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Payment for antiretroviral drugs is associated with a higher rate of patients lost to follow-up than those offered free-of-charge therapy in Nairobi, Kenya

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Summary This retrospective analysis of routine programme data from Mbagathi District Hospital, Nairobi, Kenya shows the difference in rates of loss to follow-up between a cohort that paid 500 shillings/month (approximately US$7) for antiretroviral drugs (ART) and one that received medication free of charge. A total of 435 individuals (mean age 31.5 years, 65% female) was followed-up for 146 person-years: 265 were in the 'payment' cohort and 170 in the 'free' cohort. The incidence rate for loss to follow-up per 100 person-years was 47.2 and 20.5, respectively (adjusted hazard ratio 2.27, 95% CI 1.21—4.24, $P = 0.01$). Overall risk reduction attributed to offering ART free of charge was 56.6% (95% CI 20.0—76.5). Five patients diluted their ART regimen to one tablet (instead of two tablets) twice daily in order to reduce the monthly cost of medication by half. All these patients were from the payment cohort. Payment for ART is associated with a significantly higher rate of loss to follow-up, as some patients might be unable to sustain payment over time. In resource-limited settings, ART should be offered free of charge in order to promote treatment compliance and prevent the emergence of drug resistance.

1. Introduction

Kenya, a resource-poor country in sub-Saharan Africa, is faced with a serious HIV/AIDS epidemic, with an estimated

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1.2 million of its 31 million inhabitants infected with the HIV/AIDS virus (UNAIDS, 2007) and an estimated 150 000 people dying of HIV/AIDS each year (WHO, 2005a). By June 2005, only 46 000 (19%) of the estimated 233 000 people in need of antiretroviral therapy (ART) were actually receiving treatment. Kenya thus ranks among the 20 countries identified as having the highest unmet need for ART (WHO, 2005a).

The average annual health expenditure in Kenya is US$65 per capita, and this limited health resource makes it extremely difficult to provide all that is required for effectively dealing with an epidemic of this magnitude (UNDP, 2006). Despite this challenge, the Kenyan government developed an ambitious plan for national ART scale-up, with legitimate concerns placed on sustainability. The promotion of cost-sharing schemes with external partners and individual patient contributions was thus encouraged wherever possible (MOH, 2004a).

Mbagathi District Hospital in central Nairobi, in collaboration with Médecins Sans Frontières (MSF), was one of the pioneer sites offering ART within the public sector in Kenya. From 1 February 2005 an unusual situation developed within this hospital, whereby all new patients who required ART were offered similar services but constituted one of two cohorts: one that paid out-of-pocket expenses for purchasing ART; or one that received the drugs free of charge. We were concerned that a proportion of those who paid for ART might not be able to sustain the cost in the long run and that this might result in patients dropping out of the programme (i.e. being lost to follow-up). 'Loss to follow-up' is an important adverse ART outcome, as it is likely to negatively influence treatment efficacy and overall survival on ART.

We conducted a retrospective analysis of routine programme data in order to determine if there was a significant difference in the rates of loss to follow-up between the cohort that paid for ART and those that received the medication free of charge.

2. Materials and methods

2.1. Design

A retrospective analysis of standardized treatment outcomes in HIV-positive patients started on ART between 1 February and 30 June 2005 and verified on 1 September 2005.

2.2. Study setting and population

The HIV/AIDS clinic of the Mbagathi District Hospital, the main second-line public health facility in Nairobi, was the site of the study. All ART-naive individuals aged $\geq$13 years starting ART during the study period were included in the study.

Before 1 February 2005 there were two parallel ART clinics operating within different infrastructure facilities at this hospital. The first and pioneering service was offering ART on a cost-sharing basis, with patients having to pay 500 shillings/month (approximately US$7) for ART drugs. This financial participation was felt necessary by the hospital management in the interest of long-term financial sustainability of the ART programme within a setting that was already stretched for resources. A social welfare team allowed partial or complete payment waivers (exemptions) on a case-by-case basis.

