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UPTAKE OF ISONIAZID PREVENTIVE THERAPY AND ITS ASSOCIATED FACTORS AMONG HIV POSITIVE PATIENTS IN AN URBAN HEALTH CENTRE, KENYA

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ABSTRACT

Background: Isoniazid Preventive Therapy (IPT) is an effective intervention for prevention of tuberculosis (TB) among HIV positive patients, and its use is recommended by the World Health Organization (WHO). Unfortunately the uptake of IPT in Kenya remains low (33%-40%) with limited knowledge on the factors that affect its uptake.

Objective: To determine the uptake of IPT and its associated factors among HIV-positive patients enrolled in a urban health centre.

Design: Hospital based cross-sectional study

Setting: Riruta Health Centre, Nairobi, Kenya

Subjects: HIV-positive patients ≥ 18 years who have been on care and treatment services in the health centre for at least six months preceding the study.

Results: Four hundred and thirty six participants were enrolled with a mean age of 41 years (standard deviation ± 9 years). Females were 276 (63%), anti-retroviral therapy uptake of 427 (98%) and overall IPT uptake rate of 336 (77%). On multivariate analysis, fear of acquiring TB (adjusted odds ratio (AOR) 4.6, 95% confidence interval, CI 2.6-8.1), having received IPT-associated health education (AOR 5.0, 95% CI 3.0-8.4) and having a good relationship with the healthcare worker (HCW) (AOR 2.0, 95% CI 1.2-3.4) were independently associated with initiation of IPT.

Conclusion: The uptake rate was above the current national coverage but fell below the national set target of 90%. Fear of acquiring TB, receipt of IPT-associated health education and favourable relationship with the HCWs promoted the initiation of IPT.

INTRODUCTION

The synergy between HIV and tuberculosis (TB) is strong. People living with HIV (PLHIV) are 20 to 37 times more likely to develop active TB than those without HIV thus making HIV the strongest risk factor for acquiring TB (1). Approximately one third of deaths among HIV-positive people were due to TB in 2014 (2). According to the World Health Organization (WHO), the African region accounted for 28% of the world's TB cases in 2014 (3). However, it had the most severe burden relative to population at 281 cases for every 100,000 people which was more than double the global average of 133 cases per 100,000. Africa also accounts for 74% of HIV-positive TB cases globally (3). Despite anti-retroviral therapy (ART) improving CD4

cell counts and reducing incidence of TB among HIV-infected persons, one South African study showed that TB incidence rates still remained higher among those with CD4 of greater than 700 cells/mL on long-term ART compared to HIV-uninfected persons (4).

In 1998, WHO recommended a routine package for the prevention of TB among PLHIV commonly referred to as the Three I's. The interventions include isoniazid preventive therapy (IPT), intensified TB case finding and infection prevention and control (5). IPT is the provision of isoniazid prophylaxis to people at higher risk of developing active TB disease. IPT alone lowers the risk of developing TB disease by treating latent tuberculosis infection (LTBI) and preventing its reactivation thus reducing the incidence of TB by 70-90% among PLHIV (6). However, according to

WHO Global TB 2015 report, only 933,000 PLHIV out of 36.9 million received IPT in 2014(3).

In Kenya, TB/HIV implementation guidelines recommend IPT for: all PLHIV above 12 months of age who screen negative for TB using the ICF tool, all children under five years who had close contact with a sputum positive TB case irrespective of HIV status in the past 12 months and all prisoners irrespective of HIV status (11). PLHIV are screened by health care workers in the HIV clinic at every monthly visit using a standard TB symptom screening tool. This tool inquires for the presence of any of the following - cough of any duration, fever, unintentional weight loss or night sweats. If there is any suspicion of TB disease, IPT is deferred and the individual investigated for TB. IPT is administered at a daily dose of 300mg for adults and 10mg/kg for children for six months. HIV-infected children aged less than one year, presumptive TB cases or those diagnosed with TB disease, with active hepatitis or symptoms of peripheral neuropathy are deemed ineligible for IPT. Children and adults with a previous history of poor adherence to ART are also excluded, as they are deemed likely to have poor adherence to IPT. PLHIV are educated and counselled on the benefits of IPT before, during and after initiation. Clinicians ensure that they have complete patient packs of isoniazid (INH) containing six months of prophylaxis assigned to each patient before initiation to ensure completion of course of therapy without interruption. The INH patient packs is stored at the pharmacy, from where they are dispensed with other medication during scheduled HIV clinic days. As part of the routine monthly follow-up, patients are screened for TB, monitored for adverse drug reactions and counselled to reinforce adherence. IPT implementation in Kenya begun September 2011.

