle wasting	11%	8%	0.32	17%	7%	<0.0001
Cervical or axillary lymphadenopathy	7%	6%	0.62	8%	5%	0.09
Splenomegaly	4%	11%	0.0001	5%	7%	0.27
Hepatomegaly	4%	5%	<0.61	3%	5%	0.35
Kaposi's sarcoma	4%	2%	0.14	4%	3%	0.41
Oedema	2%	5%	0.01	3%	2%	0.32

* Continuous variables are presented as mean ± standard deviation

† Gender information was missing for 11 patients

Table 4

*Initial laboratory examination among the first 1084 adult patients presenting at the Moi Teaching and Referral Hospital and Mosoriot Rural Health Centre HIV Clinics**

	Clinic site			Gender†		
	Moi Teaching and Referral Hospital (n = 790)	Mosoriot Rural Health Centre (n = 294)	P-value	Men (n = 348)	Women (n = 725)	P-value
Initial CD4 count (per mm^3) (n = 658)	231 ± 200	188 ± 180	0.03	185 ± 175	242 ± 205	0.0007
CD4 count less than 200	53%	68%	0.003	63%	52%	0.015
CD4 count (patients prescribed antiretroviral drugs) (per mm^3) (n = 338)	120 ± 107	110 ± 92	0.48	113±112	123±100	0.41
White blood cell count (per mm^3) (n = 1002)	5015 ± 2746	5370 ± 6292	0.39	5055 ± 3306	5127 ± 4209	0.77
Total lymphocytes (per mm^3) (n = 836)	1654 ± 897	1770 ± 867	0.10	1658 ± 943	1698 ± 867	0.55
Haemoglobin (gm/dL) (n = 998)	10.3 ± 2.4	10.9 ± 2.7	0.002	11.6 ± 2.6	9.9 ± 2.2	<0.0001
Platelet count (1000/mm^3) (n = 945)	243 ± 117	256 ± 132	0.19	225 ± 121	258 ± 120	0.0001
Alanine aminotransferase (IU/L) (n = 677)	25 ± 29	30 ± 34	0.11	32 ± 42	23 ± 21	0.003

* Results are presented as mean ± standard deviation or percent of subjects

† Gender information was missing for 11 patients

Patients' helper T-cell (CD4) counts were relatively low, with the mean for all patients (223 ± 197/mm^3) being close to the threshold for eligibility for antiretroviral drug therapy (Table 4). The mean CD4 counts for urban clinic patients were significantly higher than those seen at rural clinic patients. Men also had significantly lower CD4 counts than women. Upon presentation, more than half (57%) of the patients had a CD 4 count of less than 200/mm^3. This percentage was significantly higher among men and those attending the Mosoriot rural health centre (Table 4). The mean total lymphocyte count and haemoglobin were also mildly reduced compared to local laboratory norms. Alanine aminotransferase values were mostly normal. There were no urban-rural or gender differences in laboratory test results other than haemoglobin, which was lower among women, a finding significant for zidovudine-based ART. Eighteen percent of patients were found to have a chest infiltrate on chest X-ray.

Decisions to initiate antiretroviral therapy were based on the availability of drugs and either having a CD4 count of less than 200 or having tuberculosis or an AIDS opportunistic infection such as *Pneumocystic jirovecii*. Overall 393 patients (36%) were started on antiretroviral therapy, with 348 (89%) receiving the most common three-drug regimen included stavudine, lamivudine, and nevirapine. Efavirenz was used less commonly, mostly for patients receiving concurrent rifampicin for tuberculosis. The pre-treatment CD4 count among patients prescribed antiretroviral drugs was 118 ± 105 compared with 311 ± 210 among patients not prescribed antiretroviral drugs ($p<0.0001$). Male patients attending the urban clinic were significantly more likely to be on antiretroviral therapy than women. Isoniazid preventive therapy was prescribed for 50% of the patients, majority of whom were women (51% of the women versus 48% of men, $p = 0.33$) and patients from the rural clinic (54% at the rural clinic versus 48% at the urban clinic, $p = 0.12$). Men were also significantly more likely to be prescribed trimethoprim-sulfamethoxazole for prophylaxis against *Pneumocystis jirovecii* infection (56% of the men versus 44% of the women, $p = 0.0001$), while patients at the rural clinic were more often treated with fluconazole (17% at the rural clinic versus 9% at the urban clinic, $p = 0.0002$).