The second ART clinic was run by MSF and offered ART free of charge. All patients requiring ART and presenting to the out-patient department, or referred patients, were systematically informed of the existence of both clinics and the nature of the services provided. Patients were completely free to choose from which of the two clinics they would like to receive care and were subsequently followed by the same clinics. The hospital management did not in any way directly influence allocation of patients into paying or non-paying clinics. However, if a patient preferred to go to the paying clinic but did not have the means to pay for ART, the payment could be waived, at the discretion of the social welfare team.

With the aim of an eventual handover of the MSF programme to the Ministry of Health (MOH), a decision was taken to merge both parallel clinics by 1 February 2005. This meant that from that date on, all patients requiring ART from both cohorts would be seen in a unique facility (under the same roof) and would be offered exactly the same services by the same team of counsellors and clinical staff. All staff were trained to follow standardized national guidelines and were supervised by the same team. From this date (by default), two cohorts of patients thus existed in the clinic. One that paid for ART and the other that received ART free of charge. Patients who received free ART from 1 February 2005 included only a backlog of patients on the existing MSF waiting list for ART, while all other new patients were included in the paying cohort. This catch-up of the existing waiting list of MSF patients was planned as the first step in the process of an eventual handover of all patients by MSF to the Government programme. It offered a unique opportunity to compare two cohorts that otherwise received the same care.

2.3. ART regimens and treatment outcomes

The first-line ART regimen was a fixed-dose combination of stavudine (d4T), lamivudine (3TC) and nevirapine (NVP) (Triomune®). In case of d4T- and NVP-related side effects, the respective alternatives were zidovudine (AZT) and efavirenz (EFZ). Second-line regimens were available in case of first-line failure (MOH, 2004b). Patients and guardians underwent group and individual counselling sessions and were educated about HIV infection and the implications of ART. Once the patient was considered adequately prepared for ART, he/she was started on one tablet of Triomune in the morning plus one tablet of a combination of d4T/3TC (Coviro LS®) at night for a period of 14 d. This was followed by one tablet of the fixed-dose combination (Triomune) in the morning and in the evening. Patients were then requested to return for follow-up visits on a monthly basis.

Treatment outcomes were monitored and recorded each month. Outcomes were standardized and included: alive and on ART; died; lost to follow-up; stopped; and transferred out. For the purposes of this analysis, a patient was defined as being 'lost to follow-up' if placed on ART and not seen during a period of 2 months thereafter.

2.4. Data collection and statistical analysis

Patient cards as well as ART and pharmacy registers were used to gather information on basic socio-demographic characteristics and treatment outcomes. Information on patients who were exempted from payment was gathered from a specific register designed for this purpose and available at the hospital social welfare unit.

Differences between groups were compared using the χ^2 test for categorical variables and the Wilcoxon rank-sum test. Hazard ratios per 100 person-years of follow-up were used to compare rates of loss to follow-up in the two groups and were adjusted using a Cox regression model. Estimates of loss to follow-up were determined using the Kaplan-Maier method and compared using the Cox-Mantel (log-rank) test. The level of significance was set at $P = 0.05$ or less and 95% CI were used throughout. Data analysis was done using the STATA 8.2 software (Stata Corp., College Station, TX, USA).

3. Results

3.1. Characteristics of the study population and treatment outcomes

A total of 439 patients was started on ART during the study period. Four patients were exempt from payment for social reasons during the course of the study and were thus excluded from the analysis. A total of 435 patients (mean age 35.5 years, 65% female) was included in the study; 265 were in the payment cohort and 170 in the free medication cohort. Table 1 shows the characteristics and standardized ART outcomes of individuals who did and did not pay for ART.

3.2. Loss to follow-up

Patients were followed-up for a total period of 149 person-years (median = 4 months, interquartile range 2.7—5.6 months). This included a total follow-up time of 80.5 person-years in the 'payment' cohort and 68.3 person-years in the 'free' cohort, respectively. The characteristics of individuals lost to follow-up among those that did and did not pay for ART are shown in Table 2. A significantly higher proportion of females than males, and more of those with CD4 counts under 200 cells/μl than those over this threshold, were lost to follow-up. The incidence rates for loss to follow-up per 100 person-years among those who paid for ART was 47.2 compared with 20.5 among those who received ART free of charge (hazard ratio 2.17, 95% CI 1.16—4.05, $P = 0.01$). Overall risk reduction in terms of loss to follow-up attributed to offering ART free of charge was 56.6% (95% CI 20.0—76.5).

