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Medication Adherence Clubs: a potential solution to managing large numbers of stable patients with multiple chronic diseases in informal settlements

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Abstract

OBJECTIVES To assess the care of hypertension, diabetes mellitus and/or HIV patients enrolled into Medication Adherence Clubs (MACs).

METHODS Retrospective descriptive study was carried out using routinely collected programme data from a primary healthcare clinic at informal settlement in Nairobi, Kenya. All patients enrolled into MACs were selected for the study. MACs are nurse-facilitated mixed groups of 25–35 stable hypertension, diabetes mellitus and/or HIV patients who met quarterly to confirm their clinical stability, have brief health discussions and receive medication. Clinical officer reviewed MACs yearly, when a patient developed complications or no longer met stable criteria.

RESULTS A total of 1432 patients were enrolled into 47 clubs with 109 sessions conducted between August 2013 and August 2014. There were 1020 (71%) HIV and 412 (29%) non-communicable disease patients. Among those with NCD, 352 (85%) had hypertension and 60 (15%) had DM, while 12 had HIV concurrent with hypertension. A total of 2208 consultations were offloaded from regular clinic. During MAC attendance, blood pressure, weight and laboratory testing were completed correctly in 98–99% of consultations. Only 43 (2%) consultations required referral for clinical officer review before their routine yearly appointment. Loss to follow-up from the MACs was 3.5%.

CONCLUSIONS This study demonstrates the feasibility and early efficacy of MACs for mixed chronic disease in a resource-limited setting. It supports burden reduction and flexibility of regular clinical review for stable patients. Further assessment regarding long-term outcomes of this model should be completed to increase confidence for deployment in similar contexts.

keywords operational research, SORT IT, Hypertension, Diabetes Mellitus

Introduction

The increasing burden of hypertension and diabetes mellitus, combined with a growing number of patients on antiretroviral therapy, has resulted in a large number of patients in need of chronic care, straining the healthcare system. Kibera is an urban, informal settlement in Nairobi, Kenya, with an estimated population of 240 000 (MSF internal report 2009 [1]). The prevalence of hypertension and diabetes mellitus is estimated at 12.3% and 5.3%, respectively [2–4]; Ayah *et al.* 2013, Oti SO et al. 2013, Van de ViJver et al. 2013. The prevalence of HIV infection is estimated at 12.6% [5]; Dalal W et al. 2013, compared to a national average of 5.6% (Kenya AIDS indicator survey 2012 [6]. In collaboration with the Kenya Ministry of Health, Médecins Sans Frontières Médecins Sans Frontières (MSF) [7]; Sobry A et al. 2013, established HIV/Tuberculosis (TB) services within three comprehensive outpatient clinics in Kibera in 2003 and introduced hypertension and diabetes mellitus care in 2009.

Medication Adherence Clubs (MACs) have been developed in South Africa as a unique solution to managing

stable patients with HIV where they shifted care from overburdened clinics to peer groups; MSF has demonstrated improved patient outcomes such as viral load suppression, medication adherence, less loss to follow-up and reduced clinician workload [8–10] Wilkinson LS. 2013; Luque-Fernandez MA et al. 2013; MSF ART adherence club report and tool kit. 2012. Subsequently, WHO has recommended the peer group treatment model as one way to decrease the cumulative workload of follow-ups on healthcare providers and to improve patient outcomes in its 2013 HIV treatment guideline [11]. Finding solutions that give long-term, quality care to this ever-increasing cohort are of importance in other low resource settings.

To address the increasing demand for follow-up of non-communicable diseases (NCDs), in 2013, the Kibera project adopted the HIV MACs model but implemented combined MACs for hypertension, diabetes mellitus and HIV patients. In Kibera, MACs are nurse-facilitated groups of 25–35 stable hypertension, diabetes mellitus and HIV patients who meet quarterly to: (i) confirm their clinical stability, (ii) have a short health talk and (iii) receive pre-packed medications. Routine patient follow-up with clinical officers occurs yearly, when a patient develops complications or no longer meets the inclusion criteria. A rigorous literature search yielded no published studies describing the use of MACs for patients with multiple non-communicable diseases.

This study assessed the care of hypertension, diabetes mellitus and HIV patients enrolled in MACs in the informal settlement of Kibera, Nairobi, Kenya from August 2013 to August 2014. Specifically, the study determined the proportions and characteristics of patients with NCDs and HIV infection, the number and proportion of hypertension, diabetes mellitus and HIV consultations where MACs protocols were followed, the number and proportion of MACs patients referred back to clinicians for complications or instability and the proportion of patients retained in MACs at three, six and twelve months.

