Community-Based DOTS: Report from a Rapid Assessment in Kenya, June 11, 2007

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ABBREVIATIONS AND ACRONYMS

CB-DOTS	community-based DOTS
CBO	community-based organization
CHW	community health worker
CDR	case detection rate
DOTS	internationally recommended strategy for TB control
DTLC	District Tuberculosis and Leprosy Coordinator
E	ethambutol
ECSA	East, Central, and Southern Africa
Epi Info	epidemiological information software
EPTB	extrapulmonary tuberculosis
FBO	faith-based organization
GoK	Government of Kenya
H	isoniazid
KEMSA	Kenya Medical Supplies Agency
MDGs	Millennium Development Goals
MDR-TB	multidrug-resistant tuberculosis
MoH	Ministry of Health
MSH	Management Sciences for Health
NGO	nongovernmental organization
NLTP	National Leprosy and Tuberculosis Program
PTB	pulmonary tuberculosis
PTLC	Provincial Tuberculosis and Leprosy Coordinator
R	rifampicin
RPM	Rational Pharmaceutical Management Plus
S	streptomycin
SPSS	Statistical Package for Social Sciences (software)
TB	tuberculosis
TC	treatment completion
WHO	World Health Organization
Z	pyrazinamide

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Since 2001, the Rational Pharmaceutical Management (RPM) Plus program has provided technical assistance to the tuberculosis (TB) program and Ministry of Health personnel of various countries within East, Central, and Southern Africa (ECSA) to improve pharmaceutical management for TB. Most of these activities have been coordinated through the Regional Economic Development Services Office and Regional Logistics Initiative and Africa Bureau portfolios of the U.S. Agency for International Development. In August 2005, the Ministers of Health from 46 Member States of the Africa region unanimously declared TB an emergency in the region (the Maputo Declaration). In the same spirit, Kenya declared TB an emergency in March 2007. Multidrug-resistant TB (MDR-TB) has remained within low rates in ECSA countries, so one of the priorities is to control its emergence in the early stages. The use of TB medicines not following national guidelines may be contributing to the increase in MDR-TB.

RPM Plus supported this assessment of the TB treatment practices in the private sector in Kenya. The results of the study will be disseminated to ECSA countries, the WHO/AFRO office and through regional and international TB meetings.

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INTRODUCTION

Background

Located in East Africa, Kenya had an annual per capita gross domestic product in 2006 of 1,200 U.S. dollars; 50 percent of its population lives below the poverty line. The country's second Ministry of Health (MoH) strategic plan (2005–2010) was formulated with the aim of reversing the downward trends in health indicators. Among other things, the strategic plan focuses on a sectorwide approach to health care services and defines the resource envelope required to implement it. This strategic plan is mainly responsible for policy formulation and lays down the vision and mission of the country on all health matters. In particular, it sets standards for quality of services, mechanisms for monitoring and supervision, and resource mobilization and provides the overall coordination and leadership functions.

Since independence, Kenya has striven to expand its health care delivery system through a primary health care system. From the early 1990s, the country adopted the strategy of decentralization of health services to the periphery to reach the rural poor and most vulnerable populations. In addition, the MoH has been encouraging other health care providers to initiate health services in rural areas, especially in the underserved areas.

The faith-based organizations (FBOs) have taken advantage of this policy to cover the parts of the country that are considered hard to reach, where motivation rather than incentives is important in retaining health care workers. Private for-profit health facilities have rapidly increased in both urban and peri-urban areas over the same period. Hence, in many urban areas, these private health facilities outnumber the public facilities.

The current health policy in Kenya advocates the need to involve consumer communities in the decision-making process of the health facilities in their neighborhoods. As a result, the communities have joined with the government and other not-for-profit organizations to manage health services in their locality. This wave of community involvement in health care promotion has contributed greatly to the expansion of health infrastructure in Kenya.

Currently, 218 hospitals and 3,098 health centers and dispensaries serve 33 million people. Appendix A shows the distribution of health facilities in Kenya by type and provider. The majority (52 percent) of these health facilities are public, while the private sector accounts for the remaining 48 percent.

To complement the growth in the heath sector, training of medical and other health care personnel has been increasing steadily. The number of health care workers graduating from colleges and universities grew by 2.6 percent from 2002 to 2003.

Tuberculosis Services in Kenya

The National Leprosy and Tuberculosis Program (NLTP) is the Ministry of Health's agency responsible for coordinating all activities relating to treatment, prevention, and control of tuberculosis (TB) and leprosy in the country. The program was launched in 1980 when the MoH merged then-existing tuberculosis control activities that had been in place since 1956 with several leprosy control projects in the Western, Coast, and Eastern Provinces into one program—the NLTP.

The program grew, and by the end of 2005, TB and leprosy services were being delivered through 1,605 health units managed by the MoH and other stakeholders that include nongovernmental organizations (NGOs), FBOs, and other private organizations. The tuberculosis and leprosy services are integrated into the general health care services at all levels. A group of trained staff are designated to the program and are responsible for coordination, supervision, and technical advice in relation to management of TB and leprosy at each level. These include 11 Provincial Tuberculosis and Leprosy Coordinators (PTLCs) and 110 District Tuberculosis and Leprosy Coordinators (DTLCs) responsible for coordinating the delivery of TB and leprosy services at the provincial and district levels, respectively. Technical officers at the central unit of the NLTP provide technical guidance for the national response to TB and leprosy control. All the health units providing TB services in the country send their reports to the NLTP.

The total number of TB cases (all forms of tuberculosis) reported in 2005 was 108,401, an increase of 2 percent compared with 2004. Nyanza province had the highest number of smear-positive pulmonary TB (PTB) cases with a total of 8,047, while North-Eastern had the lowest at 1,300. When stratified by gender and age group, the majority of the smear-positive PTB cases was found among males (57 percent), and the most-affected age group was 25–34 years (38 percent).

Data for all reported TB cases during 2005 at the national and provincial levels, categorized by districts, age group, and types of TB are contained in Appendix B. In Appendix C, the districts providing community-based DOTS (CB-DOTS) have been listed.

Results of TB control indicated treatment success rates of 82 percent for new smear-positive PTB cases (n = 36,855), 75 percent for smear-positive retreatment cases (n = 3,257), 77 percent for new smear-negative PTB cases (n = 35,432), and 76 percent for extrapulmonary TB (EPTB) cases (n = 12,804).

Community-Based DOTS

The NTLP adopted the DOTS strategy for the control of TB in 1993 and achieved countrywide geographic coverage in 1997. In line with international trends, the NLTP launched new approaches to increase access to DOTS and expand the population covered by DOTS. One such initiative was CB-DOTS. The World Health Organization (WHO) carried out a pilot in seven sites in sub-Saharan Africa in 1997, and Kenya was one of the sites (WHO 2003). The findings from the pilot suggested that CB-DOTS is a viable and cost-effective intervention for TB

control. Community involvement in the implementation of TB control program activities is not new. The WHO Expert Committee on Tuberculosis observed in its ninth report (1974, 16) that "It is important that the community should be involved in the program, including leaders, such as village elders, tribal chieftains, or other influential persons, and the welfare organizations including the voluntary agencies and laity." Since that report, WHO has been promoting the integration of national TB control programs within the general health service to increase access to effective TB care (WHO 2003).

In Kenya, the CB-DOTS program was piloted in Machakos in 1997, as recommended by WHO. The main aim was to find an effective method of delivering DOTS to replace patient admission to hospitals. This step was important to ease the strain of dealing with the exponentially increasing TB patients who required admission for DOTS (WHO 2003). It involved decentralization of the delivery of the intensive phase of treatment to peripheral health units and the community. Registered community groups became partners in decentralized delivery of TB care at the community level. The groups included community-based distributors of contraceptives, community volunteers, traditional birth attendants, women's groups, and FBOs. As part of the decentralization strategy, the regimen was changed to a fully oral treatment regimen, substituting injected streptomycin with orally administered ethambutol: 2RHZE/6EH.[1]

The feasibility and effectiveness of this decentralized ambulatory TB care was determined in an operational study conducted by Kangangi et al. (2003). The study showed a marked reduction in the number of patients who were hospitalized during the intensive phase of treatment (from 100 percent to 4.7 percent). The treatment outcomes among new sputum smear-positive PTB patients were similar in the intervention and control groups (treatment success of 88 percent and 85 percent and death rates of 4 percent and 6 percent, respectively). The treatment completion (TC) was significantly higher among new sputum smear-negative and EPTB patients in the intervention group than in the control group (79 percent versus 48 percent, respectively).

Following the Machakos study, it was concluded that the decentralization of the intensive phase of TB treatment resulted in maintenance of good TB program performance and a saving on the cost of admission of patients to facilities during this phase of treatment. The approach was also found to be acceptable by health care workers, community volunteers, and patients and their families. The NLTP adopted the approach as part of the national policy and has since expanded it to cover 31 districts in the country; the expansion is still ongoing. For Phase I and II expansions, the following factors were considered: inclusion of large (areas) districts that had limited access to health care services and of districts with a high TB burden and well-organized community groups, FBOs, or both. (See Appendix C for a complete list of districts currently providing CB-DOTS in Kenya.)

According to the guidelines, the key objective of community TB care is to decentralize the provision of TB diagnostic and treatment services beyond health care facilities into the community to overcome reliance on the few fixed health facilities. Meeting this goal requires—

- Increasing knowledge and awareness of tuberculosis in the community

[1] Rifampicin (R), isoniazid (H), pyrazinamide (Z), ethambutol (E); regimen = 2 months RHZE and 6 months EH.

- Increasing the TB case detection rate from the current 47 percent to 70 percent by 2007
- Improving the treatment success rate from the current 80 percent to about 83 percent by 2007
- Reducing the combined default and transfer-out rates from the current 15 percent to less than 10 percent by 2007

CB-DOTS activities for community TB control are based at primary health care facilities, particularly dispensaries and health centers. These facilities are close to communities who either own them or are heavily involved in their management. The NLTP through its decentralized offices (PTLCs and DTLCs) coordinates and mobilizes the communities so that they support CB-DOTS programs. This has been achieved through a process of consensus building among stakeholders that include the communities themselves, identifying community health workers (CHWs) and treatment supporters using set criteria, training the CHWs and treatment supporters, and implementing the activities. Implementation is being carried out in phases to allow lessons to be learned, to identify challenges in the implementation process, and to build sufficient capacity at both the district and lower levels.