After adjustment for age, sex, marital status and CD4 count the hazard ratio was 2.27 (95% CI 1.21—4.24, $P = 0.01$). Figure 1 shows the probability of being lost to follow-up among patients offered ART free of charge compared with those that paid for medication.

3.3. Specific cases of ART dilutions

Five patients diluted their ART regimen to one tablet (instead of two tablets) twice daily in order to reduce the

Table 1 Characteristics of 435 patients that received free antiretroviral drugs (ART) and those that paid for medication

	Free ART ($n = 170$) n (%)	Paid for ART ($n = 265$) n (%)	P-value[a]
Gender			
Male	50 (29.4)	103 (38.9)	0.04
Female	120 (70.6)	162 (61.1)	0.04
Age (years)			
<35	101 (59.4)	144 (54.3)	0.3
≥35	69 (40.6)	121 (45.7)	0.3
Marital status			
Single/divorced/widowed	96 (56.5)	169 (63.8)	0.1
Married	74 (43.5)	96 (36.2)	0.1
CD4 count (cells/μl) [median (IQR[b])]	147 (60—215)	73 (22—154)	<0.001
Treatment outcomes[c]			
Alive and on ART	151 (88.8)	222 (83.7)	0.1
Lost to follow-up	14 (8.2)	38 (14.4)	0.05
Died	3 (1.8)	5 (1.9)	0.7
Transferred out	2 (1.2)	0 (0)	—
Duration on ART (days) [median (IQR[b])]	147 (113—188)	111 (78—139)	—

[a] χ^2 test or Student's *t*-test for continuous variables. *P*-values per category of dichotomous variables.
[b] Interquartile range.
[c] Standardized crude outcomes for new patients registered between 1 February and 30 June 2005 and verified on 1 September 2005 and defined as follows: alive and on ART = alive and has collected his/her monthly supply of drugs; died = died for any reason while on ART; lost to follow-up = was placed on ART and not seen at all during a period of 2 months thereafter; transferred out = transferred out permanently to another treatment unit.

Table 2 Characteristics of 52 patients lost to follow-up among those that received free antiretroviral drugs (ART) and those that paid for medication

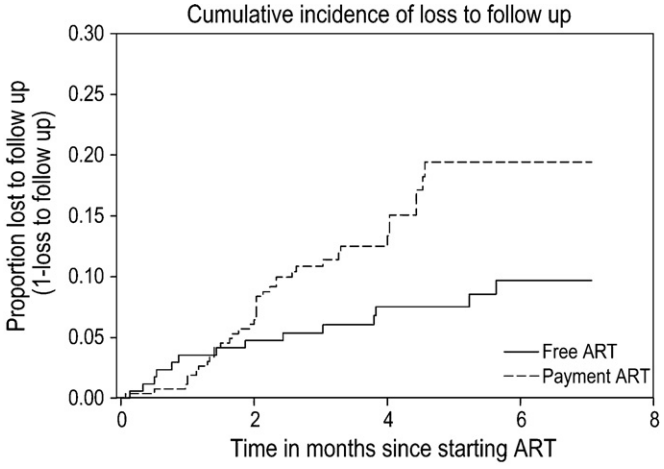
	Free ART ($n = 14$) *n* (%)	Paid for ART ($n = 38$) *n* (%)	Total ($n = 52$) *n* (%)	*P*-value[a]
Gender				
Male	6 (42.9)	11 (29)	17 (33)	
Female	8 (57.1)	27 (70)	35 (67)	<0.001
Age (years)				
<35	5 (35.7)	19 (50)	24 (46)	
≥35	9 (64.3)	19 (50)	28 (54)	0.4
Marital status				
Single/divorced/widowed	5 (35.7)	24 (63.2)	29 (56)	
Married	9 (64.3)	14 (36.8)	23 (44)	0.2
CD4 count (cells/μl)				
<200	11 (78.6)	21(55.3)	32 (62)	
≥200	3 (21.4)	17 (44.7)	20 (38)	0.01
Duration on ART (days) [median (IQR[b])]	50 (16—114)	61 (42—91)	—	

[a] χ^2 test comparing totals of dichotomous variables.
[b] Interquartile range.

monthly cost of medication by half. All these patients were from the payment cohort.

