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Modified Directly Observed Therapy to Facilitate Highly Active Antiretroviral Therapy Adherence in Beira, Mozambique:

Development and Implementation

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Summary

As resource-limited countries expand access to highly active antiretroviral therapy (HAART) treatment, innovative programs are needed to support adherence in the context of significant health system barriers. Modified directly observed therapy (mDOT) is one such strategy, but little is known about the process of designing and implementing mDOT programs for HAART in resource-limited settings. In this descriptive study, we used a mixed-methods approach to describe the process of implementing mDOT for an ongoing randomized control trial (RCT) in Beira, Mozambique. Interviews with clinic staff, mDOT peers, and participants provided information on design elements, problems with implementation, satisfaction, and benefits. Acceptability and feasibility measures were obtained from the RCT. Most (81%, N = 350) eligible persons agreed to participate, and of those randomized to mDOT (n = 174), 95% reported that their time with peers was beneficial. On average, participants kept 93% of the 30 required daily mDOT visits. Key components of the intervention's success included using peers who were well accepted by clinic staff, adequate training and retention of peers, adapting daily visit requirements to participants' work schedules and physical conditions, and reimbursing costs of transportation. This study identified aspects of mDOT that are effective and can be adopted by other clinics treating HIV patients.

Keywords

adherence; Africa; AIDS; HIV; highly active antiretroviral therapy; HIV

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As many resource-limited countries begin to expand highly active antiretroviral therapy (HAART) treatment, innovative programs that address multiple health system barriers, monitor adherence, and elicit national support to control HIV/AIDS are necessary. In most of these countries, the health care infrastructure is severely constrained by scarce human resources, underdeveloped infrastructure, weak drug procurement systems, and limited government funding. Overworked health care staff and poor access to health facilities hinder the development of patient-centered care and strong relationships between patients and providers. These factors make providing quality chronic care such as that needed to treat HIV infection difficult.[1,2]

Most importantly, these systems face profound challenges in supporting the long-term adherence of patients taking HAART, which is critical to achieving the optimal clinical benefits of HAART and preventing the emergence of resistance.[3,4] Innovative approaches that address the barriers in resource-limited settings are essential to ensure that patients on HAART are adequately monitored and adherence support is provided.

Mozambique is particularly in need of an innovative approach. Among the top 10 nations in terms of HIV/AIDS burden, with an estimated 1.9 million HIV-positive persons and an adult HIV prevalence rate of 16%,[5] Mozambique has been devastated by the AIDS pandemic. It also is among the poorest countries worldwide, with a per capita income of $210 US[6] and a per capita health expenditure of $11 US.[7] In 2003, largely because of consistent political commitment within Mozambique and increases in external funding, a national plan was developed to provide expanded access to HAART for those infected with HIV. Since the arrival of antiretroviral medications through the national plan in June 2004, the number of people on HAART has grown steadily from <4000 in May 2004 to >20,000 in January 2006.[8,9] Despite this rapid increase in the number of people on HAART, major barriers to treatment exist, including human resource constraints, lack of provider training, inadequate health care infrastructure, and a system of care unaccustomed to multidisciplinary patient-centered chronic disease management. For example, of only approximately 600 clinicians in Mozambique, approximately half reside in the capital city of Maputo and many are in administrative jobs, leaving only approximately 200 physicians to provide clinical care for the country's population of 18 million. Clinicians have tremendous patient loads, often seeing as many as 70 patients in a single morning. Many also supplement their low public sector salaries through private practice, thus limiting their availability in public clinics. Similarly, of the few pharmacists who are trained in pharmacology, many have their own practices, leaving pharmacy technicians to manage the public hospital and clinic pharmacies.

Beira, the second largest city in Mozambique, has one of the largest HIV-positive populations in the country. Of approximately 200,000 adults older than 15 years of age living in Beira, an estimated 30% (60,000) are HIV-positive, of which 15% (9000) are estimated to be eligible for HAART. Within Beira, however, there is only 1 primary large-volume public HIV clinic that offers specialized care for HIV-positive individuals. This clinic is staffed and managed by the Mozambique Ministry of Health (MOH); since opening in February 2003, it has registered approximately 12,000 people for care. With the arrival of HAART through the national system in June 2004, monthly enrollment at the clinic increased and the number of patients on HAART rose from <150 to >1300 through

December 2005. The precipitous increase in persons starting HAART presents significant additional challenges to the health care system in Beira and countrywide. Effective adherence support strategies are urgently needed that are applicable to a larger number of patients and health facilities and are suited to the human resource and infrastructure constraints of the health care system.

