Dissertation
At
National Health Mission – District Urban Health Unit, Morbi, Gujarat

A Study of Treatment Compliance of Directly Observed Treatment Short course (DOTS) for Tuberculosis in Morbi District, Gujarat

By

Nidhi Mudgil

PG/14/041

Under the Guidance of

Dr. Preetha GS

Associate Dean(Research)- IIHMR Delhi

Post Graduate Diploma in Health Management

2014-16

International Institute of Health Management Research, New Delhi

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CERTIFICATE FROM DISSERTATION ADVISORY COMMITTEE

This is to certify that **Ms. Nidhi Mudgil,** a graduate student of **Post-Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. She is submitting the dissertation titled **"A Study of Treatment Compliance of Directly Observed Treatment Short course (DOTS) for Tuberculosis in Morbi District, Gujarat", National Health Mission (District Urban Health Unit) Morbi Gujarat ,** at in partial fulfillment of the requirements for the award of the **Post-Graduate Diploma in Health and Hospital Management.**

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Dr. Preetha GS
Associate Dean (Research)
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Dr. K.L. Goswami
Additional District Health Officer
Morbi, Gujarat

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Nidhi Mudgil,** student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management research, New Delhi has undergone internship training at **National Health Mission – District Urban Programme Coordinator, Morbi Gujarat** from **15th February 2016** to **16th May 2016.**

The candidate has successfully carried out the study designated to her during Internship and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all the success in all her future endeavors.

Dr. A.K. Aggarwal
Dean, Academics and Student Affairs

IIHMR, New Delhi

Dr. Preetha GS
Associate Dean
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This is to certify that the dissertation titled **"A Study of Treatment Compliance of Directly Observed Treatment Short course (DOTS) for Tuberculosis in Morbi District, Gujarat"** and submitted by **Nidhi Mudgil,** Enrollment No. **PG/14/041** under the supervision of **Dr. Preetha GS, Associate Dean (Research), IIHMR-New Delhi** for award of Post-Graduate Diploma in Hospital and Health Management of the Institute carried out during the period from **15th February 2016** to **16th March** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this way or any other Institute or other similar institution of higher learning.

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CERTIFICATE OF APPROVAL

The following dissertation titled **"A Study of Treatment Compliance of Directly Observed Treatment Short course (DOTS) for Tuberculosis in Morbi District, Gujarat"** at **National Health Mission (District Urban Health Unit) Morbi Gujarat** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of Post Graduate Diploma in Health and Hospital Management for which it has been submitted.
It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name Signature

Dr. Dharmesh Lal PHFI

Dr Dhananjay.

CERTIFICATE OF DISSERTATION

The Certificate is awarded to **Nidhi Mudgil**, in recognition of having successfully completed her Internship at **National Health Mission (District Urban Health Unit) Morbi Gujarat**. She has successfully completed her Project on **"A Study of Treatment Compliance of Directly Observed Treatment Short course (DOTS) for Tuberculosis in Morbi District, Gujarat"**

She came across as a committed, sincere and diligent person who has a strong drive and zeal for learning.

We wish her all the best for future endeavors.

12/05/16

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FEEDBACK FORM

Name of the Student: Nidhi Mudgil

Dissertation Organisation: NHM, Gujarat

Area of Dissertation: District Morbi

Attendance: 100%

Objectives achieved She has completed the tasks assigned to her.

Deliverables: Completed a study of treatment compliance of DOTs for TB in Morbi District

Strengths: Dedicated, Focussed, zeal to learn

Suggestions for improvement: Keep the good work.

12/05/16

Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date 12/05/16

Place Morbi, Gujarat

7

Acknowledgement

At the completion of my dissertation, I would like to show my sincere gratitude to the **National Health Mission Commissionerate of Health, Gandhinagar, Gujarat** especially to the **Dr. K.L. Goswami (Additional District Health Officer, Morbi), NHM-Gujarat** for providing me such opportunity. Without his constant support and guidance it would never be a success.

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I genuinely thank my parents, family and friends for their blessings and support.

Nidhi Mudgil
PG/14/041

CONTENTS

ABOUT NATIONAL HEALTH MISSION GUJARAT

National Health Mission, state health society Gujarat has created wide network of health and medical care facilities in the state to provide primary, secondary and tertiary health care at the door step of every citizen of Gujarat with prime focus on BPL families, marginalized population and weaker sections in rural and urban slum areas.

Department also takes appropriate actions to create adequate educational facilities for medical and paramedical manpower in the state of Gujarat.

NHM in India was launched on 12th April, 2005. It was conceived mainly to provide effective health care to the rural population, especially the disadvantaged groups including women and children, by improving access, enabling community ownership and demand for services, strengthening public health systems for efficient service delivery, enhancing equity and accountability and promoting decentralization. It seeks to provide accessible, affordable and quality health care to the rural population, especially the vulnerable sections. It covers the entire country, with special focus on 18 states where the challenge of strengthening poor public health systems and thereby improve key health indicators is the greatest. These are Uttar Pradesh, Uttaranchal, Madhya Pradesh, Chhattisgarh, Bihar, Jharkhand, Orissa, Rajasthan, Himachal Pradesh, Jammu and Kashmir, Assam, Arunachal Pradesh, Manipur, Meghalaya, Nagaland, Mizoram, Sikkim and Tripura.

NHM is the combination of national programmes, namely, the Reproductive and Child Health II project, (RCH-II) the National Disease Control Programmes and the Integrated Disease Surveillance Project. NRHM also enable the mainstreaming of Ayurvedic, Yoga, Unani, Siddha and Homeopathy Systems of Health (AYUSH).

ABSTRACT

Objectives - To study the various aspects of compliance to the treatment of Tuberculosis. To analyze the effect of socio economic factors on Treatment compliance.To analyse the effect of literacy levels on compliance of treatment. To calculate the No. of Defaulters and No. of Deaths due to TB. **Methods:** The study has been carried out in two tuberculosis units in Morbi district, state Gujarat, India. All the patients who registered for DOT treatment during last quarter. Result- 256 people were enrolled in the TU, out of which 192 ared under treatment, 45 defaulted the treatment and 19 died during the treatment. People who defaulted the treatment were in the age group of 25 to 35 (75%), 80 % of the males were defaulters. Labourer class were involved with low income who left the treatment midway that is 55.5%. 70% of the people were illiterate in the defaulters list. Conclusion- The study suggests that literacy rate and socio economic conditions hampers the treatment compliance to DOTS. Hence, these factors should be taken into consideration and general knowledge about the disease should be provided to the people.