The issue of capacity building and supervision at the community level is a function of the primary health facility in-charge. According to the NLTP CB-DOTS guidelines, functions that are critical to the attainment of central-level goals, such as broad policy development, resource allocation, quality assurance, and monitoring and evaluation of program performance, are still controlled from the central level. Some specific tasks, however, have been decentralized to the community level, including the following—

- Promotion of information about TB
- Referral of TB suspects to health facility for diagnosis and management
- Support to TB patients to ensure adherence to treatment through directly observed treatment
- Defaulter tracing and bringing them back for treatment
- Referral of TB patients on treatment for follow-up sputum smears.
- Recording necessary information in DOTS cards
- Referral of TB patients who have adverse drug reactions
- Feedback of information about treatment outcome to the TB team

Community Health Workers/TB Treatment Supporters

At the lowest level of CB-DOTS are the CHWs, who are also known as TB treatment supporters. Their main role is to make sure that the patient takes every dose of anti-TB medicines as directed. They should also perform most of the tasks that have been decentralized to the community level. The community, as well as the health facility the CHWs are attached to, should

be involved in their selection, following the criteria set by the NLTP. Part of the criteria is that they should have been working with an existing health care program, community-based organization (CBO), or FBO. They should also be people trusted by the community who are committed and motivated to volunteer. CHWs generally provide voluntary services although they are given support and facilitation (for example, transportation reimbursement) either through the NLTP or by the community itself.

Pharmaceutical Management of CB-DOTS

The CB-DOTS guideline is silent about pharmaceutical management. Therefore, it has been managed through the same procedure as other MoH essential medicines and medical supplies. Currently, the three main sources of TB medicines are direct procurement by the government of Kenya (GoK); the Global TB Drug Facility; and the Global Fund to Fight AIDS, Tuberculosis and Malaria. The procured medicines are stored at the Kenya Medical Supplies Agency (KEMSA) warehouse in Nairobi, from which they are distributed to the health facilities either directly or through KEMSA regional depots. At the KEMSA regional depots, the PTLC in that region is responsible for the medicines, while the DTLC is responsible at the district drug stores. The medicines are sent out based on the distribution list provided by the pharmacist-in-charge at the NLTP. The distribution list is prepared based on the quarterly reports from the facilities indicating their demands and on available stocks.

Patients collect their medicines from the facility on a schedule depending on the phase of treatment. Those on intensive phase collect weekly, while those on continuation phase do so monthly. The patients on retreatment have to visit the health facility on a daily basis to get the streptomycin injection. In areas with CB-DOTS, the CHW or treatment supporter ensures that the patient has taken his or her medicines as required by directly observing or by using a family member to observe the swallowing of the medicines. In some instances, the CHWs may collect the medicines for their patients, especially when the patient is still sick or is unable to get to the facility for any other reason.

Monitoring and Evaluation

The activities of CB-DOTS have to be monitored, and CHWs are expected to keep proper records and send reports to the health facility for onward transmission to the NLTP through the DTLC and PTLC. It is the responsibility of NLTP to set standards for monitoring and evaluation for CB-DOTS. The tools for CB-DOTS have been developed and have been in use since the beginning of 2006, using the following key indicators—

- Case notification rates
- Number of TB patients using CB-DOTS
- Number of suspects referred by CHW for screening
- Number of TB patients under CHW who have sputum follow-up to date
- Proportion of defaulters brought back to treatment by CHWs
- Number of TB patients co-infected with HIV/AIDS receiving treatment in the community
- Number of community care groups per district involved in TB activities

- Treatment outcomes of patients receiving treatment within the initiative
- Quality of TB care delivery in the community

TB Treatment Guidelines

Health care workers need to be conversant with the treatment guidelines so that they can adequately guide the community volunteers on the best practice of TB control. They should also understand and be able to interpret the concept of DOTS and especially CB-DOTS.

Appendix D indicates the current tuberculosis treatment regimen in Kenya for adults and children.

JUSTIFICATION OF THE STUDY

The United Nations Millennium Development Goals (MDGs) targets for TB control are to reduce by half the mortality due to TB by 2010 and to halt and begin to reverse the incidence of TB by 2015 (http://www.un.org/millenniumgoals/#). As a way of controlling TB, the GoK adopted the DOTS strategy for the control of TB and had achieved countrywide geographic coverage by 1997. It has also taken up the WHO concept of community involvement in TB control and is currently implementing the CB-DOTS program in 31 districts.

Despite the adoption of these strategies, the incidence of TB cases in Kenya is still on the rise, as evidenced by the total number of cases reported in 2005, which showed a 2 percent increase over 2004. WHO estimates that the case detection rate (CDR) for 2004 was about 47 percent, whereas the treatment success rate has been steady at 80 percent since the adoption of DOTS. These indicators have not improved as anticipated in the objectives establishing the CB-DOTS program, which included the increase of CDR from 47 percent to 70 percent and an increase in treatment success rate from 80 percent to 83 percent by 2007.

Clearly, some of Kenya's TB control strategies are not working well. Should this trend remain unchecked, the country risks not achieving the MDGs.

The Machakos pilot indicated some positive results, especially with respect to reducing the number of admissions during the intensive phase of treatment as well as increasing TC rates. Nevertheless, no difference occurred in the other treatment outcomes between those in the CB-DOTS program and the non-CB-DOTS group.

The current study aimed at evaluating the success of the CB-DOTS strategy in the control of TB in Kenya. It specifically assessed commodity management for CB-DOTS and TB treatment success among patients treated under CB-DOTS. The findings of this study were expected to be useful in improving community participation in TB control activities in Kenya, and indeed in the ECSA region, as well as in charting the way forward for the CB-DOTS strategy. Finally, the findings of this study will form the baseline indicators of decentralized CB-DOTS in Kenya.

OBJECTIVES

The objectives of the study were to—

- Determine the outcome of treatment based on CB-DOTS compared with the non-CB-DOTS program
- Characterize pharmaceutical management in community DOTS
- Determine the correspondence between policy, norms, and practice regarding pharmaceutical management in community DOTS
- Establish the availability of medicines and the frequency of stock-outs
- Assess the accuracy of dispensing practices in conformance with the regimens and patient compliance with treatment

METHODOLOGY

Study Area

The study area consisted of districts implementing CB-DOTS as determined through NLTP reports. In Kenya, 31 districts, located in all eight provinces, are implementing CB-DOTS.

Study Population

The study population consisted of health care workers at the district and lower levels, the community health workers, and patients. Specifically, the study targeted the program managers coordinating CB-DOTS at the district level (DTLCs), health care workers at peripheral facilities, CHWs trained in CB-DOTS, and TB patients. The other target groups were the supervisors of CHWs, consisting of health care workers in the health center or dispensary. Finally, TB patients were also interviewed.

Study Design

A descriptive cross-sectional design was used. This design enabled the surveyors to establish the status of CB-DOTS according to the program objectives and indicators at the time of the study. This design is also relatively cheap to carry out and not time consuming, and it gives a snapshot of the current status of the program under review.

Sampling and Sample Size Determination

Of the 31 CB-DOTS implementing districts, 15 (48.4 percent) were selected for this study. The sampling technique used was both stratified and purposive. The 11 TB provincial control zones in the country were considered as strata, and at least one district was sampled from each.

The number of districts providing CB-DOTS in the eight provinces is not uniform. The number sampled therefore was dependent on the total number providing CB-DOTS. Table 1 lists the districts sampled in each province. The other criteria for sampling were the number of TB smear-positive rates as well as the duration for which the CB-DOTS program had been in operation in that district. The sampling was done so that both the rural and urban populations were represented.

Table 1. Study Sample Districts

Number	TB Control Zone	District(s)
1	Nairobi	Kamukunji
2	Central	Nyeri
3	Coast	Kwale
		Mombasa
5	Eastern South	Meru Central
		Machakos
7	Eastern North	Isiolo
8	North-Eastern	Garissa
9	Nyanza	Kisumu
		Gucha
		Nyando
8	North-Rift	Nandi
		Tran-Nzoia
10	South-Rift	Nakuru
11	Western	Busia
Total	**11**	**15**

In each district, two sites/centers providing CB-DOTS were selected. The selection of the sites was done in consultation with the DTLC, depending on the performance of the site based on reports received at the district. One site that was doing well and another that had not been doing very well were selected. At each site, simple random sampling was used to select the CHWs and patients who were interviewed.

Then, two non-CB-DOTS sites were selected, and data for these sites were collected from the DTLC's district register. These sites were not visited.

Taking into consideration the budgetary allocation, the following individuals were interviewed in each of the selected districts—

- One district-based official (DTLC)
- Two facility-based officials (one per facility practicing CB-DOTS and the in-charge of the TB clinic)
- Four community-based health providers (CHWs) providing CB-DOTS
- Eight patients under the CB-DOTS program

In total, 15 persons were interviewed per district, giving a total of 225 persons interviewed.

The necessary information from the NLTP program managers at the national level was obtained during the preparation of the study background.

Data Collection

A team of three trained field-workers collected data using interviewer-administered questionnaires. The study protocols and data collection instruments were introduced to the field-workers during a workshop.

Fieldwork commenced the week immediately after the training of the field-workers, and it took about 34 working days. There were four data-collection instruments, one for each of the following: district-based, facility-based, and community-based health workers and the patients. By the end of the field work period, the field workers had interviewed all the 225 individuals. The set of data collection tools is contained in Appendix E.

Quality control was ascertained through—

- Training of the field-workers, which ensured that the protocols and study instruments were well understood by all the members of the team.
- Regular supervision by the principal investigator to ensure that the protocols set were being followed.
- Pilot-testing to assess the feasibility of the study and pretest the study instruments. The issues identified during the pilot were addressed before commencing the main study.
- At the end of each day of interview, the data collected were cleaned so that any missing values or wrong entries could be rectified early in the process.