In resource-constrained settings such as Mozambique, where demand is high and the health service capacity is limited, a program incorporating directly observed therapy (DOT) may be a particularly useful approach to ensure adherence to HAART. The DOT model, developed by the World Health Organization (WHO) as a core component of expanding tuberculosis (TB) treatment,[10] is particularly applicable in resource-limited settings, where it provides a low-cost formalized strategy to emphasize and monitor adherence within a constrained health system. The success of TB DOT in resource-limited countries is well documented,[1,11–14] and when implemented correctly, it has been shown to limit the development and spread of TB drug resistance.[15] Moreover, several studies have found TB DOT to be more cost-effective than self-administered therapy.[16–18]

The similarities between TB and HIV treatment make the use of DOT for HAART treatment (HAART DOT) an attractive strategy.[1,19,20] The experience of HAART DOT in Haiti[21,22] and South Africa[23] as well as among nonadherent persons and those with active substance use[24–26] has demonstrated that it can be highly effective in delivering multidrug antiretroviral regimens and improving medical outcomes.[27] Observed dosing alone may be insufficient as an isolated strategy to promote adherence, however, because it lacks elements that could address the concerns and needs of the participants who would require lifelong high adherence to HAART. Recent studies have found HAART DOT to be most effective when combined with other supportive interventions,[27,28] and patients identify access to good medical care and open communication with staff as DOT's most beneficial attributes.[25,29,30] One randomized controlled trial (RCT) of HAART DOT in the United States[27] found that adherence was higher for supervised than for unsupervised medication dosing, although the authors suggest that the success of HAART DOT programs can be enhanced by incorporating additional elements such as convenience, flexibility, confidentiality, cues and reminders, responsive services, and specialized training for staff.[27] By using community workers and HIV-positive peers as DOT supervisors, DOT could also facilitate the delivery of prevention messages and psychosocial support and strengthen the linkages between patients and clinical staff.[24,31–33]

Because of its potential to institutionalize adherence support within a resource-poor setting, a small-scale modified DOT (mDOT) intervention was implemented at the Beira HIV clinic after it opened in February 2003 and was used primarily for patients starting HAART through the Columbia University Mother-to-Child Transmission (MTCT)-Plus Initiative, a pilot HIV care and treatment program. The mDOT intervention was modeled on Mozambique s TB program, in which patients are required to come to the clinic to receive their daily dose of medication. The DOT model was modified, however, to require only the morning dose of a twice-daily HAART regimen to be received under direct supervision for the first 6 weeks of HAART (mDOT). Instead of using health care staff such as nurses as DOT supervisors, trained peers were chosen from community-based HIV groups and

employed by the clinic to be the primary supervisors of DOT. The integration of HIV-positive peers into the health care team was intended to provide patients with opportunities for unique counseling and social support while being closely followed during the initial phases of HAART treatment. An early assessment of the program found a high degree of acceptance of mDOT among patients and clinic staff members; adherence of participating patients (n = 33) averaged 98%.[34]

Although the mDOT program was successful on a small scale, its feasibility and acceptability to a larger number of patients remain unknown. Given its potential to formalize and improve adherence monitoring and support at the clinic, we decided to expand the mDOT intervention to all patients starting HAART at the Beira HIV clinic.

In this article, we describe the experiences of creating and implementing a scaled-up version of an mDOT program for patients starting HAART in Beira, Mozambique. Using qualitative and quantitative methods, we describe the mDOT strategy that we developed based on the experiences of the pilot mDOT project; illustrate the experiences of the participants, peers, and clinical staff during the course of implementation; and assess the acceptability and feasibility of expanding mDOT to a larger number of patients. The goals of this study are to help identify aspects of mDOT that are effective, allow the intervention to be adapted to other settings, and provide a foundation for future research and public policy.

METHODS

This descriptive study was based on data collected during the development and implementation of an expanded mDOT program in the HIV clinic at the Beira Central Hospital in Mozambique from 2004 through 2006. This mDOT intervention was designed and implemented in the context of an RCT to evaluate whether mDOT could improve short- and long-term adherence among patients starting HAART. Data collection is to continue through 2006, and the RCT results are to be published subsequently. The findings presented here emerged from qualitative and quantitative methods that examined the creation and execution of the mDOT intervention through 3 phases of implementation (Table 1).

In the first phase, a pilot mDOT program was systematically reviewed through interviews with clinic staff and administrators, with the goal of identifying and solving potential obstacles to developing an mDOT intervention applicable to a larger number of patients. Specific topics addressed included the availability of clinic space and staffing, the process of obtaining and training qualified peers, whether patients would accept mDOT as a health care strategy, and clinic managerial capacity to handle the increase in delivery of mDOT. After these discussions, the mDOT strategy and an approach to implementing the program were designed.