Health Pyramid of Gujarat

India embarked on its journey to health after independence with a nation-wide network of efficient and effective health services based on what would later be called as the primary health care approach. Services were organized in a bottom up fashion, with a strong rural focus to attend to the needs of the underserved majority.

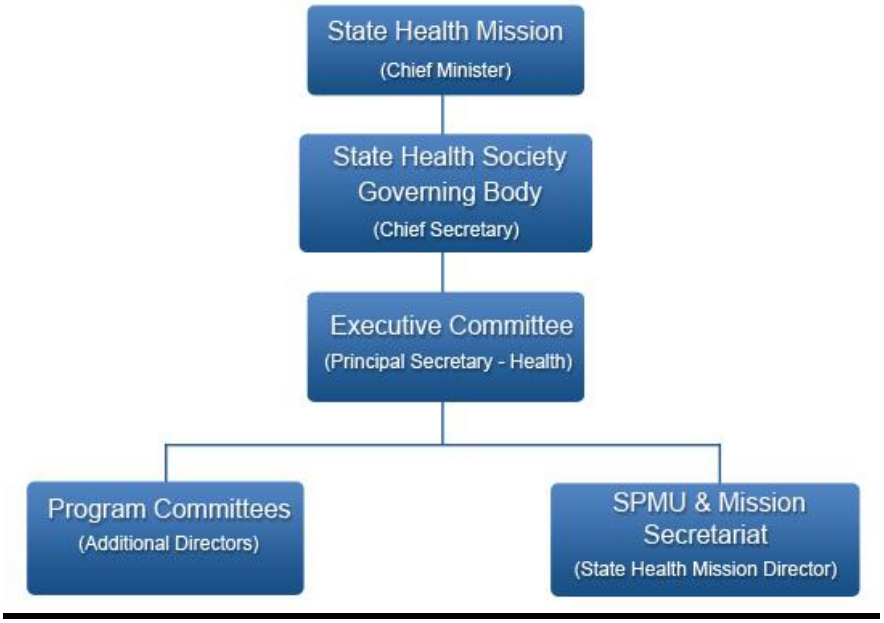
The primary tier has three types of health care institutions namely, a Sub-Centre (SC) for a population of 3000 to 5000, a Primary Health Centre (PHC) for 20,000 to 30,000 population and a Community Health Centre (CHC) for every 1,00,000 population.

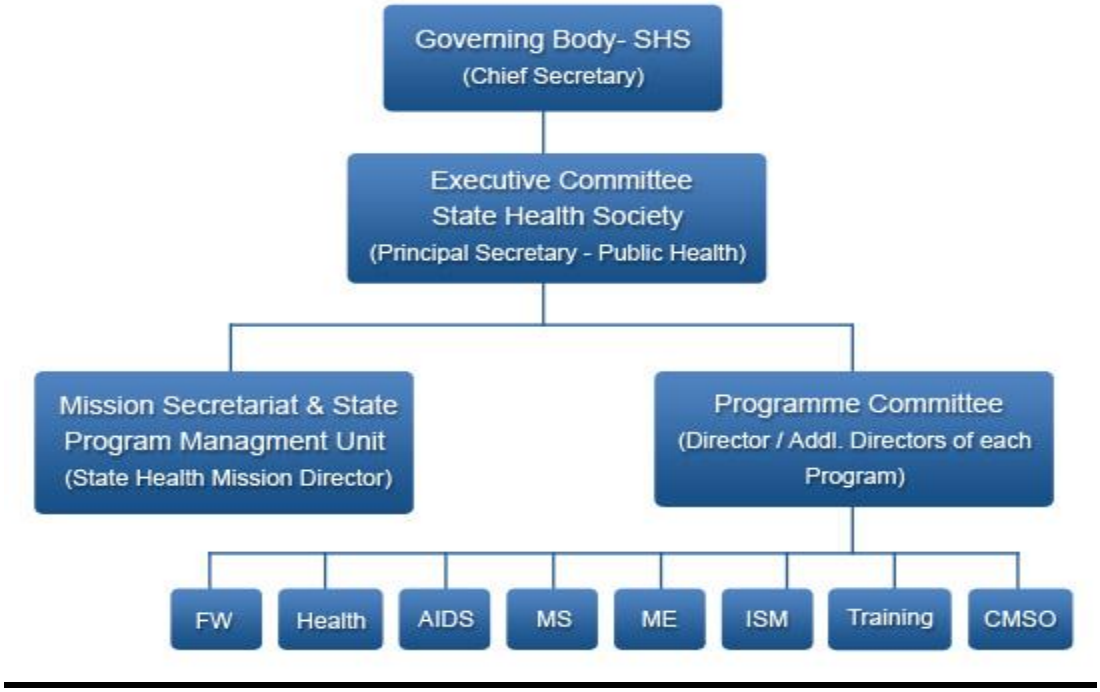
The district hospitals function as the secondary tier of care for the rural population. Tertiary health care is provided by highly specialized hospitals and health care institutions that are well equipped with sophisticated diagnostic and investigative facilities.

The health set-up in Gujarat is thus designed in a three-tier fashion:

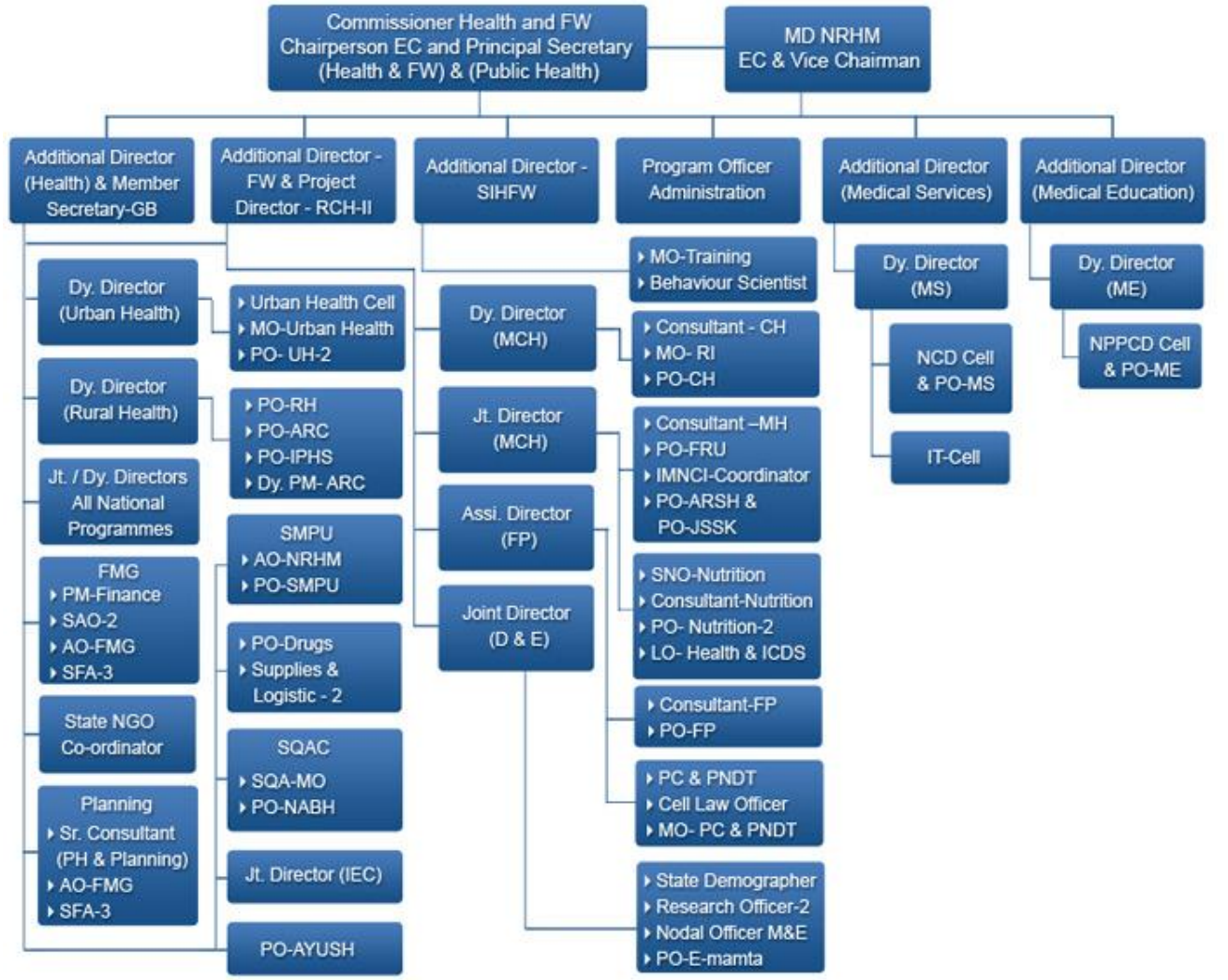
Structure

State Health Mission





Organogram


Commissioner Health and FW
Chairperson EC and Principal Secretary
(Health & FW) & (Public Health)
MD NRHM
EC & Vice Chairman
Additional Director (Health) & Member Secretary-GB
Additional Director - FW & Project Director - RCH-II
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Urban Health Cell
MO-Urban Health
PO- UH-2
Dy. Director (Rural Health)
PO-RH
PO-ARC
PO-IPHS
Dy. PM- ARC
Jt. / Dy. Directors All National Programmes
FMG
PM-Finance
SAO-2
AO-FMG
SFA-3
State NGO Co-ordinator
Planning
Sr. Consultant (PH & Planning)
AO-FMG
SFA-3
SMPU
AO-NRHM
PO-SMPU
PO-Drugs
Supplies & Logistic - 2
SQAC
SQA-MO
PO-NABH
Jt. Director (IEC)
PO-AYUSH
Dy. Director (MCH)
Jt. Director (MCH)
Assi. Director (FP)
Joint Director (D & E)
MO-Training
Behaviour Scientist
Consultant - CH
MO- RI
PO-CH
Consultant –MH
PO-FRU
IMNCI-Coordinator
PO-ARSH & PO-JSSK
SNO-Nutrition
Consultant-Nutrition
PO- Nutrition-2
LO- Health & ICDS
Consultant-FP
PO-FP
PC & PNDT
Cell Law Officer
MO- PC & PNDT
State Demographer
Research Officer-2
Nodal Officer M&E
PO-E-mamta
Dy. Director (MS)
NCD Cell & PO-MS
IT-Cell
Dy. Director (ME)
NPPCD Cell & PO-ME

Demographic, Socio-economic and Health profile of Gujarat State as compared to India figures

Indicator	Gujarat	India
Total population (In crore) (Census 2011)	6.03	121.01
Decadal Growth (%) (Census 2011)	19.17	17.64
Infant Mortality Rate (SRS 2013)	36	40
Maternal Mortality Rate (SRS 2010-12)	122	178
Total Fertility Rate (SRS 2012)	2.3	2.4
Crude Birth Rate (SRS 2013)	20.8	21.4
Crude Death Rate (SRS 2013)	6.5	7
Natural Growth Rate (SRS 2013)	14.3	14.4
Sex Ratio (Census 2011)	918	940
Child Sex Ratio (Census 2011)	886	914
Schedule Caste population (in crore) (Census 2001)	0.35	16.6
Schedule Tribe population (in crore) (Census 2001)	0.74	8.4
Total Literacy Rate (%) (Census 2011)	79.31	74.04
Male Literacy Rate (%) (Census 2011)	87.23	82.14
Female Literacy Rate (%) (Census 2011)	70.73	65.46

INTRODUCTION

Tuberculosis is an infectious disease caused by mycobacterium tuberculosis. It spreads through the air by a person suffering from YB. A single patient can infect 10 or more person in a year. Tuberculosis remains a major public health problem in India with the country according for one-fifth or 26% of all tuberculosis cases reported globally. Tuberculosis, or TB, is an infectious bacterial disease caused by *Mycobacterium tuberculosis*, which most commonly affects the lungs. It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory disease. In healthy people, infection with *Mycobacterium tuberculosis* often causes no symptoms, since the person's immune system acts to "wall off" the bacteria. The symptoms of active TB of the lung are coughing, sometimes with sputum or blood, chest pains, weakness, weight loss, fever and night sweats. A number of factors make people more susceptible to TB infections. The most important risk factor globally is HIV; 13% of all people with TB are infected by the virus.[39] This is a particular problem in sub-Saharan Africa, where rates of HIV are high. Of people without HIV who are infected with tuberculosis, about 5–10% develop active disease during their lifetimes; in contrast, 30% of those co infected with HIV develop the active disease.