Materials and methods

Study design and setting

This was a retrospective, descriptive study using routinely collected programme data in Kenya, an East African country with an approximate population of 39 million (Kenya population and housing census 2009 [12]. Nairobi, where Kibera is located, has an estimated population of three million (Kenya population and housing census 2009 [12]. The country is experiencing a rapidly growing burden of non-communicable diseases (UNAIDS report-2011 (13). The prevalence of diabetes mellitus in urban areas is almost twice the national average of 3.3% (First Kenya National forum on non-communicable disease 2011 [13]. Overall, non-communicable diseases cause over 50% of all hospital deaths and admissions (First Kenya National forum on NCD 2011 [14]. Of these deaths, 13% are due to cardiovascular diseases and 4% are due to complications of diabetes mellitus (First Kenya National Forum on NCD 2011 [14]. Of the 600 000 HIV-infected people on ART, 75.4% have achieved viral suppression (Kenya AIDS indicator survey 2012 [6]), adding to the pool of chronic, stable patients.

Currently, Kenya Ministry of Health facilities offer hypertension and diabetes mellitus treatment only at the subcounty and county referral hospital levels and not at health centres or dispensaries. Most patients have to pay user fees to access non-communicable disease services and medications. Despite decentralisation of HIV treatment where antiretroviral drugs are free, the majority of patients still pay out of pocket for treatment of opportunistic infections and laboratory tests other than those for routine HIV monitoring.

The study site was Kibera South Health Centre with an estimated catchment population of 88 000 (MSF Belgium Kibera; Annual report 2013 [15]). MSF, in collaboration with the Ministry of Health, is providing a comprehensive integrated primary health package that includes HIV, TB, non-communicable disease, general outpatient department, nutrition, maternal child health and sexual- and gender-based violence care at no cost to the client. There are 5500 active HIV patients (4700 on antiretroviral drugs, 80% with suppressed viral loads), 2200 hypertension and diabetes mellitus patients and approximately 200 patients who are comorbid with HIV and hypertension or diabetes mellitus (MSF Belgium Kibera; Annual report 2013 [15]).

The clinics are currently grappling with the challenge of large patient numbers requiring follow-up, the majority of whom are stable. On average, there are approximately 3000 HIV and 1000 hypertension and diabetes mellitus combined consultations per month. There are approximately 100 new HIV and 70 new hypertension and diabetes mellitus patients per month. The same clinical officers and nurses who care for both HIV and non-communicable disease patients also carry out outpatient department consultations averaging a total of 8000 consultations per month (MSF Belgium Kibera; Annual report 2013 [15]). This translates to approximately 45–50 consultations per day per clinician. The effect of this workload is an unacceptably long waiting time for patients at the clinics, averaging four to six hours (MSF

Belgium Kibera; patient satisfaction survey 2012 [16]. The current loss to follow-up rate for hypertension, diabetes mellitus and HIV cohorts, which is between 30 and 40% [7], (MSF Belgium Kibera; Annual report 2013 [15]), is possibly related to the long wait times and no available care on weekends.

Medication adherence clubs

HIV and non-communicable disease patients were informed about the option of joining MACs through daily health talks in waiting bays, patient empowerment meetings and posters in the clinic. Patients were screened by clinicians during routine follow–up and if they met the inclusion criteria (see below) were offered the option of attending a MAC. Some patients proposed to join a MAC independently of clinician inquiry after sensitisation. Patients were provided signed informed consent before enrolment into the groups, acknowledging that there would be hypertension, diabetes mellitus and HIV patients in the MACs, but that diagnosis disclosure was voluntary. Those declining to join MACs, yet met entrance criteria, were informed that they would continue to be seen as usual through spaced clinic appointments. The MACs were conducted on Wednesday, Thursday and Saturday afternoons between 3 p.m. and 5 p.m. Timing was structured to provide maximum flexibility for patients to attend.

Patient population

All patients who were enrolled into MACs between August 2013 and 31 August 2014 were included in the study. Inclusion criteria for the MACs for hypertension and diabetes mellitus patients were as follows: ≥25 years old, >6 months on medications, having blood pressure < 150/100 and/or HBA1c <8%; for HIV patients, the inclusion criteria were as follows: ≥25 years old, >1 year on ARVs, CD4 > 200, previous viral load was undetectable and not in WHO Stage 3 or 4 active disease.