In the second phase, we evaluated the process of implementing mDOT based on feedback from clinic staff and peers in the mDOT program and assessed the services provided during mDOT through interviews with participants. Descriptive data about the perceived benefits and satisfaction with the mDOT program were obtained in structured and unstructured interviews with clinic staff and peers after 6 months of providing ongoing mDOT services.

Participants in mDOT (n = 174) provided information on services they received during structured interviews at 6 weeks (after intervention), which included items on the amount of time involved, issues discussed with peers, and peers effectiveness in encouraging the use of treatment partners and other support groups. A general assessment of the peers' performance was also conducted through observations of peer-participant interactions by the study staff and through unstructured interviews with clinical staff.

In the third phase, we assessed the acceptability of mDOT among participants and the feasibility of the clinic to employ peers to deliver mDOT. We used multiple indicators of acceptability, including the percentage of patients initiating HAART at the clinic who were approached, the proportion of those who consented and refused to participate, and the reasons for nonparticipation. The feasibility of implementing mDOTwas assessed by the percentage of persons who met the eligible requirements (to the degree that the eligibility requirements were inclusive and representative of the patients receiving HAART); whether participants kept their mDOT appointments; whether we could recruit, train, and retain peers; and whether peers were able to provide mDOT effectively. The feasibility in obtaining peers was determined by examining the recruitment process, the number who successfully completed training, the number retained during the course of the study, and their length of service. The quality of their work was assessed by their accuracy in record keeping (recording participants' mDOT appointments).

RESULTS

Phase 1: Development of the Modified Directly Observed Therapy Intervention: Modification and Expansion From a Pilot Program

The primary obstacles to expansion identified by administrators and clinic staff included the difficulties of frequent visits to a single centralized health care facility, overcrowded waiting rooms, participants concerns with confidentiality, the need to adapt daily visit requirements to participants' physical conditions and work schedules (mDOT clinic hours were from 8:00 AM to noon), and the pharmacy's ability to handle the increase in delivery of mDOT.

The resolution of these potential barriers was achieved through a close working relationship with the Mozambican Ministry of Health administrators and staff at the HIV clinic. To address the economic burden of frequent visits to the centralized health care facility, participants' transportation costs were reimbursed at an estimated average cost of approximately $1 US per visit. To address the overcrowded and uninviting waiting room, a separate spacious room was provided for the mDOT team, allowing patients to wait inside the building. A television also was provided to present educational and informational videotapes on HAART adherence and living with HIV/AIDS. Concerns of confidentiality were reduced by the repositioning of the HIV clinic entrance to a quiet corridor of the hospital before the start of the study, thus reducing the stigma of entering and exiting the HIV care facility.

Adapting daily visit requirements to participants physical conditions and work schedules was also necessary to retain patients in the intervention. Although being physically capable of making daily visits to the clinic was an eligibility requirement for the study, participants'

health could deteriorate during the study period or unanticipated scheduling conflicts could arise, rendering it difficult for participants to attend all mDOT appointments. In these instances, the team permitted a family member or friend to retrieve the mDOT dose at the clinic and deliver it to the participant. If neither the participant nor his or her representative came to the clinic for the daily dose, a peer made a home visit later that day. Although shortening the duration of mDOT to <6 weeks was considered as a possible way to reduce the visit burden, staff involved in the pilot mDOT program did not think that this duration was overly burdensome to patients. In addition, the 6-week time frame was believed to enhance the development of social contacts with peers and covered the period of HAART during which most early side effects occur, allowing for efficient referral to other clinic staff if necessary.

To accommodate participants' work schedules, mDOT hours were expanded. Because most Mozambique businesses commence at 9:00 AM, the mDOT clinic opened at 7:30 AM, requiring the pharmacist, peers, social workers, receptionist, and other support staff to arrive early. The earlier mDOT hours and the readiness of the staff provided participants ample time to receive care before work, thus allowing participants to continue to provide economically for their families.

Another challenge was ensuring the pharmacy's ability to handle the increase in delivery of mDOT. Although not specifically part of the mDOT intervention, several pharmacy-based quality improvement measures were implemented around the start of the study to help manage the increased flow of patients on HAART. Tools were developed to help manage the large inventory of HAART medications and avoid medication out of stocks. The system of using a Ministry of Health paper-based system to track pharmacy refills was strengthened, allowing the pharmacists to participate in monitoring adherence more actively. Also, 2 additional pharmacy technicians were hired, and peers assisted these pharmacists throughout the day with the distribution of mediations and maintenance of pharmacy records.