Tuberculosis is closely linked to both overcrowding and malnutrition, making it one of the principal diseases of poverty. Those at high risk thus include: people who inject illicit drugs, inhabitants and employees of locales where vulnerable people gather (e.g. prisons and homeless shelters), medically underprivileged and resource-poor communities, high-risk ethnic minorities, children in close contact with high-risk category patients, and health-care providers serving these patients.Chronic lung disease is another significant risk factor. Silicosis increases the risk about 30-fold. Those who smoke cigarettes have nearly twice the risk of TB compared to non smokers.

Other disease states can also increase the risk of developing tuberculosis. These include alcoholism and diabetes mellitus (three-fold increase).Certain medications, such as corticosteroids and Infliximab (an anti-αTNF monoclonal antibody), are becoming increasingly important risk factors, especially in the developed world. Genetic susceptibility also exists, for which the overall importance remains undefined

One-third of the world's population is thought to be infected with TB. New infections occur in about 1% of the population each year. In 2014, there were 9.6 million cases of active TB which resulted in 1.5 million death : 5.4 million among men, 3.2 million among women and 1.0 million among children s. More than 95% of deaths occurred in developing countries. The number of new cases each year has decreased since 2000. About 80% of people in many Asian and African countries test positive while 5–10% of people in the United States population tests positive by the tuberculin test.Tuberculosis has been present in humans since ancient times. Tuberculosis (TB) is a major global health problem. It causes ill-health among millions of people each year and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of death worldwide. There were also 1.5 million TB deaths (1.1 million among HIV-negative people and 0.4 million among HIV-positive people), of which approximately 890 000 were men, 480 000

were women and 140 000 were children. The number of TB deaths is unacceptably high: with a timely diagnosis and correct treatment, almost all people with TB can be cured.

2 million people die every year due to tuberculosis, it is curable but kills 5000 people every year.98% of deaths are mostly in developing countries, and young adults in their productive age are mostly infected. If left unchecked, with in 20 years TB will kill a further of 35 million people. Global TB incidence is still growing at 1% a year due to rapid increase in Africa. TB mostly affects the vulnerable population i.e. the poorest and mal nourished. 1 in 10 people infected with the TB bacilli will become sick with active TB. TB is contagious and spreads through the air like the common cold, each person with active TB infection average 10 to 15 people every year.

TB is a worldwide pandemic, through the highest rates per capita are in Africa(a quarter of all TB cases), half of all new cases are in six Asian countries(Bangladesh, Pakistan, India, Indonesia, China, The Philippines).8.8 million mew TB case.

India is the country with the highest burden of TB. The WHO statistics for 2014 gives an estimate incidence figure of 2.2 million cases of TB for India out of 8 million global burden. It is estimated that about 40% of the Indian population is infected with TB bacteria, the vast majority of whom have latent rather than active TB. Incidence of TB cases are 1.98 new TB cases an% and 12%-17% cases in re-treatment. TB predominantly affects economically productive age group leading to huge socio-economic impact to the country.

Compliance to therapy is one of the important factors that affect the outcome of therapy. Compliance can be defined as the extent to which a patient's behaviour coincides with medical advice. Non-compliance to self administered multi-drug tuberculosis treatment regimens is common and most important cause of failure of initial therapy and relapse. Non-compliance may also result in acquired drug resistance, requiring more prolong and expensive therapy that is less likely to be successful than the treatment of drug susceptible tuberculosis.1 Studies on acquired resistance (drug resistance among previously treated cases) from Gujarat (1980-86) showed an increase resistance to isoniazid and Rifampicin and MDR - TB rates of 30%.The adoption of DOT has been associated with reduced rate of treatment failure, relapse and drug resistance.

Despite the impressive gains in compliance associated with the use of DOT, non-compliance with DOT also occurs when patients fail to make themselves available for the administration of drug therapy. To understand the various aspects of compliance in DOT, we conducted cross sectional study among tuberculosis patients on DOT, in Morbi district of Gujarat, India.

REVIEW OF LITERATURE

Tuberculosis is a pandemic, it is a global burden according to WHO. The major thrust of RNTCP is strict adherence to directly observed treatment. Defaulting from the treatment has been one of the major obstacles to treatment management and an important challenges for TB control. A study was conducted in Ahmedabad city, Gujarat to evaluate the socio-demographic profile and treatment related risk factors of default among tuberculosis patients treated under DOTS. In the following study 200 patients were enrolled, and the following outcome came. Overall defaulter rate was 12.50% and was highest in above 50 years of age group and significantly higher in males as compared to females. High defaulter rate was observed among re-treatment patients (category 20). Feeling better was the commonest reason for defaulting followed by temporary migration during illness.

Tuberculosis has remained a major public health problem worldwide, and considering this Government of India declared TB as notifiable disease in year 2012. A study was conducted in the Sahara district to asses the trend of TB cases registered under district Revised National Tuberculosis Control Programme (RNTCP).

