DEFAULTING FROM DOTS AND ITS DETERMINANTS IN THREE DISTRICTS OF ARSI ZONE, OROMIA REGIONAL STATE, *ETHIOPIA*

BY

BETRU TEKLE, MD

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Dept. of Community Health
Faculty of Medicine

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Betru Tekle, MD

Department of Community Health
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ሕክምና ፋካልቲ
Dept. of Community Health
Faculty of Medicine

Approved by the Examining Board

Dr. Yemane Berhane **Chairman, Department Graduate Committee**	
Dr. Damen H/mariam **Advisor**	
Dr. Johannis Leeuwenburg **Examiner**	
Dr. Getnet Mitike **Examiner**	

DEDICATION

TO MY WIFE AND TWINS

Without my wife Roman

these works would not have been

part of my life

Without my twin sons

Moti and Mosisa

I could not have written

this thesis

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List of Abbreviations

AAU	*Addis Ababa University*
AFB	*Acid Fast Bacilli*
AIDS	*Acquired Immuno – Deficiency Syndrome*
DCH	*Department of Community Health*
DOTS	*Directly Observed Treatments, Short Course*
IUATLD	*The International Union Against Tuberculosis and Lung Diseases*
SPSS	*Statistical Package for Social Sciences*
MDR-TB	*Multiple Drug Resistance – Tuberculosis*
TB	*Tuberculosis*
WHO	*World Health Organization*

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Abstract

A case-control study, on defaulting from DOTS was performed in three districts of Arsi Zone, Oramia Regional State, among patients registered during the period of July 1, 1997 to December 31, 1999 to determine the rate of defaulting and to identify factors associated with it.

A health record review of 1367 new tuberculosis patients put on DOTS during a period of 30 months (July 1997 to December 1999) was carried out in order to determine the rate of defaulting. All the study subjects were registered and put on DOTS after June 30, 1997 and completed treatment or declared cured before January 1,2000. The cases and controls were traced actively and interviewed by trained interviewers using a pre-tested structured questionnaire. The two groups were compared by social, demographic and health services variables. The overall defaulter rate and specific rate by month of defaulting, health institutions, districts and distance from health institutions were calculated. All defaulters and the non-defaulters were selected by paired matching of sex and age using the lottery method. Two controls were matched individually to each case.

One hundred fifty five cases and one hundred sixty controls were included in the study. The overall defaulting rate from DOTS was calculated to be 11.3%. The rate of defaulting in case of sputum smear positive pulmonary tuberculosis was found to be 11.6%. The rate of defaulting was higher in Etheya clinic and Hitosa District. Highest (80%) rate of

defaulting occurred during the continuation phase. Medication side effect was found to be significantly associated with defaulting from DOTS (OR= 4.20 with 95% CI 1.51 to 11.66). Adequate knowledge and family support were found to be important possible protective factors for defaulting (OR=0.04 with 95% CI 0.02 to 0.10 and OR=0.19 with 95% CI 0.08 to 0.46 respectively). Distance from health units and drug intolerance were the major reasons mentioned for defaulting. However, there is no significant difference between cases and controls regarding distance, employment status, attitude to treatment center, level of education and average monthly income.

The rate is slightly higher than the critical level of 10% set by WHO. The major factors contributing to high rate of defaulting were lack of family support, inadequate knowledge about duration of treatment and presence of medication side effects. Health programme that are intended to enhance family support and knowledge about duration of DOTS treatment and Drug tolerance should be strengthened.

1. INTRODUCTION

We have known for over 100 years that Mycobacterium tuberculosis causes tuberculosis. We have had effective anti-tuberculosis drugs for nearly 50 years. Yet the tuberculosis problem is now bigger than ever. More people are dying of TB than in any other year in history. The main problem in the control of this disease is lack of proper usage of the available treatment. Properly organized and implemented short-term chemotherapy has been effective in this regard. This is because this type of approach minimizes the emergence of drug-resistant strains of the mycobacterium which is usually associated with control program failure (1,2,3,4,5).

Treatment adherence is necessary for tuberculosis control. If adherence is achieved, patients will be cured and the emergence of drug resistance will be prevented. In the past such adherence to therapy in the critical early months of therapy was typically achieved through hospitalization. However, with limited health facilities and in the face of rising of tuberculosis cases (largely associated with HIV/AIDS), this option is no longer feasible in developing countries (1).

Non- adherence (defaulting from treatment) gives the tuberculosis bacteria the opportunity to become resistant to one or more drugs resistance. This makes the disease more difficult and expensive to cure. Transmission of such resistant strains within the community creates vicious cycle of drug resistance. In October 1997, WHO warned of the emergence of

multidrug-resistant TB "hot zones" around the world. These are areas where TB could become incurable for anyone who does not have access to the most expensive health care. Multiple drug resistant raises tuberculosis treatment costs 100 fold and greatly reduces the chances of survival. Treatment of it costs up to US $250,000 per patient in industrialized countries (2,3,4). Therefore, from the public health perspective partly supervised and incomplete treatment is worse than no treatment.

In response to problem of drug resistance due to incomplete treatment, WHO came up with DOTS (Directly Observed Treatment, Short course) in 1993 and is trying to ensure that it is available everywhere in the world. Currently about 12% of TB cases worldwide are treated with this approach. Its effectiveness is shown by an overall cure rate of nearly 80 % (6,7).

The purpose of DOTS is to ensure patient adherence to treatment. DOTS is not the direct outcome of recent basic or clinical research, but of subsequent operational research. The drugs used for treatment in the DOTS system are not new. They have been available for three decades and have been almost 100% effective in curing tuberculosis when used correctly (7).

The main strategies of DOTS are case finding, chemotherapy and patient monitoring without hospital admission. On top of curing, DOTS also prevents relapses, reduces the chance of development of drug resistance and prolongs the lives of people with TB and HIV (1,7,8).

Since 1993, more than 100 countries have adopted DOTS. Of the 22 countries in the world with the highest incidence of tuberculosis, 21 countries have adopted DOTS. However many of these countries still have low DOTS coverage (8).

The HIV/AIDS epidemic is causing a rapid increase in tuberculosis. This is particularly the major problem in Sub-Saharan Africa and South-East Asia. In 1997, it was estimated that there were over 10 million people in the world infected with both TB and HIV, of which more than 7 million were in Africa and over 3 million in South East Asia. In some parts of Sub-Saharan Africa, 70-80% of TB cases are due to HIV. In Malawi and Tanzania, for example, both countries with good TB Control Programme, the number of TB cases has tripled as a result of HIV epidemic (8).

It was about 50 years back that tuberculosis started to be recognized as a public health problem in Ethiopia. In 1998/1999, a total of 73,363,460 patients were registered at out patient department of health units. Of these, 53.42% (n = 1,796,894) visited the health institutions, due to the leading 15 cases, of which tuberculosis accounted for 3.52% (n = 118,513)(9).