Outcomes

Outcome measures included the number and proportion of: (i) non-communicable disease consultations where the patients' blood pressure and/or blood sugar were below MACs threshold, (BP <150/100 mmHg, Hba1c <8.0%, respectively) whose weight was recorded and routine blood workup was requested as per the non-communicable diseases protocol; (ii) HIV consultations where patients' weight and blood pressure were recorded and routine blood workup was requested as per the HIV protocol; (iii) non-communicable disease and HIV consultations where the patients were referred from MACs for clinical consultation for NCD, HIV or non-NCD/HIV-related problems (annual review by the clinical officer was not included as a referral back to clinic); and (iv) retention at months three, six and twelve. Lost to follow-up was determined 3 months after a patient failed to attend a MAC session, pick up their medication and was not reported in any of the following outcomes: referred to regular clinic, transferred out or died.

Data collection and analysis

Patients' demographic and baseline clinical characteristics were collected from the MACs register. Double data entry and validation was performed using EpiData Entry software (version 3.1, EpiData Association, Odense, Denmark). HIV variables were extracted from a FUCHIA database (version 1.7.1 Epicentre, Paris, France) and were merged with those from an EpiData database, which served as the non-communicable diseases database. File reviews were performed for patients whose variables were missing on the electronic databases. Descriptive analysis was performed using EpiData Analysis software (version 2.2.2.182, EpiData Association, Odense, Denmark).

Ethics

Ethics approval was received from Kenya AMREF Ethics and Scientific Review Committee. The study met the Médecins Sans Frontières (MSF) Ethics Review Board (Geneva, Switzerland) approved criteria for studies of routinely collected data and was also approved by the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France.

Results

A total of 1432 patients (64% female) were enrolled in 47 MACs with 109 sessions conducted between August 2013 and August 2014. Table 1 shows the demographic characteristics and clinical status of the patients at enrolment. The HIV population was younger and had been on treatment longer than the hypertension/diabetes mellitus cohort. All patients met the admission criteria.

Table 2 shows adherence to protocols in the MACs (appropriateness of the MACs nurse in taking weight, blood pressure and ordering routine blood tests for each patient based on the treatment guidelines). From a total of 2208 consultations, for both HIV and HT/DM patients, adherence appears to be high with blood

Table 1 Characteristics of patients at enrolment into Medication Adherence Clubs in an MSF primary care clinic stratified by morbidity, Kibera, Nairobi, Kenya from August 2013 to August 2014

Variables	HIV positive *n* (%)	Non-HIV *n* (%)	Total *n* (%)
Total	1020	412	1432
Sex			
Male	405 (40)	108 (26)	513 (36)
Female	615 (60)	304 (74)	919 (64)
Age (years)			
25–45	745 (73)	168 (41)	913 (64)
>45–75	265 (26)	243 (59)	508 (35)
Not recorded	10 (1)	1 (0)	11 (1)
Duration on treatment at time of enrolment (months)			
>6 months < 12 months	2 (<1)	8 (2)	10 (0.7)
>12 months-24 months	1 (<1)	54 (13)	55 (4)
>24 months	1009 (99)	346 (84)	1355 (95)
Not recorded	8 (0.8)	4 (1)	12 (0.8)
Hypertensive	12 (1)	352 (85)	364 (25)
Diabetic	0 (0)	60 (15)	60 (4)
Median systolic pressure (IQR)	122 (114–135)	137 (125–150)	127 (117–141)
Median diastolic pressure (IQR)	73 (67–80)	80 (74–88)	76 (69–84)
Median HBA1c (IQR)	n/a	8 (8.0–8.0)	
CD4 for HIV			
≤200 mm^3	47 (5)	n/a	n/a
>201 mm^3	969 (95)	n/a	n/a
Viral load			
≤ 450 copies/ml	999 (98)	n/a	n/a
> 451 < 1000 copies/ml	20 (2)	n/a	n/a

n/a, not applicable.

pressure checked in 99%, weight checked in 98% and blood tests ordered correctly in 98–99% of patients.

Selected outcome indicators are shown in Table 3. Of 2208 consultations, 43 (2%) were referred back to the regular clinic. The reasons for referral were as follows: diabetes/hypertension management related in 28% (12), HIV management related in 14% (6), non-HIV or non-diabetes/hypertension related in 30% (13) and not specified 28% (12). The overall loss to follow-up (LTFU) was 3.5% (30). LTFU occurred only between the 1st and 2nd MAC attendees. There were no known mortalities of MAC patients during the study period.

Discussion

This is the first documented study employing a group treatment model for patients with multiple chronic diseases, including HIV. There was a high degree (99%) of compliance with protocols and a small percentage (3.5%) of loss to follow-up. There were minimal referrals (2%) back to the regular clinic for cases needing clinical officer review. However, there was some amount of selection bias within this group of patients as they represent a subcohort that was already likely highly compliant because of the study inclusion criteria.