Tuberculosis (TB) has remained a major public health threat worldwide and considering this, Govt. of India declared TB as notifiable disease in year 2012. To assess the trend of TB in Satara district, India and to evaluate outcome of new sputum positive TB cases registered under district Revised National Tuberculosis Control Programme (RNTCP). A retrospective record based cross-sectional study was conducted in District Tuberculosis Centre (DTC), Satara district, Maharashtra, India during March 2013. All Registered TB cases under DTC from the year 2002 to 2012 were included as study subjects. The district RNTCP records since the year 2002-2012, for all TB cases were viewed and analyzed by investigator according to RNTCP outcome evaluation indicators. The trend of TB was statistically analyzed for the period of eleven years by using chi-square trend test. Results: Annual the total TB case detection rate was 117.94/lakh for year 2002 which decreased to 98.30/lakh for year 2012. The proportions of pulmonary TB cases decreased from 92.23% to 81.0% since year 2002 to 2012 whereas proportions of HIV-reactive TB cases increased from 3.11% to 25.3% since year 2009 to 2011. Proportions of male TB cases were almost the double of females; however child TB cases increased continuously with maximum TB cases belonged to pulmonary type. The proportional trend of New Sputum

Positive (NSP) cases showed periodic fluctuations ranging from 34% to 50% since year 2002 to 2012. The performance of outcome evaluation indicators of NSP cases during evaluation period as viz., cure rate ranging from 79.91% to 87.02% with periodic fluctuations, sputum conversion rate continuously increased from 78.5% to 93.5%, treatment success rate ranging from 82.7% to 90% with apparent difference, whereas defaulter rate decreased from 7.5% to 3.8% by year 2011, treatment failure rate continuously decreased to 2.1% whereas Death rate ranging from 5.2% to 10.4%. The proportional trends of outcome evaluation indicators of NSP-TB cases showed statistically significant difference over period of year 2002 to 2012. Data indicates that TB is still big problem in rural area of western Maharashtra, India and need to strengthen the awareness programme about TB and involvement of private health sector to control the burden of TB.

India has the highest burden of TB in the world, an estimated 2 million cases annually. It is also estimated by the World Health Organisation (WHO) that 300,000 people die from TB each year in India. Non-adherence to treatment has been recognized as a major problem for cure of TB. To study the outcome of the treatment of tuberculosis patients under Directly Observed Treatment Short course (DOTS) and to determine the risk factors influencing the treatment outcome of tuberculosis. This prospective observational study was carried out in five dots centers, Cuddalore district, TamilNadu. The patients registered from January to December 2014 were included in this study. Data of their treatment outcome was analyzed using standard statistical methods. Results: The study included 282 patients among them males were 203(72%) and females were 79(28%). Out of 282 subjects 218(77%) patients had pulmonary tuberculosis and 64(23%) patients had extra pulmonary tuberculosis. Treatment outcome among total 282 subjects was, 161(57%) were completed the treatment, 78(61%) patients got cured, 27(10%) patients were treatment defaulter, 12(4%) patients died and four (1%) patients were failure to treatment. Cure rate among New Smear Positive (NSP) patients and retreatment patients was 67% and 43% respectively. Overall treatment Success rate was 85% and the major reason for the failure rate was irregular treatment, defaulting, alcoholism.

RATIONALE

Tuberculosis is a global burden and a great pandemic. It is a highly communicable disease. The treatment course for TB is 6months. Patient has to take medicine on alternate days in a week. Globally, 9 million people are suffering from TB, out of this 2.1 million people are in India itself and awns one-third of the population. A TB patient can infect 5 people at an average. Therefore, complete treatment is mandatory. If treatment left incomplete then it changes to MDR-TB i.e. multi drug resistant TB. In this type of situation the patient becomes resistant to the normal 6months course of DOTS. Therefore, a new treatment regime is started which is of 9months.

There are several factors responsible for the incomplete treatment of TB. These factors consists of income, educational levels, knowledge, availability of resources, social stigma, etc. Therefore, it is important to figure out the main reasons for compliance to DOTS. Hence, this study is required to be done. Morbi is newly formed district so there was a need of this study.

OBJECTIVES

- **General Objective**

- To study the various aspects of compliance to DOTS and their effect to the treatment of Tuberculosis

- **Specific Objectives**

- To analyse the effect of socio economic factors.
- To analyse the effect of literacy levels on compliance of treatment.
- To calculate the default rate, cure rate and death rate due to disease.

Definitions

Compliance - Compliance can be defined as the extent to which a patient's behaviour coincides with the medical advice. Non-compliance may also result in acquired drug resistance

Defaulter rate - Default from treatment for drug resistant TB (DR-TB), (now classified as lost to follow-up), defined as interruption of TB treatment for two or more consecutive months, is a problem that is reported by TB control programmes globally.

Death rate – It is defined as the ratio of total deaths to total population in a specified community or area over a specified period of time, also called as fatality rate.

Criteria of poor outcome

- Defaulted in treatment
- Deaths due to tuberculosis

METHODOLOGY

A cross sectional, descriptive study was conducted in the Morbi district, Gujarat. It is divided into five tuberculosis units. For the study two tuberculosis umits were selected randomly out of five. All patients enrolled for treatment in the second quarter of the year, i.e. from January to March were selected as the sample size for the treatment.

Study Design

For the study cross sectional study type was selected and it was descriptive un nature.

Study Area

The whole district has 5 tuberculosis units (TU), out of which 2 TU were randomly selected for the ongoing study. Sampling technique used was connivance random sampling.

Sample Size

In the second quarter of the year 2015-2016, the 2 TU selected for the study had 256 patients enrolled for treatment. Therefore, the sample size for the study includes all 256 patients.

Tools and Techniques

For conducting an effective study tool is the most important part,Therefore, for this study the tools used for the data collection were a structured questionnaire which I included close ended questions and for patient details secondary data was used which was available in the TU records and the quertly reports. All the patients were asked questions and initially consent forms were are given to them for their approval.

Study duration was of 3months and MS Excel was used for the analysis of the data collected.

OBSERVATIONS

256 patients were enrolled for treatment in the second quarter of the year. The data collected shows that out of 256 cases, 45 patients were those who left their treatment in half. It also showed that 19 patients were died due to TB or some other opportunistic infections. Hence, dead patients were ruled out from the study.