Drugs used for tuberculosis treatment in Ethiopia are streptomycin, ethambutol, rifampicin, thiacetazone, isoniazide, and pyrazinamide. Streptomycin is administered in injection form while others are taken orally. All taken as single, daily doses, preferably on empty stomach, the drugs used for DOTS are safe and effective (10). There is reliable drug supply

in the study area throughout the year.

The requirements for adequate chemotherapy are appropriate combination of drugs prescribed in the correct dosage and taken regularly by the patient for a sufficient period of time (10,11).

There is no sufficient study on the rate of defaulting from DOTS and potential risk factors for it in Ethiopia. In Arsi, efforts have been made for eight years to implement DOTS. This has been undertaken with the support of the Italian Government. Arsi Zone was considered to be the pilot-project for DOTS expansion and advocacy. It was established in order to test new solutions for the control of the disease and determine their applicability to the rest of the country before wider implementation. The zone was chosen because of the magnitude of the problem and the presence of the Italian-funded projects in the same area. The programme was initiated in 1991 and became operational in the field in January 1992 (33,34). The actual magnitude of defaulting from DOTS and its determinants in Arsi are not known. No study has looked into this aspect of the problem. It is, therefore, the responsibility of the health system to monitor the actual magnitude of defaulting from DOTS and to find the reasons for it. The outcome of such active investigation helps to take the appropriate steps to retrieve patients and to reshape the control programme in the right direction. Thus, this study was designed to provide information on actual magnitude of defaulting and its determinants.

2 LITERATURE REVIEW

Tuberculosis kills nearly three million people each year. This makes it the biggest infectious killer of youth and adults in the world. TB also accounts for one third of AIDS deaths worldwide. It is the single biggest killer of young women. Eighty percent of TB patients are in the most economically productive years of their lives. TB sends many self-sustaining families into poverty. If the breadwinner of a family is not properly diagnosed or treated, he/she will lose, on average, a full year of work (3,12).

Multidrug-resistant TB has emerged as a major threat in some countries. Poorly managed treatment practices are the main cause of multiple-drug resistance. Drug resistance can develop when patients get the wrong drugs, drug supply is unavailable or patients stop taking their medicine because they feel better. Multidrug-resistant TB strains are 100 times more expensive to treat and often cannot be cured (10,12).

To date, DOTS is the most effective strategy available to control tuberculosis. It was developed from the collective best practices, clinical trials and programmatic operations of TB control. DOTS involves direct observations of treatment and requires government commitment. It also requires microscopy services, reliable drug supply and monitoring (3,10,12).

The strategy can be integrated successfully within the general health services. It does not require hospitalization or isolation. Patients can remain in their homes and return to work in a few weeks. DOTS is one of the most affordable ways of extending the life of HIV positive persons (12).

The World Bank considers DOTS one of the most cost-effective health strategies available. A six-month course of drugs for DOTS costs as low as US $ 10 to US $ 20 in some developing countries. For instance, it was estimated that proper use of DOTS in Thailand could save the country US $ 2.3 billion over twenty years (12).

2.1. Development of DOTS application in Tuberculosis Control Programme

In the era before anti-TB drugs, treatment was intended to strengthen patients' resistance to TB. In early 1949, the value of the addition of streptomycin in to bed rest was revealed. This happened to be the initial trial. Furthermore, the emergence of bacterial resistance to streptomycin alone was decreased with combination treatment that was introduced in 1949. Moreover, the search and affordable regimen of thiacetazone and para aminiosalicylic acid was conducted in 1958 to 1967 (12).

Treatment in the sanatorium was expensive and available to a small number of patients. After the early 1959, home chemotherapy was found to be as effective as when given in

sanatorium, suggesting that home chemotherapy did not increase the rate of infection in the family. Gradually, both developed and developing countries had started to abandon hospitalization. Initiation of the full supervision of chemotherapy (DOTS) was later conducted in 1958, and then implemented in Hong Kong and Madras. The inclusion of rifampicin or pyrazinamide in the regimen of streptomycin and isoniazide have reduced relapse rate. This was the first demonstration undertaken in 1970 and applied in 1972. In the modern short-term chemotherapy, pyrazinamide was confined to the first intensive phase while rifampicin persisted throughout the continuation phase. Both drugs have got sterilizing effect (11,13).

In Tanzania in the 1970s, Dr. Styblo of the IUATLD has developed a model of TB control, based on a managerial approach to case - finding and treatment. For few years, long course treatment was used. However, it did not achieve high cure rate (13).

The Tanzanian National Tuberculosis Control Programme was the first of the IUATLD model programmes with successful nation-wide coverage. The idea of using an existing basic management unit (the district) was also proposed by Dr. Styblo. The unit allowed the technical aspects of the TB control to be integrated within the existing general health services. It would have the staffs and resources to diagnose, initiate treatment, record and report patient treatment progress, and manage supplies in a population area of 100,000 to 150,000. WHO began promoting the idea of Styblo's strategic package known by the brand-name DOTS. The package comprises technical and management aspect (13).

The number of countries using DOTS increased from only 10 in 1990 to 102 in 1997. The percent of patients treated under DOTS increased from less than 1 percent in 1990 to 16 percent in 1997 (4,6,13).

It was great realization during the 1960s that organizational and administrative factors were considered to be more important than technical factors in the success of tuberculosis control programme. This produced noticeable changes in tuberculosis policy (10,11).

The development of short-course regimens has been the biggest advance in the chemotherapy of tuberculosis in the past 25 years. It has reduced the burden on the patient and on the clinic staff. The chance of relapse and initial drug resistance is decreased since multiple and potent drugs are used in the initial phase of treatment (3,11).

The overall objective of the DOTS TB Control Programme is to reduce mortality, morbidity and disease transmission and also to prevent the development of drug resistance. The strategy is to provide standardized short-course chemotherapy under direct observation at least during the initial phase of treatment in all identified smear-positive TB cases. Regular, uninterrupted supply of drugs is the element of the DOTS strategy (3,10).

A progress in DOTS implementation in 22 high burden countries between 1995– 98 has shown a population coverage rate ranging from 25 to 43%. Global service coverage was

43%. The percentage of smear-positive to new pulmonary cases in the same year was 64. According to treatment results of the 1994-1997 cohort in DOTS areas globally, 75% of the registered cases were cured. Another six percent completed treatment without demonstrating cure. The estimated proportion of new smear-positive cases detected by DOTS programme between 1995 and 1998 ranged from 8.8% to 19.7% (6).

In 1998, service coverage for Ethiopia was 64%. The estimated new case of TB (thousand per year) was 49. The number of cases notified were 69,472. However, new cases of TB attributable to HIV (thousand per year) were 47. There is no information regarding new TB cases in active age group (15-45 years), prevalence of MDR-TB in case not previously treated, and male to female ratio of new infectious TB cases in Ethiopia. The estimated proportion of new smear-positive cases detected by DOTS programmes between 1995 and 1998 ranged from 14.7% to 28%. The percentage of new smear-positive to new pulmonary cases notified in 1998 was 40 (6,14).