As a way of addressing first objective of the study, facility-specific data on TB activities were obtained from the district records office/DTLC during the field visits. This information was obtained for both the CB-DOTS and the non-CB-DOTS facilities.

Data Analysis

Data entry was done in both Epi Info and SPSS computer applications. Analysis was done in SPSS after extraction from Epi Info. Microsoft Excel was used where applicable.

The choice of software depended on the task at hand and the versatility of the software. A data entry clerk performed data coding and entry with the guidance of the principal investigator and the statistician.

The data from the district hospital records were also entered into the SPSS package, and frequency charts and cross tabulations were done. Statistical analysis was also done using the chi-square test. The analysis was done on the basis of the monitoring and evaluation indicators described earlier.

Data Presentation

The data are presented in frequency tables, cross tabulations, and bar graphs. From these frequency tables, it will be possible to determine whether CB-DOTS pharmaceutical management is being carried out according to applicable policy, norms, and procedures.

RESULTS

In this study, four questionnaires were used to collect data. The results derived from data from each of these questionnaires are presented below.

Findings on District-Level Health Facilities

Number of Patients

Sixteen districts were sampled for this study, but two DTLCs were not available for interview and the data from one district were misplaced during transmission. Hence, 13 DTLCs provided the data analyzed here. A total of 23,386 patients were seen in 2005, which rose to 24,858 in 2006—a 6.3 percent increase. The average number of patients was 1,376 in 2005 and 1,381 in 2006. The rise in number of patients treated could indicate improvement in case detection by the TB program. Patients treated under CB-DOTS were 16.1 percent of patients treated for TB in 2006 in the population studied, or 3,995. Hence, only a minority of TB patients were treated under CB-DOTS strategy.

Table 2. Number of TB Patients

Number of TB Patients in 2005	Number of TB Patients in 2006	Number of TB Patients under CB-DOTS in 2006
23,386	24,858	3,995

TB Patients per District

According to the DTLCs interviewed, an average of 16.1 percent of TB patients in the study area were treated using the CB-DOTS strategy (see Table 2). However, 64.9 percent of patients actually said they had a CHW attached to them as a treatment supervisor.

Table 3. TB Patients per District

District	TB Patients 2005	TB Patients 2006	CB-DOTS TB Patients 2006	Percentage CB-DOTS
Kwale	332	388	8	2.1
Kitale	517	405	43	10.6
Nandi	593	704	51	7.2
Busia	756	639	32	5.0
Mombasa	807	1,433	58	4.0
Molo	874	993	45	4.5
Gucha	912	878	323	36.8
Kitale	971	1,300	—	0.0
Kwale	1,047	1,075	36	3.3
Nyeri	1,057	1,249	60	4.8
Garissa	1,164	1,128	213	18.9
Busia	1,252	1,460	158	10.8
Meru	1,309	1,280	125	9.8
Molo	1,727	1,913	134	7.0
Kamukunji	2,769	2,318	2,318	100.0
Machakos	3,057	2,924	12	0.4
Kisumu	4,242	4,319	339	7.8
Mombasa	—	452	40	8.8
Total	**23,386**	**24,858**	**3,995**	**16.1**

All respondents (n = 18) correctly identified RHZE for two months as the regimen for the intensive phase for both facility-based and community-based DOTS. Only one of the respondents incorrectly quoted EH for five months instead of six months as the regimen for the continuation phase for both facility-based and community-based DOTS.

Most CHWs (95.5 percent, n = 17) reported that they were supporting TB patients during both intensive and continuation phases of treatment, while 4.5 percent (n = 1) was involved during the intensive phase only.

Frequency of once weekly collection of medicines from the health facility in the intensive phase was 55.6 percent (n = 10). Once a week medicine collection by CHWs is what is recommended by NLTP, or daily medicine intake at the health facility by patients without a treatment supporter. For CHWs running a CBO as a treatment center, monthly medicine collection is allowed.

Table 4. Frequency of Collecting Medicines during Intensive Phase

Frequency	n	Percentage
Once and for all (the whole patient pack)	1	5.6
Daily	1	5.6
Twice a week	3	16.7
Once a week	10	55.6
Every month	1	5.6
Every two months	2	11.1
Total	**18**	**100.0**

For the continuation phase, 83 percent of CHWs (n = 15) said that TB medicines were picked up from the health facility on a monthly basis.

Table 5. Frequency of Collecting Medicines during Continuation Phase

Frequency	n	Percentage
Once and for all	1	5.6
Every month	15	83.3
Every two months	1	5.6
No response	1	5.6
Total	**18**	**100.0**

Most of the CHWs (77.8 percent, n = 14) were issued with a complete dose of medicines for their patients to last until their next visit—usually one month.

Table 6. Record of Medicines Delivered

Response	n	Percentage
Not recorded	2	11.1
Bulk delivery to the CHWs with reference to individual patients	2	11.1
Complete dose until the next visit	14	77.8
Total	**18**	**100.0**

Frequency of CHW's treatment report to the health facility varied from daily (5.6 percent, n = 1) to once a month (38.9 percent, n = 7), according to DTLCs interviewed. This confusion may be because the reporting interval is not clearly stipulated in the current CB-DOTS manual. However, a report from the CHW is expected during the monthly visit to the base health facility.

Table 7. Frequency of CHW's Treatment Report to Health Facility

Frequency	n	Percentage
Once a week	6	33.3
Every month	7	38.9
Twice a month	1	5.6
Twice a week	1	5.6
Every quarter	2	11.1
Daily	1	5.6
Total	**18**	**100.0**

When CHWs were asked the same question (how often a treatment report was given by the CHW to the health facility), however, their responses ranged from daily (3 percent, n = 1) to every month 48.5 percent (n = 16).

Medicines left behind by defaulting patients or those who had died were returned to the health facility (88.9 percent, n = 16) or discarded (5.6 percent, n = 1). Time taken to return these medicines to the health facility ranged from less than a week (50.0 percent, n = 9) to one month (5.6 percent, n = 1)

Table 8. Frequency of Returning Medicines to Health Facility

Frequency	n	Percentage
Less than 1 week	9	50.0
7 days	5	27.7
1 month	1	5.6
2 weeks	1	5.6
Don't know	2	11.1
Total	**18**	**100.0**

A patient defaulter list was present in a majority of the DTLC clinics visited (83.3 percent), while 16.7 percent (n = 3) of facilities did not have such a list. However, from the peripheral heath facilities visited, the number of health facilities without a defaulter tracer list was 54.5 percent.

Findings from the Peripheral Health Facility Providers

This study was carried out in 16 districts spanning the whole country; in each district one health facility practicing CB-DOTS was visited. The health care worker found working on the TB desk/clinic was interviewed and data were collected from the facility's TB register.

Respondents ranged from 25 to 57 years of age, with an average of 38.3 years. Most respondents (72.7 percent, n = 24) were female; 24.2 percent (n=8) were male. This finding is usual given that the majority of health care workers in Kenya are female, particularly nurses.

The following key areas on TB patient management were evaluated.

TB Treatment Regimen

Intensive Phase

There was no difference in treatment regimen for facility-based and community-based patients, with 97 percent of respondents quoting the correct regimen and number of months (2RHZE). However, one health care worker/facility provider recorded the correct regimen but missed the duration of treatment.

Continuation Phase

There was no difference in knowledge of regimen quoted for facility-based and community-based respondents for the continuation phase treatment regimen.

Table 9. Continuation Phase Regimen

Regimen	CB-DOTS		Non-CB-DOTS	
	n	Percentage	n	Percentage
4RH	1	3.0	—	—
6EH	31	93.9	32	97.0
EH	1	3.0	1	3.0
Total	**33**	**100.0**	**33**	**100.0**

CHWs were involved in both intensive and continuation phases according to 90.9 percent (n = 30) of respondent health care workers. However, in three health facilities sampled, 9.1 percent of health care workers reported that CHWs were supporting TB patients during the continuation phase only.

On the question of retreatment regimen, 90.9 percent (n = 30) of the facility providers correctly stated that the retreatment regimen was different from the regimen for treatment of new TB patients.

All responses to the question on regimen used in retreatment cases were wrong, including the length of treatment and the actual medicines used during the continuation phase (should be 2RHZE, 1RHZE, 5RHE). The choices given for the question were also wrong. However, the study could not establish whether the choices given influenced the incorrect responses elicited. See Appendix D for the treatment regimens approved by the NLTP.

Table 10. Regimen Used in Retreatment Cases

Regimen	n	Percentage
2SRHZE/4	1	5.6
1RHZE/2SRHZE/5RHZ	17	94.4
Total	**18**	**100.0**

Note: S = streptomycin, E = ethambutol, R = rifampicin, H = isoniazid, Z = pyrazinamide.

When health care providers were asked the frequency with which CHWs picked up medicines from the health facility during the intensive phase, their responses ranged from daily (3 percent, n = 1) to once a week (69.7 percent, n = 23). For the continuation phase, the highest frequency was once every month (84.8 percent, n = 28) as shown Table 11.

Table 11. Frequency of Picking Up Medicines from Health Facility

	Intensive Phase		Continuation Phase	
Frequency	**n**	**Percentage**	**n**	**Percentage**
Daily	1	3.0	0	0
Once a week	23	69.7	1	3
Every two weeks	7	21.2	1	3
Every month	1	3.0	28	84.8
Every two months	1	3.0	2	6.1
Every three months	0	0	1	3
Total	**33**	**100.0**	**33**	**100.0**

According to facility providers, 9 percent (n = 33) of the CHWs attached to the health facility received medicines on behalf of the TB patient under their care. Twelve percent of medicine deliveries were not recorded as required. The majority, however, received a complete dose to provide to their patients until the next scheduled visit.

Table 12. TB Medicines Record

Finding	**n**	**Percentage**
No records	4	12.1
Bulk delivery to the CHW without reference to individual patients	1	3.0
Bulk delivery to the CHW with reference to individual patients	2	6.1
Complete dose until the next visit	26	78.8
Total	**33**	**100.0**

Frequency of treatment reports given by CHWs to the health facility ranged from daily (3 percent, n = 1) to every month 48.5 percent (n = 16).

