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Community-based treatment of multidrug-resistant tuberculosis: early experience and results from Western Kenya

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Background: In the light of the 2010 World Health Organization estimation of 650 000 cases of multidrug-resistant tuberculosis (MDR-TB) globally, the need to develop, implement and scale up MDR-TB treatment programs is clear. The need is greatest and urgent in resource-poor countries, such as Kenya, with a high TB burden and an anticipated rise in reported cases of MDR-TB with increasing access to drug susceptibility testing.

Objectives: To describe the set-up of a community-based program, early clinical outcomes, challenges and possible solutions.

Setting: The Moi Teaching and Referral Hospital (Moi Hospital) catchment areas: Western and North Rift Provinces, Kenya.

Design: Program description and retrospective chart review.

Results: An MDR-TB team established a community-based program with either home-based DOT or local facility-based DOT. Following referral, the team instituted a home visit, identified and hired a DOT worker, trained family and local health care professionals in MDR-TB care and initiated community-based MDR-TB treatment. In the first 24 months, 14 patients were referred, 5 died prior to initiation of treatment and one had extensively drug-resistant TB. Among eight patients who initiated community-based DOT, 87% underwent culture conversion by 6 months, and 75% were cured with no relapse after a median follow-up of 15.5 months. Multiple challenges were experienced, including system delays, stigma and limited funding.

Conclusion: Despite multiple challenges, our model of an MDR-TB team that establishes a community-based treatment system encircling diagnosed cases of MDR-TB is feasible, with acceptable treatment outcomes.

In 2010, the World Health Organization (WHO) estimated that there were 650 000 cases of multidrug-resistant tuberculosis (MDR-TB, defined as resistance to rifampin and isoniazid) among the world's estimated 12.0 million cases of TB. Only 16% of the estimated 290 000 MDR-TB cases among all notified TB cases were started on treatment.[1] Among all incident TB cases worldwide, 3.6% were estimated to be MDR-TB.[2] With the scale-up of and increased access to drug susceptibility testing (DST), the number of notified cases of MDR-TB is likely to increase.

Kenya continues to experience high rates of TB, ranking thirteenth on the WHO list of high-burden countries and the fifth highest burdened African nation.[2] In 2010, Kenya reported 106 083 new TB cases,[3] of which an estimated 1.9% (>2000 cases) were MDR-TB.[2] The Kenya Central Reference Laboratory, the only public laboratory with DST capacity in the country, identified 82, 102, 150 and 112 MDR-TB cases in respectively 2007, 2008, 2009 and 2010.[3–5] DST is performed only on retreatment patients, with less than 69% of retreatment cases captured for testing in 2010.[3] Only 33% (50/150) and 62% (70/112) of the patients diagnosed with MDR-TB in Kenya were initiated on treatment in respectively 2009 and 2010.[3,4] This underscores the urgent need to develop more capacity to diagnose, manage and treat MDR-TB in cost-effective ways.

Kenya's country-wide plan for MDR-TB care was formulated in 2006, and originally emphasized an in-patient model located at the Kenyatta National Hospital in the capital city, Nairobi. However, the distance and possible long-term separation from family support limited MDR-TB referrals. Moi Teaching and Referral Hospital (Moi Hospital), located in Eldoret, 350 km northwest of Nairobi, is the second referral hospital in Kenya. It serves a network of 26 referring district hospitals and a catchment area of over 10 million people. With no isolation wards for in-patient MDR-TB treatment, Moi Hospital initiated a community-based MDR-TB treatment program with the permission of the Division of Leprosy, TB and Lung Disease (DLTLD).

The objectives of this article are to describe the design and functioning of our community-based treatment program, the treatment outcomes of our initial cohort and the challenges encountered with providing and monitoring treatment in the community, with potential solutions.

METHODS

In this paper, we describe the program and retrospectively review outcomes. For the purpose of publication, ethical review was obtained from both the Institutional Review and Ethics Board of Moi University School of Medicine and the Institutional Review Board of Lifespan (Providence, RI, USA).