2.2. Recording and Reporting System in Ethiopia

The quarterly reporting on patients diagnosed with TB and the outcome of treatment is very important for the assessment of the programme. Regular assessment is done at the district, zonal and regional levels. Uniform recording and reporting formats are prepared and distributed throughout the country. There are general principles that apply to the National Tuberculosis Control Programme. The health centre is the focus of activities and the base

for programme supervision. The district is the administrative basis for all patient-related statistics. All forms and registers are identical throughout the country. Forms and registers used in tuberculosis include District Tuberculosis Registers and Unit Tuberculosis Registers (11).

2.3. Defaulting

In accordance with the guidelines of the Ethiopian National Tuberculosis Control Programme, a defaulter is defined as a patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for more than 8 consecutive weeks or for a cumulative period of more than 12 weeks (10).

The public health priority of a national tuberculosis control programme is to cure cases while avoiding drug resistance. Ensuring adherence is necessary to achieve treatment success. For various reasons, patients stop treatment before the end of treatment schedule. Treatment interruption is a problem of the patient, health staffs and the government. Therefore, promoting adherence to treatment is the main element of the control programme. Supervisors must ensure that patients are taking the right drugs in the right dose and interval. If a TB patient missed attendance, it is necessary to find that patient and make sure that she/he continues the treatment (8,10). The direct observation of treatment is the best method of avoiding treatment interruption, though there may still be some level of defaulting during the continuation phase of treatment which is self administered (3,8,10).

2.4 The magnitude of defaulting from DOTS

A study conducted by Tsogt and Levy on a DOTS pilot project on 169 smear positive TB cases in Mongolia indicated a defaulter rate of 1% (15). Nuwaha, in his study to examine the control programme of tuberculosis in Uganda, has found a defaulting rate of 7.5% (16). In a randomized trial carried out to see the impact of counseling on treatment adherence of tuberculosis patient in Sialkot, Pakistan, the defaulting rate was 54% in the control group and 47% in the intervention group in which the difference was statistically significant (17). A study done by Kumeresan and et al, to examine the tuberculosis control programme in Bangladesh, has shown a 10% defaulter rate (18). Netto and Dye have documented progress in global tuberculosis control between 1995 and 1996, with the emphasis on 22 high-incidence countries and have shown an average of 6% defaulter rate (19).

According to treatment outcomes evaluated for smear-positive cases in 22 high burden countries in 1997, the defaulter rate was 6.4%. Of these, Pakistan, Nigeria, and Uganda documented the highest defaulter rates. The rate for Ethiopian was 11.7 percent (6).

Surveys done in Africa up to 1994 have shown defaulter rates (from DOTS) that ranged from 4 to 15% (20). In Ethiopia, defaulting from standard treatment (long course) was earlier reported to be between 50 to 82%. A study of short course therapy in Addis Ababa found that patients on standard treatment had higher defaulter rate (49%) compared to those treated with four drugs for 8 months (27%) (21).

A study done in Harar on the prevalence of resistance bacilli to one or more anti-tuberculosis drugs revealed that about 37% of sputum smear positive patients were resistant to one or more drugs. Initial resistance was 32% while the acquired resistance was 52%. History of previous treatment was the strongest predictor of anti-tuberculosis resistance, which could show non-compliance (defaulting) from anti-tuberculosis drugs to increase the chance of developing drug resistance bacilli (22).

Out of the 12 Zones of Oromia Region, eight were covered by DOTS at the time of this study. Of these, Arsi Zone, which has a population of 2.5 million, started DOTS programme in 1992 with the support of the Italian government, under the Arsi Bale Ethio-Italian TB control project. The level of defaulting in Arsi had been reported between 1992-1998 to vary from 10% to 26% (23).

2.5. Reasons for defaulting from tuberculosis treatment

Reasons for defaulting have been analyzed by Comolet and Rakotomalala in a study to examine factors determining compliance with tuberculosis treatment in an urban environment in Madagascar. In this case-control study, defaulting appeared to be significantly linked to transportation time, sex of the patient, patient information and the quality of communication between patients and health workers (24).

The most often cited causes of defaulting in developing countries are patients' lack of

motivation, the impression of being completely cured once chemotherapy begins to take effect, drug side effects, economic problems, transport difficulties, and socio - psycological factors. Male patients and those who live more than one hour away from the treatment centres were more likely to default from treatment. Lack of information about the disease and its treatment was significantly more frequent among defaulters (24).

A randomized control intervention trial of 1091 adult tuberculosis patients in Pakistan has shown intensive counseling as having significant impact on treatment adherence. It has stronger impact in women and in those with poor knowledge of the disease (17).

A study done in an Urban University Hospital in Malaysia on attitudes and knowledge of newly diagnosed tuberculosis patients regarding the disease and factors affecting treatment compliance showed that compliance with treatment and follow up were not affected by age, sex, ethnic group, educational level or occupation, extent of knowledge, hospitalization for tuberculosis or duration of the prescribed treatment regimen (25).

An analysis of tuberculosis patients was carried out in 1996, in four districts of Vietnam, to explore gender differences in compliance to tuberculosis treatment. Women were found to be more compliant than men. Insufficient knowledge and individual cost during treatment were reported as the main obstacles to compliance among men. Sensitivity to interaction with health staff and stigma in society were reported as the main obstacles among women (26). A case-control study of the Singapore TB Control Unit showed that defaulters (n=44)

were ten times as likely to be living on their own or with friends, rather than with family (OR = 10.2, 95% CI 1.2 – 85.8)(35).

2.6. Rationale for the present study

In Arsi, there is passively obtained data, from health records and reports, which are related to defaulter rate from DOTS in cases of only smear positive pulmonary tuberculosis. But there is no information in all tuberculosis patients defaulting from DOTS. The aim of this study is to find out the actual magnitude of tuberculosis patients defaulting from DOTS and to assess its determinants. Arsi zone was chosen for this study since it has a relatively strong Tuberculosis Control Programme that was started eight years ago.

3. OBJECTIVES

3.1. General Objective

To assess determinants of defaulting in DOTS in Arsi Zonal Tuberculosis Control Programme and come up with recommendations for improved performance.

3.2. Specific Objectives

3.2.1 To determine the defaulter rate in all category of TB patients put on DOTS;

3.2.2 To identify factors associated with defaulting.

4. RESEARCH METHODOLOGY

4.1. Study area

Arsi Zone is one of the 12 zones of the Oromia National Regional State. This zone has a population of 2.5 million. Health institutions found in Arsi Zone comprise of 2 hospitals, 10 health centres and 107 health stations. Tuberculosis Control Programme utilizing the Directly Observed Treatment, Short-Course (DOTS) is currently run in the two hospitals, all the health centres and in 69 of the health stations.