Table 13. Frequency of CHW Report to Health Facility

Frequency	**n**	**Percentage**
Once a week	12	36.5
Every month	16	48.5
Twice a week	2	6.0
Three times a month	1	3.0
Every quarter	1	3.0
Daily	1	3.0
Total	**33**	**100.0**

The facility providers reported that 85 percent of CHWs (n = 28) returned to the facility the medicines left behind by defaulting or deceased patients. One facility provider had no experience of CHWs returning anti-TB medicines because of patient death or default.

Table 14. Action Taken with Medicines Left Behind

Action	n	Percentage
Return to health facility	28	84.8
Discard	2	6.1
No experience	3	9.1
Total	**33**	**100.0**

Defaulter tracing registers were not available in more than half the peripheral health facilities (54.5 percent, n = 18) and in 16.7 percent (n = 3) of chest clinics manned by DTLCs.

Findings Extrapolated from the CHW Questionnaire

Sixty-seven CHWs identified by the DTLCs of the 16 districts involved in this study were interviewed. The number of CHWs per district ranged from three to six. A slight majority (50.7 percent, n = 34) were female, and 49.3 percent (n = 33) were male. They ranged from 20 to 58 years of age, with a mean of 37.9 years.

Table 15. CHW Ages

Item	Years
Mean	37.9
Mode	31.0
Standard deviation	10.3
Minimum	20.0
Maximum	58.0

The number of patients supported per CHW ranged from 2 to 67.

Table 16. Number of Patients per CHW

Item	n
Mean	12.3
Median	7.0
Mode	2.0
Standard deviation	12.6
Minimum	2.0
Maximum	67.0

Only 4.5 percent (n = 3) of the CHWs had patients' appointment cards with them at the time of the interview. CHWs do not usually come to health facilities without the appointment cards of patients under their care; however, one needs to bear in mind that most of these CHWs had not come to the facility for their usual monthly visit to the clinic but rather had been invited specifically to take part in this study.

The majority of CHWs (54.7 percent, n = 36) were active in both intensive and continuation phases of new and retreatment patients.

Table 17. CHWs' Observation of Patients: Intensive and Continuation Phases

Phase	n	Percentage
Only continuation phase of new patients	4	6.0
Both intensive and continuation phases of new patients	25	37.3
Only continuation phase of new patients and relapses	2	3.0
Both intensive and continuation phases of both new and retreatment patients	36	53.7
Total	**67**	**100.0**

Twelve percent (n = 8) of CHWs administered streptomycin to patients under the supervision of health care providers while 88 percent (n = 59) referred patients to the nearest health facility to be injected.

A variety of venues were used to administer medicines to the patients, as shown in Table 18. Most (65.7 percent) patients swallowed their medicines at home.

Table 18. Venue of Medicine Administration

Venue	n	Percentage
Patient's house	44	65.7
Community center	22	32.8
Hospital	1	1.5
Total	**67**	**100.0**

Fourth-fifths (n = 52) of the CHWs observed TB patients as they take their medication. Most CHWs (75 percent, n = 39) did weekly observation.

Table 19. Frequency of Observation of Patients Taking Medicines

Observation	n	Percentage
Daily	4	7.5
Twice weekly	2	3.8
Weekly	39	75.0
Monthly	6	11.5
Twice a month	1	1.9
Total	**52**	**100.0**

If the CHW was not available to observe TB patients take their medication, alternative observers did it. Household members were the alternative observers in 90 percent of the cases, while 5 percent of cases were observed by other people, and the remaining 5 percent were not observed.

Asked what they did if a patient stopped taking their medicines during treatment, 76 percent (n = 51) of CHWs said they would inform the health care provider, encourage the patient, or both.

Table 20. Action Taken if Patient Stopped Medication

Action	n	Percentage
Inform the health provider	27	40.3
Inform the DTLC	3	4.5
Encourage patient to take medication, warning about consequences	12	17.9
Inform the health provider and encourage the patient	24	35.8
No response	1	1.5
Total	**67**	**100.0**

If a patient complained or showed signs of adverse reactions to medication, 98.5 percent (n = 6) of CHWs would inform the health care provider immediately, while 1.5 percent (n = 1) would inform the district health officer.

The main incentive given to CHWs in their line of duty was training on TB (49.3 percent, n = 33). Others are as indicated in Table 20.

Table 21. Incentives Given to CHWs

Incentive	n	Percentage
Training on TB	33	49.3
Money	10	14.9
Free medical kits and clothing	2	3.0
Recognition from the community	3	4.5
Former TB patients volunteering	5	7.5
All of the above	9	13.4
None	5	7.5
Total	**67**	**100.0**

Findings from Patients' Questionnaires

Data were collected for 134 patients from 16 districts, sampled from all over the country, with between 7 to 10 patients from each district. Fifty-three percent (n = 71) were male, and 47

percent (n = 63) were female. Patients ranged from 15 to 79 years of age, with an average of 38.9 years.

Table 22. Patient Ages

Item	Years
Mean	38.9
Mode	25.0
Standard deviation	13.0
Minimum	15.0
Maximum	79.0

Treatment

Three-quarters of the patients (n = 100) were receiving TB treatment for the first time while a quarter was on retreatment. Seventy-five percent of patients had appointment cards with them at the time of the interview while the rest had not carried theirs. Sixty-four percent (n = 86) of the appointment cards were fully updated while the rest (36 percent, n=15) were incompletely filled out.

Stock-Outs

One of every 10 patients (n = 14) had his or her treatment stopped at some point because of lack of medicine.

The majority of the patients—65 percent (n = 87)—interviewed were supported by a CHW. Of those supported by CHWs, 11.7 percent (n = 13) had their treatment interrupted after the CHW failed to bring them medicine.

DOTS

Of the CHWs, 27 percent (n = 30) observed patients take their medication on a daily basis. The main reason given for inability of the CHWs to observe patients taking their medicine was CHW lack of time caused by competing personal duties. Other reasons are summarized Table 23.

Table 23. Reasons for CHW's Failure to Observe

Reason	n	Percentage
CHW not available	45	70.3
Patient declined	5	7.8
Other (for example, distance)	14	21.9
Total	**64**	**100.0**

Besides the CHWs, other persons who observed patients take medicines included family members, friends, and health workers (Table 24). Three in 10 patients did not have someone to observe them as they took their medication.

Table 24. Alternative Observer

Supporter	n	Percentage
Family member	86	64.2
Self (*not* observed)	40	29.9
Friend	3	2.2
Health worker	1	0.7
Other	4	3.0
Total	**134**	**100**

When TB patients were asked if they are given medicines to take home from the health facility, 95 percent (n = 128) answered in the affirmative. More than half of these patients (57 percent, n = 73) received their medication on a weekly basis during the intensive phase. During the continuation phase, 96 percent (n = 94) received medicines on a monthly basis.

Table 25. Frequency of Patient's Picking Up Medicines from Health Facility

	Intensive Phase		Continuation Phase	
Frequency	*n*	*Percentage*	*n*	*Percentage*
Daily	4	3.1	0	0
Once a week	73	57.0	1	1.0
Once a month	50	39.1	94	95.9
Every two months	1	0.8	2	2.0
Every three months	0	0	1	1.0
Total	**128**	**100**	**98**	**100.0**

Findings on DOTS Outcomes

Data were available for 15 districts for analysis of TB treatment outcomes; data from one district (Kirinyaga) were misplaced during transmission. In each district, data were colleted from two health facilities previously purposefully selected. One facility was practicing CB-DOTS while the other was not (non-CB-DOTS). One questionnaire from a non-CB-DOTS facility in Nandi district was misplaced during transmission from the field. As a result, 15 CB-DOTS and 14 non-CB-DOTS health facilities are analyzed here.

In total, the facilities had 7,483 patients for the period under investigation. TB treatment outcomes for these patients were as indicated in the following tables.

Cure Rates

Overall, TB cure rates were higher in non-CB-DOTS than in CB-DOTS facilities. But more important, the overall cure rates for both CB-DOTS and non-CB-DOTS centers surveyed in this study were below 50 percent.

Table 26. Cure Rates

	CB-DOTS			Non-CB-DOTS		
District	Cured (n)	Cure Rate (Percentage)	Total Number of Patients	Cured (n)	Cure Rate (Percentage)	Total Number of Patients
Nyeri	18	14.5	124	240	34.4	697
Kwale	24	9.6	251	18	22.8	79
Mombasa	16	40	40	17	56.7	30
Athi River	27	45.8	59	0	0.0	44
Garissa	278	36.2	769	19	14.2	134
Machakos	202	26.8	755	0	0.0	120
Isiolo	9	25	36	173	33.9	511
Kamukunji	215	38.9	553	341	38.3	890
Gucha	65	21.2	307	8	9.2	87
Kisumu	80	40	200	149	21.9	680
Nyando	76	55.9	136	85	31.4	271
Nakuru	143	49.0	292	138	56.8	243
Nandi	75	36.8	204	—	—	—
Trans-Nzoia	153	27.9	548	7	17.9	39
Busia	72	35.0	206	18	64.3	28
Total	**1,453**	**32.4**	**4,480**	**938**	**31.2**	**3,003**

Chi square: $x^2(1) = 26.30$, $p = 0.390$ (2-tailed)

Treatment Completion Rate

Treatment completion rate averaged 41.2 percent for CB-DOTS and 46.7 percent for non-CB-DOTS facilities.

Table 27. Treatment Completion Rate

	CB-DOTS			Non-CB-DOTS		
District	TC (n)	TC Rate (Percentage)	Total Number of Patients	TC (n)	TC Rate (Percentage)	Total Number of Patients
Nyeri	63	50.8	124	326	46.8	697
Kwale	152	60.6	251	31	39.2	79
Mombasa	12	30.0	40	7	23.3	30
Athi River	24	40.7	59	38	86.4	44
Garissa	322	41.9	769	100	74.6	134
Machakos	353	46.8	755	84	70.0	120
Isiolo	24	66.7	36	283	55.4	511
Kamukunji	196	35.4	553	353	39.7	890
Gucha	145	47.2	307	50	57.5	87
Kisumu	85	42.5	200	289	42.5	680
Nyando	60	44.1	136	179	66.1	271
Nakuru	68	23.3	292	50	20.6	243
Nandi	37	18.1	204	—	—	—
Trans-Nzoia	208	38.0	548	8	20.5	39
Busia	98	47.6	206	7	25.0	28
Total	**1,847**	**41.2**	**4,480**	**1,403**	**46.7**	**3,003**

Chi square: $x^2(1) = 27.0$, $p = 0.305$ (2-tailed)

Treatment Success Rate

Success rate is cure rate combined with treatment completed rate. Success rates for both sites were as shown in Figure 1. Average treatment success rate was higher in non-CB-DOTS facilities than in CB-DOTS facilities (78.0 percent compared with 72.3 percent). The success rate in the non-CB-DOTS sites compares well with the national rate (about 80 percent).