Community-based treatment program

Program design

An MDR-TB team comprising a medical officer (MO), an administrative assistant, a data manager, a nutritionist, a pharmaceutical technician, a social worker and DLTLD regional representatives was established. Referrals to the program were called to the team by the district tuberculosis and leprosy coordinators (DTLC) or by clinicians on receipt of MDR-TB DST results. A home visit was then scheduled.

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KEY WORDS
community DOTS-Plus; MDR-TB; resistant tuberculosis; Kenya

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Home visit

During the initial home visit, the following were ascertained: clinical history, contact and exposure history, patient's socio-economic status and identification of a private location on patient's property or health care facility where medications, including an injection, would be administered. Baseline blood work was performed after written commitment to comply with and complete treatment was obtained, where possible in the presence of a local administrative figure, village chief, or sub-chief. Basic information regarding infection control was reviewed with the patient, family and DOT nurse. Patients were provided with social services support that included food supplementation program and transport incentives.

At the time of this visit, the MDR MO identified household contacts at risk and performed symptom screening. Symptomatic contacts were referred for sputum microscopy (a free service under the national program), and culture and DST were recommended. During this visit, the MO also provided an educational MDR-TB review for the local facility caring for the patient.

DOT nurse

A nurse living in proximity to the patient was identified (often by the patient) and contracted by the program to supervise DOT at the patient's house. For ambulatory patients with no local DOT nurse available, the nearest local health facility within walking distance was identified for supervision of treatment; this was generally the site where the patient had been receiving care prior to the diagnosis of MDR-TB.

The DOT nurse (an enrolled community nurse or a registered community nurse) was given training in basic infection control measures, use of N95 mask, charting, recording treatments cards and screening for side effects. The nurse was compensated US$2/day during the injection phase and US$1.30/day during the continuation phase.

Treatment and monitoring

The standardized DLTLD MDR-TB regimen was utilized: this consisted of an intensive phase with capreomycin (CPM), ofloxacin, cycloserine, prothionamide and either pyrazinamide or ethambutol, until the endpoints of 6 months and culture conversion were reached. During the continuation phase, patients were treated with the same oral drugs, but without CPM, for an additional 18 months. The DOT nurse was supplied with a 2-week medication box and charting forms. The administrative assistant coordinated with the pharmacy and ensured that drugs were delivered on time to the DOT nurse. Following the charting of a daily side effects query form, the DOT nurse administered the morning oral doses and the only injectable for the day, while a household member (who had been instructed on the importance of adherence to treatment) supervised the evening doses. All patients were screened for human immunodeficiency virus (HIV) infection and were referred to the nearest HIV care center for initiation on cotrimoxazole and antiretroviral treatment (ART), as dictated per national guidelines (this report predates current recommendations for universal ART in all TB patients). The MDR-TB MO supplied consultative care by telephone to the DOT nurse and local health facility clinician, and made visits to evaluate the patient if severe concerns were raised. During this time, Moi Hospital, in conjunction with the DLTLD, established an isolation house on its grounds that became available for admission as deemed medically necessary.

The MDR-TB administrative assistant tracked all clinical data, including DOT sessions, side effects, drug supplies and laboratory results. Expert consultation from Kenyan and North American consultants was available to the MDR-TB MO. Cohort reviews were held (involving the MDR-TB MO, expert consultants and health care workers) on at least a quarterly basis. Problematic cases were reviewed as needed.

Outcomes

Outcomes were defined by standard programmatic definitions. Cure was defined as negative sputum smears and cultures throughout the last 12 months of treatment, and treatment failure as culture-positive at the end of treatment or persistent positive cultures necessitating a change of regimen. Adverse effects were classified as asymptomatic (laboratory test abnormality only), mild (not limiting daily activities), moderate (limiting daily activity), and severe (life threatening, requiring hospitalization or change of regimen). Adherence was computed and expressed as a percentage of the number of doses taken divided by twice the number of days in that month.