4.2. Study design

The study design utilized was case – control design. The records of new patients registered and put on DOTS between July1, 1997 to December 31, 1999 were reviewed. The records were obtained from the respective health institutions of the study area. Study subjects were classified into defaulter (cases) and non-defaulters (controls).

Each case was matched by sex and age categories to two controls to increase the power of the study. Both cases and controls were interviewed on the same study variables. Both cases and controls were selected from a cohort of patients who started their treatment eight or more months before the start of the study (from those put on DOTS between July 1, 1997 to December 31, 1999). Those patients who were declared cured or who completed

treatment were designated as non-defaulters. Patients considered to be cured if two sputum samples collected at the end of the second or the fifth month, and near the end of treatment were smear-negative for AFB. Those individuals who did not have the final test to prove their cure status were included in the control group since they had completed their treatment without demonstrating cure.

Active tracing of study subjects was undertaken in three districts (Hitosa, Tiyo and Limuna Bibilo) of the study zone. Cases and controls were identified from registration books from the same study area. In situations where the number of controls that could be matched to cases turned out to be more than two, two were selected and matched by the lottery method.

4.3 Study population

All new tuberculosis patients who were registered and put on DOTS during the period of July 1, 1997 to December 31, 1999 in the three districts of Arsi zone were the study population.

Out of one thousand nine hundred sixty nine newly diagnosed tuberculosis cases, six hundred two were excluded according to the set exclusion criteria. Therefore, one thousand three hundred sixty seven new tuberculosis patients covered with DOTS were eligible for the study. During an initial chart review, one hundred fifty five (155) were found to be defaulters and the rest (1212) were found to be non-defaulters. However, only 80 of the 155 defaulters were interviewed by active tracing.

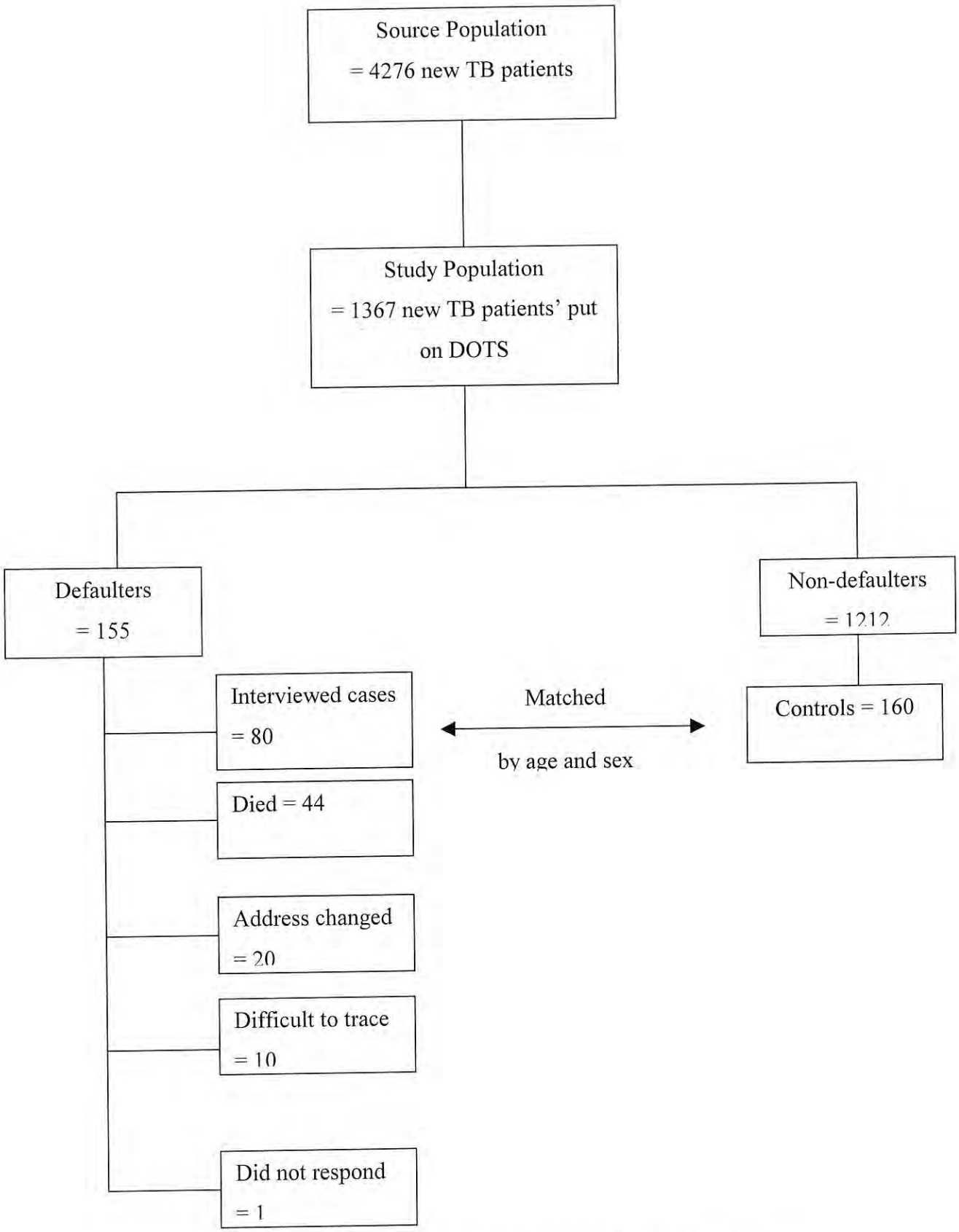


Figure 1 :- Selection Procedure of Cases and Controls

Exclusion criteria used:

a) Tuberculosis patients whose addresses were out of the three study districts,
b) All tuberculosis patients who were diagnosed in health institutions found in the three districts but were referred to health institutions out of the three districts for their follow up,
c) All tuberculosis patients whose addresses were not complete on their treatment record.
d) Patients who were registered during the period and were still on treatment course after January 1, 2000.
e) Patients who defaulted after being on treatment for less than 30 days. This was based on the definition given by the National Tuberculosis Control Program of Ethiopia (10).

4.4 Outcome measure

The outcome variable measured was defaulting from DOTS. Using formats for data collection, data were collected for each defaulter and non-defaulter from the records and then through interviews at their residential area.

4.5 Exposure measures

The exposure variables measured were: employment status, distance from health units, education, knowledge about duration of DOTS treatment, attitude about DOTS center,

medication side effect, income status, and family support. A list of these possible determinants were drawn up, based on literature review and on views of health personnel and public health administrators involved in DOTS programme. These exposure variables were measured in the following manner.

4.5.1 Educational level

The study subjects were asked to read a text and were asked if they had ever been to school in order to know whether they were literate or illiterate.