DISCUSSION

We describe adult patients with HIV cared for at two HIV/AIDS clinics in resource limited environment in Kenya. Patients seen in these HIV clinics were mainly younger women who were married and in monogamous relationships or were widows. This finding is consistent with global trends where HIV/AIDS incidence is now higher among heterosexual women than among men (1,15,16). The Kenya demographic health survey (KDHS) 2003 also found a prevalence rate of 9% in adult women compared to 5% in adult men (2). This is partly explained by gender inequality regarding decision-making in Kenyan communities with women's inability to make decisions regarding sexual intercourse for themselves. Women are usually infected with HIV by their spouses who, due to substantial stigma associated with HIV, often refuse treatment for themselves and their wives until they are dead (17). This is supported by our finding that female patients more often had spouses who had died of AIDS.

Our data on symptoms, physical examination, and diagnostic tests support the notion that men are sicker on presentation and are more often eligible for, and in need of, antiretroviral drugs than women. Similar findings have been reported in other studies where men have more advanced disease and significantly lower CD4 counts at presentation to health care facility compared to women (18,19). This suggests that the more common pattern of HIV transmission is for the husband to be the index case in a household, followed by secondary infections in his wife and children. These facts bring to attention the need to focus HIV education and prevention efforts towards men and the position of women in the Kenyan society. Alternatively, the predominance of married, monogamous women may be explained by testing bias at our site. As an MTCT-plus site, voluntary counseling and testing is routinely offered as part of prenatal care with subsequent free care offered to all infected women and their spouses. One hundred and sixty six of the 725 women described here (22.8%) entered the programme through the MTCT plus programme. No such programmes of routine HIV testing with free care access targeting men are available. These findings have important policy implications for HIV treatment and prevention in Kenya and other developing countries. Programmes that target men to encourage earlier counseling and testing as well as entry into care systems need to be developed.

The findings of HIV risk factors on our extensive baseline psychosocial history provides targets for prevention initiatives. Approximately one-quarter to one-third of the HIV positive patients had diseased spouses, but the cause of death was largely not known. Additionally, only 11-38% of the couples knew the spouses HIV status. Lack of disclosure of HIV status is common among spouses in this setting. This low rate of spousal disclosure is consistent with HIV being a heavily stigmatised disease (20,21). Additionally, extramarital sex was common and nearly four out of every ten men admitted to having extramarital affairs and a similar proportion of women suspecting their husbands of having extramarital sex. Condom use was remarkably low. Prevention efforts focused on spousal disclosure, limitation of sexual partners, and condom use should be emphasised.

Weight loss and other symptoms were more prevalent among patients attending the HIV clinic at Mosoriot, suggesting greater illness severity among more isolated rural patients. The high prevalence of reported weight loss and other constitutional symptoms, along with low CD4 counts among these patients with documented HIV infection suggest that these patients are presenting with more advanced disease than their urban counterparts. This suggests that rural patients present later in the course of HIV infection. However one must consider whether stigma, transportation difficulties, or fiscal barriers may also contribute to delayed diagnosis in rural settings. Research is needed to ascertain which of these barriers are amenable to interventions.

The use of an electronic medical record system (10-14) allowed the routine recording and analysis of patients cared for in these HIV clinics. Access to such data will be key to delivering high-quality, cost-effective care to the millions of Kenyans infected with HIV. However, there are some limitations to such data. Obtaining data on the medical history, symptoms, and the physical examination, relied on physicians or their clinical assistants checking boxes on paper encounter forms. It is possible that not all questions on initial visit encounter form were asked and answered by all patients. This may falsely bias some risk estimates likely leading to underestimates of the true prevalence in many situations. We were also unable to perform extensive laboratory evaluations on the entire population. This is a limitation dictated by available financial recources: additional tests (e.g. viral loads) were available but too costly to perform routinely. Hence, the laboratory test results reported may not be generalisable to all patients visiting these HIV clinics.

Our findings begin to describe the clinical, social, and demographic features of patients with HIV/AIDS seeking care in Kenya. This information is critical to designing local treatment and prevention programmes in similar situations where patients present with relatively advanced stages of HIV infection, with little prior treatment with antiretroviral drugs. Ongoing epidemiologic studies will be needed to enable targeted programmatic efforts to improve access to and outcomes of care for millions of persons affected by HIV/AIDS in sub-Saharan Africa.

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