SMOKING PATTERNS AND PREDICTORS OF SMOKING RELAPSE AMONG MALE TUBERCULOSIS PATIENTS IN UDUPI DISTRICT OF KARNATAKA STATE

DR. DEEPAK KG

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DEDICATION

The work embodied in this dissertation is dedicated to my Appa and Amma, my wife Vijayashree, and in particular my little daughter, Prachi. Their unconditional support and inspiration made this work possible.

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DECLARATION

I hereby declare that the work embodied in this dissertation titled, **'Smoking patterns and predictors of smoking relapse among male Tuberculosis patients in Udupi district of Karnataka state'** is the result of original research and has not been submitted for any degree in any other university or institution.

Dr. Deepak KG

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram

October 2008

Certificate

I hereby certify that the work embodied in this dissertation titled **'Smoking patterns and predictors of smoking relapse among male Tuberculosis patients in Udupi district of Karnataka state'** is a bonafide record of original research work undertaken by **Dr. Deepak KG** in partial fulfillment of the requirement for the award of the degree of Master of Public Health, under my guidance and supervision.

Dr. K R Thankappan MD, MPH (Research Guide)

Professor and Head

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram, Kerala, India

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Dr. A S Pradeep Kumar MBBS, MPH (Co-Guide)

Zonal Malaria Officer

Directorate of Health services

Thiruvananthapuram, Kerala

TABLE OF CONTENTS

ABSTRACT

Background:

Smoking is causally linked to tuberculosis but very little data exists on smoking pattern among TB patients. Objectives of this study were to assess the smoking pattern, type and pattern of quit smoking messages received by TB patients and to identify the predictors of smoking relapse.

Methods:

Two hundred and two male TB patients above 18 years who had completed treatment at least six months before the date of interview were selected using stratified random sampling for this community based cross sectional study. Information on demographics, disease history, tobacco use at eight time points, self reported quit smoking advice from health providers, craving, and perception about links between TB and tobacco, was collected using a pre-tested, semi-structured interview schedule. Data were analyzed in SPSS. Descriptive and multivariate logistic regression analyses were done.

Results:

Six months prior to diagnosis of TB, 75.7 percent of patients were ever smokers and 51 percent were current smokers. Although 86 percent of current smokers had quit smoking soon after diagnosis, 37 percent relapsed by six months post treatment. Only 15 percent relapsed during the treatment and 57 percent relapsed within three months post treatment. Cessation advice was received by 85 percent of smokers from primary care physicians and 90 percent of the messages were TB specific but they were not followed after treatment. Patients who had post treatment craving were nine times more likely to smoking relapse compared to their counterparts (OR 8.5, 95% CI 2.9-24.3). Compared to those who used smoking and smokeless tobacco one week prior to diagnosis of TB the smokers only group was more likely to relapse to smoking (OR 3.4, 95% CI 1.1-10.9).

Conclusions:

Health staffs and DOTS providers need to be trained to help patients coping craving. Post treatment follow up cessation activities are also equally important.

CHAPTER 1

Literature Review

1.1 Introduction:

In this chapter, I have reviewed various literatures and recent studies available on 'Tuberculosis and smoking' before stating rationale and objectives for this study.

In the background information burden of Tuberculosis (TB) and smoking is explained in terms of prevalence, incidence and mortality rates at various levels and its trends in occurrence. Evolution of DOTS, post DOTS developments and RNTCP are covered briefly under strategies of TB control. Some salient aspects of tobacco control are also covered here.

In the second part of this chapter, how active and passive smoking is causally associated with infection, case fatality and relapse of TB is explained.

In the third part of this section, emphasis on studies which have highlighted the need, feasibility and practical basis for incorporation of tobacco control interventions in TB control program is done. Finally problems related to the implementation of such interventions, rationale and objectives of this study are stated.

1.2 Background Information:

1.2.1 The global burden of TB:

Tuberculosis (TB) remains a major global public health problem.[1] World Health Organization (WHO) has declared Tuberculosis as a "Global Emergency" in 1993 considering its disastrous effect on people's health and the wider social and economic impact on overall development of a country.[2]

WHO estimates that 9.2 million new cases have occurred in the year 2006 (139 per 100000 population), of which 4.1 million (44%) cases were new smear- positive cases and eight percent were Human Immuno Deficiency Virus (HIV) co infected cases (0.7

million).[1] Today, TB is a leading cause of death among people who are HIV-positive. Worldwide, an estimated one-third of the nearly 40 million people living with HIV/AIDS are co-infected with TB.[3]

The prevalence of TB cases globally was 14.4 million and multi drug-resistant Tuberculosis (MDR-TB) was 0.5 million cases in 2006. TB has caused 1.5 million deaths among HIV-negative people and 0.2 million deaths among people infected with HIV in 2006.[1]

WHO report 2008 claims that highest incidence rate per capita was observed in the African region (363 per 100 000 population). Asia (South-East Asia and Western Pacific regions) accounts for 55 percent of global cases and Africa accounts for 31 percent. There are 22 high-burden countries (HBCs) that collectively account for 80 percent of TB cases globally and India, China, Indonesia, South Africa and Nigeria rank first to fifth respectively in terms of absolute numbers of cases.[1]

1.2.1a Global trends in Tuberculosis burden:

The global annual TB incidence rate was increasing at 1.5 percent in the mid 1990s but decreased and reached 1.0 percent increase rate in 2003 and 2004, likely due to the slowing down of the HIV epidemics in sub-Sahara Africa.[4] Further the incidence has decreased slowly at the global level between 2005 and 2006 (-0.6%) having peaked around 2003.[1] However, the total number of new TB cases are still rising slowly.[5] By 2006, TB incidence per capita was approximately stable in the European Region and in slow decline in all other WHO regions. Globally prevalence and death rates per capita are falling, and faster than TB incidence. If these trends of past five years sustained, Stop TB partnership targets could be achieved in all regions except in African and European regions which are far from the targets affecting global level target achievements.[1] It was

estimated that the global incidence rate will be about 150 per 100,000 in 2015, generating more than 10 million new cases.[5]