A final challenge was ensuring the adequate selection, training, and retention of peers for the larger scale mDOT program. Following the model of the pilot mDOT program, additional peers were chosen from among patients at the HIV clinic and participants in community-based groups through self-nomination or nominations by clinic staff. Eligible candidates were at least 18 years of age, HIV-positive, currently receiving HAART at the clinic, active in community-based HIV support groups, successful adherers to clinic care according to staff reports of their consistently keeping appointments and self-reporting good adherence to prescribed regimens, not currently experiencing any debilitating physical or mental illness, and socially skilled (as defined, albeit subjectively, by staff).

The peers were specifically trained to serve as (1) role models who reinforced the benefits of adherence, (2) resources for coping techniques, (3) confidants for emotions that patients may find difficult to discuss with family members, and (4) nonthreatening behavioral monitors. Partly based on the informational, motivation, and behavioral skills (IBM) model developed by Fisher and Fisher,[35] peers were taught to provide a set of core support strategies to the participants that addressed each aspect of the model, with the ultimate goal of developing skills to incorporate medication taking into their daily lives.[33,35]

Peers attended a 1-week initial training session. Training topics included HIV/AIDS transmission, the benefits and side effects of HAART, stigma, safe sex behavior, and the availability and locations of community-based support groups and nutritional resources. They were trained to provide informational support, which included sharing experiential knowledge, providing advice, giving suggestions for strategies to enhance adherence, providing information on side effects, and discussing the risks of nonadherence. They were encouraged to address special food and fluid requirements and to provide information about other organizations from which patients could obtain nutritional information and support. The peers confirmed patients' adherence to self-administered HAART doses through self-report and reinforced consistent dose timing. The peers were trained to enhance adherence motivation by assisting participants in developing a social support network and worked with patients on perceived vulnerability by addressing disclosure and stigma concerns. Peers were instructed not to give any medical advice to the participants but, rather, to encourage participants to present questions to health care providers, thus serving as a bridge to clinic staff. Because the system of chronic care was new for most patients, the frequent interaction with health care staff during mDOT was designed to develop participant skills to maneuver within this new health care setting.

Although peers were assigned to meet with the participants each weekday at the clinic, the actual "dosage" of the intervention was designed to be flexible depending on each participant's social support needs, with the goal of maximizing benefits and minimizing negative side effects. As with all support interventions, this adaptability is at once its strength in terms of potential efficacy and exportability and a weakness in terms of standardization. Peers kept ongoing records of all the contacts with participants to measure the integrity of the intervention over time, however.

Phase 2: Evaluation of the Implementation of the Expanded Modified Directly Observed Therapy Program

Clinic Staff Evaluation of Peers and the Modified Directly Observed Therapy Protocol—

Overall, the staff reported a high degree of satisfaction with the peers (mean = 3, range: 1–4), peers' work with the participants (mean = 3, range: 1–4), and the benefit the peers provide to the clinic (mean = 3.6, range: 1–4). In addition, clinic staff were quite satisfied with the mDOT program in general (mean = 3.6, range: 1–4). In unstructured interviews, the clinic staff also expressed their satisfaction with the mDOT intervention and the contribution of the peers to the overall HIV care provided at the clinic. They thought that the peers emphasized the vital importance of adherence, assisted the participants in developing medication-taking skills, had good rapport with participants, and were helpful and flexible. Although most of the clinic staff thought that the peers improved participants' follow-up with appointments, a few thought that this area still needed improvement. Two areas of concern were delay in returning medical charts and dispensing medication in a more efficient manner. The staff made 5 other recommendations for peers: (1) spend more time with "special cases" (ie, those having a difficult time adhering because of nonmedical reasons such as stigma or other social problems); (2) develop a more rigorous and comprehensive follow-up schedule for all patients (eg, periodically make home visits to verify residency and spend more time with participants to establish a better rapport; (3)

improve their chart management; (4) schedule daily mDOT appointments at a specific time for each participant; and (5) improve coordination with other hospital care units.

Casual observations by research staff revealed that many participants developed their own informal support groups among themselves during their daily visits. Groups of men and women were observed meeting regularly in the halls, visiting, and often leaving together. Relationships between mDOT participants and providers seemed to be enhanced, because many clinicians often greeted the participants by name as they passed in the halls.

Peers' Evaluation of Modified Directly Observed Therapy Protocol—Peers were similarly satisfied with the mDOT program (mean = 3.1, range: 1–4), their contribution to the clinic operations (mean = 4, range: 1–4), and work with the participants (mean = 4, range: 1–4). They enjoyed teaching and working with participants to develop strategies to maintain adherence and good attendance. They disliked most looking for medical charts and the lack of priority given to addressing nonadherence. Their recommendations for improvements included having more time to develop better relationships with participants, more flexibility in the time medication is delivered, more opportunities to exchange ideas with peers for other clinics, and special training for peers to improve their support for difficult patients.