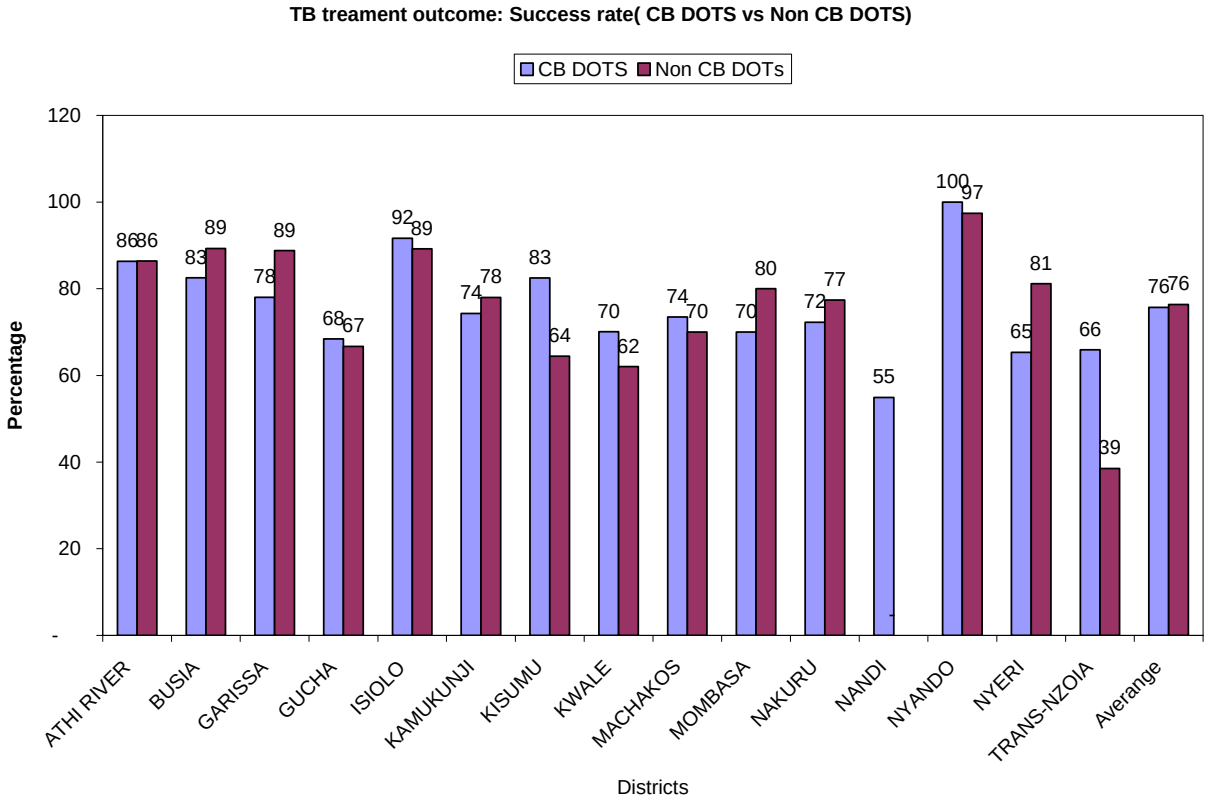

Figure 1. Treatment success rate

Other TB Treatment Outcomes

In Table 28 one can see that the overall out-of-control rate for CB-DOTS was slightly higher (11.3 percent, n = 508) than that of non-CB-DOTS (10.7 percent, n = 321). More deaths were reported in CB-DOTS facilities than in non-CB-DOTS facilities. More patients were transferred in the CB-DOTS facilities than in non-CB-DOTS facilities. There were eight more treatment failure instances in CB-DOTS facilities than in non- CB-DOTS facilities.

Table 28. Other TB Treatment Outcomes

	Out of Control				Death Rate				Transfer Out				Treatment Failure			
	CB-DOTS		Non-CB-DOTS		CB-DOTS		Non-CB-DOTS		CB-DOTS		Non-CB-DOTS		CB-DOTS		No-CB-DOTS	
District	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Nyeri	26	21.0	30	4.3	11	8.9	55	7.9	6	4.8	33	4.7	0	0	13	1.9
Kwale	24	9.6	15	19.0	22	8.8	9	11.4	27	10.8	4	5.1	2	0.8	1	1.3
Mombasa	0	0.0	2	6.7	2	5.0	1	3.3	9	22.5	3	10	1	2.5	0	0
Athi River	7	11.9	2	4.5	0	0.0	4	9.1	1	1.7	0	0	0	0	0	0
Garissa	20	2.6	5	3.7	42	5.5	4	3.0	107	13.9	6	4.5	0	0	0	0
Machakos	75	9.9	17	14.2	60	7.9	17	14.2	65	8.6	2	1.7	0	0	0	0
Isiolo	1	2.8	12	2.3	1	2.8	31	6.1	1	2.8	12	2.3	0	0	0	0
Kamukunji	54	9.8	87	9.8	33	6.0	27	3.0	48	8.7	79	8.9	7	1.3	3	0.3
Gucha	54	17.6	15	17.2	23	7.5	8	9.2	19	6.2	6	6.9	1	0.3	0	0
Kisumu	21	10.5	137	20.1	9	4.5	38	5.6	4	2.0	65	9.6	1	0.5	2	0.3
Nyando	0	0.0	4	1.5	0	0.0	2	0.7	0	0.0	0	0	0	0	0	0
Nakuru	56	19.2	23	9.5	9	3.1	9	3.7	15	5.1	3	1.2	1	0.3	0	0
Nandi	28	13.7	—	—	35	17.2	—	—	29	14.2	—	—	0	0	—	—
Trans-Nzoia	130	23.7	18	46.2	17	3.1	5	12.8	40	7.3	1	2.6	0	0	0	0
Busia	12	5.8	3	10.7	17	8.3	0	0.0	7	3.4	0	0	0	0	0	0
Total	**508**	**11.3**	**321**	**10.7**	**281**	**6.3**	**141**	**4.7**	**378**	**8.4**	**174**	**5.8**	**13**	**0.3**	**5**	**0.2**

DISCUSSION

Patients interviewed during this study averaged 39 years of age. This finding is noteworthy given that the majority of TB patients in Kenya fall in the age bracket 25–34 years (Adatu et al. 2003). Seventy-five percent of the patients interviewed were new TB patients. The rest (25 percent) were retreatment patients; this percentage was higher than the national average for retreatment patients, which stood at 11 percent in 005 (NLTP 2005).

Because of the vague definition of CB-DOTS, the proportion of TB patients under CB-DOTS varied depending on how it was interpreted by the respondents. The DTLCs interviewed reported 16.1 percent CB-DOTS coverage, health care workers from peripheral facilities responded with 33 percent, and results from patients interviewed showed 65 percent CB-DOTs coverage. Treatment outcomes from both non-CB-DOTS and CB-DOTs facilities were comparable.

The same results are clear in the comparison of treatment outcomes between CB-DOTS patients and non-CB-DOTS patients. Cure rates for CB-DOTS patients were higher than for non-CB-DOTS, but the difference was not statistically significant. Essentially, more patients completed treatment without sputum test in non-CB-DOTS facilities than in CB-DOTS facilities. Treatment success rate was also higher in non-CB-DOTS facilities than in CB-DOTS facilities although it was not statistically significant. This finding agrees with two other similar studies done previously by Kangangi et al. (2003) and Adatu et al. (2003), who found that treatment success rates were the same in the control and intervention periods. However, Kangangi et al. in one of the Machakos studies documented that CB-DOTS was more cost-effective than health facility–based DOTS.

Not all patients in CB-DOTS health facilities were attached to a CHW, however, and therefore although the outcomes of CB-DOTS and non-CB-DOTS facilities were comparable, it would be naive for one to conclude that the two are the same. In future, only patients attached to a CHW should be considered when reviewing the outcomes of CB-DOTS.

Other treatment outcomes, such as patients out of control, treatment failure, death, and transfer-out rates, were higher in CB-DOTS patients than in non-CB-DOTS patients (11.3 percent compared with 10.7 percent, 0.3 percent compared with 0.2 percent, 6.3 percent compared with 4.7 percent, and 8.4 percent compared with 5.8 percent, respectively). This finding is in contrast to similar studies carried out in Machakos district, Kenya, by Kangangi et al. (2003) and the Adatu et al. (2003) study in Kiboga district, Uganda. Those studies also found that the proportion of patients who failed treatment was significantly lower and the proportion of patients who defaulted was significantly higher in the intervention period than in the control period ($p < 0.01$). However, they found no significant difference in deaths and transfer rates between patients in the intervention and control periods, the same as in this study, although the rates were lower in intervention than in control periods, unlike in this study, where the opposite is true.

Although parallels can be drawn between this study and the Kangangi study, fundamental differences could have influenced the outcomes. Unlike the Kangangi study, which was piloted in one district, this study was countrywide. The other and probably more significant reason is the

difference in the methodology of execution of the two studies. The Kangangi study was carried out in the same district over different time periods (control and intervention). That study also segregated outcomes of different forms of TB (sputum smear positive from sputum smear negative and pulmonary from extrapulmonary), whereas this study did not differentiate such categories.

A study carried out by Clarke et al. (2003) in Kwa Zulu Natal in South Africa revealed findings similar to those of this study. There was no difference in treatment outcomes between CB-DOTS (TB patients supported by traditional healers in the community) and non-CB-DOTS patients. However, the study in Natal showed that patients under care by traditional healers had higher levels of satisfaction with the quality of care they were receiving.