1.2.1b Burden in developing countries:

TB has done horrendous impact on developing world. Ninety five percent of all TB cases and 98 percent of TB deaths occurred globally belongs to developing world. Most of the TB cases (≈75 percent) occurring in this part of the world happens in the most economically productive years.[2] In most developing countries TB would continue to be a serious health threat even in the absence of HIV/AIDS due to the public health challenges posed by poverty, high illiteracy, and poor sanitation.[3]

1.2.2 Tuberculosis burden in India:

India is the highest TB burden country in the world. In India 1.8 million (168/100000) tuberculosis cases occur annually, accounting for one-fifth of the world's new TB cases and two-thirds of the cases in the South-East Asia Region.[6] It was estimated that two of every five Indians are infected with the TB bacillus and among them at least 10% will develop TB disease during their lifetime. Of the 1.8 million new TB cases occurring annually, around 0.8 million have sputum positive pulmonary TB. One sputum positive patient can infect 10–15 persons in a year if left untreated.[6]

According to National Family Health Survey (NFHS-3), the prevalence of TB in India was 445/100000 and medically treated TB was 418/100000 population.[3] But according to WHO, prevalence estimation was 299/100000 population.[1]

In India men has higher prevalence (554/100000) as compared to women (334/10000). Rural population has higher prevalence of 502/100000 as compared to urban prevalence of 319/100000. The prevalence among 60+ aged population was 1066/100000 when compared to 555/100000 of 15-59 aged population and 110/100000 of less than15 aged population.[3]

1.2.2a Prevalence of Tuberculosis by state:

The prevalence of TB by state indicates geographical clustering of the disease. Most of the states of east and north eastern region show higher prevalence levels when compared to national average of 418 per 100,000. The prevalence levels of Northern states falls below the national average. A middle level of prevalence was observed in Chhattisgarh (280), Madhya Pradesh (331), and Uttar Pradesh (425) which are large states in central India. The states in the South Region show a mixed prevalence of TB: low in Karnataka (136) and Kerala (268), and higher in Andhra Pradesh (409) and Tamil Nadu (483).[3]

Arunachal Pradesh has the highest prevalence of 1111/100000 population and Jammu and Kashmir has the lowest prevalence of 104/100000 population.[3]

Karnataka: The prevalence of TB in Karnataka state, the site of present study, is 141/100000 which is next to Jammu and Kashmir among lowest burden states.[3]

1.2.2b Economic burden due to TB in India:

According to RNTCP data 2006, it states that TB affects mostly young adults. In India 70 percent of TB cases occur in economically productive age group (15-54). More than 80 percent of deaths are premature deaths which is a main cause of burden of TB. India incurs an escalating economic loss of about 17 crores workdays and US$ 3 billion (more than Rs.13, 000 crores) lost annually.[6] As per WHO estimates in 2006, approximately 325,000 persons in India died of tuberculosis (mortality rate 28 per 100,000 persons).[1]

1.2.3 Targets and Strategies of TB control:

Even after the invent of effective chemotherapy, Tuberculosis is persistent due to the neglect of TB control by governments, poorly managed TB control programs, poverty, population growth, migration and significant rise of HIV infection.[7]

In 1991 the forty fourth World Health Assembly highlighted TB as growing public health problem and reassessed the ongoing TB control efforts with special emphasis on cost effective control methods using available tools.[8]

A new framework for effective TB control as a global strategy called DOTS was introduced.[7] Directly Observed Treatment, Short-course (DOTS) is a combination of technical and managerial components. Five key elements of this strategy are political commitment, good quality diagnosis through sputum microscopy, directly observed short course chemotherapy under proper case management conditions, uninterrupted drug supply and standardized recording and reporting system.[7]

1.2.3a History of development of DOTS:

Before the invention of anti-TB drugs, treatment was intended to strengthen the patient's resistance to TB but death rates were very high and after the invention of chemotherapy in 1950s, long course treatment (for one year) without the need for hospitalization has reduced TB mortality rates drastically. Later introduction of Rifampicin in 1970s as a part of a combination of anti-TB drugs reduced treatment to six to eight months.[2]

In 1970s, Dr Karel Styblo of the International Union Against Tuberculosis and Lung Disease (IUATLD) has developed a model of TB control based on managerial approach to case-finding and treatment. Later in 1993, WHO's Global Tuberculosis Program (GTB) accepted Styblo's model as global strategy to control TB with the brand name as DOTS.[2]

1.2.3b Post –DOTS developments:

In 1998, 'Stop TB Initiative' a global partnership was established by WHO to link health, social and economic sectors in the fight against TB.[9] In 2000, 20 high burden countries endorsed the "Stop TB Partnership" in "Amsterdam Declaration". Global targets for TB control were then reaffirmed.[9]

WHO has launched ‘Stop TB strategy’ and a ‘Global Plan’ in the year 2006 to achieve the 2015 impact targets as well as the targets for case detection and treatment success.[10] The six major components of ‘Stop TB Strategy’ are[10]: (i) DOTS expansion and enhancement; (ii) addressing TB/HIV, MDR-TB and other challenges; (iii) contributing to health system strengthening; (iv) engaging all care providers; (v) empowering patients, and communities; and (vi) enabling and promoting research.

1.2.3c Global TB control targets:

1. Millennium Development Goal (MDG) 6, Target 8: Halt and begin to reverse the incidence of TB by 2015.[11]

Targets linked to the MDGs and endorsed by the Stop TB Partnership[10,11]

2. by 2005: detect at least 70 percent of new sputum smear-positive TB cases and cure at least 85 percent of these cases.