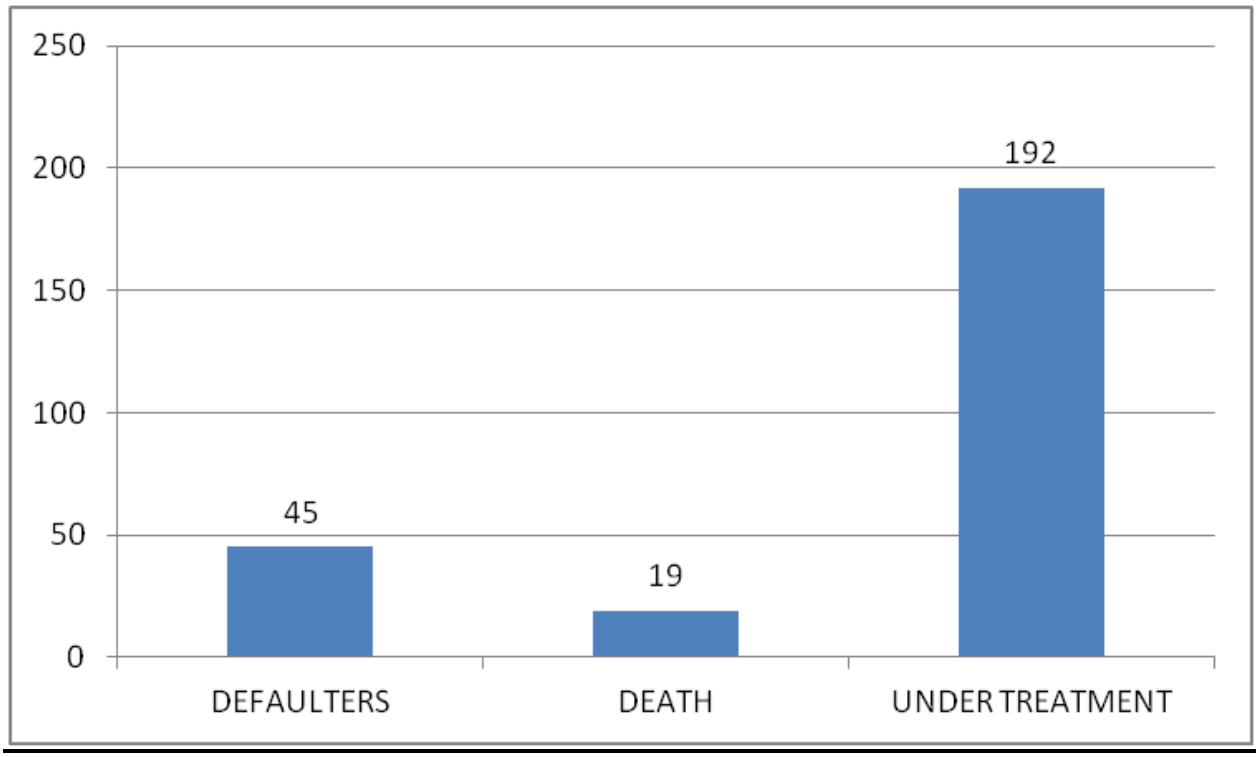

FIGURE-1- NUMBER OF DEFAULTERS, DEATHS AND UNDER TREATMENT

During the data analysis, various factors came into light due which people leave their treatment incomplete. Some of the common factors are listed below-

1. Socio- demographic factors. It consists of the following
    - Age
    - Sex
    - Profession
    - Literacy i.e. education about TB.
2. Migration – District Morbi is known as the ceramic hub og Gujarat. There are more than 2000 ceramic factories located in city. Therefore, there is consistent movement of migrants.
3. Medical conditions includes the following
    - Allergic to Rifampicin and INH.
    - Red urination due to rifampicin. People leave the treatment because they think is blood in their urine and leave without any medical consultation.
    - It is seen that after the treatment regime starts, within 2 months the symptoms starts to disappear, and patient thinks that TB is cured. Due to this myth too they leave the treatment incomplete.
4. DOTS and DOTS centres
    - Unavailability of DOTS.
    - Long waiting hours.
    - Long treatment regime.

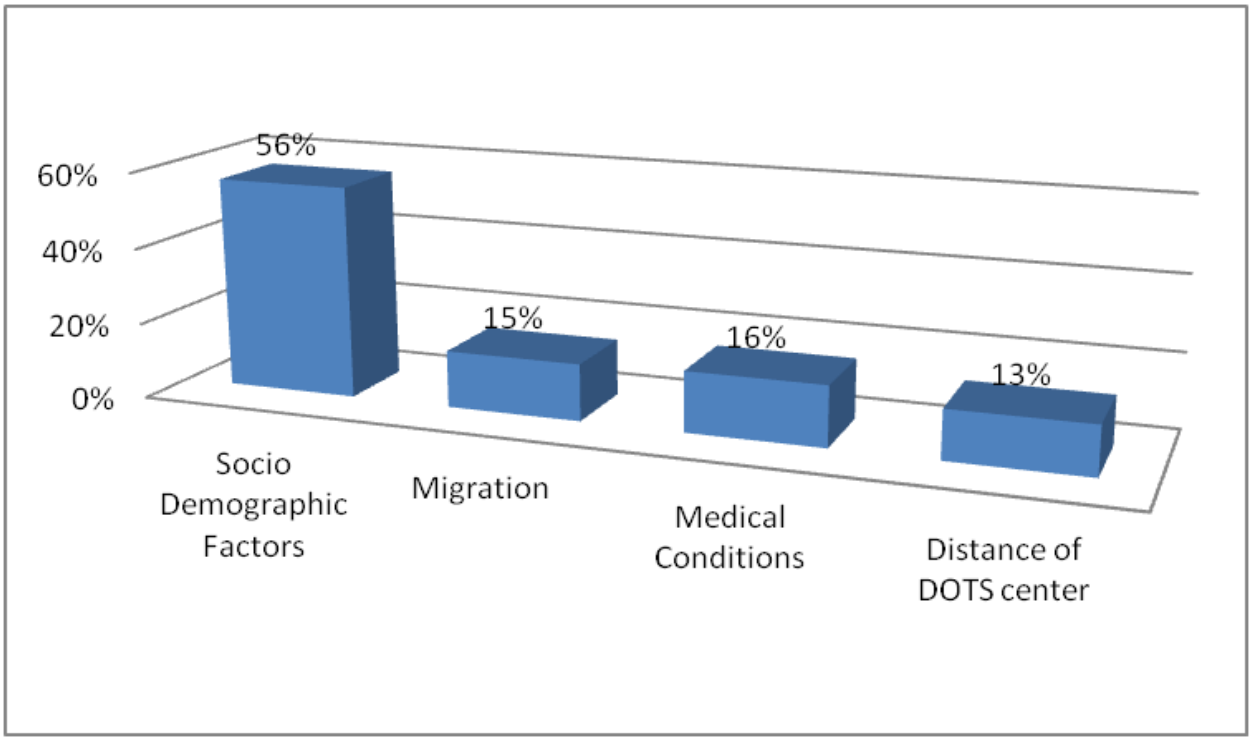

FIGURE- 2:-FACTORS AFFECTING COMPLIANCE TO DOTS

The study findings suggested that literacy levels play an important role in the treatment compliance. People who defaulted the treatment were maximum in the category of illiterate. Therefore, primary education or knowledge about the disease should be provided to every single person.