The current study looked mainly at the role of CHWs in TB treatment as far as swallowing of TB medicine by the patient was concerned. Nevertheless, it has been appreciated that TB treatment supporters do more than just observe patients take their medication. A study by Escott and Walley (2005) in Swaziland concluded that "it is important to recognize that the actual role of the treatment supporter is much more than just directly observing the treatment and includes psychological support and encouragement, practical help with lack of food and funds, and mediation in family disagreements, tackling the fear and stigma that is sometimes present."

The current study also analyzed the data to evaluate the incentives and motivation CHWs have been receiving in their work, but it did not look into the challenges that CHWs face in their line of duty. Such aspects need to be looked at in future studies. Factors that play a vital role in the motivation of CHWs are support from health services staff and the community, supervision and training, adequate supplies, and a reasonable workload. Financial incentives may come from three sources—the government, NGOs, and the community itself—and local preferences must be considered if sustainability is to be ensured (WHO 2003).

About 6 in 10 patients (57 percent) collected medicines on a weekly basis during intensive phase treatment, and 96 percent collected medicines on a monthly basis during continuation phase treatment. The frequency of picking up medicines from health facilities during the intensive phase is lower than expected, given that NLTP guidelines on TB management stipulate that medicines should be picked up on a weekly basis.

Eighty percent of the CHWs picked up medicines from the health facility on a monthly basis during both intensive and continuation phases. The same proportion of CHWs took back the treatment report and forms to the health facility on a monthly basis. Ninety percent of CHWs returned the medicines left behind by dead or defaulting patients to the health facility. Nine of 10 CHWs returned these medicines within one month. However, 10 percent did not know what to do with the medicines and often discarded them. This gap needs to be addressed to avoid medicine wastage. Along the same theme of commodity management is the failure of 12 percent of the DTLCs to record delivery of anti-TB medicines collected by CHWs.

It is evident that there is frequent contact between CHWs and the health workers that could be used for on-the-job training of CHWs by the health worker. Such training would in turn eliminate incidents such as those where CHWs throw away unused medicines.

Ten percent of the patients had experienced unavailability of medicines at some point in their treatment. This figure is significant because frequent stock-outs in TB facilities can discourage patients from coming back for treatment, especially when considered in the light of the poor socioeconomic status of most of the patients.

Almost a third of patients (30 percent) had nobody to observe them while taking their daily medication. This finding brings into question whether the country is really implementing directly observed therapy requiring a TB patient to have someone observe them take their anti-TB medicines.

Community-based DOTS was seen as a good way of involving the community in TB management, mainly through CHWs. Sixty-five percent of the patients said they were supported by a CHW; for that 65 percent, 80 percent of CHWs regularly observed patients take their medication. A majority of CHWs (95 percent) were involved in both intensive and continuation phases. More than a quarter of the CHWs (27 percent) were doing an excellent job of observing patients take their medication on a daily basis. One-third of patients had their medicines administered at a local community center. All these patients show quite a proportional amount of community ownership of TB management. However, one in seven patients cited some instances when a CHW would fail to visit them because the CHW was busy with other day-to-day chores. This failure led to about 12 percent of the patients' missing their medication. This finding is significant and needs to be critically looked into.

Almost half of CHWs (49 percent) cited training on TB as their motivation in their work, with 15 percent citing money. The CHWs need be motivated in their work through innovative incentives. This is more urgent considering that 12 percent of retreatment patients received therapy through CHWs. If patients on retreatment missed their medication for a long period, they would risk developing MDR-TB.

CHWs involved in TB work averaged 38 years of age. This finding is good, considering that it is about the same age as patients in the study (mean age = 39 years). The youngest CHW was 20 years of age and the oldest 58. The youngest patient was 15 years of age, while the oldest was 79.

The majority of CHWs (13) had two patients under their care. The average number of patients a CHW had to take care of was 12. This is above the number of 10 patients per CHW as recommended by the NLTP to avoid overworking CHWs and thereby reducing their efficiency. One CHW had 67 patients under his care; however, it could not be established if this CHW was referring to the total number of TB patients under his direct care or the total number of patients in their village CBO.

The majority of the CHWs displayed knowledge of what action to take in case a patient showed adverse effects due to medication. Almost all CHWs (98 percent) would inform the health care worker immediately in case of such an eventuality. The same number would encourage the patient to continue medication and at the same time inform the health care worker in the event that a patient stopped taking medicine. This finding shows a good level of knowledge on the part of the CHW, which is essential for success of DOTS expansion.

The number of TB patients seen in 2005 in the study districts was 23,386, representing a 6.3 percent increase over the 2004 figures. This increase is 3 times higher than the national average (2 percent) over the same period (NLTP 2005). DTLCs reported that 16 percent of patients were under CB-DOTS, although 65 percent of patients claimed to be attached to a CHW who was their treatment supporter. The case is complicated further by the peripheral health facility health care workers, who said that only a third (33 percent) of the patients was attached to a CHW.

DTLCs exhibited high levels of knowledge of TB management. All respondents correctly identified the regimen and period of treatment for the intensive phase. However, 5.6 percent of the respondents incorrectly cited EH for five months as the regimen for continuation for new TB patients instead of six months according to NLTP guidelines. This finding is significant because DTLCs are the TB technical managers in the district and are thus mandated the task of guiding other health care workers on TB management.

The majority of in-charges for health facilities (97 percent) correctly said there was no difference in regimen for community-based and facility-based patients. Facility providers showed good knowledge of TB treatment regimens, with 97 percent quoting the correct regimens. However, some 3 percent quoted the correct regimen for the intensive phase without noting the length of time to be taken. The PTLCs and DTLCs need to follow up with the health care workers to see that they have the correct information to avoid incorrect prescriptions.

A defaulter tracing register was not available in more than half of the peripheral health facilities (54.5 percent) and 17 percent of the DTLC's chest clinics. Essentially, the same proportions of health facilities were not following those patients who defaulted, which makes follow-up of such patients difficult. The NLTP guideline requires that every health facility offering TB care services maintain an updated TB register.

What this study unveils is that CB-DOTS does not in itself improve the outcomes of TB treatment; however, CB-DOTS offers the community opportunities to be involved in TB management. This finding in itself is a huge milestone because it will gradually erode the stigma associated with TB, and eventually better TB treatment outcomes will be realized as the community takes it upon itself to encourage more suspects to be tested and those found to have TB to complete their medication as prescribed.

Some sets of data in this study look contradictory or varying at best. The reason for this outcome is that different questionnaires were used for health care workers, patients, and CHWs. Thus, different responses for the same questions would be elicited. An example is the percentage of patients under CB-DOTS. Health facility in-charges said that only 33 percent of their patients were under CHWs' support. However, the patients themselves maintained that 65 percent of them were under CHWs' observation. The example makes evident that twice as many patients as health care workers mentioned were actually benefiting from the services of CHWs in their ongoing TB care. The difference in the data set could have stemmed from biased responses: either some of the patients could have confused family member support for CHWs or health care workers may have kept poor records of the correct number of patients under CB-DOTS.

Another example is the period CHWs take to return unused TB medicines to the health facility. Health care workers reported that only 85 percent of CHWs returned medicines within one month, but the CHWs reported that 90 percent of them return medicines within one month. In this instance, the CHWs most likely were overestimating their performance.

Limitations of the Study

Conclusive deductions from the study may not be as accurate as one would like because sampling of patients and CHWs may not have been as random as would be desirable. The investigating team understands that the CHWs interviewed were hand-picked by DTLCs.

Although CB-DOTS health facilities were sampled in this study, not all patients in these facilities were under CHW support. This aspect could have skewed the data. The investigating team was not in a position to determine the difference between TB patients under CB-DOTS attached to a CHW and those from the same facility who were not supported by a CHW.

This study looked into only one aspect of CB-DOTS, that is, how CHWs assist TB patients swallow their medication. First, the investigators acknowledge that CHWs do more than just observe treatment; they improve community knowledge on TB and offer counseling of TB patients, TB suspects, and their families, among other duties.

Second, the investigators concur with other TB experts who recognize the wider CB-DOTS fraternity, including family members and community-based health institutions such as CBOs and Bamako initiatives (WHO 2003). Studies elsewhere have shown that both CHW- and family-observed DOTS have similar TB treatment outcomes (Newell et al. 2006). That study proposes that TB therapy observed by any person other than a trained health care worker be considered as community-based DOTS.

Reliability and Validity

Data collection was conducted by NLTP program officers; thus the issue of bias (intentional or unintentional) cannot be ruled out. In future, it would be prudent to have non-NLTP staff in such stages of survey.

CONCLUSION AND RECOMMENDATIONS

Conclusion

Although CB-DOTS is a good way of involving the community in TB management and in essence reduce stigma against TB patients in the community, in this study CB-DOTS was not associated with an appreciable positive effect on TB treatment outcome. Assuming the broad definition of CB-DOTS that includes family members, CHWs, and CBOs, one is persuaded to conclude that most (65 percent) TB patients in Kenya are treated under a CB-DOTS strategy in both CB–DOTS- and non-CB-DOTS-designated health facilities.

