Perceived stigma among patients receiving antiretroviral treatment: A prospective randomised trial comparing an m-DOT strategy with standard-of-care in Kenya

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Abstract

HIV and AIDS remain highly stigmatised. Modified directly observed therapy (m-DOT) supports antiretroviral treatment (ART) adherence but little is known about its association with perceived stigma in resource-constrained settings. In 2003, 234 HIV-infected adults enrolled in a two-arm randomised trial comparing a health centre-based m-DOT strategy with standard self-administration of ART. Data on perceived stigma were collected using Berger's HIV stigma scale prior to starting ART and after 12 months. This was a secondary analysis to examine whether perceived stigma was related to treatment delivery. Perceived stigma scores declined after 12 months of treatment from a mean of 44.9 (sd=7.6) to a mean of 41.4 (sd=7.7), (t=6.14, P<0.001). No differences were found between the mean scores of participants in both study arms. Also, no difference in scores was detected using GLM, controlling for socio-demographic characteristics and baseline scores. Findings indicate that a well managed clinic-based m-DOT does not increase perceived HIV-related stigma.

Keywords: HIV/AIDS, perceived stigma, attitudes, Africa, directly observed therapy.

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Résumé

Le VIH et le SIDA restent fortement stigmatisés. Le traitement modifié sous surveillance directe (m-DOT) favorise l'adhésion au traitement antirétroviral (ARV) mais il existe peu d'informations sur son association à la stigmatisation perçue dans des environnements pauvres en ressources. En 2003, 234 adultes infectés par le VIH étaient inscrits à un essai randomisé à deux bras comparant une stratégie m-DOT se déroulant dans un centre de santé à une auto-administration standard des ARV. Des données sur la stigmatisation perçue ont été collectées en utilisant l'échelle de stigmatisation du VIH de Berger avant d'entamer les ARV puis 12 mois plus tard. Une seconde analyse a été réalisée afin de déterminer si la stigmatisation perçue était associée au mode d'administration du traitement. Les résultats de la stigmatisation perçue ont baissé au bout de 12 mois de traitement, passant d'une moyenne de 44,9 (σ = 7,7), (t = 6,14, p<0,001) à une moyenne de 41,4 (σ =7,7), (t=6,14, p<0,001). Aucune différence n'a été observée entre les résultats moyens des participants dans les deux branches de l'étude. De plus, aucune différence de résultat n'a été observée en utilisant le MLG, qui permet de contrôler les caractéristiques sociodémographiques et les résultats de base. Les conclusions indiquent qu'un m-DOT se déroulant dans un centre médical bien géré n'augmente pas la stigmatisation perçue associée au VIH.

Mots clés: VIH/SIDA, stigmatisation perçue, attitudes, Afrique, traitement sous surveillance directe.

Introduction

In Kenya, there were 1.6 million adults and children living with HIV in 2007 (UNAIDS & WHO, 2008). As of March 2007, about half of the 263 000 HIV-infected individuals who required antiretroviral treatment (ART) had initiated it (PEPFAR, 2008). Rapid scale up of ART in the country began in 2004 when Kenya received nearly $92.5 million from the Presidential Emergency Fund for AIDS Relief, in addition to substantial support from the Global Fund to fight AIDS, tuberculosis and malaria. Non-adherence to ART is a formidable barrier to treatment success. Health programmes in sub-Saharan Africa and other parts of the world still grapple with low adherence and drug resistance issues. Inadequate adherence is associated with detectable viral loads, declining CD4 counts, disease progression, episodes of opportunistic infections, drug resistance, poorer health outcomes and death (Bangsberg et al., 2006; Carpenter, Cooper, & Fischl, 2000; Conway, 2007; Pearson *et al.*, 2007). Several studies have reported high levels of adherence across treatment programmes in sub-Saharan Africa (Conway, 2007; Mills, Nachega, Buchan *et al.*, 2006; Sarna *et al.*, 2008). However, a systematic review by Mills, Nachega, Bangsberg *et al.* (2006) showed that non-adherence to ART in adult populations in a diverse range of settings varied between 33%-88%, depending on how adherence was defined and evaluated. Moreover, an increasing number of programmes are reporting poor retention and adherence overtime (Chen *et al.*, 2008; Gill, Hamer, Simon, Thea, & Sabin, 2005; Rao, Kekwaletswe, Hosek, Martinez, & Rodriguez, 2007; Wakabi, 2008) . Adherence is expected to drop as treatment expands beyond the initial select privileged cohorts that belonged to well funded programmes and those that had not started experiencing long-term side-effects of treatment, for example neuropathy and lipodystrophy (Bangsberg, Ware, & Simoni, 2006; Kip, Ehlers, & van der Wal, 2009; Malangu, 2008; Murray *et al.*, 2009). Conway (2007) makes a strong argument that sub-optimal adherence continues to be one of the most frequent reasons for poor treatment outcomes in ART programmes.