4.5.2 The distance of the study individuals residence from DOTS treatment center

The interviewers measured the distance based on the time taken by them to reach the patients' residence from the treatment centre. Two hours walking distance was estimated to be equal to 10 kilometers.

4.5.3 Occupational status

Study subjects were asked if they were employed by any governmental, non-governmental or private organization. Based on this subjects were classified into employed and unemployed. Self employed farmers were taken as employed. Those who did not apply for employment were taken as unemployed. These include those above 55 years of age and those below the age of 14 years.

4.5.4 Medication side effects

Regarding to medication side effects, study subjects were asked if they remember illness or problems they associate with DOTS treatment. This was studied with the aid of the responses provided to open and closed ended questions. Depending on their response they were grouped as those with possible side effect and those without possible side effect.

4.5.5 Study subjects' knowledge about duration of DOTS

Study subjects were asked about the duration of DOTS. This was studied by open-ended questions and were grouped into two; those with adequate knowledge (those who replied "8 months") and those without adequate knowledge (those who replied below or above 8 months).

4.5.6 Attitude towards the DOTS centre

Study subjects were asked their choice and feeling about the DOTS centre. Based on the response, subjects were grouped into two; those who have positive attitude towards DOTS center and those who do not have positive attitude. Those who chose the DOTS center were labeled as having positive attitude while those who did not choose the center were taken as having negative attitude. In the case of young children, they were their parents or

their close relatives who were interviewed. The reasons were asked using open-ended questions.

4.5.7 Household income

Peasant households were asked the total amount of product they earned from farming and cattle rearing. These were converted to cash in Birr based on average local market. For others, the average monthly income (salary) of the family was used and the results were classified into two groups: below 200 Birr per month and above 200 the Birr per month.

4.5.8 Family support

Patients were asked whether they supported by their families during their illness or not. Any type of help a sick-family member gets from his/her member of family or relative in order to complete the course of treatment was taken as family support.

4.6 Data collection and management

Initially chart reviews carried out by trained interviewers, using data collection form. This was based on inclusion and exclusion criteria. Training was given for all of them. A questionnaire was developed in English which was then translated to Amahraic by a different person with back translation into English (annex 1). Data collection form in English was used as it was (annex 2). Both were pretested in Digelu-Tijo district, Arsi Zone, which is a neighbouring district to the study districts (annex 3). After the pretest,

minor changes and restructuring were made. The pretest was done on patients who had been on the same course of treatment for the same period as of the study subjects. All defaulters and controls were matched by sex and age category. These were done by the investigator. Then the study subjects and their addresses were given to interviewers on daily basis.

Study subjects were actively traced and interviewed by the trained interviewers, using pre-tested structured questionnaire. The questionnaire was administered to the patients or the closest caretaker or relatives. Categories used in matching for age in years were: 0-14, 15-29, 30-44, 45-59, and above 59. New cases and defaulters have been categorized according to age groups adopted by the programme for reporting. Visits were repeated in case of absence of respondents. Filled questionnaires were submitted to the investigator on daily basis. The questionnaires were edited every day after data collection. Every incomplete questionnaire was sent back to the corresponding data collectors so that the incomplete questionnaire is corrected by revisiting the house of the interviewee. Strict unscheduled supervision was done each day by the investigator. Data collection was conducted in April and May 2000.

4.7 Data Analysis

Data collected was entered using the EPI info version 6 statistical package. Overall defaulter rate and specific rate by distance, district, health institution and month of

defaulting were calculated. Appropriate bivariate and multivariate statistics were computed to assess the presence and degree of associations between defaulting and determinant factors.

4.8 Ethical consideration

Initially, consent was secured from concerned local officials and respondents. Following this, charts of the patients were reviewed with maximum confidentiality. During the interview patients were told about the aim of interview and possible benefit of the study. In addition, defaulters were advised to resume and complete treatment. Health education on the consequences of treatment interruption were also given by interviewers. Moreover, ethical clearance was obtained from Faculty of Medicine Research Ethics Committee.

5. RESULT

5.1 Description of the study subjects

Over a period of 30 months (between July 1, 1997 to December 31, 1999), a total of 4276 new tuberculosis patients were recorded in the health institutions of the three districts of Arsi Zone. These 4276 patients were cases put on two chemotherapeutic regimens (long and short course). Of the total 4276 new tuberculosis cases, 1969 (46%) were started on DOTS. Among these, 602 (30.5%) were excluded from the study. The remaining 1367 (69.5%) eligible subjects who met the inclusion criteria were taken as the study population. Among the eligible, 758 (55.5%) were males and 609 (44.5%) were female.

Socio-demographic characteristics of the respondents are presented in table 1. The majorities of defaulters were males and are within economically productive age group (14-45 years). Seven hundred forty (54%) and 244 (18%) were followed up in health centers and hospital respectively, while 383 (28%) were followed-up in health stations (Table 2). There were 968 patients with smear positive pulmonary TB (70.8%), 324 with smear negative pulmonary TB (23.7%), and 75 with extra-pulmonary TB (5.5%)(Table 3). All cases (1367) were diagnosed and treated in the government health institutions

Case Fatality Rate from all new cases put on DOTS (1367) was 5.4%. These were patients who had died before their next appointment date and who had been documented on registration book as dead. As determined by the active house to house survey, the overall Case Fatality Rate in defaulters was found to be 28.4%.

Table 1. Distributions of the respondents by different exposure variables in the three districts of Arsi Zone, July 1997 – December 1999.

Variable	Category	*Interviewed Subjects (n = 240)
Sex	Female	90 (37.5%)
	Male	150 (62.5%)
Age	0 – 14	48 (20%)
	15 – 29	111 (46.25%)
	30 – 44	60 (25%)
	45 – 59	18 (7.5%)
	> 60	3 (1.25%)
Education	Illiterate	68 (28.3%)
	Literate	172 (71.6%)
** Employment Status	Employed	79 (32.9%)
	Unemployed	149 (62.1%)
Household income per month	< 200 Birr	173 (72.1%)
	> 200 Birr	67 (27.9%)
Distance from health	Nearest (< 10 km)	160 (66.67%)
institutions	Furthest (> 10 km)	80 (33.33%)

** Since cases and controls were balanced on matched variables, these distributions were not analysed in terms of cases and controls*

*** The total do not come to 240 because they do not apply for employment and there were missed information in some subjects.*

5.2 Defaulting

The overall rate of defaulting was found to be 11.3%. This includes all category (smear positive, smear negative, and extra-pulmonary TB) of tuberculosis patients defaulted from treatment (DOTS). The rate of defaulting was higher in patients who were followed in the health stations (21.4%)(Table 2). But the rate of defaulting in case of smear positive pulmonary tuberculosis was 11.6% (Table 3). Fifty of the eighty (62.5%) defaulters were living nearest to health institutions (either health stations, health center or hospital).

Table 2. Rates of defaulting by level of health institution in the three districts of Arsi Zone, July 1997 – December 1999.