Participants' Perceptions of Peer Involvement—mDOT participants reported spending an average of 15 minutes (SD = 15 minutes, range: 1 minute to 2 hours) at each visit with their peers, and most (95%) reported that the time spent with the mDOT peers was beneficial. Participants reported receiving informational and emotional support from the peers through discussions of stigma and other social problems. In postintervention interviews, participants reported discussing with peers issues pertaining to treatment and adherence (93%), side effects (50%), information about clinic appointments and procedures (19%), and social problems (4%). In addition, participants in the mDOT program were more likely than those not receiving mDOT to report having at least 1 treatment partner other than the peer (80% vs. 70%, $\chi^2 = 4.8$; $P < 0.05$) and attending community support groups (36% vs. 21%, $\chi^2 = 8.57$; $P < 0.01$).

Phase 3: Assessment of the Acceptability and Feasibility of Modified Directly Observed Therapy

Recruitment and Retention of Participants—During the 6-month study enrollment period, 683 persons started HAART at the Beira HIV clinic. Of these, 25 (3.6%) were not referred to the study. Although nonreferral to the study was most notable during the early phase of recruitment, providing a monetary incentive for the increase in workload to the pharmacist and adding pharmacy support staff greatly improved referral to the study team. Of the 658 individuals referred, 225 participants (34%) were ineligible: 84 had significant mental (n = 24) or physical impairments (eg, being bedridden [n = 60]), 76 resided outside the study area, 38 were younger than 18 years old, and 27 were in another DOT program (MTCT-Plus Initiative [n = 20] or TB DOT [n = 7]). Of the 433 patients (64%) who were referred to the study and were eligible, 350 (81%) agreed to participate. The most common reason for refusal to participate was being "too busy" (n = 71), which included reference to

work (n = 61), school (n = 2), or child care (n = 8). The second most common reason for refusal was because of out-of-town travel for >2 days per week (n = 10). One person refused to be randomized, and 1 person declined to specify the reason for refusal. Table 2 displays the differences in demographic and clinical characteristics among eligible persons who consented and refused to participate in the study.

Notably, many of the excluded patients asked if the eligibility requirements could be expanded to allow them to participate in the study. Initially, "significant physical impairment" was conservatively defined as those who could not walk on their own, but when physically impaired potential participants assured us that they could get to clinic with the help of family or friends and wanted the opportunity to participate, we modified our exclusion criteria to include only those persons who were bedridden or hospitalized. Similarly, we had a number of requests from persons residing outside Beira to be included in the study, with assurances that they would make the daily trips to the clinic or move into the city if randomized to mDOT. In response, we slightly expanded the eligible geographic area to include residents of a nearby town, but because of limited funds to reimburse transportation costs and concerns about long-term follow-up, we did not expand further.

Modified Directly Observed Therapy Appointments Kept—Among participants randomized to mDOT (n = 174), a record of daily visits maintained by peers was available for 159 participants (91%). On average, participants kept 93% of the 30 required daily visits (range: 37%–100%, SD = 11%). A significant minority (n = 64 [40%]) came to every single mDOT appointment, whereas 32 (20%) missed 1, 21 (13%) missed 2, 27 (17%) missed between 3 and 5, and 15 (10%) missed >6 appointments. For all but 5 participants, each of these missed doses was picked up by a family member or friend (98%) or home delivered by a peer (2%).

Employing Peers: Recruitment, Training, Retention, and Quality of Work—Eleven peers were successfully recruited and trained and worked during the study mDOT period from October 2004 through August 2005. Table 3 displays the demographic characteristics of the peers trained to deliver the mDOT intervention and their motivation for working as peers. Only 1 expressed worries about stigma resulting from work as a peer, although 3 expressed concerns about stigma in general. One peer would tell his friends that he was HIV-negative; when questioned about working as a peer at the HIV clinic, he would explain that "not all people working in the clinic are HIV-positive." In general, peers thought that their work at the clinic had increased their social status. One year after the study started, all peers were still working at the HIV clinic and the average period of employment was 1.5 years (range: 0.7–2.5 years).

The stability of peers impressed clinic administrators and clinic staff, as did the improvement in their work over time. The role of the peers expanded to other clinic support activities such as assisting the pharmacist with maintaining pharmacy records and preparing medication for delivery, assisting the receptionist with pulling and filing medical records throughout the day as needed, and helping the social worker with home visits and general outreach.

DISCUSSION

Culturally sensitive, feasible, and practical programs are needed to ensure that HAART is properly distributed and adherence support is provided as resource-limited countries expand access to this therapy. In Mozambique, like other countries rapidly expanding access to HAART treatment, this need is particularly acute, given the constraints of the health care infrastructure and limited human resources. To address these issues, we developed an expanded peer-supervised mDOT intervention for HAART that was based on the TB DOT model and the experiences of a pilot mDOT program. The mDOT intervention was designed to enhance access, support and monitor adherence, manage side effects, and address patients' concerns. As such, this intervention involves more than just observed dosing: it is a system that promotes patient-centered care with support from HIV-positive peers.