Kenya ranks fifteen out of the twenty-two high TB burden countries in the world and fifth in sub-Saharan Africa. It has a HIV prevalence of 5.6%(7) with a HIV co-infection rate of 37% among TB patients(8). The capital city, where this study took place, had a TB case notification rate of 387/100,000 and a TB/HIV co-infection rate of 45% in 2015 (8). Despite the evidence of its benefits, initiation of IPT remains low. Even in the presence of adequate stocks, factors affecting the uptake of IPT at the facility level remain poorly understood. We, therefore, conducted this study with the aim of determining the uptake of IPT and patient-associated factors among HIV-infected individuals enrolled in HIV care at an urban health center in Nairobi, Kenya.

MATERIALS AND METHODS

Study design: This was a cross-sectional hospital-based study.

Study Setting: Kenya is located in the East African

region and is bordered by Indian Ocean and Somalia in the east, Ethiopia and Sudan in the north, Uganda in the east and Tanzania in the south. Its total area is 582,646 square kilometres with an estimated population of 46 million in 2015 with children accounting for half of this population. Approximately 25% of the total population is concentrated in the urban areas (9). Kenya's Gross Domestic Product(GDP) was worth 63.40 billion US dollars in 2015 and growing by 5.6 per cent in 2015 but with 46% of the population living below the poverty line (10). An estimated 1.5 million infected adults live with HIV/AIDS, 950,000 of these enrolled on care (7).

We conducted this study in Riruta Health Centre, a high volume primary health-care centre, in the northern part of Nairobi, the capital city of Kenya. Its catchment population includes informal settlers of low socio-economic status. It offers outpatient care for common ailments as well as comprehensive HIV care and treatment services. The number of HIV patients enrolled on care are 3,206 with an average of 1,500 patient-visits per month. IPT Programme was rolled out in Riruta in 2014.

Study Subjects: The study participants were adult HIV-positive patients (≥ 18 years) who had been on care and treatment services in the health centre for at least six months preceding the study, regardless of whether they were on ART or not. We excluded HIV-positive patients who did not consent to participate in the study, those who were on treatment for TB during the study period and patients who attended clinic on the day they were not scheduled.

Sample size and sampling: We based our sample size calculations on a study done in health facilities of similar setting in Addis Ababa, Ethiopia where the IPT uptake rate was 31% (12). Using Epi-info 7 software, we found a minimum sample size of 329 assuming a precision of 5% and 95% level of significance. The daily appointment register was used to generate daily line lists from which eligible patients were recruited systematically. We interviewed ten patients daily until the desired sample size was achieved. Where a patient either was ineligible or failed to attend on their appointment date, the next eligible patient was enrolled.

Data Collection: We collected information using a structured pre-tested questionnaire through face-to-face interview. We collected information on socio-demographics such as age, sex, employment status; knowledge on IPT, HIV care and management-initiation and adherence to ART and other factors associated with uptake of IPT.

Data Analysis: We used Microsoft Excel and Epi Info version 7 to clean and analyse data. Categorical variables were summarised by percentages and proportions while continuous variables were summarised using means and medians. IPT uptake rate was calculated as the proportion of HIV-positive

patients enrolled in the study who were initiated on IPT. Multivariate logistic regression was used to determine factors independently associated with the uptake of IPT. Significance level of $P < 0.2$ in the bivariate analysis were entered into the model. Factors with P-values less than 0.05 were considered significant.

Ethical approval: Informed consent was obtained from the participants. Ethical approval was obtained from Moi University/Moi Teaching and Referral Hospital Institutional Review and Ethics Committee (IREC). Permission to conduct the study in a public health facility was granted by Nairobi County Health Office.

RESULTS

Socio-demographic and Clinical characteristics: We interviewed a total of 436 participants. Table 1 shows the socio-demographic characteristics of the

participants. Females accounted for 276 (63%). The average mean age of the participants was 41 years (standard deviation, $SD \pm 9.4$ years) while 92% had acquired basic schooling (primary school and beyond).

Table 2 shows the clinical characteristics of the patients. Ninety eight percent (427) of the participants were already on anti-retroviral therapy (ART) with the average duration of therapy of 4.2 years ($SD \pm 0.2$ years). History of previous TB treatment was reported among 112 (26%) of the participants while 322 (74%) reported to have received information on IPT from health education offered by the health care workers at the facility. Counselling prior to initiation of IPT was given to 329 (75%).

Disclosure of HIV status was done by 401 (94%) of the participants with 354 (88%) disclosing to their sexual partners. Adherence to scheduled clinic appointments was reported among 79% (321) of the participants.