Level of Institutions n = 9	No. of Patients n = 1367	Overall defaulters n= 155	Interviewed defaulters n = 80
Health stations	383	82 (21.4%)	44(53.66%)
Health centers	740	50 (6.8%)	26 (52%)
*Hospital	244	23 (9.4%)	10 (43.48%)
Total	1367	155 (11.3%)	80(51.61%)

- =It does not include TB patients seen between July 1, 1997 – December 31, 1997 because the registration book was not available in the hospital, Zonal Health Department and Oromia Health Bureau

Table 3. Category of patients put on DOTS in three districts of Arsi Zone, July 1997 – December 1999. (n = 1367)

Category	No. of Patients (n = 1367)	No. of defaulters (n = 155)	%
Smear – Positive Pulmonary TB	968	112	11.6
Smear – Negative Pulmonary TB	324	29	9
Extra – Pulmonary TB	75	14	18.7
Total	1367	155	11.3

Among the health centers, the highest rate of defaulting was found in Asela health center. Defaulter rate in Hitosa district was the highest. The rate was highest in the third month (31%) followed by the second and fifth month (18.7%)(Table 4). As it is seen in this table, more than 80% of subjects defaulted after the intensive phase.

Table 4. Distributions of the overall defaulters by time (month) to default from following treatment in the three districts of Arsi Zone, July 1997 – December 1999. (n = 155).

Month of defaulting	Number	Percent
*Second month	29	18.7
Third month	48	31
Fourth month	24	15.5
Fifth month	29	18.7
Sixth month	14	9
Seventh month	11	11.16
Total	155	100

* Second month = include all period of the initial phase greater than one month.

Table 5. Distributions of defaulters by health institutions and districts of Arsi Zone, July 1997 – December 1999.

Name of districts n = 3	No. of Institutions n = 9	No. of Patients n = 1367	Overall defaulters n = 155	Interviewed defaulters n = 80
Limu & Bibilo	Bokoji health center	214	7 (3.3%)	4 (55.14%)
	Siltana health station	40	5 (12.5%)	4 (80%)
	Meraro health stations	21	7 (33.3%)	3 (57.14%)
	Sub Total	275	19 (6.9%)	11 (58.89%)
Tiyo	Asela hospital	244	23 (9.4%)	10 (43.48%)
	Asela health center	378	33 (8.75%)	14 (42.42%)
	Golja health stations	50	8 (16%)	1 (12.5%)
	Sub total	672	64 (9.5%)	25 (39.06%)
Hitosa	Huruta health center	148	10 (6.8%)	8 (80%)
	Eteya health stations	219	48 (21.9%)	26 (54.17%)
	Bor Jawi health stations	53	14 (26.4%)	10 (71.43%)
	Sub total	420	72 (17.1%)	44 (61.15%)
Grand total		1367	155 (11.3%)	80 (51.61%)

Of all health institutions, the highest rates of defaulting were observed in Meraro, Boru Jawi and Eteya health stations (Table 5).

5.3 Matched case-control study

Matched case-control analysis was done on 80 cases and 160 controls. The matched cases and controls were compared by distance from their home to the treatment center, educational level, employment status, presence or absence of drug intolerance, attitude to the treatment centre, knowledge about the duration of DOTS, family support for the patients during the course of treatment and average monthly income. Factors significantly associated with defaulting in the bivariate analysis were level of education (OR = 2.4 with 95% CI of 1.21 to 4.89) and medication side effects (OR = 0.03 with 95% CI of 0.01 to 0.10) and presence of family support (OR = 0.15 with 95% CI of 0.06 to 0.32)(Table 6). There was no significant difference between cases and controls with regard to employment status, distance of their home from treatment centre, attitude towards treatment centre, and average family income per month.

Table 6. Variables evaluated for possible association with defaulting from DOTS in the three districts of Arsi Zone, July 197 – December 1999.

Variable	Case (n = 80)	Control (n = 160)	*OR (95%CI)	**AOR(95%*CI)**	P-Value
Employment Status					
Employed	31	48			
Unemployed	49	100	1.67(0.83,3.43)	1.37(0.6,3.15)	0.462
Distance from *H.I.					
Nearest	50	100			
Furthest	30	50	1.3(0.72,2.35)	0.46(0.18,1.15)	0.097
Education					
Literate	49	123			
Illiterate	31	37	2.4 (1.21,3.43)	1.49 (0.64,3.53)	0.354
Knowledge about duration of DOTS					
Inadequate	53	10			
Adequate	27	150	0.03(0.01,0.1)	0.04(0.02,0.10)	0.000
Attitude towards DOTS Center					
Positive	75	150			
Negative	5	10	1(0.3,3.89)	1.11(0.26,4.74)	0.891
Medication Side effect					
Absent	63	148			
Present	17	12	3.14(1.34,7.73)	4.20(1.51,11.66)	0.006
Household income per month					
**< 200 Birr	61	112			
> 200 Birr	19	48	0.35(0.73,2.61)	0.80(0.35,1.84)	0.592
Family support					
Negative	35	16			
Positive	45	144	0.15(0.06,0.32)	0.19(0.08,0.46)	0.000

*CI = Confidence Interval

*OR = Mantel – Hanzhel matched Odds Ratio

*AOR = Adjusted Odds Ratio

*HI = Health Institution

**<200 = includes equal to 200 Birr

By using open-ended questions cases were asked for their reasons of defaulting from DOTS. The most frequently mentioned reasons for defaulting were: 1) Distance (16.4%), 2) drug side effect (13.7%), and 3) lack of knowledge about duration of treatment (13.7%)(Table 7).

Table 7. Reasons given by patients as the cause of their defaulting in three districts of Arsi Zone, July 1997 – December 1999. (n = 73)

Reason	Number	Percent
Far distance	12	16.4
Medication side effect	10	13.7
Lack of knowledge	10	13.7
Clinical improvement	9	12.3
Social and personal reasons	9	12.3
Don't remember	8	11
Lack of money	8	11
Others	7	9.6
* Total	73	100

* The total do not come to 80 because there were missing of information on some variables.

Table 8. Types of family supports given for patients during the course of treatment in three districts of Arsi Zone, July 1997 – December 1999.

Kind of family support	Cases n = 45	Controls n = 144
Supply of food	19 (42.2%)	70 (48.6%)
Provision of money	7 (15.6%)	25 (17.6%)
Provision of transport	7 (15.6%)	19 (13.2%)
Advice	6 (13.3%)	9 (6.3%)
Necessary materials	6 (13.3%)	21 (14.6%)
Total	45 (100%)	144 (100%)

* *The total came to 45 and 144 because the remaining 35 and 16 had negative or no family support.*

Family support was more closely assessed. The types of family support reported by the study subjects were food supply, provision of money, transport (like horse), advice and providing of other necessary materials (Table 8).