Program financing

Funding for the program was acquired from a variety of sources. Eli Lilly (Indianapolis, IN, USA) donated CPM, and the DLTLD supplied the remainder of the MDR-TB drugs. The United States Agency for International Development–Academic Model Providing Access to Health Care (USAID-AMPATH) supplied the time of a medical officer 2 days per week, laboratory evaluations for HIV co-infected patients, and the food equity program for all. The DLTLD, through the Global Fund Against AIDS, Tuberculosis and Malaria (Global Fund), supplied transport funds for patients cared for at the local health facility up to a maximum of US$4 per day and the laboratory evaluations for non-HV-infected patients. Philanthropic funds were used to compensate the DOT worker. Food security was supplied by USAID-AMPATH until Global Fund money was available.

Data collection

Data were obtained by chart review as well as from the MDR database maintained by the MDR administrative assistant. A descriptive analysis of the data was performed.

RESULTS

Treatment outcomes

Between March 2008 and March 2010, 14 patients were referred to the community-based DOTS-Plus program (Table 1). Patients were screened for MDR-TB only after completing at least two courses of treatment for presumed drug-susceptible TB; the identification of MDR-TB thus occurred at least 18 months after these patients initiated TB care. Five patients died between referral to the program and initiation of treatment. The median time from referral to death was 5 weeks (range 2–8). Only one patient in this cohort had second-line DST results, as this is not available in Kenya. This patient's resistance pattern was consistent with extensively drug-resistant TB (XDR-TB, defined as MDR-TB with additional resistance to any fluoroquinolone and to an injectable second-line drug), and she was hospitalized by the DLTLD at the MTRH housing facility; no community-based treatment was initiated in her case (Table 1).

The remaining eight patients initiated community-based treatment. The average time from program notification to MDR-TB team home visit was 2 weeks (range 1–4). Of the 8 patients, 6 were treated at their local health facility, while 2 had home-based DOT; 5 patients had culture conversion by 3 months, 2 had culture conversion by 6 months of treatment and 1 never converted. Of

TABLE 1 Patient profiles at registration

No.	Date registered	Age years	Sex	Previous courses of treatment	Category	Resistance pattern	HIV status	Type of DOT
01	6 March 2008	33	Male	2	Failure after retreatment	RHE	+	Died before treatment
02	28 August 2008	27	Female	2	Failure after retreatment	RHZES	+	Died before treatment
03	18 April 2009	64	Male	2	Failure after retreatment	RH	−	Died before treatment
04	11 March 2010	30	Male	2	Failure after retreatment	RH	−	Died before treatment
05	26 March 2010	17	Female	3	Failure after retreatment	RHE	−	Died before treatment
06	4 June 2009	45	Female	2	Failure after retreatment	XDR*	+	DOT†
07	12 March 2008	42	Male	3	Failure after retreatment	RHES	+	Home-based DOT
08	22 March 2008	45	Male	2	Failure after retreatment	RH	−	Facility-based DOT
09	22 March 2008	34	Male	2	Failure after retreatment	RHS	+	Facility-based DOT
10	20 May 2008	21	Female	2	Failure after retreatment	RHS	−	Facility-based DOT
11	20 August 2008	45	Female	2	Failure after retreatment	RHES	+	Facility-based DOT
12	22 August 2008	41	Male	3	Failure after retreatment	RHE	−	Facility-based DOT
13	15 October 2008	15	Female	2	Failure after retreatment	RHE	−	Home-based DOT
14	19 June 2009	36	Female	2	Failure after retreatment	RHS	+	CB DOT

*Pan-resistant to RMP, INH 0.1, INH 0.4, ofloxacin, EMB, ethionamide, amikacin, SM, capreomycin, kanamycin.
†In-patient housing facility DOT.
HIV = human immunodeficiency virus; DOT = directly observed therapy; R, RMP = rifampin; H, INH = isoniazid; E, EMB = ethambutol; + = positive; Z = pyrazinamide; S, SM = streptomycin; − = negative; XDR = extensively drug-resistant; CB = clinic-based.

all patients initiated on treatment, six (75%) were cured. No relapse had been reported after a median follow-up of 15.5 months (range 1–21) at time of this report. One patient who had culture converted died of community-acquired pneumonia at month 20 of treatment. The patient who failed to convert underwent an empiric regimen change at month 10 to cover XDR-TB, but died at month 16 of respiratory failure (Table 2).