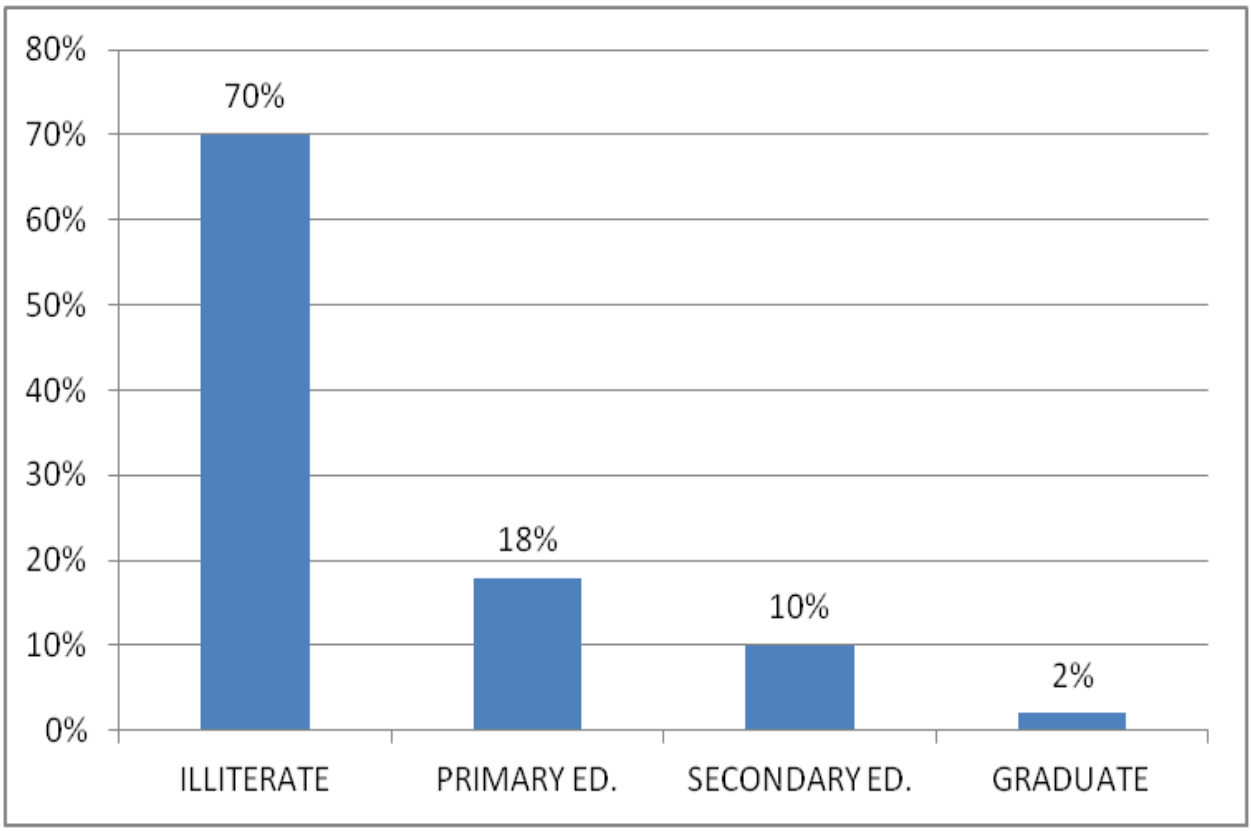

FIGURE-3:- LITERACY LEVELS COMPLIANCE TO DOTS

The study finding displayed that about 85% of the population who defaulted the treatment belongs to the labour class, so their income is low. Due to this they would have defaulted the treatment as it would be difficult for them to continue due to their long working hours.