This descriptive study of the design and implementation of mDOT was designed to determine whether peer-supervised mDOT is acceptable to participants and clinic staff and whether it is feasible to rely on peers to distribute HAART and provide adherence support in a resource-constrained setting. Preliminary data and initial impressions suggest that peer-supervised mDOT is an acceptable and feasible strategy.

Specifically, peer recruitment, training, retention, and quality of work were good, and there was no turnover during the study period. Periodic training was sufficient to maintain the necessary number of peers, and peers were valued and respected members of the clinic staff. Peers and clinic personnel worked well together and provided not only mDOT but care and counseling to the other HAART patients; the peers assisted in the pharmacy and helped with receptionist activities such as filing and maintenance of medical records as well. As noted in the clinic appointment data (91% complete), peers' record keeping also was impressive. These observations suggest that trained and supervised peers can be effective for observing treatment, educating and counseling patients, and strengthening relationships between patients and their health clinics and communities.

Our results also suggest that mDOT is a strategy applicable to a substantial number of patients starting HAART. Of those eligible, 81% agreed to participate, and even some of those who were ineligible entreated the study team to enroll them. Additionally, those who were randomized to the mDOT intervention demonstrated exceptional attendance, with 87% missing <5 of the 30 required visits. mDOT participants reported that their time with peers was beneficial, and various topics of HIV care were discussed. Peers were also successful in encouraging participants to recruit a treatment partner and attend other community support groups.

If mDOT is to be acceptable to and practicable for a wide variety of patients, it must be provided in a comfortable and confidential setting, participants must be reimbursed for the costs of transportation, and clinic hours and mDOT visit requirements must be adapted to accommodate participants' work schedules and physical conditions. We found that the reimbursement for transportation was particularly critical to expand access to mDOT.

To be successful, the strategy requires a long-term commitment to quality care improvement by all mDOT team members, including pharmacists, peers, social workers, nurses, and

clinicians. Frequent oversight and training were required by clinic managers and the study team to help peers solve implementation problems and to integrate their activities into the routine health care setting. Because the success of the intervention is dependent on peer motivation and active management by the clinic staff, maintaining the participation of the entire clinic team is fundamental to the sustainability of this intervention over time.

In this article, we have described our experience in scaling up a peer-supervised mDOT program and attempted to demonstrate the acceptability and feasibility of implementing peer-supervised mDOT in a resource-constrained setting. Prior research has identified interventions other than mDOT that have been successful in enhancing HAART adherence, such as increased family involvement and relapse prevention.[36] Adherence support needs to be multifaceted and tailored to an individual's needs: mDOT is not a "magic bullet" that is appropriate for all individuals on antiretroviral medications. There may be individuals who are unable to participate because of psychiatric impairment or lack of interpersonal skills necessary to communicate effectively with peers. Although concern about stigma was expressed by only a few individuals approached to participate in the study, this issue has been recognized as a valid concern for DOT programs[37] and would need to be acknowledged when implementing mDOT in any HIV care setting. Even for those individuals for whom mDOT is helpful, additional strategies may be necessary to ensure acceptable levels of adherence over the long term.

Additionally, there are methodologic limitations to our analyses and interpretations. First, we did not study participant-peer relationships beyond the 6-week postintervention period; thus, the durability of the effect remains unknown. These relationships may help to sustain the intervention over time and improve patient outcomes, but further documentation of this benefit is necessary. Second, our descriptive data may have benefited from additional measures to assess the quality of care provided by the peers and whether other types or forms of care were needed or expected from participants. Finally, continual process evaluations of mDOT are recommended. Patients' needs and adherence patterns change over time, making it necessary to adjust peer roles.

Despite these limitations, our results suggest that mDOT with peer support can be a feasible intervention in resource-limited settings, with high rates of patient participation and acceptance. Ultimately, however, the value of this intervention is likely to be determined by its ability to improve adherence to HAART over the short and long term, translate into beneficial clinical outcomes, and ascertain whether these effects justify the costs of maintaining the mDOT system.