Adherence

Average monthly medication adherence was >99.9% during the intensive phase, and >95% during the continuation phase. One patient left treatment for 2 weeks during the continuation phase to seek employment. He was located and returned to therapy supported with food and financial incentives.

Adverse events

No major adverse events were reported. Three patients developed anemia, only one of whom (20 weeks pregnant) required pregnancy-related transfusion. Two reported symptoms consistent with peripheral neuropathy towards the end of treatment; therapy was not changed. Two patients had hypokalemia on several occasions, with response to supplementation. Two patients required admission, one for community-acquired pneumonia and the other for the delivery of her baby. Both were culture-negative at the time of admission and were admitted to local facilities.

Contact tracing and screening

During the home-based contact investigation, one secondary case was discovered, the 11-year-old son of an index case. Chest radiography revealed a small unilateral effusion. Acid-fast bacilli sputum smear and culture were negative. He was treated with standard therapy for drug-susceptible TB, with clinical response.

Challenges

Multiple challenges at the national level and at the community program level were encountered. Delays were experienced at different stages in the diagnosis and treatment of MDR-TB. Table 3 details challenges experienced and suggested solutions.

DISCUSSION

This program demonstrates the feasibility of out-patient-based MDR-TB treatment in settings such as ours. Our MDR-TB team, acting as an implementation unit, was able to set up an MDR-TB treatment program in the patient's community. As the country decentralizes MDR-TB care, the expertise to manage these complex patients is difficult to maintain. The MDR-TB service team acts as a resource for training both DOT and local health facilities and also as the source of expert clinical consultation. Our unit was able to serve a large geographical area, managing cases in two provinces of Kenya.

TABLE 2 Outcomes of patients initiated on treatment

Type of DOT	Date of registration	Age years	Sex	Resistance pattern	HIV status	Month of culture conversion	Number of admissions during treatment	Treatment outcome
Home-based	March 2008	42	Male	RHES	+	6	None	Cured
Home-based	October 2008	15	Female	RHE	−	3	None	Cured
Facility-based	March 2008	45	Male	RH	−	3	None	Cured
Facility-based	March 2008	34	Male	RHS	+	3	Once for CAP	Died
Facility-based	May 2008	21	Female	RHS	−	3	None	Cured
Facility-based	August 2008	45	Female	RHES	+	16*	Once for delivery	Died
Facility-based	August 2008	41	Male	RHE	−	3	None	Cured
Facility-based	June 2009	36	Female	RHS	+	6	None	Cured

*Died at month 16 of treatment while still sputum-positive.
DOT = directly observed therapy; HIV = human immunodeficiency virus; R = rifampin; H = isoniazid; E = ethambutol; S = streptomycin; + = positive; − = negative; CAP = community-acquired pneumonia.

TABLE 3 Challenges and suggested solutions

Challenges	Suggested solutions
National-level	
Delay in diagnosis of MDR-TB	Strengthening of TB programs with emphasis on early screening for drug resistance when treatment failure is suspected Decentralization of DST services to improve turnaround time for results Institution of rapid diagnostic tests (currently underway in the country)
Lack of second-line DST	Scale-up of DST services to include second-line DST
Community-level	
Delay in home visits	Relieving the MDR-TB team from other duties to create a more dedicated team; this is expected with the increase in number of patients under care
Difficulties in identifying and recruiting DOT worker	Widespread health education may eliminate stigma and ease the DOT recruiting process
Labor-intensive: daily injections	Regimens without daily injections are needed; this will allow less skilled community health workers and other adherence supporters to assist in DOT
Delays in follow-up and monthly evaluations	As above, a full-time dedicated team will improve the quality of monitoring
Inadequate contact tracing and screening	Increased funding will allow for comprehensive contact tracing

MDR-TB = multidrug-resistant TB; TB = tuberculosis; DST = drug susceptibility testing; DOT = directly observed therapy.