5.4 **Multivariate analysis**

In order to know the independent effect of each, the specific variables in the prediction of defaulting, logistic regression was done using SPSS. This was done to control the confounding effect the determinants may have on each other. In this analysis, the factors that remained independently associated with defaulting were medication side effect (OR = 4.20 with 95% CI of 1.5 to 11.7), knowledge about duration of DOTS treatment (OR = 0.04 with 95% CI of 0.02 to 0.10), and family support given for the patient (OR = 0.19 with 95% CI of 0.08 to 0.46) (Table 6).

5. DISCUSSION

Patient compliance remains to be one of the most important factors in the success of TB control programs. A better understanding of the determinants accounting for defaulting from treatment could help to achieve better compliance. According to the literature on factors associated with treatment interruption, defaulting from treatment may be attributable to lack of drugs at the DOTS center or to carelessness or forgetfulness on the part of the patient, or it may be a result of faulty organization of treatment programme. Therefore, factors for defaulting can be attributed both to patients and to health systems (17,24,25).

In this study, overall defaulting rate from DOTS was found to be 11.3%. The rate of defaulting from DOTS in case of sputum smear positive pulmonary tuberculosis was calculated to be 11.6%. This is slightly higher than WHO standards (the expected rate of smear positive pulmonary tuberculosis defaulting from DOTS is less than 10%). Even though the rate found in the present study is almost the same as those figures obtained by WHO for Ethiopian (11.7%) and Africa (11.8%), it is very high when compared with rates for the 22 high burden countries (6.4%) reported by WHO (6).

The present study has shown that rate of DOTS coverage in the study areas to be 46%. This is lower than the percent of patients covered by DOTS in Ethiopia in 1997 and 1998 (48 and 64 percent respectively). But this (46%) coverage is higher than the rate reported for 22 high burden countries (6). The present study found out high defaulter rate in the

health stations which are considered to be the most accessible institutions. The possible explanation for this is that, in addition to direct observation of treatment, DOTS requires microscopic services for diagnosis and follow-up. In Arsi, a patient is first diagnosed at the health center or hospital level, as these are the only health institutions where laboratory facilities are available. After diagnosis and registration, however, a patient can be assigned for treatment to a health station nearest to his/her home. Tests are done at the second, fifth and seventh months in health centers or hospital level. Patients sent from the health stations to diagnostic centers for tests have to pay for traveling and the like. In other words, those who follow-up in the health stations have to face the hardship of long walking hours and high expense to get laboratory test. The health station would have microscopic services that use to follow-up the sputum. The other possible explanation could be the presence of senior staffs in the hospital and health centers that attract people to these centers.

Most of the defaulters interrupted treatment after the completion of the intensive phase. Eighty one percent of the defaulters interrupted treatment during the continuation phase. This can be explained either by the favorable attitude of patients towards the streptomycin injection, by the fact that they think they are cured or due to sputum follow-up outside the accessible unit (health stations). Three times sputum follow-up could also inconvenient for the patient in the present set up. The other possible explanation for interruption of treatment during the continuation phase is that the medications are self-administered at home, and the patients reviewed every month. This may suggest that patients who proved themselves adherent during the initial phase may not be trusted to go on self- administered

therapy subsequently.

In the present study, a significant protective effect of patients' knowledge about the duration of treatment was observed. Risk of being a defaulter was higher in those with inadequate knowledge about the duration of DOTS treatment. The association of patients' knowledge about treatment duration with treatment compliance has also been shown in other studies (24,25). The present study suggests that patients who had inadequate knowledge could be more likely to be non-adherent to treatment. This may be due to the fact that they had the impression of being completely cured after some months of treatment.

Another finding of the present study was a significant protective effect of family support. It was found that the risk of being a defaulter was lower in those with family support. It is plausible that family support can alleviate economic and social problem of the patient. Family members can also observe patients taking their medications provide encouragement and remind to keep medical appointment. A study done in Thailand has also shown the role of family member involvement in the implementation of DOTS (17).

Medication side effect was found to have a significant effect for treatment (DOTS) interruption. Medication side effects were also found to be possible risk factor for being a defaulter in other studies (24).

An interesting result found in the present study was the insignificant effect of far distance as a possible risk factor for defaulting. This finding is contrary to the expectation. The majority of patients who defaulted in the study districts were living in the accessible area. A study has shown long traveling hour to health institution as being an established factor for non-adherence (24). Even though far distance is not significantly associated with non-compliance in the present study, the effect of far distance for a defaulter is still an important risk factor. To the open ended question, nearly 16% of defaulters gave far distance as the reason for defaulting, suggesting that the effects of far distance could not be excluded from being causal factors for defaulting. The possible reasons why nearer patients defaulted more could be that health professionals might be reluctant to explain the nature of treatment. This finding is similar to the result of the study finding on defaulting from long course chemotherapy in Addis Ababa (21). One of the important risk factors for defaulting from treatment in developing countries is the patient's lack of motivation (24). Patients who live far away from the treatment center might be motivated; in order to come during the initial visit. This could be explained by the selective effect of patient information and the quality of communication between patients and health workers. Time taken during the initial encounter to explain the nature of treatment is likely to be crucial. As they came from far area, health professionals might have given much attention to them during initial contact. Besides, inaccessible patients may give much attention to medical advice.

Case Fatality Rate determined in overall defaulters was 28.4%. Moreover, Case Fatality rate of death in all new cases put on DOTS (1367) was 5.4%, which was higher than the rate (4.7%) for Ethiopian (14). The exact causes of death were not known. However, it might be associated with HIV/AIDS.

There were no health institutions that made attempts to trace defaulters in the area. As a result all of the patients that were defaulters and non-defaulters were comparable with respect to determinants.

Strengths and Limitations of the Present Study

Strengths

There is no sufficient information about defaulting from DOTS in Ethiopia. This preliminary investigation of the problem made attempts to provide the first insight on the actual magnitude and determinants of defaulting in the rural set up. It exposes major potential factors which are easily identifiable at initial contact. These factors which predict risk of defaulting would alert the treating health professional to patients. Moreover, matched-case-control was done both on design and during analysis. Data collection was carried out by vigorously trained interviewers using pretested structured questionnaire. Unscheduled strict supervision was made throughout the course of the study. Regular

meeting in the evening and weekly were held between the data collectors and the principal investigator. Conducts and mistakes found were discussed and decisions were reached. From these efforts, one could understand that the quality of data was kept to an acceptable level. Finally, conditional logistic regression was done to come up with unbiased estimates.

Limitations

The study areas were not randomly selected. The areas were assumed to be convenient for the intended study, within limited period of time and cost. Selection was based on the findings of the field visit and considered to be feasible.