3. by 2015: reduce TB prevalence and death rates by 50 percent relative to 1990.

4. by 2050: eliminate TB as a public health problem (One case per million population).

1.2.3d TB control in India:

The Revised National Tuberculosis Control Program (RNTCP) is in the 11th year of its implementation having been formally launched in 1997 following a pilot phase from 1993-96. The program has expanded rapidly since then and succeeded to cover the whole nation by March 2006. The emergence of TB-HIV co-infection and multi drug resistant TB (MDR-TB) poses an important challenge to the TB control efforts in India. RNTCP Phase II (2006-11) is following the components of WHO Stop TB Strategy and in 2007, it has launched DOTS Plus services for the management of MDR- TB patients which is a landmark achievement in the history of Indian TB control.[6]

1.2.4 Global burden of smoking:

Tobacco is the second major preventable cause of death in developed and low mortality developing countries and sixth in high mortality developing countries and it is currently ranked fourth in the world in its contribution to years of life lost.[12] Worldwide, approximately 1.3 billion people currently smoke cigarettes or use other tobacco products, with more than 900 million tobacco users living in developing countries. The total global prevalence in smoking is 29 percent (47.5% of men and 10.3% of women over 15 years of age smoke).[13]

Tobacco kills one person every six seconds. Today, tobacco use causes one in 10 deaths among adults worldwide – more than five million people a year.[14] Almost half of the lifetime users of tobacco smoke dies and 50 percent of such deaths occur in the middle age (35-69years).[13]

Globally deaths due to tobacco use are rising alarmingly. In 2005 there were 5.4 million deaths, if proper control measures are not taken to reduce tobacco consumption, annual mortality is anticipated to rise to the level of 6.4 million in 2015 to 8.3 million in 2030 and of which 80 percent will be in developing countries.[14] Of the more than 1 billion smokers alive today, around 500 million will be killed by tobacco.[15]

Another estimate of global tobacco attributable deaths in 2000 highlights that 100 million deaths have occurred in 20th century[4] and if present trend persists during this 21st century, tobacco could kill up to one billion people.[16]

Tobacco use is a risk factor for six of the eight leading causes of death in the world. Those are Ischaemic heart disease, cerebrovascular disease, Lower respiratory infections, chronic obstructive pulmonary disease, TB, and Trachea, bronchus and lung cancers.[14]

1.2.5 Burden of tobacco use in India:

According to the third NFHS- 3 report based on the survey conducted on nationally representative sample (15-49) in 2005 reveals that the prevalence of any form of tobacco use among males was 57 percent and in females it was 10.8 percent. Prevalence of current use of Cigarette/bidi smoking among males was 32.7 percent and in females it was 1.4 percent.[3]

All forms of tobacco use in India increased during the 7 year period between the second and third National Family Health Survey. Tobacco users among young people aged 15-24 years have increased drastically. Smoking prevalence has also increased among males but has decreased among females over the same period.[3,17]

According to India Global Youth Tobacco Survey 2006 (GYTS) prevalence of current use of any tobacco product among youths aged 13-15 in males was 17.3 percent and in females was 9.7 percent. Prevalence of current cigarette smoking among males was 5.9 percent and in females was 1.8 percent. About 26.6 percent and 40.3 percent of them were exposed to smoke at home and outside home respectively. Fifteen percent of never smokers are likely to initiate smoking next year.[18]

A study from Chennai claims that a 25 percent of smokers would be killed by tobacco at ages 25-69 years and will be loosing 20 years of life expectancy. It also estimated that smoking causes half the male TB deaths and of a quarter of all male deaths in middle age in India. About 700,000 deaths per year can be attributed to smoking in India due to respiratory or vascular disease. Among them about 550000 men aged 25-69 years.[19]

In India excess mortality among smokers is mainly due to TB, other respiratory diseases, vascular and neoplastic disease. One estimate states that in 2010, smoking will cause about 930,000 adult deaths in India, of which 70 percent will be between the ages of 30 and 69 years. Burden of smoking in India, mainly due to premature deaths which is

increasing among economically productive age group.[20] The annual number of deaths from smoking must be expected to double between 2000 and 2025.[19]

1.2.5a Burden in Karnataka state:

Karnataka State now ranks seventh in the country in the Human Development and sixth in the Gender Development Index (GDI).[21] According to NFHS-3, in Karnataka the prevalence of current use of any form of tobacco use among males was 44.7 percent and among females was 4.8 percent. The prevalence of current use of Cigarette/bidi smoking was 27.9 percent among males and 0.1 percent in females.[3] There has been an increase in smoking among males and slight decrease among females from 1998 to 2005 in Karnataka.[3,17]

1.2.5b Shifting tobacco epidemic:

Despite of well known hazards of tobacco use, its consumption pattern is taking new spectrum. Tobacco epidemic is shifting towards poor countries due to stringent laws in industrialized counties and also due to marketing strategies of tobacco companies. These tobacco companies are developing new markets and also shifting pattern in consumption of products among youths, women in these countries. Apart from health consequences it causes significant economic burden on families and societies because money is spent for tobacco use rather spending for essential needs like education and food.[4]

1.2.6 Tobacco control efforts:

The WHO Framework Convention on Tobacco Control (FCTC), a multilateral treaty with more than 150 parties, was the first step in the global fight against the tobacco epidemic. To further implement FCTC, WHO has come up with MPOWER package with six effective and evidence based tobacco control policies. India has signed the FCTC on 10th Sep 2003 and the ratification was done on 5th February 2004.[18]

1.3 Tuberculosis and Tobacco Use:

Associations between tobacco use and Tuberculosis (TB) outcomes have long been suspected and since 1918 Studies have been conducted to investigate the association between smoking and TB.[22] Though few decades back Lowe demonstrated through a case control study that TB patients were more likely to be heavy smokers than control patients (without controlling for confounding variables),[23] but until recently there was a strong view that existing studies were not enough or adequate to demonstrate the causal link. This section reviews more recent studies and some recent reviews of existing studies which provide an evidence to prove the link between active and passive tobacco smoking and a range of TB outcomes.