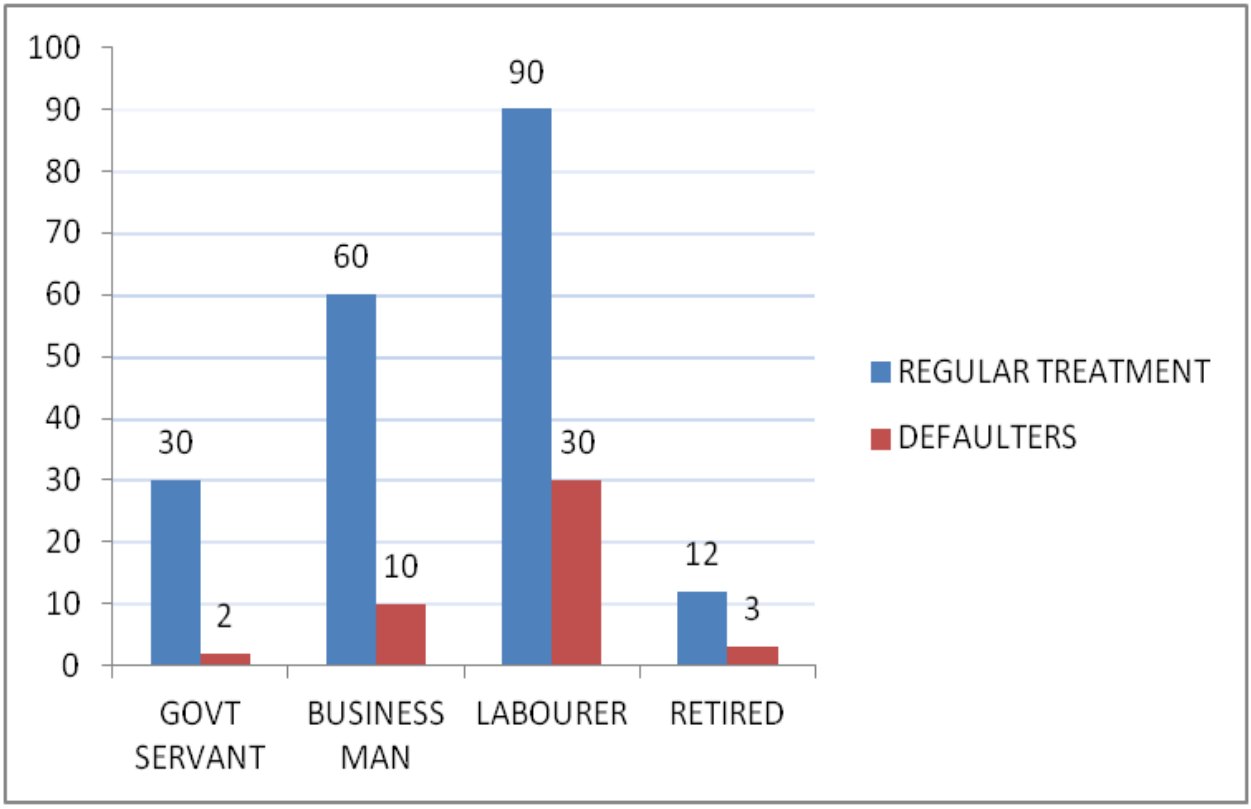

FIGURE-4 –SOCIO-ECONOMIC FACTORS AFFEXTING COMPLIANCE TO DOTS

RESULT

Almost for the last quarter 256 patients were registered for the DOTS, in district Morbi, Gujarat. Calculations showed that 192 patients (80%) of the patients are taking regular treatment. 45 patients defaulted the treatment and 19 patients died during the second quarter.

Therefore, common factors that were responsible for the compliance to treatment were found to be literacy levels and socio economic conditions.

People who defaulted the treatment were in the age group of 25 to 35 (75%), 80 % of the males were defaulters.

Labourer class were involved with low income who left the treatment midway that is 55.5%.

70% of the people were illiterate in the defaulters list.

Migration is common in the district but 67.7% were from Morbi and staying there for more than 6 months.

The reason of defaulting the treatment were disappearing of symptoms 48% , red urination due to rifampicin 10% and allergic to some drugs 42%.
Out of the patients who were defaulting the treatment, 80% were having DOTS centre available in the radius of 5km from their home. In this study, the poor out come of DOT was studied which was 12%. The case fatality rate (5.5%) was higher than the National average which is 4% since implementation. The similar mortality was observed in the study of a south Indian district . The present study-shows that 93% of study population was compliant to the DOT. These results are good if compared to the other studies. The study done by Tekle et al, who found that 11.3% of all study population in Ethopia in 1997 - 99 were noncompliant.16 Study from China revealed that TB treatment was completed by 73.1% of patients within 9 months while 28.9% failed to complete their regime. The studies on the association of demographic characteristics of patients to compliance of anti-tuberculosis therapy have given inconsistent results. 9,15 The present study revealed that the socio-demographic factors (age, sex, education, occupation and socio-economic status) were not associated signifi cantly with adherence (Table-I). Ashry Gad et al in their study also portrayed the same fact that the factors like age, sex, work and education had no association with adherence of treatment.9 But Johansson et al had found that patient's economic situation is an important determinant of compliance and noncompliance.17 The main risk factors for non-compliance were studied and they were role of health education, toxicity of drugs, cost of investigation and therapy, timing of therapy, travel for therapy, long waiting period for treatment and role of DOT provider.

Out of them the health education had major effect for non-compliance. The study revealed that the compliance of DOT was significantly high among those who have good knowledge about various aspects of disease. Similar observation has been documented by other authors in their study.The adequate knowledge about disease was found to be protective factor for defaulting to therapy in Ethiopia 200216. In addition to knowledge about disease, toxicity of medication is also thought to be associated with non-compliance. The present study also revealed same fact. It was observed that majority of patients on DOT stopped treatment because of toxicity of drugs. The other reasons were feeling better during treatment and lack of knowledge about various aspects of TB and its treatment (10.5%). Tekle et al had revealed in their study, medication side effects were signifi cantly associated with defaulting.16 It was observed that those with adequate knowledge about disease defaulted less and this will also help in reducing the toxicity. The innovative strategies in health education are the need of the hour.

Conclusion and recommendations

The study concludes that there are various factors responsible for the treatment compliance to DOTS.

There were 256 patients enrolled for treatment of TB in the selected district. Out of them 192 patients are on the treatment of DOTS, 45 Patients are defaulters and 19 died during the treatment course.

Various factors were socio demographic

Age, Sex, Literacy rate, Profession, Migration, awareness about the diseases symptoms and consequences of leaving the treatment and availability of DOTS and diagnostic centre.

Therefore proper monitoring of the patients and the affecting factors should be done on regular bases.

Basic knowledge about the disease should be provided and patients should be encouraged to complete their treatment course.

- Involvement of health staff should be enhanced.
- Reporting from the urban sector should be increased.
- Basic information about the disease to be given to the general population.
- Counseling of the patients should be done to minimize dropout rate.
- The Best example from the previous cases should be projected to encourage people to continue the treatment despite of all the odds.

Limitation of study

- Newly form district due to which there is lack of human resource in the TU.
- Language barrier

- Sample size is small

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ANNEXURE

QUESTIONAIRE

1. **Socio-demographic factors**

Q.1. What is your age?
a). 15-25 b). 25-35 c). 35-45 d). 45-55

Q.2. Gender of the patient?
a). Male b). Female

Q.3. What is your profession?
a). Govt. servant b). Business men c). Labourer d). Retired

Q.4. What is your education?
a). Illiterate b). Primary c). Secondary d). Graduation

2. **Migration**

Q.1. Are you from Morbi?
a). Yes b). No

Q.2. If yes, from what duration?

a). 3months b). 6months c). 1year d). More than 1 year

3. **Awareness in patients about the treatment.**

Q.1. Do you take regular treatment?

a). Yes b). No

Q.2. If not, what is the reason of leaving?

a). Allergic to some drugs b). Symptoms disappear c). Red urination due to medicine d). Any other reason

Q.3. Do you know the consequence of leaving the treatment mid-way?

a). Yes b). No

4. Availability of DOTS and DOTS centres.

Q.1. Is DOTS centre available near your place?

a). Yes b). No

Q.2. At what distance the DOTS centre located?

a). Within 1 km b). 3 km c). 5 km d). More than 5 km

Q.3. Medicine available in DOTS centre?

a). Yes b?. No