4. Discussion

This study shows that payment for ART in a routine district hospital programme setting is associated with a significantly higher rate of loss to follow-up than when medication is offered free of charge. The risk reduction attributed to free medication was 57%.



Log-rank test $\chi^2 = 6.31$, $P = 0.01$

Time (months)		0	1	2	3	4	5	6	7
Free ART	At risk	170	163	158	141	122	97	54	14
	Lost to follow-up	–	6	2	1	3	0	2	0
Payment for ART	At risk	265	262	246	170	105	44	22	10
	Lost to follow-up	–	5	12	11	4	6	0	0

Figure 1 Probability of being lost to follow-up among 435 patients offered antiretroviral drugs (ART) free of charge and on payment.

The strengths of this study are that ART outcomes were standardized and thus comparable, and the setting provided a rather unusual but ideal programme situation in which loss to follow-up could be compared between a cohort that paid for ART and another that received medication free of charge. However, one of the limitations of this study is that, unlike a randomized trial (which would not have been possible on ethical grounds anyway), the analysis is based on simple observational data; as such, it is not possible to know the cause(s) for the difference in the rates observed between the two cohorts. Furthermore, data on socio-economic status, educational level and cost of transport to the ART facility and other possible confounders that could influence acceptability and compliance was not available, as this information was not routinely gathered. Despite these limitations, the magnitude of the difference between the two groups (i.e. the clinical significance between them) is considerable, suggesting that a powerful effect was taking place. In a setting such as Mbagathi Hospital, where two clinics were running in a parallel manner, we also do not know why certain patients still opted to go to a paying clinic when they could get treatment free of charge. Possible explanations might involve the manner in which services are offered, the approach of staff, confidentiality, waiting time etc., but other specific studies are required to answer this question.

The characteristics of both groups were similar except that more men than women paid for treatment, perhaps reflecting a higher earning capacity or liquid cash in this group. More single, divorced and widowed status patients paid for ART than those who were married, and this seems to be contrary to ability to pay. This observation might be related to the fact that the paying clinic had fewer patients and no waiting list, implying faster access to ART. Widowed or divorced individuals might have been in haste to access ART after having lost a partner or having been divorced due to HIV, and thus such individuals might have opted to go to the paying clinic. Marriage status might also have been

biased by confidentiality issues, and thus inferences that can be made about this group are limited.

A significantly higher proportion of women than men were also lost to follow-up, and this proportion was higher among those that paid for treatment. This finding is in contrast to another study in Kenya (although from predominantly rural areas) that showed that more men than women were likely to be lost to follow-up (Wools-Kaloustian et al., 2006). More individuals with lower CD4 counts were also lost to follow-up in this analysis, and this finding is similar to that of another study from Kenya that showed an association between low immune status and loss to follow-up (Karcher et al., 2007). A proportion of these patients might actually have died or have migrated but were declared as lost to follow-up because reliable ascertainment of deaths or other status is often not practically feasible (Yu et al., 2007). The mean CD4 count on starting ART was lower among those that paid for ART, and this finding might be related to undue delays associated with trying to find enough money to pay for ART.

Keeping the rates of loss to follow-up in ART programmes to a minimum is important to ensure that patients continue treatment in an uninterrupted manner and optimally reap the survival benefits induced by ART (Harries et al., 2001; WHO, 2003). In the cohort that paid for ART, it is reasonable to believe that some patients who started ART might have been unable to sustain it after the first few months, as the ability to pay might have disappeared with time. In the absence of social security and medical insurance, many patients are financially dependent on relatives for transport, buying drugs and other related indirect costs. The economic burden of HIV/AIDS illness for households in developing countries has been shown to be cumulative and catastrophic, accounting for many times the local per capita income (Russel, 2004). In Kenya, where the per capita income is US$540 per year, the cost of ART alone amounts to 16% of monthly income and is substantial even without including indirect costs (World Bank, 2006). Thus, beyond a certain threshold, households are understandably unable to cope with the continuing financial burden of treatment. Although a social waiver system was in place to identify and exempt individuals who were unable to pay, the experience with waiver systems in settings where the median income is well under absolute poverty is that they are insensitive in detecting 'ability to pay' and thus repeatedly fail (Sepehri and Chernomas, 2001). The fact that five patients in our study diluted ART doses in order reduce the monthly cost of medication by half suggests that the waiver system failed to provide sufficient support to those unable to pay and could not be calibrated to adjust for fine changes in the ability to pay.