1.3.1 Biological plausibility of tobacco smoke and TB association:

Chronic exposure to tobacco smoke impairs normal clearance of secretions on the trachea-bronchial mucosal surface which allows Mycobacterium tuberculosis to reach alveoli escaping first level of host defenses.[24] Tobacco smoke impairs the phagocytic ability of pulmonary alveolar macrophages (AMs) and reduces its secretion of pro-inflammatory cytokines.[25] Nicotine is hypothesized to act directly on nicotinic acetylcholine receptors on macrophages to decrease intracellular tumor necrosis factor-α production and thus impair intracellular killing of M. tuberculosis.[26] Another hypothesis claims that smokers' AMs defense mechanism gets impaired due to elevated iron content through reduced production of both tumor necrosis factor-α and nitric oxide.[27]

1.3.2 Risk of Tuberculosis infection and tobacco smoke:

Passive exposure to tobacco smoke was significantly associated with tuberculosis infection among children in household contact with adults with pulmonary TB (OR=2.7, with 95% confidence interval [CI] 1.5-4.7).[28,29]

Nisar et al showed that Heaf test positivity grade was directly related to pack-years of smoking in residential homes for the elderly in Liverpool.[30] Association between pack-years (active tobacco exposure) and a significant TST reaction was also observed in a cross-sectional population survey in a high TB incidence area in South Africa.[31]

Cohort studies may be required to further prove this linkage as there is not yet single cohort study on this link.[22,32]

1.3.3 Risk of developing tuberculosis disease and tobacco smoke exposure:

Strong association between tobacco smoke and TB has been demonstrated and also showed dose response relationship in a case control study in the state of Tamil Nadu of India.[33] Another case control study from Estonia revealed association with both passive and active tobacco smoke exposure to developing the TB disease.[34]

Passive smoking increases the risk of pulmonary TB immediately following infection in children[35] and also in children with history of TB contact.[36] Among young adults also cigarette smoking is a risk factor for getting PTB and there was an evident dose response relationship.[37]

In a Hongkong study among elderly it was demonstrated that current smokers had an excess risk of getting PTB when compared to never smokers.[38]

1.3.4 Clinical manifestations of Tuberculosis and tobacco smoke exposure:

Leung et al found that ever smokers were more likely to have cough, dyspnoea, chest radiograph appearances of upper zone involvement, cavity and miliary appearance and positive sputum culture which are signs of aggressive lung involvement.[39] In another study smokers had higher odds of getting pulmonary disease (OR 1.5), cavitary lesions (OR 1.9) and they required more extended hospitalization.[40]

1.3.5 Delay in the diagnosis and treatment of tuberculosis and tobacco smoke: Smoking was not associated with delay in diagnosis and treatment of TB but having given

up smoking was shown to be associated with a total delay of more than 60 days in Recife, Brazil.[40,41]

1.3.6 Anti TB drug resistance and tobacco smoke exposure:

Very little data exists on this link. Barroso et al found in their case control study that smoking was a risk factor for Multi-drug resistance in univariate analysis but in multi variate analysis "smoking and alcoholism together" was only found significant risk factor.[42]

1.3.7 TB mortality and tobacco smoke exposure:

The risk of death from tuberculosis was 2.3 times higher among male smokers than never tobacco users in Mumbai.[43] In a cohort study of smoking among male British doctors by Doll et al states that relative risk of dying from Pulmonary TB for smokers was higher compared to never smokers.[44]

In a study from south India, it was found that in both rural and urban areas death rate from tuberculosis was about four times among ever smokers than in never smokers[19] and in South Africa 20 percent excess death was attributable to smoking.[44]

However, it is not clear that smoking causes additional mortality risk in persons who already have active TB[45] and another limitation of these studies is that probable misclassification of cause of death, magnification of the association between smoking and mortality due to TB might have occured.[22]

1.3.8 Risk of relapse and tobacco smoke exposure:

A study looking at the predictors of relapse among pulmonary TB patients demonstrates that smokers were three times more likely to relapse TB compared to non smokers.[46]

1.3.9 Outcome of TB treatment and tobacco smoke exposure:

A study from South India investigating risk factors of TB treatment outcomes revealed that smoking was significantly associated with default and failure (among patients

without MDR-TB) as compared with success only in univariate analysis but no association was found with death.[47] In a cohort study it was found that smokers were more likely to die from any cause during follow-up than ex smokers and never smokers.[38]

1.3.10 Bacteriological conversion and tobacco smoke exposure:

Leung et al states that smoking did not have any effect on sputum smear or culture conversion after two months of anti-tuberculosis treatment[39] but in another study[48] delay in smear conversion was found in expatriate smokers and smokers with advanced disease.