A randomised control group was considered before study implementation, but it was felt only equitable to offer this more flexible care model to all qualifying patients because of the immediate benefits expected. Time saved and increased appointment flexibility in an informal settlement context potentially translate into increased employment opportunities and less poverty. This was reflected in the fact that patients were independently requesting a referral to join the MACs. To limit this, option of increased flexibility did not appear ethical.

Medication Adherence Clubs coped with 2208 consultations that would have been included in the regular clinic during the first year of implementation. With further scale-up, a greater number of single provider clinic visits can be offloaded. Although specific time measurements were not recorded, the MAC group visits typically

Table 2 Number of patients in Medication Adherence Clubs who were appropriately evaluated as per protocol at the time of visit in an MSF primary care clinic, Kibera, Nairobi, Kenya from August 2013 to August 2014

Variables	HIV *N* = 1482 consultations Protocol Followed (%)	Non-HIV *N* = 726 Consultations Protocol Followed (%)
Blood pressure checked*	1460 (99)	718 (99)
HbA1c or fasting glucose ordered (*n* = 59)*†	n/a	58 (98)
Weight checked	1452 (98)	714 (98)
Total cholesterol ordered (*n* = 231)*	n/a	228 (99)
Creatinine ordered (*n* = 211)*	n/a	209 (99)
CD4 ordered (*n* = 300)*	294 (98)	n/a
Viral load ordered (300)*	296 (99)	n/a

n/a: not applicable.
*N varies depending on the number of patients eligible at time of data closure.
†Fasting glucose was performed as an alternative to HbA1c at a time when the HbA1c machine was broken down.

lasted less than 2 hours, which likely significantly reduced the amount of patient time during these visits.

These findings reflect stringent eligibility criteria for stable patients in MACs and suitable protocols for monitoring them. The study supports the development of MACs as an efficacious method of reducing clinicians' workload, caring for multiple different types of stable chronic disease patients simultaneously and increasing the flexibility of care delivery for patients. It also demonstrates a low loss to follow-up (3.5%), likely reflecting patient satisfaction, a key element in care of chronic conditions. Offering free care and medications may have been another strong incentive for patients to remain in care.

Strengths of the study were a relatively large sample size (1432), and representative of patients enrolled into MACs. Due to good management, data loss was minimal. The study was carried out during routine project operations therefore reflecting true programmatic conditions. We reported the results according to STROBE Guidelines [3].

There are limitations. The study was conducted within the first year of MACs implementation, an interval that was too short to evaluate other outcome indicators over time. However, gathering this information early in the programme provides reassurance that this model is working well. In addition, it was not possible to ascertain the amount of selection bias among the results because of the lack of a randomised control group.

Only one other study in sub-Sahara Africa (SSA) has described a similar model, but it was limited to a single chronic disease (HIV) and included fewer (500) patients [8]. This study's findings are in line with the positive results from the other study, reinforcing the soundness of the concept. Both studies showed programme similarities including urban environment, informal settlements, Clinical or Medical officer's review occurred once yearly and demonstrated improved early outcomes.

To promote further adoption and replication, the study results were shared with the Kenyan Ministry of Health and other healthcare stakeholders to enable sustainable access for chronic care treatment in resource-constrained settings.

In conclusion, this study demonstrates the feasibility and early efficacy of Medication Adherence Clubs as a novel group treatment model to care for stable patients with mixed chronic diseases in an urban, resource-constrained, informal settlement. It supports reducing the burden of regular clinical follow-up among stable patients and improves the flexibility of care delivery. Further assessment on the long-term outcomes of this model should be considered to increase confidence of deploying it in similar contexts.

Table 3 Outcomes for Medication Adherence Clubs August 2013 – August 2014, Kiberia, Nairobi, Kenya

	1st MAC			2nd MAC			3rd MAC		
	Total	HIV	Non-HIV	Total	HIV	Non-HIV	Total	HIV	Non-HIV
Attended Macs (*n*)	1432	1020	412	596	361	235	166	94	72
LTFU (%)	–	–	–	15 (3)	15 (4)	0 (0)	0 (0)	0 (0)	0
Referred to regular clinic (%)	17 (1)	11 (1)	6 (1)	5 (<1)	2 (<1)	3 (1)	2 (1)	1 (1)	1
Transferred out (%)	2 (<1)	1 (<1)	1 (<1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0
Died (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0

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