Table 1

Socio-demographic characteristic of HIV positive patients attending HIV care in Riruta Health Centre

Characteristic		Cases n=436 (%)
Sex	Female	276 (63)
	Males	160 (37)
Age in years	18-24	10 (2)
	25-34	101 (23)
	35-44	177 (41)
	45-54	102 (23)
	≥ 55	47 (11)
Marital status	Married	222 (51)
	Not married	214 (49)
Employment	Salaried Worker (Formal employment)	66 (15)
	Informal employment	231 (53)
	Self employed	83 (19)
	Unemployed	56 (13)
Level of Education	No formal education	35 (8)
	Primary (1-8 years)	226 (52)
	Secondary	154 (35)
	Tertiary	21 (5)
Religion	Christian	336 (77)
	African Tradition Religion	93 (21)
	Others	7 (2)

Table 2
Clinical characteristic of HIV positive patients attending HIV care at Riruta Health Centre.

Characteristic		N= 436 (%)
Duration of knowing their HIV status	<1 year	14 (3)
	1-5 years	158 (36)
	6-10 years	200 (46)
	>10 years	64 (15)
Initiated on ART	Yes	427 (98)
Disclosure of HIV status	No	35 (6)
	Yes	401(94)
	Partner	354 (88)
	Relative	125 (30)
	Friend	68 (16)
	Fellow patient	11 (3)
Missed \geq 2 most recent clinic appointments	Yes	90 (21)
	No	335 (79)
Screening for TB using ICF tool	Yes	410 (92)
Previous history of TB treatment	Yes	112 (26)
	No	324 (74)
Heard about benefits of IPT	Yes	375 (86)
Source of Information	Health Education by HCW	329 (88)
	Fellow patient	43 (11)
	Radio	14 (4)
	IEC materials	7 (3)
Reasons for accepting IPT	Fear of acquiring TB	210 (48)
	Because clinician is right	281 (64)
	Understood the benefits	114 (27)
Being a member of HIV Support group	Yes	38 (9)
	No	398 (91)
Incur costs when seeking care	Yes	223 (51)
	No	213 (49)

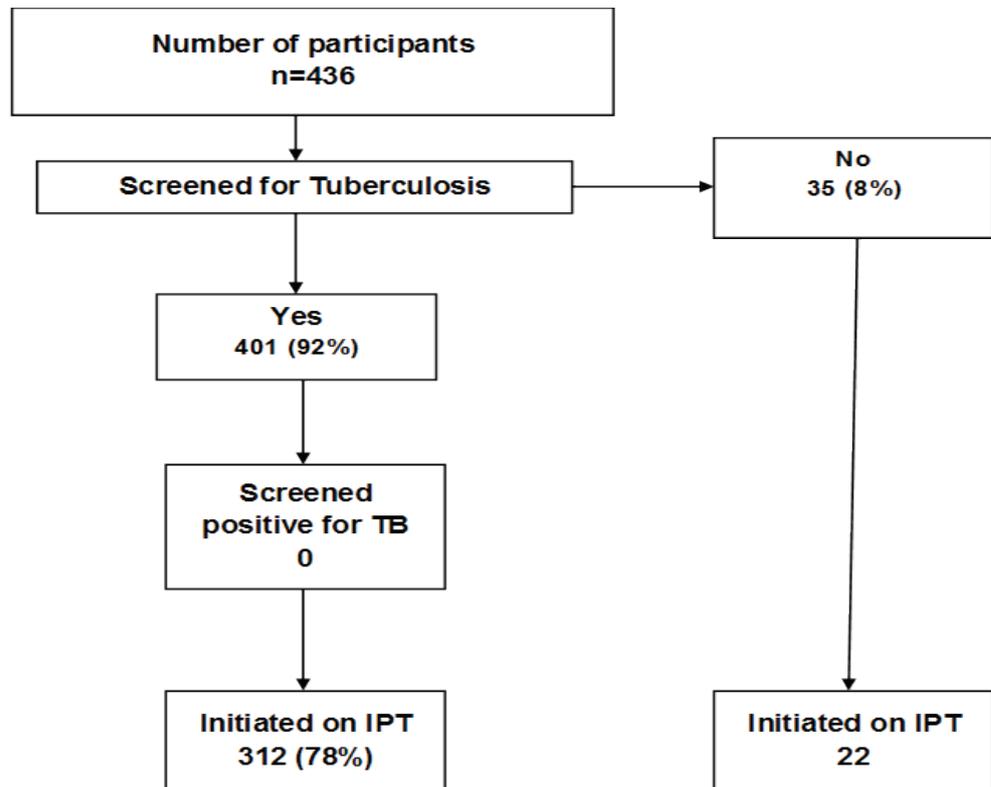
HIV- Human Immunodeficiency Virus; IPT- Isoniazid Preventive Therapy; IEC - Information, Education and Communication materials; HCW – healthcare worker