1.4 Tobacco Cessation Interventions:

1.4.1 Need for Tobacco cessation intervention for TB patients:

Smoking is causally associated with active TB. Author strongly argues for the need of counseling and assistance in stopping tobacco use for TB patients[22] and there is a need to devise effective strategies for counseling patients about the impact of smoking on their cure.[46]

One systematic review concludes that TB control programs should focus on interventions aims at reducing tobacco and indoor air pollution exposures among those at high risk for exposure to TB.[32] Bates et al highlights that Tuberculosis control policies should incorporate tobacco control and also smoking prevention and cessation efforts should be a priority in TB control program.[45]

There is a need to look beyond DOTS program which could bring down TB rates moderately but its progress seemed to have plateaued and much importance to be given to prevention to reinforce population based TB control.[49] In another meta analysis by Bates et al highlights the shortcomings of new Stop TB strategy in terms of not addressing population based preventive interventions.[45]

An article of educational series on 'Tuberculosis and tobacco' urges that tobacco cessation is essentially has to be included in the guidelines of TB control program. Standard monitoring process should include patient's smoking information.[50]

Another study from Kerala demonstrates the unmet need for tobacco cessation, while exploring the patterns of tobacco use and cessation activities among male TB patients while undergoing treatment.[51]

1.4.2 Feasibility of tobacco cessation interventions:

In Sudan study it was demonstrated that brief tobacco cessation intervention is feasible to implement and also effective within routine TB services.[52]

Tobacco use screening and repeated brief cessation advice is one of the foremost effective preventive services in terms of health gains and effectiveness, but also cost saving measure which can be given in any medical practice.[53] Cessation counseling and interventions can be incorporated into existing health system and DOTS program cost effectively.[22]

1.4.3 Practical basis for smoking cessation strategies in health system:

Author argues that Tuberculosis patients who are registered for treatment are often ill and suffering due to symptoms. They will be receptive and ready to adopt any behavior changes advised by the health personnel in order to get better. Simple and not time consuming brief interventions increase cessation rates.[54]

US Public Health Service has developed 'A Clinical Practice Guideline', which suggests and recommends evidence based methods to promote the treatment of tobacco dependence by brief clinical interventions, intensive clinical interventions and system changes.[55]

A project 'Quit Tobacco International' known for tobacco cessation research activities

developing culturally appropriate approaches and interventions to tobacco cessation within the health sectors of India and Indonesia.[56]

Tobacco dependence is conceptualized as a chronic disease state. The typical smoker progresses through a series of remissions (successful cessation episodes) and exacerbations (relapse episodes) during their battle with the disease. This chronic disease model of advising and counseling was adopted to treat tobacco dependence was 5 A's model.[57]

In 5 A's model all patients should be routinely asked for tobacco use. Those who are found to be tobacco users advised to quit in a clear, strong, and personalized manner. Next step is to assess if they are willing to make a quit attempt and assisting those who are willing to quit. Lastly arranging for follow-up contact regarding the quit effort. Smokers unwilling to make a quit attempt should be offered a brief motivational intervention which involves 5 Rs. The message should be relevant to the patient. Tell risks of continued tobacco use. Explain rewards of cessation. Enquire about roadblocks to quitting. Finally, when dealing with the non motivated patient, repetition of the quit message is essential. Regardless of intensity, all interventions should involve three key components: (1) pharmacologic treatment, (2) clinician-provided social support, and (3) information on problem- solving and skills training.[57]

1.5 Problem statement:

In India tobacco consumption is increasing in all regions, sectors and classes. Even in Karnataka and Udupi district, the present study setting, is also not an exception.[3,17] India has a highest burden of Tuberculosis. Even in Karnataka, though prevalence is relatively less compared to other states[3], unfavorable outcomes are very high.[6] At present tobacco control is a low priority public health area in India. Unless we give enough effort to curb the epidemic of tobacco, TB burden cannot be reduced, and also its negative impact on

overall growth. There are very few data on the prevalence and patterns of smoking among TB patients and not many studies have examined predictors of quitting, relapse and persistence of smoking except a recent study from Kerala which highlights that smoking prevalence among TB patients at the time of diagnosis is two and a half times of general population and it stresses for proactive cessation efforts in TB control program.[58] In India very little data exists on whether tobacco cessation advice is extended to TB patients and how messages are understood.

1.6 Rationale:

- By 2030, there will be more than eight million deaths every year due to tobacco epidemic and more than 80 percent of these deaths will be in developing countries.
- Smoking is associated with higher morbidity and mortality of Tuberculosis patients.
- Very little research has been reported on Tobacco use prevalence among TB patients from India.
- Smoking among women is very low in India.
- Hence this study aims to assess smoking patterns and predictors of smoking relapse among male TB patients in order to help developing appropriate smoking cessation strategies.

1.7 Objectives:

- To assess the smoking patterns among male TB patients at different time points.
- To study the type and pattern of quit smoking advice received by TB patients.
- To identify the predictors of quitting and smoking relapse.

CHAPTER 2

Methodology

2.1 Study Design:

Cross Sectional Survey

2.2 Study period:

Total study period was four and half months. Data were collected from 15 June 2008 to 15 Sep 2008. Data entry, analysis and thesis write-up were done from 15 September 2008 to 31 October 2008.

2.3 Study setting:

There were 29 districts in Karnataka state. Udupi district, the site of the present study, was one of the coastal districts of Karnataka. Its population as per Census 2001 was 1,112,243 of which 18.5 percent were urban. Udupi district was ranked third according to Human Development Index.[21] All the three Tuberculosis units (TU) in the districts were selected for the study. They were Karkala, Kundapura and Udupi TB units.

2.4 Sample frame:

List of all male TB patients (≥18 years) in TB register who had cured or completed treatment in all the three TB units of Udupi district during last two quarters of 2007 (i.e. 3rd and 4th quarters of 2007) was collected. At least six months period was ensured between the date of interview and date of treatment completion. There were 431 eligible former male TB patients in the sample frame in the end.

2.5 Sample size:

Sample size was calculated using Statcalc, Epi info version 6 based on an expected smoking prevalence rate of 75 percent among TB patients.[51] Keeping the worst acceptable result as 70 percent, for 95 percent Confidence Interval sample size was estimated to be 173.

Anticipating difficulties in tracing patients due to incorrect addresses, migration and death, I decided to contact 250 patients to obtain at least 173 for the study.