Several strategies have been utilised to optimise adherence, for example: self-efficacy building, medication management skills, patient education and use of treatment buddies (Ickovics & Meade, 2002; Nachega *et al.*, 2006; Remien *et al.*, 2005; Sabin *et al.*, in press; Safren, Hendriksen, Desousa, Boswell, & Mayer, 2003; Safren *et al.*, 2001; Samet *et al.*, 2005; Sampaio-Sa *et al.*, 2008; Simoni, Amico, Pearson, & Malow, 2008; Smith, Rublein, Marcus, Brock, & Chesney, 2003; Tuldra *et al.*, 2000; Weber *et al.*, 2004; Wong, Lawrence, Struthers, McIntyre, & Friedland, 2006). These strategies have mainly been evaluated in high-income countries. Most adherence studies in Africa have focused on home-based support, building self-efficacy and assessing ART costs and adherence (Diabate, Alary, & Koffi, 2007; Hardon *et al.*, 2007; Mukherjee, Ivers, Leandre, Farmer, & Behforouz, 2006; Ramadhani *et al.*, 2007; Simoni *et al.*, 2008; Weidle *et al.*, 2006).

Innovative strategies such as modified directly observed therapy (m-DOT) have been used in ART programmes to support adherence (Abusabha & Woelfel, 2003; Altice, Maru, Bruce, Springer, & Friedland, 2007; Christopher, 2006; Farmer *et al.*, 2001; Macalino *et al.*, 2007; Mills, Nachega, Bangsberg *et al.*, 2006; Mitchell, Freels, Creticos, Oltean, & Douglas, 2007; Munoz *et al.*, in press; Page-Shipp *et al.*, 2007; Pearson *et al.*, 2007; Pearson *et al.*, 2006). The m-DOT strategy typically involves clinic staff or trained peers observing patients ingesting only some of their ART doses while the rest of the medication is self-administered by the patient (Page-Shipp *et al.*, 2007; Simoni *et al.*, 2008). Observations are tapered at some point under the assumption that the patients have internalised the drug-taking behaviour and will maintain adherence to all medication without further support (Simoni *et al.*, 2008). Unlike other adherence interventions, m-DOT helps address daily challenges to pill-taking, provides emotional and informational support, and is a strong link with health care services (Mukherjee *et al.*, 2006). This strategy has been found to be feasible and successful in supporting adherence in community-based ART programmes in resource-constrained settings and for patients in closed settings such as long-term care facilities, prisoners and for people enrolled in methadone clinics in developed countries (Altice *et al.*, 2004; Christopher, 2006; Farmer *et al.*, 2001; Liechty & Bangsberg, 2003; Pearson *et al.*, 2007; Santos, Adeyemi, & Tenorio, 2006; Sarna *et al.*, 2008).

The availability of ART and subsequent change in perceptions of HIV and AIDS as a manageable chronic disease has led to a decrease in stigma and discrimination in the industrialised world (Herek, Capitanio, & Widaman, 2002). The situation is different in countries in Africa (UNAIDS, 2007) where ART has only recently become available to a large number of people. In several recent studies, people living with HIV and AIDS have still

reported being stigmatised, because HIV is perceived as a signal of immoral or deviant behaviour (Greeff & Phetlhu, 2007; Katamba *et al.*, 2005; Wolfe *et al.*, 2006). A recent qualitative study from Tanzania revealed that the national antiretroviral scale-up led to an emergence of a new source of stigma that was associated with ART provision (Roura *et al.*, 2009).