Uptake of IPT and its associated factors; Overall, the number of participants who were initiated on IPT was 334 (77%). Screening for signs and symptoms of TB prior to IPT initiation was done in 401 (92%) of the participants, of whom 312 (78%) were initiated on IPT (Figure 1). Out of the 35 participants who were not screened for TB, 22 (63%) were initiated on IPT. Of those screened, none screened positive for TB using the intensified case finding tool. Reasons that motivated participants to accept IPT were: 281 (64%) believed that the clinician was right, 210 (48%) had fear of acquiring TB and 112 (26%) understood the benefits of IPT (Table 2).

On multivariate analysis, factors associated

with IPT initiation were the fear of acquiring TB (odds ratio, OR=4.4), IPT-associated health education (OR=5.6), and screening for TB (OR=2.1) (Table 3). After adjusting for the effects of other confounders those who were afraid of acquiring TB were 4.6 times more likely to be initiated on IPT (Adjusted OR=4.6, 95% Confidence Interval, CI=2.6-8.1, P<0.001) while those who received IPT-associated health education were five times more likely to be initiated on IPT (AOR=5.0, 95% CI=3.0-8.4, P<0.001). Participants who reported a favourable relationship between them and health care workers were also twice as likely to be initiated on IPT (AOR=2.0, 95% CI= 1.2-3.4, P=0.01).

Figure 1
Flow diagram for HIV positive patients screened for TB in Riruta Health Centre.



TB – Tuberculosis, IPT – Isoniazid Preventive Therapy

Table 3
Factors associated with IPT uptake among HIV positive persons attending care in Riruta Health Center.

Characteristics	Initiated on IPT n=334	Crude OR (95% CI)	Adjusted OR (95% CI)	P-value
Gender	207 (62)			
Female	127 (38)	0.8 (0.5-1.2)		-
Male				
Fear of acquiring TB				
Yes	187 (56)	4.4 (2.6-7.3)	4.6 (2.6-8.1)	<0.001
No	147 (44)			
Health Education on IPT				
Yes	280 (84)	5.6 (3.5-9.1)	5.0 (3.0-8.4)	<0.001
No	54 (16)			
Screening of tuberculosis				
Yes	312 (93)	2.1 (1.1-4.3)	1.3 (0.6-2.7)	NS
No	22 (7)			
Knowledge on the benefits				
Yes	73 (23)	0.1 (0.06-0.1)	-	-
No	256 (77)			
Reported having a good relationship				
Yes	219 (66)	1.3 (0.8-2)	2.0 (1.2-3.4)	0.01
No	115 (34)			
History of previous TB treatment				
Yes	86 (26)	1.4 (0.9-2.5)	1.5 (0.8-2.9)	NS
No	248 (74)			
Keeping appointment dates				
Yes	265 (80)	1.0 (0.6-1.7)	0.9 (0.6-1.7)	NS
No	69 (20)			
Believing that the clinician was right				
Yes	210 (62)	0.7 (0.5-2.5)	-	-
No	124 (38)			
Disclosure of HIV status				
Yes	317 (95)	1.6 (0.7-3.8)	1.5 (0.6-3.6)	NS
No	17 (5)			
Motivated by the short term regimen				
Yes	1 (0.3)	0.3 (0.02-4.9)	-	-
No	333 (99.7)			
Cigarette smoking				
Yes	11 (3)	0.8(0.3-2.7)	-	-
No	323 (97)			
Support group				
Yes	24 (7)	0.5(0.3-1.1)	-	-
No	310 (93)			
Alcohol consumption				
Yes	32 (10)	0.9(0.4-1.8)	-	-
No	302 (90)			
Incur costs				
Yes	162 (48)	0.6 (0.4-1)	-	-
No	172 (52)			

TB – tuberculosis; IPT – Isoniazid Preventive Therapy; OR – Odds Ratio; CI – Confidence Interval; NS – P-value not significant at cut-off of $P \leq 0.05$

DISCUSSION

Among the first studies in Kenya on IPT uptake at Programme level, this study has shown that almost eight-in-ten PLHIV were initiated on IPT. Though it fell short of the set national target of 90%, this rate is higher than the current national uptake of 33%. Fear of acquiring TB among patients, health education on IPT and perceived good relationship with the health care worker were found to be independently associated with initiation on IPT.