I was able to contact and conduct interviews of 202 former male TB patients of the 250 selected patients. Among the 250 patients, 18 died and rest 30 could not be traced due to migration or incorrect addresses.

All patients agreed to participate in the study and gave informed consent. Female patients were excluded from the study, as smoking among females is very low in Karnataka.[3]

2.6 Sample selection procedures:

Stratified Random Sampling Method was adapted to select the subjects. As a first step, all the three TB units of the district (Kundapura, Karkala and Udupi) were selected. Subjects of each TB unit who fulfilled the selection criteria were listed separately. From each of the three TUs, a sample of patients proportionate to the total number of TB patients detected in that TU was selected randomly. This was done at the district TB office using TB registers from each of the TB Unit. Then the cases were arranged or grouped according to the Peripheral Health Institutions for convenient data collection.

2.7 Data collection techniques:

2.7.1 Primary data:

Information was collected using semi structured interview schedule from the study subjects. Patients were visited at their home or workplace or at their convenient place and time, with prior consultation through health worker of concerned peripheral health institute (PHI).

I collected information on demographics, disease history, tobacco use history, alcohol consumption, others' smoking status, quit smoking advice from health providers, craving, withdrawal symptoms, readiness to quit and patient perceptions about links between TB and tobacco.

Tobacco use histories were collected at eight time points in relation to TB diagnosis and treatment completion. Those were

1. Six months prior to diagnosis of TB
2. One week prior to diagnosis of TB
3. One week after diagnosis of TB
4. During IP: during the last week of Intensive phase of treatment
5. During CP: during the mid period of the continuation phase of treatment
6. On completion of treatment
7. Three months after the treatment
8. Six months after the treatment

I anticipated that recall might become a hurdle. But once I started interviewing the patients I found that most of the patients were able to report smoking behavior during the times queried because TB diagnosis and treatment were major landmarks in their life.

2.7.2 Secondary data:

Information on several variables was obtained from the patient treatment card which was available in the corresponding health facility. Details about type of TB, type of patient, duration for sputum conversion, treatment category, duration of treatment, treatment outcome and any significant additional information noted on the TB treatment card were collected.

2.8 Study tools:

1. Semi structured interview schedule:

   Pre-tested and translated to Kannada, the local language.

2. TB treatment cards

2.9 Outcome Variable:

Patterns of smoking among TB patients at different time points.

2.9.1 Measurement of outcome variable: Self reported smoking status by TB patients.

2.9.2 Definitions of outcome variables:[58]

All the ever smokers were asked about their tobacco use status at each eight time points in relation to diagnosis and completion of treatment. They were categorized into three types at each reference time point.

1. Persistent smoker: if the person had never quit smoking from the time of diagnosis to the reference point in question;

2. Quitter if the person had quit smoking from the previous reference point to the focal reference point;

3. Relapsed smoker if the person had resumed smoking after having quit for a period of time captured by any of the previous reference points.

Finally at six months after completion of treatment (8^{th} point) ever smokers were grouped into three groups. They were

1. Persistent smoker: continued smoking even after diagnosis and never quit smoking

2. Permanent quitter: quit smoking permanently after diagnosis

3. Relapsed smoker: if the person had resumed smoking after having quit for a period of time captured by any of the previous reference points.

2.9.3 Inclusion criteria:

Sputum positive and sputum negative pulmonary tuberculosis cases and extra-pulmonary tuberculosis patients who completed the treatment during last two quarters in 2007.

2.9.4 Exclusion criteria:

The patients below 18 years, female patients, transferred-out cases (other districts), died patients.

2.10 Measurement and relevance of predictor variables:

1. Age: To assess the relation between age and pattern of quitting and relapse of smoking. Age was assessed by self reported age by the participant in completed years but not collected from treatment cards as I observed variations in age entered in the treatment cards and reported age by participants.

2. **Marital status**: Data were collected to analyze its influence on smoking prevalence as self reported current marital status at the time of interview. It was categorized into Unmarried (never married) and married (ever married that includes married with spouse, separated, divorced and widowed) for further analysis.

3. **Household size**: The actual number of people who shared the same kitchen in the last six months was taken as the number of people living in the same house. This information was used to calculate average monthly household expenditure.

4. **Monthly house hold expenditures on food and non food items:** This data were collected to calculate the average monthly household expenditure which is an indirect estimate of participant's economic status.

Average monthly household expenditure =

$$\frac{\text{Total monthly household expenditures on food +non food items}}{\text{House hold size}}$$

5. **Residence**: Life style, social values for tobacco use and consumption pattern widely varies across rural and urban dwellers which influences on pattern of smoking. Data were collected on locality of participant after confirming his permanent address from treatment card.

6. **Years of schooling**: Knowledge, attitude and perception were greatly determined by education which in turn influences tobacco use behavior. Since TB patients are known to acquire low education status, I collected information on education as continuous variable

(self reported completed years of schooling). Later they were grouped as literates and illiterates.

7. **Occupation:** Some occupation requires more alertness, awakening at night. Often times it is perceived that smoking helps while at work and used as a relaxing tool in between and end of hard work. Occupation was grouped into unskilled labor (also included daily wage worker in private informal sector), skilled labor (also included employees of government and private formal sector and petty shop keeper), farmer who does agricultural activities in his own land, unemployed (includes able to work, unable to work and retired persons).

8. **Type of family**: family members smoking status, structure and values of family can influence smoking behavior. Participants were grouped as nuclear and joint family members based on their self reported family structure. A family was grouped as nuclear if married participant was staying only with his wife and children and in case of unmarried if he was staying with his parents and unmarried brothers and sisters. A family was grouped as joint or extended if anybody other than participant's wife and children also stayed with him and in case of un married participant if he was staying with married sister or married brother or anyone other than parents.