Other studies conducted in resource-limited settings have shown that cost of ART is an insurmountable obstacle for many individuals, contributing to loss to follow-up, poor adherence to treatment, reduced ART efficacy and reduced access to HIV care, particularly for marginalized groups (Bission et al., 2006; Ivers et al., 2005; Laurent et al., 2005; Oosterhout et al., 2005). The clear way forward to avoid this obstacle is to abolish any fee associated with ART. However, this is often a challenge for government officials and programme managers. Pessimism that domestic sources are not sufficient for free provision, combined with lack of confidence that donors will meet the costs of HIV-related services in the longer term, has led many countries with a high HIV prevalence like Kenya to encourage cost-recovery policies. There is, however, ample rationale from a number of perspectives to opt for free ART access at the point of service delivery.

Firstly, from an economic and public health perspective, universal free access to HIV care and the resulting dramatic reductions in AIDS-related mortality and morbidity have the potential of generating substantial public savings brought about by reduced burden on health services (direct medical costs). For example, in Brazil universal free access to ART from 1996 resulted in savings for public health expenditure for the national programme of US$1.1 billion over the period 1997—2001 (Remien et al., 2003). Recent macroeconomic models (Bell et al., 2004; Ventelou and Drouhin, 2003) also show that providing free ART access preserves social capital and productive labour, which is a net gain to the economy.

Secondly, from the perspective of sustainability, asking patients to pay for treatment adds up to minimal sums (at best to less than 10%) of overall costs incurred in providing HIV/AIDS care (Laniece et al., 2003). Sustainability can thus only be achieved through long-term commitments from governments that are supported by donors.

Finally, the association between end-user cost and adherence confirms observations from Senegal (Laniece et al., 2003), Uganda (Byakika-Tusiimi et al., 2005) and Botswana (Weiser et al., 2003; WHO, 2005b). Lack of compliance has immediate implications for the development of resistance to first-line ART regimens and leads to increased costs in the future, as second-line regimens cost five to ten times more than first-line regimens. Mortality rates while on ART are also likely to be higher over time (Braitstein et al., 2006).

The results of this study encouraged the Mbagathi District Hospital management to phase-out ART payment and offer medication free of charge for all. However, the hospital management now faces the practical challenge of replacing the funds that were being generated by user fees. These fees played an important role in solvency at management level and in the motivation of staff. The lost revenue needs to be compensated, and failure to do so might end up being counterproductive, i.e. end-user costs may either be shifted to other services or recovered informally by providers (WHO, 2005b). With the endorsement by the United Nations member states in September 2005 to move towards universal access for HIV treatment by 2010, health sector financing strategies must now ensure that resource-limited governments are provided with sufficient funds to be able to offer free HIV/AIDS care to all patients. The principle of free treatment should be applicable to AIDS, as is the case with tuberculosis or other infectious diseases of public health importance. Access to free treatment is a human right and a moral obligation, although it is clearly of economic benefit too.

Authors' contributions: RZ, MMas, MMan, LK and AS were involved with the conception and study design; IVE, RZ, MMas, MMan and AS were involved with supervision, analysis and interpretation of data; MP and MB considerably improved the analytical methods and contributed significantly in improving the intellectual content of the paper; RZ wrote the first draft of the paper and all co-authors read

and approved the final manuscript. RZ and IVE are guarantors of the paper.

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Conflicts of interest: None declared.

Ethical approval: General measures are provided in the Mbagathi District Hospital ART facility to ensure patient confidentiality, consent for HIV testing and counselling and support for those who receive a positive HIV test result. As this paper was a retrospective evaluation of an existing programme and was conducted with the full knowledge and approval of the Mbagathi District Hospital and the Ministry of Health, formal ethics approval was not required. Data used for analysis in this study were kept anonymous.

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