According to Goffman (1963), stigma has two components, which include stigma as a trait and also as an outcome of possessing that trait. Firstly, stigma as a trait is a characteristic that is viewed negatively by society, and secondly, stigma as an outcome occurs when the negative social meanings that are attached to the discrediting characteristic become labelled to an individual (Berger, Ferrans, & Lashley, 2001; Goffman, 1963). HIV-related stigmatisation is an example of this negative social labelling which alters the way people living with HIV are viewed and treated by others (enacted stigma), and how they view themselves (self-stigma) (Thorsen, Sundby, & Martinson, 2008). In Berger and colleagues' (2001) view, perceived stigma of HIV occurs in the context of two factors, namely: the individual's knowledge of having or living with the HI virus, and her or his perception of societal attitudes toward people living with HIV and AIDS. Both views negatively affect an individual's self concept and emotional reactions towards perpetrators of stigma. People with perceived stigma sometimes attempt to avoid or minimise actual stigma by closely guarding disclosure of their HIV status.

Several studies have shown that HIV-related perceived stigma may result in negative health behaviour such as non-adherence, avoiding HIV testing, non-disclosure of HIV status and poor patterns of accessing health care (Dlamini *et al.*, 2009; Greeff & Phetlhu, 2007; Makoae *et al.*, 2008; Mills, Nachega, Bangsberg *et al.*, 2006; Mills, Nachega, Buchan *et al.*, 2006; Nyblade & MacQuarrie, 2006; Peltzer, Mosala, Shisana, Nqueko, & Mngqundaniso, 2007; Plummer *et al.*, 2006; Pulerwitz, Michaelis, Lippman, Chinaglia, & Diaz, 2008; Wolfe *et al.*, 2006).

A literature review using search terms 'DAART' or 'DOT' or ' 'm-DOT' and 'HIV stigma' or 'perceived stigma' or 'internalised stigma' or 'attitude' of the period 1980-2009 identified articles on the effect of DOT on study participants' (mainly drug users) adherence, viral loads, CD4 cell counts and drug resistance (Macalino *et al.*, 2007; Mitchell *et al.*, 2007; Pearson *et al.*, 2007). Two cross-sectional studies [in South Africa: (Page-Shipp *et al.*, 2007); in the US: Santos *et al.*, 2006)] focused on attitudes to directly-observed ART. Some participants thought that the m-DOT approach was unnecessary (since they could self-administer the drugs) and intrusive due to loss of privacy, and interference with family, work or home life. However, those who wanted to receive m-DOT indicated that they would prefer to receive it from the primary health centre rather than a colleague or family member. They also expressed a desire for secrecy and a fear of disclosure beyond family members. A recent longitudinal study promoting adherence to ART using m-DOT strategy among Mozambicans did not find an increase in stigma over time (Pearson *et al.*, in press). However, this study did not compare stigma between the m-DOT and standard-of-care arms. More recently, a community-based DOT accompaniment cohort study in Peru by Munoz *et al.* (in press) observed a significant reduction in stigma among participants in the DOT arm compared to the control arm.

We set out to explore changes in perceived stigma among a cohort of HIV-infected persons initiating ART in a clinic-based m-DOT intervention to promote adherence in Mombasa, Kenya. We examined perceived stigma among HIV-infected persons prior to starting ART and after 12 months of follow-up, and investigated whether m-DOT was associated with increased perceived stigma. The stigma study was a secondary analysis of data collected as part of a larger trial that was assessing the efficacy of m-DOT in improving adherence to ART. One key finding from this trial, published elsewhere, showed that adherence with m-DOT intervention was 4.8 times greater with adjustments for depression and HIV-related hospitalisations. However, the effects were not sustained after cessation of the intervention (Sarna *et al.*, 2008).

Methods

Study setting and antiretroviral treatment programme in Mombasa Kenya

In June 2003, a joint Government of Kenya (GOK) and USAID programme to introduce ART for the management of HIV-infected persons was approved by the Ministry of Health (MOH) and began at the provincial public hospital in Mombasa (Coast Province General Hospital-CPGH). It was designed to serve as a learning site for the anticipated massive scale-up of ART in the public. This programme was a collaboration between the MOH, Family Health International (FHI), Horizons project of the Population Council and MSH RPMPlus Project. The MOH

Table 1. Items from the Berger's HIV stigma scale[a] that were used to assess perceived stigma among study participants

Items[b]