9. **Details of TB treatment**: Type of TB disease, severity, symptoms, duration of treatment, and category of treatment can influence smoking pattern. Data were collected from patient' treatment card.

10. **Co-morbidity**: Presence of chronic disease can influence smokers to quit either by its symptoms or due to physician's disease specific messages. Also it can affect access and affordability to tobacco products in case of physically challenged and stroke patients. Self reported co- morbidity and its duration were collected.

11**. Alcohol consumption:** Alcohol increases craving for nicotine among tobacco users and smoking has been reported to be higher among alcohol users compared to non-users. It hampers quitting efforts. This information was captured by self reported consumption of alcoholic drinks such as beer, whisky, rum, gin, brandy, toddy, or arrack in the last one month.

12. **Use of smokeless tobacco**: Many times patients substitute smoking with smokeless tobacco while quitting. Self reported consumption of any form of chewing tobacco like ghutka, mava, chaini- khaini, Madhu, beetle quid with tobacco leaves and snuff were included.

13. **Quantity of smoking**: Tobacco use dependence depends on quantity of smoking and quantity of tobacco used might influence quitting tobacco. Self reported numbers of cigarettes and bidis smoked were numerically added together to obtain an aggregate score of the quantity smoked daily though data were collected separately for bidis and cigarettes. While estimating mean quantity of smoking, quantity smoked by non daily smokers was also included by converting their per week quantity into per day quantity though data were collected separately for daily and non-daily smokers.

14. **Family members smoking status**: *S*elf reported current smoking status of any family member living with the participant was collected.

15. **Friend's smoking status**: Smoking is a social behavior. Peer influence is one of the major factors which determine the smoking behavior. Where smoking is accepted in friends, quitting is unlikely and when they quit relapse will be quite often. Data were collected by self reports on current smoking status of any friends whom the participant considered as close ones.

16. **Co-workers smoking status**: Self reported current smoking status of coworkers.

17. **Type of DOTS provider**: Since the DOTS providers are the one who will be in regular touch with patients throughout the treatment they can influence the patients by their own personal behavior, by cessation advices and through commitments. Data were collected form treatment card which were confirmed by patient.

18. **Smoking cessation advice**: Health care interaction is an opportunity to change the tobacco use behavior of a patient as the patient is receptive at that time to any advice given by the health professional which is likely to change his risky behavior. Participants were asked about cessation advice in terms of when they received the advice in relation to TB treatment, which health professional gave the message and the type of cessation message they received.

19. **Post treatment anti smoking advice**: Follow up cessation advice after completion of TB treatment may help quitters to stay abstinent and prevent relapse smoking. Data were collected by self reported visit to any physician for TB related or any other physical complaints and whether or not they received any cessation message from them.

20. **Family members quit smoking advice**: Family members like wife, children, and parents can have significant influence on smoking pattern. Information gathered by self reported anti smoking advice received from family members.

21. **Perception and Knowledge**: Asking questions about their knowledge regarding link between tobacco use and various illnesses and in particular, with regard to relapse of TB was important. Perceived quantity of smoking which can cause relapse of TB and also safe level for a TB patient in different stages was assessed by asking unprompted questions.

22. **Craving after initial quitting**: Many patients relapse to smoking due to craving, and it can continue for much longer after quitting due to conditioning. Information was

collected by asking patients whether he had suffered due to strong urge to smoking after quit. This question was asked only to permanent quitters and relapsed smokers.

23. **Withdrawal symptoms at the time of quitting**: Abstinence usually results in a period of discomfort, with recognized symptoms which leads to strong craving for smoking. Patients asked whether they had any such symptoms after quitting. This question was asked only to initial quitters.

24. **Factors motivated to quit**: Only initial quitters were asked with an open ended structured question to tell about salient factors which prompted them to quit and later it was coded for analysis.

25. **Reasons for restarting smoking**: Only relapsed smokers were asked about the reasons, for which they restarted smoking, to know more in depth qualitative reasons for relapse.

26. **Readiness to quit**: This was asked to both persistent smokers and relapsed smokers who were current smokers at the end of study period, to know their readiness to quit which is a starting point of transition from being an established smoker to initiating cessation.

27. **Reasons for wanting to quit**: This information may give an input to develop culturally appropriate cessation interventions as well as it may throw a light on lack of reasoning to quit among current smokers. Information was collected by asking the question as to why they want to quit.

2.11 Data storage and Statistical analysis:

All the information collected from the respondents was checked before data entry. Data entry was done through Epidata 3.1 version. Data cleaning was done before proceeding to

the analysis. Survey data were analyzed using SPSS 15.0 version statistical software program.

Descriptive statistical analyses were performed to find out prevalence of any form of tobacco use, patterns of smoking and cessation advice received by the patients.

Outcome variable in my study was mutually exclusive three groups namely permanent quitter, relapsed smoker, persistent smoker. For analysis purpose they were grouped into two combinations. They were

1. Permanent quitter and relapsed smoker- To identify the predictors for relapse.

2. Persistent smoker and Initial quitters: Initial quitters include both permanent quitter and relapsed smokers as both of them had quit smoking initially at the time of diagnosis of tuberculosis. This comparison was to know the predictors for initial quitting.

Bivariate analysis was performed between above combinations and relevant predictors like socio-demographic characteristics, quantity of smoking, smokeless tobacco use, co-morbidity, type of DOTS provider, and type of quitting message, perception and knowledge. Chi square test was done to compare proportions between two groups and Independent sample T test to compare means. Forward stepwise multiple logistic regression analysis was done to identify independent predictors of smoking relapse and a p value <0.05 was considered statistically significant.

2.12 Ethical considerations:

1. Institutional review board (IRB) approval was obtained from the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

2. Before administering the survey, I have explained the purpose of the study to all patients.

3. The voluntary nature of participation and the anonymous and confidential nature of the interview schedules were strongly emphasized.