Recommendations

1. To fully appreciate the contribution of CB-DOTS strategy in TB control, NLTP needs to carry out a study on all the three components of CB-DOTS: CHWs, CBOs/Bamako Initiatives, and family and household members

2. NLTP should come up with guidelines and standard operating procedures for implementation of CB-DOTS that stipulate proper record keeping on medicines; defaulter tracing; and what should be done with medicines left behind by deceased or defaulting patients

3. TB guidelines should be disseminated and distributed regularly to all health care workers to update them on current TB management

4. NLTP should provide a stipend in addition to other incentives to CHWs so they can devote more time to support TB therapy

5. Patients should be encouraged to identify their own DOTS supporters

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APPENDIX A. DISTRIBUTION OF HEALTH FACILITIES IN KENYA BY TYPE AND PROVIDER

	MoH		FBO/NGO		Private for Profit		Total
Type of Facility	**n**	**Percentage**	**n**	**Percentage**	**n**	**Percentage**	
Hospital	109	50	67	30.7	42	19.3	**218**
Health Center	460	80	100	17.4	15	2.6	**575**
Dispensary	1,537	60.9	595	23.6	391	15.5	**2,523**
Nursing and maternity	0	0	11	58	180	94.2	**191**
Medical care	43	0.1	72	10.2	592	83.7	**707**
Total	**2,149**	**51**	**845**	**20.1**	**1,220**	**29**	**4,214**

APPENDIX B. DATA FOR ALL REPORTED TB CASES, 2005

District	Type	New Smear Positive	Retreatment					New Smear Negative			New Extrapulmonary			Total
			Sm.pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total	
Kamakunji	SCC	1159	176	197	1	6	380	192	581	773	49	327	376	2688
	Percentage	43	7	7	0	0	14		29			14		100
Langata	SCC	1221	222	402	0	31	655	505	1354	1859	103	657	760	4495
	Percentage	27	5	9	0	1	15		41			17		100
Kiambu	SCC	690	38	48	0	27	113	126	668	794	25	204	229	1826
	Percentage	38	2	3	0	1	6		43			13		100
Kirinyaga	SCC	578	20	6	1	22	49	92	241	333	15	82	97	1057
	Percentage	55	2	1	0	2	5		32			9		100
Nyeri	SCC	669	51	34	0	12	97	119	593	712	20	229	249	1727
	Percentage	39	3	2	0	1	6		41			14		100
Kwale	SCC	487	22	104	1	10	137	114	561	675	35	103	138	1437
	Percentage	34	2	7	0	1	10		47			10		100
Mombasa	SCC	2937	258	246	1	58	563	310	1456	1766	115	488	603	5869
	Percentage	50	4	4	0	1	10		30			10		100
Taita Taveta	SCC	228	17	9	3	9	38	25	170	195	16	51	67	528
	Percentage	43	3	2	1	2	7		37			13		100
Embu	SCC	428	28	36	1	5	70	257	1024	1281	12	118	130	1909
	Percentage	22	1	2	0	0	4		67			7		100
Kitui	SCC	608	78	149	0	5	232	170	701	871	59	194	253	1964
	Percentage	31	4	8	0	0	12		44			13		100
Mwingi	SCC	241	42	29	0	1	72	66	220	286	16	75	91	690
	Percentage	35	6	4	0	0	10		41			13		100
Machakos	SCC	893	80	159	3	29	271	257	1103	1360	77	456	533	3057
	Percentage	29	3	5	0	1	9		44			17		100
Meru	SCC	559	40	13	2	21	76	127	460	587	12	84	96	1318
	Percentage	42	3	1	0	2	6		45			7		100
Isiolo	SCC	232	36	38	0	0	74	48	272	320	9	36	45	671
	Percentage	35	5	6	0	0	11		48			7		100
Nyambene	SCC	755	27	34	1	40	102	137	547	684	87	147	234	1775
	Percentage	43	2	2	0	2	6		39			13		100

District	Type	New Smear Positive	Retreatment					New Smear Negative			New Extrapulmonary			Total
			Sm.pos. Relapse	Other Relapse	Failure	R.A.D.	Total	<15 yrs	15+ yrs	Total	<15 yrs	15+ yrs	Total	
Garissa	SCC	550	40	54	1	0	95	82	255	337	56	126	182	1164
	Percentage	47	3	5	0	0	8		29			16		100
Wajir	SCC	396	27	63	1	3	94	71	330	401	46	73	119	1010
	Percentage	39	3	6	0	0	9		40			12		100
Kisumu	SCC	1332	105	178	3	35	321	281	1939	2220	46	323	369	4242
	Percentage	31	2	4	0	1	8		52			9		100
Siaya	SCC	759	77	61	5	15	158	34	477	511	69	223	292	1720
	Percentage	44	4	4	0	1	9		30			17		100
Gucha	SCC	304	24	41	1	44	110	54	354	408	12	78	90	912
	Percentage	33	3	4	0	5	12		45			10		100
Kuria	SCC	158	13	15	0	19	47	18	137	155	21	68	89	449
	Percentage	35	3	3	0	4	10		35			20		100
Suba	SCC	357	16	10	0	2	28	27	241	268	11	98	109	762
	Percentage	47	2	1	0	0	4		35			14		100
Bondo	SCC	631	72	41	2	13	128	67	508	575	11	150	161	1495
	Percentage	42	5	3	0	1	9		38			11		100
Nyando	SCC	728	11	5	0	2	18	112	428	540	44	150	194	1480
	Percentage	49	1	0	0	0	1		36			13		100
Kericho	SCC	691	37	35	0	15	87	102	431	533	20	143	163	1474
	Percentage	47	3	2	0	1	6		36			11		100
Nakuru	SCC	1769	76	91	1	74	242	473	1671	2144	101	498	599	4754
	Percentage	37	2	2	0	2	5		45			13		100
Nandi	SCC	359	26	30	1	51	108	91	354	445	27	101	128	1040
	Percentage	35	3	3	0	5	10		43			12		100
Trans Nzoia	SCC	419	26	8	0	16	50	378	544	922	39	89	128	1519
	Percentage	28	2	1	0	1	3		61			8		100
Koibatek	SCC	92	10	0	0	0	10	3	138	141	12	34	46	289
	Percentage	32	3	0	0	0	3		49			16		100
Busia	SCC	392	25	48	2	9	84	160	534	694	47	160	207	1377
	Percentage	28	2	3	0	1	6		50			15		100
Teso	SCC	119	6	15	0	15	36	30	137	167	14	76	90	412
	Percentage	29	1	4	0	4	9		41			22		100

APPENDIX C. DISTRICTS IMPLEMENTING TB CARE SERVICES (CB-DOTS)

1. Busia
2. Kapsabet
3. Nakuru
4. Kisumu
5. Langata
6. Nyeri
7. Machakos
8. Wajir
9. Taita Taveta
10. Kwale
11. Tharaka
12. Meru Central
13. Nyambene
14. Isiolo
15. Mandera
16. Garissa
17. Kitui
18. Kericho
19. Kirinyaga
20. Koibatek
21. Kiambu
22. Teso
23. Kamukunji
24. Trans Nzoia
25. Tana River
26. Gucha
27. Mwingi
28. Kuria
29. Suba
30. Siaya
31. Moyale
32. Nyando
33. Bondo

APPENDIX D. CURRENT TB TREATMENT REGIMENS IN KENYA

Treatment regimen for new adult smear-positive patients and other seriously ill cases of tuberculosis, such as TB meningitis, military TB, and TB of vital organs is 2RHZE/6EH

Category I and III Patients

Phase	
Intensive	**Continuation**
2RHZE,daily observation for 8 weeks	6EH, daily self-administered for 6 months
Medicines used: ethambutol (E), rifampicin (R), isoniazid (H), pyrazinamide (Z)	Medicines used: ethambutol (E), isoniazid (H)

Retreatment regimen for relapse (R), treatment failure (F), or treatment resumed (TR), with active tuberculosis disease and who have a positive sputum smear or culture result is 2SRHZE/5RHE.

Category II Patients

Phase		
Intensive		**Continuation**
2SRHZE, daily observation for 8 weeks	Daily supervised for 4 weeks	5RHE, daily self-administered for 5 months
Medicines used: streptomycin (S), ethambutol (E), rifampicin (R), isoniazid (H), pyrazinamide (Z)	Medicines used: ethambutol (E), rifampicin (R), isoniazid (H), pyrazinamide (Z)	Medicines used: ethambutol (E), rifampicin(R), isoniazid (H)

Treatment regimen for new smear-negative and extrapulmonary tuberculosis patients younger than 15 years is 2RHZ/4RH.

Children

Phase	
Intensive	**Continuation**
2RHZ, daily observation for 8 weeks (once a week supervised)	4RH, daily self-administered for 6 months
Medicines used: rifampicin (R), isoniazid (H), pyrazinamide (Z)	Medicines used: rifampicin (R), isoniazid (H)

APPENDIX E. DATA COLLECTION TOOLS

Data Collection Guide for the Patient

Start time----------
End time----------

Province _____ **District** _____

Health Facility _____

Name of interviewer _____

Date _____

Age---------- Sex----------

1. When did you start the current treatment? ----------
   (Month and year)

2. Are you being treated for TB for the first time?
   Yes ☐ No ☐

3. Do you have your appointment card with you now?
   Yes ☐ No ☐

4. If yes to number 3, ask for the card and check for completeness.

   Yes well filled ☐
   Not well filled ☐

5. Have you ever had to stop your treatment because there were no medicines?
   Yes ☐ No ☐

6. Are you supported by a CHW?
   Yes ☐ No ☐

7. f yes to 6 above, have you ever had to stop your treatment because the CHW did not bring you your medicines?
   Yes ☐ No ☐

8. If yes to 6 above, does the CHW observe you as you swallow every single dose?

   Yes ☐ No ☐

9. If no to 6 above, what are the reasons?
    a. Did not want
    b. CHW not available
    c. Others (be specific) _____

10. If the CHW is not observing you, who observes you when you take your daily doses?
    a. Family member
    b. Friend
    c. Self
    d. Other (be specific)

11. Are you given any medicines to take home? Yes ☐ No ☐

12. If yes to number 11, for what duration is the dose that you are given during the intensive phase?
    a. 7 days (or 1 week)
    b. 2 weeks
    c. 1 month
    d. 2 months
    e. 3 months
    f. a full course of treatment

13. If yes to number 11, for what duration is the dose that you are given during the continuation phase?
    a. 7 days (or 1 week)
    b. 2 weeks
    c. 1 month
    d. 2 months
    e. 3 months
    f. a full course of treatment

14. If you are given the medicines to take home, where do you store them?
    a. Under the bed
    b. In a cupboard/shelf
    c. On a table
    d. Other (be specific) _____

Signature of interviewer ----------

Data Collection Guide for the Community Health Worker

Start time----------
End time----------

Province _____ **District** _____

Health Facility _____

Name of interviewer _____

Sex---------- **Age----------**

Date _____

1. How many TB patients are you supporting? _____

2. Do you have their appointment cards here with you?
   Yes ☐ No ☐

3. If no, where are they? _____

4. If yes, ask for the card and check to see if they are properly filled out and record the numbers below:
   a. Number of cards available to you_____
   b. Number of cards you examined _____
   c. Number of cards properly filled out according to NLTP guidelines_____