Disclosure concern factors

1. In many areas of my life no one knows I have HIV
2. Telling some one that I have HIV is risky
3. I work hard to keep my HIV status a secret
4. It is easier to avoid new friendships than worry about telling someone that I have HIV
5. I am very careful whom I tell that I have HIV
6. I never feel the need to hide the fact that I have HIV (R)

Negative self-image factors

1. I feel guilty because I have HIV
2. Peoples' attitude about HIV make me feel worse about myself
3. I feel I am not as good a person as others because I have HIV
4. I never feel ashamed of having HIV (R)
5. Having HIV makes me feel unclean

Concern with public attitudes about people with HIV

1. People with HIV loose their jobs when their employers find out
2. People with HIV are treated like outcasts
3. Most people believe that a person who has HIV is dirty
4. Most people are uncomfortable around someone with HIV
5. I worry that people may judge me when they learn I have HIV

Note:

R = reverse score

[a]Berger *et al.*, 2001

[b]Participants responded using a 4-point Likert-type scale (*1.Strongly disagree 2.Disagree 3.Agree 4.Strongly agree*)

Table 2. Characteristics of study participants at entry to the modified directly observed therapy trial in Kenya

Variables	Total (N=183)	m-DOT (n=88)	Control (n=95)	X^2 statistic	P-value
Age: mean years (SD)	37.4 (7.9)	37.6 (8.3)	37.2 (7.7)	0.33*	0.74
Gender					
Female	63.4 (116/183)	63.6 (56/88)	63.2 (60/95)	0.01	0.95
Marital status					
Married/cohabiting	50.0 (91/182)	48.3 (42/87)	51.6 (49/95)		
Never married	11.5 (21/182)	11.5 (10/87)	11.6 (11/95)		
Divorced/separated	15.4 (28/182)	12.6 (11/87)	17.9 (17/95)		
Widowed	23.1 (42/182)	27.6 (24/87)	19.0 (18/95)	2.38	0.50
Highest education level					
Primary/no schooling	54.7 (99/181)	57.0 (49/86)	52.6 (50/95)		
Secondary education	38.1 (69/181)	39.5 (34/86)	36.8 (35/95)		
Post secondary	7.2 (13/181)	3.5 (3/86)	10.5 (10/95)	3.35	0.19
Employment status					
Unemployed	80.8 (147/182)	85.1 (74/87)	76.8 (73/95)	1.97	0.16
Depression					
None	35.4 (63/178)	31.3 (26/83)	39.0 (37/95)		
Mild	33.7 (60/178)	30.1 (25/83)	36.8 (35/95)		
Moderate/severe	30.9 (55/178)	38.6 (32/83)	24.2 (23/95)	4.27	0.12
Disclosed status to regular partner	47.0 (77/164)	44.7 (34/76)	48.9 (43/88)	0.28	0.60
Gets support from family/friends	85.2 (155/182)	83.9 (73/87)	86.3 (82/95)	0.21	0.65
Duration since HIV diagnosis					
≤1 year	50.3 (92/183)	50.0 (44/88)	50.5 (48/95)		
>1 year	49.7 (91/183)	50.0 (44/88)	49.5 (47/95)	0.01	0.94
Number of opportunistic infections					
0-1	52.5 (96/183)	46.6 (41/88)	57.9 (55/95)		
>1	47.5 (87/183)	53.4 (47/88)	42.1 (40/95)	2.34	0.13
CD4 cell count: mean cells/mm^3 (SD)	104.1 (54.9)	109.4 (57.6)	99.2 (52.1)	1.25*	0.21

*Two independent samples t-test. SD: standard deviation. Results are % (n/N) unless stated

provided the human resources, existing health services (including medications for the management of opportunistic infections) and health service infrastructure.

FHI implemented the programme and MSH RPM Plus offered technical advice on drug logistics and rational pharmaceutical use. Horizons Program (Population Council), in collaboration with International Centre for Reproductive Health (ICRH), designed and tested a two-arm randomised controlled trial comparing a comprehensive health centre-based m-DOT strategy to promote adherence with standard self-administration of ART medications (Sarna *et al.*, 2008). The study was conducted at two public hospitals and one private (not-for-profit) hospital in Mombasa which is a coastal city in Kenya.