Our patients tolerated treatment well, with acceptable adherence levels. Adverse effects were either asymptomatic or mild and were managed in the community, with no patients requiring hospitalization or a change of regimen. Two patients were hospitalized transiently, one for pneumonia and the other prior to delivery. Although our program demonstrates the feasibility of care in the out-patient setting despite complicated and potentially toxic regimens, we recognize the need for in-patient support for transient admissions in case of major side effects or for other medical needs. This program was initiated specifically because we had no TB in-patient unit with appropriate infection control. Lack of in-patient care availability had been the major barrier to the initiation of MDR-TB care in our region.

Although we had a small inception cohort, 87% (7/8) of the patients had sputum culture conversion by 6 months and 75% (6/8) were cured. This compares favorably to other in- and out-patient settings.[6,7] The high early mortality (occurring between registration and mobilization of treatment) was related to late diagnosis, with documented treatment delays of over 18 months. Adherence to national guidelines for MDR-TB screening at the first sign of treatment failure is critical to bringing patients into care in a timely fashion.

A major challenge to our program was the series of delays that occurred from TB diagnosis to the time of initiation of MDR-TB treatment. Delay between patient referral and initiation of treatment could have contributed to various extents to the deaths of the five patients who died prior to treatment. It was time-consuming to arrange transport (we cover a large geographic area) and to free the MDR-TB team from routine clinical duties to perform the initial home visit. This delay of up to 4 weeks should be reduced to 24 hours. If a DOT worker was identified at the home visit, care began immediately. However, if no home DOT worker was available, DOT at the patient's nearest health facility was postponed until after education of the health center staff regarding infection control and MDR-TB care and stigma alleviation. Major challenges still exist within the health care systems even once an MDR-TB care program becomes functional.

An estimated 2000 MDR-TB cases are diagnosed each year in Kenya, spread throughout the country.[2] Decentralization of services increases access, but compromises economy of scale. Our present program requires that a 'mini' MDR-TB unit be established around each patient, with identification of the DOT nurse and intensified health education for both the family and the local health care system. This type of program addresses both patient needs (continued treatment at home with family support) and health system needs (out-patient costs lower than in-patient services and prevention of nosocomial transmission).[8,9] However, this individualized approach remains labor-intensive.

Financing our program was both a challenge and a strength. We pulled together multiple partners to address the needs collectively and to utilize available resources. For example, the AMPATH HIV care program had a pre-existing food equity program; we therefore utilized this program for all MDR-TB co-infected patients. Stockouts of drugs were prevented by using the MTRH-AMPATH philanthropic program to purchase medications. Shared resources ensured continuity of care and should serve as a collaborative model for building programs.

CONCLUSION

MDR-TB has been described as a time bomb; as with drug-susceptible TB, the greatest burden is in resource-constrained settings. Despite multiple challenges, community-based treatment programs are feasible, as demonstrated in our setting, with acceptable cure rates. Utilization of all settings, both out- and in-patient, will be needed to curb the tide of this major health threat.