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References

1. Friedland G, Abdool Karim S, Abdool Karim Q, et al. Utility of tuberculosis directly observed therapy programs as sites for access to and provision of antiretroviral therapy in resource-limited countries. Clin Infect Dis. 2004; 38(Suppl 5):S421–S428. [PubMed: 15156433]
2. Friedland, GH. AIDS Clin Care; Meeting report from the XV International AIDS Conference. Adherence; 2004. p. 74-75.
3. Bangsberg DR, Hecht FM, Charlebois ED, et al. Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population. AIDS. 2000; 14:357–366. [PubMed: 10770537]
4. Paterson DL, Swindells S, Mohr J, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. Ann Intern Med. 2000; 133:21–30. [PubMed: 10877736]
5. Mozambique Ministry of Health. Maputo, Mozambique. 2005.
6. UNICEF. [Accessed February 20, 2006] At a glance: Mozambique the big picture. Available at: http://www.unicef.org/infobycountry/mozambique.html
7. World Health Organization. World Health Report 2005. Geneva: World Health Organization; 2005.
8. Mozambique Ministry of Health. Bulletin on HIV/AIDS in Mozambique. Maputo: Department of Medical Care, Mozambique Ministry of Health; 2006.
9. Mozambique Ministry of Health. Guide for Treatment of HIV Infection in Adults. Maputo: Mozambique Ministry of Health; 2004.
10. World Health Organization. An Expanded DOTS Framework for Effective Tuberculosis Control: Stop TB Communicable Diseases. Geneva: World Health Organization; 2002.
11. Rusen ID, Enarson DA. FIDELIS—innovative approaches to increasing global case detection of tuberculosis [Epub November 2005]. Am J Public Health. 2006; 96:14–16. [PubMed: 16317206]
12. Clarke M, Dick J, Zwarenstein M, et al. Lay health worker intervention with choice of DOT superior to standard TB care for farm dwellers in South Africa: a cluster randomised control trial. Int J Tuberc Lung Dis. 2005; 9:673–679. [PubMed: 15971396]
13. Mitnick C, Bayona J, Palacios E, et al. Community-based therapy for multidrug-resistant tuberculosis in Lima, Peru. N Engl J Med. 2003; 348:119–128. [PubMed: 12519922]
14. Chauhan LS, Tonsing J. Revised national TB control programme in India. Tuberculosis (Edinb). 2005; 85:271–276. Epub Oct 2005. [PubMed: 16253562]
15. Yew WW. Directly observed therapy, short-course: the best way to prevent multidrug-resistant tuberculosis. Chemotherapy. 1999; 45(Suppl 2):26–33. [PubMed: 10449895]
16. Khan MA, Walley JD, Witter SN, et al. Costs and cost-effectiveness of different DOT strategies for the treatment of tuberculosis in Pakistan. Directly observed treatment. Health Policy Plan. 2002; 17:178–186. [PubMed: 12000778]
17. Nganda B, Wang'ombe J, Floyd K, et al. Cost and cost-effectiveness of increased community and primary care facility involvement in tuberculosis care in Machakos District, Kenya. Int J Tuberc Lung Dis. 2003; 7(Suppl 1):S14–S20. [PubMed: 12971650]
18. Weis SE, Foresman B, Matty KJ, et al. Treatment costs of directly observed therapy and traditional therapy for Mycobacterium tuberculosis: a comparative analysis. Int J Tuberc Lung Dis. 1999; 3:976–984. [PubMed: 10587319]
19. Behforouz HL, Farmer PE, Mukherjee JS. From directly observed therapy to accompagnateurs: enhancing AIDS treatment outcomes in Haiti and in Boston. Clin Infect Dis. 2004; 38(Suppl 5):S429–S436. [PubMed: 15156434]
20. World Health Organization (WHO). Two Diseases One Patient, HIV and TB One Community, One Patient. Geneva: WHO; 2003.
21. Koenig SP, Leandre F, Farmer PE. Scaling-up HIV treatment programmes in resource-limited settings: the rural Haiti experience. AIDS. 2004; 18(Suppl 3):S21–S25. [PubMed: 15322480]
22. Farmer P, Leandre F, Mukherjee J, et al. Community-based treatment of advanced HIV disease: introducing DOT-HAART (directly observed therapy with highly active antiretroviral therapy). Bull World Health Organ. 2001; 79:1145–1151. [PubMed: 11799447]