Ethical approval for the study was obtained from the national Kenyan ethical review committee (KNH-ERC) as well as the Institutional Review Board of the Population Council. Researchers received specific training on confidentiality and on how to obtain written informed consent from study participants before administering the questionnaires.

Study design and procedures
Between September 2003 and November 2004, ART naïve adults (aged 18 years and above), living in Mombasa who were eligible for ART (CD4 cell count <200 cells/mm^3, or WHO clinical stage 3

or 4) were invited to participate. A sample size of 230 was chosen to detect a 20% difference in adherence between study groups (80% adherence with m-DOT versus 60% in controls) assuming 40% death or loss to follow-up, an alpha of 0.05 and power of 0.80 (Sarna *et al.*, 2008). Study participants (234 total: 149 women and 85 men) were randomly assigned to either the m-DOT or standard-of-care strategies. Computer generated random-number assignment was used, allocating an equal number of participants to treatment and control groups. Allocation concealment was maintained with sequentially numbered, opaque sealed envelopes. Prior to ART initiation, participants were randomly assigned to study groups in blocks of 40. It was not feasible to blind the m-DOT strategy, given the visible and obvious nature of the intervention. However, laboratory personnel were blinded to the study group allocation.

Treatment and care were provided within routine services at HIV clinics in participating facilities. Following initiation of ART, study participants visited treatment centres every four weeks for clinical follow-up. In addition to receiving standard-of-care, those in the intervention arm received m-DOT for a period of six months. This entailed twice weekly visits to a health facility, where participants met with a nurse who observed the ingestion of one dose, dispensed more medication and provided individualised adherence support. After six months of ART, study participants were changed to standard adherence case management, where

they were required to attend the clinic once a month for follow-up and collection of a months' supply of their medication. Community workers traced participants who missed visits or were unable to visit the health centre. In order to avoid possible increases in stigma resulting from home visits by community worker's known to be HIV carers, participants were encouraged to nominate a person who would actively trace and follow them up if they missed a visit. Some participants preferred to be traced by community workers unknown in their neighbourhoods.

Study questionnaires were translated into the local language (Swahili) and back translated to English. Trained researchers collected data using semi-structured questionnaires in face-to-face interviews. Researchers received training on how to obtain information from study participants in a non-judgmental way. Questions included background information such as age, sex, education level, marital and employment status, depression, disclosure of HIV status, family support and history of opportunistic infections.

Socio-demographic variables collected at baseline were categorised as follows: marital status was classified as married/cohabiting, never married, divorced/separated, and widowed; education as: none/primary education (0-8 years of school attendance), secondary education (9-12 years), and post-secondary education (>12 years); employment into currently employed and unemployed. Family support was assessed by asking participants whether family members supported them after disclosure of their HIV status, and categorised as a binary response (received support/did not receive support). Duration since HIV diagnosis was assessed by asking participants how long they had know their HIV status (weeks/months/years). For further analysis, this information was categorised as a binary response (1year or less/more than 1 year). The number of opportunistic infection episodes were collected from patients' medical records and categorised into two groups (0 to1 episode, or more than one episode) (see Table 2).

Information on perceived stigma was obtained prior to the start of treatment and after 12 months (0 and 48 weeks; two data points). Perceived stigma was assessed using a 16-item scale (Cronbach's alpha of adapted scale: 0.81) derived from Berger's HIV stigma scale (Cronbach's alpha: 0.96) (Berger *et al.*, 2001), and field tested for translation accuracy and comprehension before use. This scale covered three domains: disclosure concerns (6 items); negative self-image (5 items); and concerns with public attitudes about people with HIV (5 items). The items are displayed in Table 1. Berger's HIV stigma scale has four domains, but in this study the

personalised stigma domain was not included, because similar questions regarding respondent's personal experiences with stigma were addressed in a separate section of the questionnaire. The Berger scale requires participants to respond on a four-item Likert scale (strongly disagree=1, disagree=2, agree=3 and strongly agree=4) to statements about their feelings and opinions regarding how people treated them because of their HIV status. The scale assesses perceived stigma cross-sectionally without a recall period. All items were coded so that a higher score indicated more stigma and vice versa. The range of possible scores for each item was 1 to 4; therefore, possible summed scores ranged from 16-64. Total stigma scores were categorised into four stigma levels: minimal (16-28), low (29-40), moderate (41-52) and high (53-64). For further analysis the scores were categorised into two categories (minimal or low (16-40), or moderate or high stigma (41-64)). The change score was derived as follows: baseline stigma scores were subtracted from follow-up stigma scores (i.e., follow-up score minus baseline score) to obtain the difference over the 12 month period after initiation of ART.