A limitation of this study is the potential lack of generalisability of its findings to other facilities in the country. We also do not report on the immunological and clinical profiles of these patients which may have added more information. Despite these limitations, the study had several strengths, including using a relatively large sample size and completeness of data with very few missing variables. The conduct and reporting of this study also followed the STROBE Guidelines and sound ethics principles (13,14).

Fear of acquiring TB among the participants was found to be one of the factors independently associated with the initiation of IPT. Generally, TB is perceived by the community as a severe disease associated with debilitating effects and a high mortality, particularly among HIV co-infected patients. Indeed, TB is the commonest opportunistic infection and the leading cause of mortality among HIV positive patients (15). Thus, fear of acquiring TB and dying from it, could be a motivating factor for the patient to take up IPT as an intervention that confers protection from TB. This finding was similar to a study conducted in Tanzania, where completion of IPT was associated with fear of acquiring TB and its complications (16). Further, TB is often perceived as a hallmark for HIV positivity and thus, HIV associated stigma is transferred to TB-infected individuals following the diagnosis (17). This is particularly a concern in areas where the prevalence of HIV infection and HIV-TB co-infection is high, where the link between the two diseases has contributed significantly to stigmatisation of these patients. This may lead to HIV positive patients fearing to acquire TB because the community will suspect of their HIV status especially those who have not disclosed it. Consequently, this leads to rejection in fear of contracting both diseases by the community (18). This stigma is often associated with a sense of shame and may lead to self-discrimination and isolation by the infected person from perceived negative judgement from the community about the disease.

This study also found that those who received health education on IPT were more likely to be initiated on IPT compared to those who were not. Health education is known to be a critical process in motivating a patient to adopt behaviours that are beneficial to their health (19). This is because when

patients understand the role of IPT in prevention of TB, they easily make informed decisions and accept the intervention when offered. They also have more bargaining power to demand for the same especially when it is not offered. This, therefore, demonstrates positive responses and impact of a health education programme in increasing the likelihood of a patient being initiated on IPT.

Another important factor that was found to be associated with a favorable IPT uptake was a good relationship between the patients and the health care workers. This may have led to a conducive environment to trust the clinician and have open communication which results in sufficient information being passed to the patient and hence, the patient taking up IPT. Further, it may have allowed the patients to ask questions in order to seek clarity on issues that may arise and as a result, give the patients confidence in taking up therapy from a knowledgeable and experienced source. Good patient-provider relationship is known to be the primary bond that offers social support ultimately influencing health choices that patients make. These findings compliment a study in Ethiopia where a weak patient-provider relationship was reported to be one of the reasons that had a negative impact on the initiation of IPT by the clinicians (20).

Possible implications of this study include the need to re-inforce factors leading to improved IPT uptake like healthcare worker education. Though high clinician to patient ratios may not allow adequate time to address this adequately, task-shifting to the other cadres is possible. Each HIV care centre should be able to integrate IPT messages in their regular health education forums, often carried out to groups of patients on specific days and help establish patient support groups which reinforce these messages. National TB and HIV Programmes should also make available or integrate IPT messages into the Information, education and communication (IEC) materials provided to patients or general public.

Healthcare workers should also be reminded often of the need to establish and continue building good provider-patient relationship. Though there is no single way to achieve this, continued addressing of HCWs concerns and providing them with a conducive working environment is key.

The finding that none of the four hundred and one patients screened for TB turned out to be symptomatic for TB (screened positive) is intriguing. We expected at least some patients would have screened positive by the tool. Likewise 22 of 35 patients not screened for TB were still initiated on IPT despite guidelines requiring IPT initiation to be preceded by symptomatic screening. Whether screening was actually done and not just indicated on the screening tools is a possibility. Likewise, clinicians may just be ticking the screening checkboxes as a requirement

by the Programme without actually considering the relationship with presence/ absence of these symptoms. Nevertheless, these point to a serious problem in the processes. The national Programmes should now embark on qualitative evaluation of the IPT and screening processes, including addressing those issues pertinent to this processes. Use of point-of care data entry tools like smart phones Programmed with mandatory/required fields and check algorithms may help address these problems, at least partially.

In conclusion, this study found the uptake rate of IPT to be high and better than the current national coverage. Fear of acquiring TB among the HIV positive patients, health education on IPT and favourable relationship between the patient and health care worker were associated with high initiation rates for IPT. We recommend other strategies that promote uptake of IPT such as integration of more health education and counselling sessions to patients through formation of support groups.

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