23. Jack C, Lalloo U, Karim QA, et al. A pilot study of once-daily antiretroviral therapy integrated with tuberculosis directly observed therapy in a resource-limited setting. J Acquir Immune Defic Syndr. 2004; 36:929–934. [PubMed: 15220699]
24. Mitty JA, Macalino GE, Bazerman LB, et al. The use of community-based modified directly observed therapy for the treatment of HIV-infected persons. J Acquir Immune Defic Syndr. 2005; 39:545–550. [PubMed: 16044005]
25. Wohl AR, Garland WH, Squires K, et al. The feasibility of a community-based directly administered antiretroviral therapy program. Clin Infect Dis. 2004; 38(Suppl 5):S388–S392. [PubMed: 15156427]
26. Lucas GM, Weidle PJ, Hader S, et al. Directly administered antiretroviral therapy in an urban methadone maintenance clinic: a nonrandomized comparative study. Clin Infect Dis. 2004; 38(Suppl 5):S409–S413. [PubMed: 15156431]
27. Altice FL, Mezger JA, Hodges J, et al. Developing a directly administered antiretroviral therapy intervention for HIV-infected drug users: implications for program replication. Clin Infect Dis. 2004; 38(Suppl 5):S376–S387. [PubMed: 15156426]
28. Khan MA, Walley JD, Witter SN, et al. Tuberculosis patient adherence to direct observation: results of a social study in Pakistan [Epub Sep 2005]. Health Policy Plan. 2005; 20:354–365. [PubMed: 16183735]
29. Davidson H, Smirnoff M, Klein SJ, et al. Patient satisfaction with care at directly observed therapy programs for tuberculosis in New York City. Am J Public Health. 1999; 89:1567–1570. [PubMed: 10511842]
30. Mishra P, Hansen EH, Sabroe S, et al. Adherence is associated with the quality of professional-patient interaction in directly observed treatment short-course, DOTS. Patient Educ Couns. 2006; 63:29–37. [PubMed: 16242297]
31. Funck-Brentano I, Dalban C, Veber F, et al. Evaluation of a peer support group therapy for HIV-infected adolescents. AIDS. 2005; 19:1501–1508. [PubMed: 16135904]
32. Wang S, Keats D. Developing an innovative cross-cultural strategy to promote HIV/AIDS prevention in different ethnic cultural groups of China. AIDS Care. 2005; 17:874–891. [PubMed: 16120504]
33. Simoni JM, Frick PA, Huang B. A longitudinal evaluation of a social support model of medication adherence among HIV-positive men and women on antiretroviral therapy. Health Psychol. 2006; 25:74–81. [PubMed: 16448300]
34. Micek, M.; Gimbel-Sherr, S.; Gimbel-Sherr, K., et al. Modified DOT strategy for HAART in Beira, Mozambique [poster]. Presented at: 15th International AIDS Conference; 2004; Bangkok.
35. Fisher, JD.; Fisher, W. Handbook of HIV Prevention. New York: Kluwer Academic/Plenum; 2000.
36. Simoni JM, Kurth A, Pearson CR, et al. Self-report measures of antiretroviral therapy adherence: a review with recommendations for HIV research and clinical management. AIDS Behav. 2006; 10:227–245. [PubMed: 16783535]
37. Liechty CA, Bangsberg DR. Doubts about DOT: antiretroviral therapy for resource-poor countries. AIDS. 2003; 17:1383–1387. [PubMed: 12799560]

TABLE 1

mDOT Descriptive Study: Topics, Method, and Sample at Each Phase

Phase 1: Development of the mDOT intervention: modification and expansion from a pilot program
Identification of concerns, challenges, and problems in scaling up mDOT intervention
Focus groups and open-ended interviews with clinic staff and administrators
Phase 2: Evaluation of the implementation of the expanded mDOT program
Evaluation of peers
Structured and unstructured interviews with clinic and study staff
Evaluation of the mDOT protocol
Structured and semistructured interviews with peers and clinic staff
Perception of peers' involvement (services delivered during mDOT, including type, quality, and amount)
Structured interview with participants after intervention
Phase 3: Assessment of the acceptability and feasibility of mDOT
Assessment of the recruitment and retention of participants, rates of refusal, and reasons for refusal
Review of RCT study records and structured interviews with participants
Assessment of the mDOT appointments kept
Medical chart review
Assessment of employing peers: recruitment, training, retention, and quality of work
Unstructured interviews with peers and clinic staff and review of RCT study records

TABLE 2

Demographic and Clinical Characteristics of Individuals Eligible for the Study by Those Who Consented and Refused (N = 433)

	Consented (n = 350)	Refused (n = 83)	Test Statistic	*P*
Mean age, years (SD)	36 (9)	40 (12)	$t = 3.53$	<0.001
Male	56%	70%	$\chi^2 = 7.25$	<0.01
Education <7 years	57%	47%	$\chi^2 = 2.80$	0.09
Mean CD4 count, cells/mm^3 (SD)	127 (95)	148 (99)	$t = 1.80$	0.07

TABLE 3

Demographic Characteristics of MDOT Peers and Their Motivation for Working as Peers

Employing peers, training, retention		
Number employed	11	
Mean age, years (SD)	30 (6)	
Education >7 years	11	100%
Motivation for working as a peer (n = 9)		
Wanting to help others	4	44
Opportunity for work	4	44
Opportunity to receive better HIV care	3	33
Asked by a community association	3	33