Depression was assessed at baseline, and weeks 24, 48 and 72 (four data points), using a culturally adapted 21 item Beck's Depression Inventory version I® (Cronbach's alpha: 0.86) translated into Swahili (Cronbach's alpha for the Swahili BDI: 0.84). The tool assesses depression over the past four weeks. Depression was categorised as none (0-9), mild (10-18), moderate (19-29) and severe (30-63) as per BDI guidelines (Beck & Mendelson, 1961). CD4 cell counts were determined at baseline and weeks 24, 48 and 72 using PARTEC (four data points) using PARTEC (Partec-GmBH, Münster, Germany) and FACS counters (Becton & Dickinson Immunocytometry Systems, California, USA). For the stigma analysis presented in this paper only two data points (0 and 48 weeks) were used for all variables: perceived stigma, depression and CD4 counts.

Data management and analysis

Data were double-entered by separate clerks in a Microsoft Access 2003 database and analysed using SAS version 9.1. Chi-square and Student's t test were used to compare socio-demographic characteristics and selected variables between the groups, and to confirm that the randomisation procedure successfully removed any potential confounding factors. As outcomes were integer-level data (stigma scores at 12 months and change in stigma scores), we used generalised linear models (GLM) to assess whether having received m-DOT was associated with stigma scores, after controlling for socio-demographic characteristics and baseline stigma scores.

Table 3. Perceived stigma mean scores among study participants at baseline and 12 months after initiating antiretroviral treatment

Variables	Baseline (*n*=183) Mean(SD)	Follow-up (*n*=183) Mean(SD)	t[a]	*P-value*
Total stigma score	44.9 (7.6)	41.4 (7.7)	6.14	<0.001
Domains				
Disclosure	17.9 (3.1)	17.2 (3.5)	2.67	0.008
Negative self-image	12.2 (3.4)	10.4 (3.5)	6.25	<0.001
Public attitudes	14.8 (3.1)	13.6 (3.4)	4.23	<0.001

t[a]: paired t-test   SD: standard deviation

Table 4. Perceived stigma baseline, follow-up and change mean scores among study participants by study arms

Variables	m-DOT(*n*=88) Mean(SD)	Control (*n*=95) Mean(SD)	t^b	*P*-value
Baseline stigma				
Total stigma score	44.6 (7.7)	45.1 (7.5)	-0.49	0.62
Domains				
Disclosure	17.7 (2.9)	18.2 (3.3)	-1.07	0.28
Negative self-image	12.2 (3.5)	12.1 (4.1)	0.13	0.89
Public attitudes	14.7 (3.1)	14.8 (2.9)	-0.24	0.81
Follow-up stigma				
Total stigma score	41.7 (8.2)	41.1 (7.2)	0.56	0.58
Domains				
Disclosure	17.1 (3.5)	17.4 (3.5)	-0.59	0.56
Negative self-image	10.6 (3.6)	10.1 (3.4)	0.93	0.35
Public attitudes	13.8 (3.5)	13.5 (3.4)	0.66	0.51
Change stigma				
Total stigma score	2.9 (7.7)	4.0 (7.4)	-1.03	0.30
Domains				
Disclosure	0.6 (3.4)	0.8 (3.6)	-0.40	0.69
Negative self-image	1.6 (3.9)	2.0 (3.9)	-0.72	0.47
Public attitudes	0.9 (3.6)	1.3 (3.5)	-0.87	0.39

t^b: Two independent samples t-test   SD: standard deviation

Results

Background characteristics of study participants

Eight of the 234 participants did not initiate ART (two withdrew from the study, two died, one was lost to follow-up and three could not participate due to severe illness). A year after ART initiation, 21 people had died, 11 were lost to follow-up and 11 had discontinued study participation (five transferred to other hospitals and six had discontinued ART). No difference was detected between the baseline stigma scores of participants who completed the study, died or were lost to follow-up (*F*=2.20, *P*=0.114). This paper is based on findings from 183 study participants who had baseline stigma data and completed 12 months follow-up.