The statistically insignificance of the effect of distance could be ascribed to the ways it was subjectively measured. This is likely to result in limitation in measuring distance. The present study has been based on the data after the occurrence of the events within 30 months. Recalling of events of such long period of time may be unreliable due to a tendency for memory to be selective. Records of the past events might be incomplete with respect to variables that are deemed important. For instance, it is very difficult to validate the statistically significant effect of medication side effect for the prediction of defaulting from DOTS. It would have been more reliable if the side effects were recorded during the follow-up of treatment, by health professionals. Inadequate knowledge about the duration of DOTS could be a cause or a consequences for low case-holding. As defaulters interrupt subsequent follow-up, they may lack continuous health education about the disease and

treatment duration. As a result it is reasonable to take into account that being defaulted could be a barrier for continuous information that may create difference between defaulters and non-defaulters.

In the present study, considerable efforts were made to minimize the risk of bias associated with a sense of guilt among defaulters. For this reason, the tendency to blame an external cause for their non-adherence to treatment was high. Because of these, it is possible that some answers might not be entirely honest.

6. CONCLUSIONS

In the absence of sufficient knowledge about defaulting from DOTS in Ethiopia, the present study was intended to determine rate of defaulting from DOTS, its potential determinants and to come up with recommendation to improve TB control programme through DOTS application.

Delayed diagnosis and treatment, and non - adherence causes persistence transmission of TB in the community. Adherence remains one of the most important aspects of TB management.

The rate of defaulting was slightly higher than the critical level of 10% set by the WHO. It indicates presence of some problems in the control programme of the study area. Higher rate of defaulters were found in the area where the home of patients were geographically accessible and in those patients followed-up in the health stations. There were no health institutions that made attempts to trace defaulters in the study areas. Most of the patients were defaulted during the continuation phase. This could suggest the importance of direct observation during the continuation phase until treatment completion. Medication side effect was found to be the major risk factor for defaulting. Adequate knowledge about the duration of DOTS and family support were observed to be the main protective factors. Attention paid to these potential factors right from the time of initial contact, diagnosis and treatment initiation could diminish the likelihood of defaulting. The study has, therefore,

revealed the importance of minimization of drug side effect, provision of adequate knowledge on the duration of DOTS and strengthening of family support.

7. RECOMMENDATIONS

1. An effective mechanism to trace defaulters needs to be introduced. This could be undertaken through the participation of local community (community-centered DOTS), which will have a network with the nearby health institutions. Active participation of the influential people in the community strengthens local ownership and foster local disease support group that motivate the patient in order to complete the treatment.
2. Family support, interest and participation should be stimulated through appropriate mechanisms. These include education, counseling and encouragement of the family member, with whom the patient has special relationship, at the presence of TB patients.
3. Ways to maximize drug tolerance should be explored. Patients should be taught the side effect of each drugs and possible ways to reduce drug intolerance.
4. Continuous health education by the appropriate trained person, on the duration of DOTS and risk of interruption of treatment needs to be given.
5. In order to reduce high rate of defaulting in the health station, the frequency of sputum follow-up should be reduced from three to at least two (at second and end of the treatment) times.
6. Further operational research should be undertaken in order to devise strategies that improve the performance of the DOTS program.

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10. ANNEXES

Questionnaire for the Assessment of defaulting from Directly Observed Therapy, Short Course and its determinants, in Arsi zone, Oromia Regional States, Ethiopia.

Introduction:-

This research is intended to find out the problems of Tuberculosis patient put on Directly Observed Therapy, Short Course. What I am hoping to accomplish with this research is to provide good information about the defaulting/treatment interruption/from DOTS and problems related to it. With this information I am going to plan, in cooperation with Oromia Health Bureau, to improve patient compliance to treatment. The goal of this research is to help improve the performance of Tuberculosis Control Programme.

All the information which you are being asked to provide in this questionnaire will be kept strictly confidential by the undersigned investigators. You are not required to answer any questions you do not want to answer.

I hope that you will be frank and honest in providing answers to the following questions. Before I start I would like to ask you for your commitment to answer the following questions:-

Do you agree to answer the following questions to the best of your ability?

Yes No

If you answered yes, please continue responding to the interviewer,

Thank you very much

1. Full name of the Patient_____

   Address, Woreda, district_____

   Town Kebele_____

   Peasant association_____

   Name of the person interviewed_____

2. Name of the treatment centre_____

3. Treatment Status of the Patient.

   3.1. defaulter_____

   3.2. Non-defaulter_____

4. If died, when? / filled from informats/

   4.1. during the course of treatment_____

   4.2. after defaulting treatment_____

5. Distance of the treatment centre from patients residential area (home)/ filled by interviewer/.

   5.1. > 10 km /greater than 2 hrs walk/ _____

   5.2. < 10 km / less than 2 hrs walk /_____

6. Age of the patient _____

7. Sex

   7.1. Male_____

   7.2. Female _____

8. Occupation :

8.1. Government employee_____

8.2. Farmer_____

8.3. Student_____

8.4. House-wife_____

8.5. Merchant_____

8.6. Other (specify)_____

9. Educational level

9.1. Illiterate_____

9.2. Read and Write_____

9.3. Elementary_____

9.4. Secondary_____

9.5. Above secondary _____

10. What is the average monthly income of your family (in birr)?

_____

11. Knowledge about Directly Observed Treatment, Short Course (DOTS)

11.1. Do you know the duration of treatment

11.1.1. Yes____

11.1.2. No____

11.2. If yes, how long does it take? (in months)_____

12. Attitude towards the TB treatment (DOTS) centre.

12.1. If you have the choice, do you prefer to got to the TB treatment (DOTS) center?

12.1.1. Yes_____

12.1.2. No_____

12.1.3. Do not know_____

12.2. If yes, why?

12.2.1. I am well cared in the TB treatment (DOTS) center_____.

12.2.2. The center is near to me_____.

12.2.3. The time is convenient to me_____.

12.2.4. It is free of charge _____.

12.2.5. Other reasons (specify)

_____

12.3. If not, why?

12.3.1. The service is not good _____.

12.3.2. It is far from my home_____.

12.3.3. The opening hours are not convenient_____.

12.3.4. I don't want to be seen in TB treatment center _____.

12.3.5. Other reasons (specify) _____

13. Did you have any problem or compliant while you were on DOTS?

13.1. Yes_____

13.2. No_____

13.3. Don't remember

14. If yes (Q = 13.1), what problems did you have ?

_____

15. Did you ever stop treatment?

15.1. Yes_____

15.2. No_____

15.3. If yes, why?

_____

_____

_____

16. Did any body come to your residence to advice you to resume your treatment?

16.1. Yes_____

16.2. No_____

16.3. If yes, then what did you do?

_____

_____

_____

_____

17. Did you get support from your family to complete your treatment ?

17.1. Yes_____

17.2. No_____

17.3. If yes, what kind of support ?

_____

_____

_____

18. Do you want to resume your treatment?

18.1. Yes_____

Because of what?

_____

_____

_____

18.2. No_____

18.3. If not, why?

_____

_____

_____

Name of interviewer :_____

Signature :_____

Date :_____