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Contexte : La nécessité d'élaborer, de mettre en œuvre et d'étendre des programmes de la tuberculose multirésistante (TB-MDR) est évidente vu l'estimation en 2010 de l'Organisation Mondiale de la Santé concernant les 650 000 cas mondiaux de TB-MDR. La nécessité est la plus marquée et la plus urgente dans des pays à ressources limitées comme le Kenya, où le fardeau de la tuberculose (TB) est élevé et où l'on s'attend à un accroissement des cas déclarés de TB-MDR en raison de l'accessibilité croissante aux tests de sensibilité aux médicaments.
Objectifs : Décrire la mise en route d'un programme basé sur la collectivité, les résultats cliniques précoces, les défis et les solutions possibles.
Localisation : Zone de recrutement du Moi Teaching and Referral Hospital (Moi Hospital) : Provinces de l'Ouest et du Nord Rift au Kenya.
Schéma : Description du programme et révision rétrospective des dossiers.
Résultats : Une équipe TB-MDR a élaboré un programme basé sur la collectivité comportant soit un traitement directement observé (DOT) basé sur la maison, soit un DOT basé sur les services locaux. Après référence, l'équipe a institué une visite domiciliaire, identifié et payé un travailleur DOT, formé la famille ainsi que les professionnels locaux de soins de santé au sujet des soins de la TB-MDR et mis en route le traitement de la TB-MDR basé sur la collectivité. Au cours des 24 premiers mois, 14 patients ont été référés. Le décès est survenu chez cinq d'entre eux avant la mise en route du traitement ; un de ceux-ci souffrait d'une TB ultrarésistante. Chez huit patients qui ont commencé le DOT basé sur la collectivité, la négativation des cultures est survenue dans les 6 mois chez 87% et la guérison a été obtenue sans rechute dans 75% des cas après un suivi médian de 15,5 mois. On a rencontré de nombreux défis, comportant les délais du système, la stigmatisation et les limitations de financement.
Conclusion : En dépit de défis multiples, notre modèle d'une équipe TB-MDR qui met en route un système de traitement basé sur la collectivité pour soutenir les cas diagnostiqués de TB-MDR est réalisable et obtient des résultats acceptables de traitement.

Marco de referencia: A la luz del cálculo de la Organización Mundial de la Salud de 650 000 casos de tuberculosis multidrogorresistente (TB-MDR) en el mundo, es clara la necesidad de formular, aplicar y ampliar los programas de tratamiento de esta enfermedad. Esta obligación es mayor y más apremiante en los países con escasos recursos como Kenia, donde existe una alta carga de morbilidad por TB, un incremento anticipado de los casos notificados de TB-MDR y un aumento progresivo del acceso a las pruebas de sensibilidad a los medicamentos.
Objetivo: Describir la puesta en marcha de un programa comunitario, definir sus desenlaces clínicos iniciales, las dificultades encontradas y proponer las soluciones posibles.
Entorno: La zona de influencia del hospital universitario y de referencia Moi (Moi Hospital): las provincias del norte y del oeste del Valle del Rift en Kenia.
Método: Se llevó a cabo una descripción del programa y un examen retrospectivo de los expedientes clínicos.
Resultados: Un equipo experto en TB-MDR estableció un programa comunitario basado en la administración domiciliaria o en un centro local del tratamiento directamente observado (DOT). Tras la remisión de los pacientes, el equipo programó una visita domiciliaria, escogió y contrató a un agente DOT, capacitó a las familias y a los profesionales sanitarios locales en la atención de la TB-MDR e inició la administración del tratamiento comunitario. Durante los primeros 24 meses se remitieron 14 pacientes. Cinco pacientes fallecieron antes de comenzar el tratamiento; de los ocho pacientes que iniciaron el tratamiento DOT comunitario, el 87% alcanzó la conversión del cultivo a los 6 meses y el 75% logró la curación, sin recaída, tras un seguimiento con una mediana de 15,5 meses. Se presentaron muchos obstáculos, entre ellos los retrasos debidos al sistema, la estigmatización y la insuficiencia del financiamiento.
Conclusión: Pese a las múltiples dificultades, el modelo propuesto de un equipo que establezca el sistema de tratamiento comunitario de pacientes con diagnóstico de TB-MDR es factible y ofrece desenlaces clínicos aceptables.

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