Mean age of the 183 participants was 37.4 years (sd=7.9 years; Table 2). Sixty-three percent were female, half (50%) were married and about one quarter (23.1%) were widowed. There were no differences noted between the m-DOT and standard-of-care groups with regard to the socio demographics and other variables, as would be expected with random allocation to treatment group (see Table 2).

The majority of respondents reported receiving support from family and friends (85.2%). However, less than half (47%) of the participants had disclosed their HIV status to a regular partner.

Perceived stigma

Prior to initiating treatment, about three quarters (72.2%) of study participants reported moderate to high levels of perceived stigma. There was no difference in the proportion with moderate or high levels of perceived stigma between the m-DOT and standard-of-care groups (69.8%, [60/87] versus 74.5%, [70/94]; *P*=0.48) (data not shown in tables). At the 12 month follow-up visit, the proportion of study participants who had moderate to high stigma scores declined from 72.2% (130/180) at baseline to

56.1% (101/180; *P*<0.001)). Again, there was no difference noted between the m-DOT and standard-of-care groups (56.3% [49/87] versus 55.9% [52/93]; *P*=0.96) (data not shown in tables).

Table 3 shows perceived stigma means scores among study participants at baseline and 12 months after initiating antiretroviral treatment. Overall, perceived stigma scores declined after 12 months of treatment from a mean of 44.9 (sd=7.6) to a mean of 41.4 (sd=7.7), (*t*=6.14, *P*<0.001). Results from the three stigma domains each followed a similar trend, with total mean scores declining; disclosure concerns (17.9 vs. 17.2, *t*=2.67, *P*=0.008), negative self-image (12.2 vs. 10.4, *t*=6.25, *P*<0.001), and public attitude concerns (14.8 vs. 13.6, *t*=4.23, *P*=<0.001) (see Table 3). No differences, however, were detected between the mean scores of participants in the m-DOT and standard-of-care arms (see Table 4).

GLM was used to analyse the relationship between m-DOT and perceived stigma scores. No significant association was detected between m-DOT and perceived stigma after controlling for age, sex, level of education, marital status and baseline stigma (see Table 5). In this analysis, the mean stigma score at 12 months was 0.90 higher in the m-DOT group than the controls, but the confidence interval included the null effect (95%CI= -1.06 to 2.87; *P*=0.36). The results were very similar when the outcome change in stigma score was assessed in a second GLM (data not shown). Mean stigma score at 12 months, however, was 4.54 points lower for people with post-secondary education compared with those with no or only primary education (95%CI= -8.58 to -0.49; *P*=0.03).

Discussion

Our study found that m-DOT strategy did not increase perceived stigma among persons receiving ART. These findings were similar

Table 5. GLM analysis to assess the effect of m-DOT on perceived stigma among study participants after 12 months of antiretroviral treatment

Variable	Coefficient	Standard error	(95% CI) Lower	Upper	t value	P-value
Intercept	21.81	4.14	13.65	29.98	5.27	<0.001
Treatment Group	-	-	-	-	-	-
m-DOT	0.90	0.99	-1.06	2.87	0.91	0.36
Baseline Stigma	0.51	0.067	0.37	0.64	7.56	<0.001
Age (years)	-0.064	0.069	-0.20	0.072	-0.93	0.36
Sex						
Female (ref)	-	-	-	-	-	-
Male	-0.59	1.18	-2.92	1.74	-0.50	0.62
Marital status						
Married/cohabit (ref)	-	-	-	-	-	-
Never married	-1.17	1.60	-4.33	1.99	-0.73	0.46
Divorced/separated	1.50	1.46	-1.38	4.38	1.03	0.31
Widowed	0.94	1.35	-1.73	3.61	0.69	0.49
Highest education level						
No schooling/primary(ref)	-	-	-	-	-	-
Secondary	-1.74	1.08	-3.87	0.39	-1.61	0.11
Post secondary	-4.54	2.05	-8.58	-0.49	-2.21	0.028

to a community-based DOT cohort study in Peru (Munoz *et al.*, in press) that observed a significant reduction in stigma among participants in the DOT arm compared to the control arm. Pearson and colleagues' (in press) assessment of stigma among Mozambicans who had been on a one year ART regimen did not find a change in stigma; however, stigma increased with depression and decreased with disclosure of HIV status to a friend.