5. Do you provide medicines for:
   a. Only the continuation phase of new patients
   b. Both the intensive and continuation phases of new patients
   c. Only the continuation phase of both new patients and relapses
   d. Both the intensive and continuation phase, of both new patients and retreatment

6. If you provide medicines for the intensive phase of retreatment patients, do you administer streptomycin (for category II patients)? Yes ☐ No ☐

7. If no, where is streptomycin administered? _____

8. Where do you administer the medicines?
   a. My home
   b. Patient's house
   c. Community center
   d. Other (be specific) _____

9. Do you observe the patient taking a dose of his/her medicine:
   Yes ☐ No ☐

10. If yes to 9 above, how frequent do you observe
    a. Every single dose to the patient
    b. Once weekly when patients collect the medicines
    c. Once monthly when the patient collect the medicines
    d. Other (be specific)_____

11. If no to 9 above, then why? _____

12. If you don't observe daily, who does it?
    a. Household member
    b. Patient him/herself
    c. Other (specify)

13. Have there been any interruptions of treatment to any of your patients? Yes ☐ No ☐

14. If yes to number 13, what were the reasons?
    a. The medicines were out of stock in the facility where I normally pick them from
    b. I could not go to the health facility to pick up the medicines due to personal problems
    c. Other (be specific)_____

15. What do you do if a patient stops taking their medicines during treatment (tick all that apply)
    a. Inform the health provider at the facility
    b. Inform the district TB officer
    c. Encourage patient to start taking medicines again warning about the consequences if medicines are not taken
    d. Other (be specific)_____

16. What do you do if a patient complains or show signs of an adverse reaction to the medicines?
    a. Inform the health provider at the facility right away
    b. Inform the district health officer right away
    c. Tell the patient to stop taking the medicine
    d. Other (be specific) _____

17. What incentives do you receive for your services to the community (tick all that apply)
    a. Money
    b. Training to learn about treating tuberculosis
    c. Recognition from members of my community
    d. Other (be specific) _____

Signature of the interviewer----------

Data Collection Guide for the Facility Provider

Start time----------
End time----------

Province _____ **District** _____

Health Facility _____

Name of interviewer _____

Date _____

Sex---------- **Age----------**

1. Number of TB patients treated in 2005 in this facility (check on register) _____
2. Number of TB patients treated in 2006 in this facility (check on register) _____
3. Number of patients treated under community DOTS strategy in this facility in the year 2006 _____
4. Calculate the percentage of TB patents under community DOTS in 2006
5. Who supports the TB activities in this facility?
    a. MoH
    b. Faith-based NGO
    c. Other NGO
    d. Other (be specific) _____
6. What regimen do you use in this facility for new TB cases (use acronyms and indicate for both intensive and continuation phase)
    For intensive phase _____
    _____
    For continuation phase_____
    _____
7. What regimen do you use in the community for new TB cases (use acronyms and indicate for both intensive and continuation phase)
    For intensive phase _____
    _____
    For continuation phase_____

8. Who is responsible for the administration of medicines and recording of patients' appointment cards?
   a. Facility provider
   b. Community health worker
   c. Treatment supporter (relative, neighbor, household member)
   d. Other (be specific)_____

9. At what phase are the services of a CHW used?
   a. Intensive phase only
   b. Continuation phase only
   c. Both intensive and continuation phases
   d. Other: (be specific)_____

10. Does the CHW support the treatment of retreatment cases (category II)?
    Yes ☐ No ☐

11. If yes to number 10 above, at what phase of treatment?
    a. Intensive phase only
    b. Continuation phase only
    c. Both intensive and continuation phases
    d. Other: : (be specific)_____

12. Is the treatment regimen the same as for the new TB patients that are treated in this facility? Yes ☐ No ☐

13. If no to number 12 , indicate the regimen used in the re-treatment cases (use acronyms): _____

14. Who picks up the medicines from the treatment center?
    a. Patient alone
    b. CHW alone
    c. Treatment supporter alone (relative, neighbor, household member)
    d. Either patient or the CHW or treatment supporter
    e. Other: (be specific)_____

15. How often are medicines picked up during the intensive phase of treatment?
    a. Only once and enough for the whole treatment
    b. Every three months
    c. Every two months
    d. Every month
    e. Two times a month
    f. Once a week
    g. Other: (be specific) _____

16. How often are medicines picked up during the continuation phase of treatment?
    a. Only once and enough for the whole treatment
    b. Every three months
    c. Every two months
    d. Every month
    e. Two times a month
    f. Once a week
    g. Other (be specific) _____

17. How is the delivery of medicines to the CHW registered in the health facility?
    a. Not registered
    b. As a bulk delivery to the CHW (without reference to individual patients)
    c. As a bulk delivery to the CHW (with reference to individual patients)
    d. As a complete dose for the recommended duration of treatment before the next visit
    e. Other (be specific) _____

18. Where are medicines administered by CHWs?
    a. House of the CHW
    b. House of the patient
    c. Community center
    d. Other (be specific) _____

19. Should the CHW fill out the drug administration cards?
    Yes ☐ No ☐

20. How often does the CHW report treatment information to the health facility?
    a. Once a week
    b. Twice a month
    c. Every month
    d. Every two months
    e. Every quarter
    f. Other (be specific)_____

21. Where are medicines stored?
    a. Home of CHW
    b. Home of patient
    c. In a shed outside home of CHW or patient
    d. Other (be specific) _____

22. Where exactly in the choices identified (name the choice) in 18 above are these medicines stored?
    a. On the floor
    b. In a cupboard
    c. Other (be specific) _____

23. What does the CHW do with medicines not used due to default or death?
    a. Returns them to the health facility
    b. Keeps them for future patients
    c. Trashes them
    d. Other (be specific)_____

24. If returned to the health center, how long before they are returned
    a. less than 7 days
    b. 7 days (1 week)
    c. 1 month
    d. 2 months
    e. 3 months
    f. more than 3 months
    g. Other (be specific)_____

25. Do you have a defaulter list in this facility? Yes ☐ No ☐

Signature of interviewer

Data Collection Guide for the District Level

Start time----------
End time----------

Province _____ **District** _____

Name of interviewer _____

Date _____

1. The total number of TB patients treated in 2005 in the district (refer to the register) _____

2. The total number of TB patients treated in 2006 in the district (refer to the register) _____

3. The total number of patients treated under community DOTS strategy in this district in the year 2006 _____

4. Calculate the percentage of TB patents under community DOTS in 2006 in the district _____

5. Who supports the TB activities in this facility?
    a. MoH
    b. Faith-based NGO
    c. Other NGO
    d. Other (be specific) _____

6. What regimen do you use for new TB cases (use acronyms and indicate for both intensive and continuation phase)
    For intensive phase _____
    _____
    For continuation phase_____
    _____

7. What regimen is used in the community for new TB cases (use acronyms and indicate for both intensive and continuation phase)
    For intensive phase _____
    _____
    For continuation phase_____
    _____

8. Who is responsible for the administration of medicines and recording of patients' appointment cards?
    a. Facility provider
    b. Community health worker
    c. Treatment supporter (relative, neighbor, household member)
    d. Other (be specific)_____

9. At what phase are the services of a CHW used?
    a. Intensive phase only
    b. Continuation phase only
    c. Both intensive and continuation phases
    d. Other: (be specific)_____

10. Does the CHW support the treatment of re-treatment cases (category II)?
    Yes ☐ No ☐

11. If yes to number 10 above, at what phase of treatment?
    a. Intensive phase only
    b. Continuation phase only
    c. Both intensive and continuation phases
    d. Other: (be specific)_____

12. Is the treatment regimen the same as for the new TB patients that are treated in the district? Yes ☐ No ☐

13. If no to number 12, indicate the regimen used in the retreatment cases (use acronyms): _____

14. Who picks up the medicines from the treatment center?
    a. Patient alone
    b. CHW
    c. Treatment supporter alone (relative, neighbor, household member)
    d. Either patient or the CHW or treatment supporter
    e. Other: (be specific)_____

15. How often are medicines picked up during the intensive phase of treatment?
    a. Only once and enough for the whole treatment
    b. Every three months
    c. Every two months
    d. Every month
    e. Two times a month
    f. Once a week
    g. Other (be specific) _____

16. How often are medicines picked up during the continuation phase of treatment?
    a. Only once and enough for the whole treatment
    b. Every three months
    c. Every two months
    d. Every month
    e. Two times a month
    f. Once a week
    g. Other (be specific) _____

17. How is the delivery of medicines to the CHW registered in the health facility?
    a. Not registered
    b. As a bulk delivery to the CHW (without reference to individual patients)
    c. As a bulk delivery to the CHW (with reference to individual patients)
    d. As a complete dose for the recommended duration of treatment before the next visit
    e. Other (be specific) _____

18. Where are medicines administered by CHWs?
    a. House of the CHW
    b. House of the patient
    c. Community center
    d. Other (be specific) _____

19. Should the CHW fill out the patient appointment cards?
    Yes ☐ No ☐

20. How often does the CHW report treatment information to the health facility?
    a. Once a week
    b. Twice a month
    c. Every month
    d. Every two months
    e. Every quarter
    f. Other (be specific)_____

21. Where are medicines stored?
    a. Home of CHW
    b. Home of patient
    c. In a shed outside home of CHW or patient
    d. Other (be specific) _____

22. Where exactly in the choices identified (name the choice) in 18 above are these medicines stored?
    a. On the floor
    b. In a cupboard
    c. Other (be specific) _____

23. What does the CHW do with medicines not used due to default or death?
    a. Returns them to the health facility
    b. Keeps them for future patients
    c. Trashes them
    d. Other (be specific)_____

24. If returned to the health center, how long before they are returned?
    a. less than 7 days
    b. 7 days (1 week)
    c. 1 month
    d. 2 months
    e. 3 months
    f. more than 3 months
    g. Other (be specific)_____

25. Is there a defaulter list in all the health facilities in this district? Yes ☐ No ☐

Signature of the interviewer----------