Although the results from our study did not show differences in perceived stigma between the m-DOT and standard-of-care groups, overall, the level of stigma among study participants after 12 months of ART was still high. This supports the view that HIV stigma remains a problem in developing countries, and that there is a pressing need for effective stigma reduction interventions to facilitate normalisation of HIV and AIDS (Greeff & Phetlhu, 2007; Katamba *et al.*, 2005; Munoz *et al.*, in press; Pearson *et al.*, in press; Pulerwitz *et al.*, 2008; Sayles, Wong, Kinsler, Martins, & Cunningham, 2009; UNAIDS, 2007; Wolfe *et al.*, 2006).

A few previous studies indicated that patients did not favour m-DOT due to confidentiality concerns (Liechty & Bangsberg, 2003; Page-Shipp *et al.*, 2007; Santos *et al.*, 2006). Therefore, despite the findings of our study, concerns about confidentiality, together with persisting high levels of stigma, show that much care still needs to be taken to ensure that HIV-related interventions do not increase stigma. Liechty and Bangsberg (2003) noted that both the Haitian (Farmer *et al.*, 2001) and Rhode Island (Mitty, Stone, Sands, Macalino, & Flanigan, 2002) m-DOT initiatives were successful because the interventions were carefully designed to minimise stigma. In rural Haiti, accompagnateurs, who originally supervised therapy for tuberculosis in the 80s, delivered antiretroviral drugs to patients in the community, and were believed to be less stigmatising than witnessed dosing (Farmer *et al.*, 2001). Additionally, the community-based DOT study by Munoz *et al.* (in press) used paid community health workers to perform DOT at home, and offered additional emotional support

to study participants. This led to behaviour change among family members and providers. Another example is the m-DOT study in Mozambique in which researchers repositioned the HIV clinic entrance to a quiet corridor of the hospital prior to the start of the study to reduce the stigma of entering and exiting the HIV care facility (Pearson *et al.*, 2006).

There are several reasons why our m-DOT intervention did not increase stigma. One major plausible explanation was that our intervention was tailored using qualitative information from formative research (Sarna *et al.*, 2008). Findings from formative research showed that patients preferred to select the sites where they would be observed ingesting their medication, and the community health workers who would trace them when they failed to show up for their clinic visits. Moreover, they confirmed that they wanted a family member or close friend to accompany them for the clinic visits. In our study, m-DOT participants were observed twice a week by well trained nurses in confidential rooms at several sites selected by patients. Home visits were restricted to participants who had missed clinic appointments. Trained community health workers, who were selected by patients, delivered medications and provided emotional support. Additionally, study participants were encouraged to bring a family member or friend to the twice-weekly m-DOT clinic visits and counselling sessions. Our study suggests that formative research is useful in tailoring m-DOT to ensure that it does not increase stigma. Further research is needed to confirm this observation.

Another observation that warrants further research is the relationship between the duration of the m-DOT and level of stigma. In the community-based DOT by Munoz and colleagues (in press), participants were supported for 12 months; with Pearson *et al.* (in press) m-DOT was done for six weeks; and our m-DOT intervention was conducted for six months. Does the length of m-DOT have an effect on perceived stigma? More research needs to be done to answer this pertinent question.

This study has several limitations. First, some aspects of stigma may be specific to local settings, limiting the generalisability of the findings. Second, the study was done in a health facility, and it is therefore uncertain whether we would find similar findings if m-DOT services were primarily community-based. Third, given that each patient only received six months of m-DOT services, more research is needed to assess the impact of a longer m-DOT intervention on perceived stigma. Fourth, the Berger HIV stigma scale mainly measures perceived stigma and may not capture compound or layered stigma (Nyblade, 2006). Fifth, the follow-up data collection exercise was done six months after the m-DOT intervention had been completed, and the time lag between measures could have influenced our findings to some extent. A dedicated m-DOT stigma study is warranted to explore the relationship of stigma and the duration of m-DOT implemented in clinic- and community-based settings.

The larger RCT demonstrated that the use of m-DOT did increase adherence; and evidence from this secondary analysis indicates that perceived stigma did not increase post m-DOT. These findings suggest that m-DOT could be a useful strategy to improve adherence in resource constrained settings.

Acknowledgments

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