4. Written informed consent from each patient was taken individually.

5. It was assured to the respondents that confidentiality will be maintained regarding the information given by all the respondents which was in the safe custody of principal investigator and were used only for the research purposes.

6. At the end of the study, tobacco cessation advice was given to encourage persistent and relapse smokers to quit and for permanent quitters to stay abstinent from smoking.

7. Official permission from District Health Officer, District TB Officer, Medical officers-TB Control and local medical officers of the peripheral health institutions were taken.

CHAPTER 3

Results

In this chapter, I have presented the results of statistical analysis for the data of 202 former male tuberculosis patients. But II, III, and IV part includes further analysis confined to only 103 subjects who were current smokers at six months before diagnosis.

First part: Sample characteristics and prevalence of different forms of tobacco use among study subjects are given in the first part.

Second part: includes descriptive analysis of smoking status, quantity of smoking, smoking relapse by type of DOTS provider, smokeless tobacco use across eight study points.

Third part: includes type and patterns of smoking cessation advice received by them.

Fourth part: Results of bivariate and multivariate analysis for predictors of smoking relapse and initial quitting are given in the fourth part.

3.1 Sample Characteristics and prevalence of tobacco use (n=202):

This part of the chapter explains the sample characteristics of male TB patients by smoking status at six months prior to diagnosis.

3.1.1 Age, education and occupation related characteristics:

Mean age of the study subjects was 48.1±15.6 years. Age range was 18 to 80years. Nineteen percent of TB patients were current smokers below the age of 50 years and about a third of TB patients were current smokers above the age of 50 years compared to only three percent never smokers aged above 50 years.

Mean years of schooling was 4.5±3.7years. One third of TB patients were literate current smokers but only two percent of the patients were illiterate never smokers.

Table 3.1 Age, education and occupation related characteristics 2008 (n = 202)

Characteristics	Current Smoker n (%)	Former Smoker n (%)	Never Smoker n (%)	Total n (%)
Age group				
18-49	39 (19.3)	21 (10.4)	43 (21.3)	103 (51)
50-80	64 (31.7)	29 (14.4)	6 (3)	99 (49.0)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
Education				
Literates	67 (33.2)	39 (19.3)	45 (22.3)	151 (74.8)
Illiterates	36 (17.8)	11 (5.4)	4 (2)	51 (25.2)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
Occupation				
Unskilled laborer	42 (20.8)	21(10.4)	18 (8.9)	81 (40.1)
Skilled laborer	16 (7.9)	8 (4)	11 (5.4)	35 (17.3)
Farmer	12 (5.9)	4 (2)	4 (2)	20 (9.9)
Unemployed	28 (13.9)	15 (7.4)	9 (4.5)	52 (25.7)
Others*	5 (2.5)	2 (1)	7 (3.5)	14 (6.9)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
*Others-Government/private formal employees and petty shop keepers				

Source: Primary survey, 2008 Udupi

Two fifth of the patients were unskilled laborers. About a quarter of patients were unemployed. About a fifth of the patients were currently smoking unskilled laborers. Fourteen percent of study subjects were unemployed current smokers. Two percent of the patients were farmers who never smoked.

3.1.2 Locality, marital status and type of family related characteristics:

Most of the TB patients were rural residents. Almost half of the patients were rural resident current smokers. Only six percent of patients were urban resident current smokers.

About three quarters of patients were currently married. Nearly 42 percent of patients were married current smokers and 11 percent were married never smokers. Only seven percent were never married current smokers. There were no divorced or separated patients in my sample. Thirty one percent of patients were current smokers living in joint family. Indirect estimation of economic status revealed that current smokers were poorer than other two groups.

Table 3.2 Locality and other related characteristics of study subjects 2008 (n = 202)

Characteristics	Current Smoker n (%)	Former Smoker n (%)	Never Smoker n (%)	Total n (%)
Locality				
Urban	12 (5.9)	5 (2.5)	8 (4)	25 (12.4)
Rural	91 (45)	45 (22.3)	41 (20.3)	177 (87.6)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
Marital Status				
Currently married	85 (42.1)	38 (18.8)	23 (11.4)	146 (72.3)
Never married	14 (6.9)	7 (3.5)	26 (12.9)	47 (23.3)
Widower	4 (2)	5 (2.5)	__	9 (4.5)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
Type of Family				
Nuclear	41 (20.3)	25 (12.4)	20 (9.9)	86 (42.6)
Joint/Extended	62 (30.7)	25 (12.4)	29 (14.4)	116 (57.4)
Total	103 (51)	50 (24.8)	49 (24.3)	202 (100)
HH expenditure(SD)* (Range**)**	832.2±570.1 (220-4500)	998.3±555.6 (222-2500)	918.3±493 (400-2500)	892.9±551.4 (220-4500)
*Mean monthly average house hold expenditure				

Source: Primary survey, 2008 Udupi

3.1.3 Morbidity related sample characteristics:

About four fifth of the patients had pulmonary disease. Forty two percent of TB patients who had pulmonary disease were current smokers. Only nine percent of the patients had extra-pulmonary disease and were current smokers.

Table 3.3 Morbidity related sample characteristics 2008 (n = 202)

Characteristics	Current Smoker n **(%)**	Former Smoker n (%)	Never Smoker n (%)	Total n (%)
Type of disease				
Pulmonary	85(42.1)	44(21.8)	35(17.3)	164(81.2)
Extra-pulmonary	18(8.9)	6(3)	14(6.9)	38(18.8)
Total	103 (51)	50(24.8)	49(24.3)	202(100)
Outcome				
Cured	68(33.7)	34(16.8)	30(14.9)	132(65.3)
Treatment completed	35(17.3)	16(7.9)	19(9.4)	70(34.7)
Total	103 (51)	50(24.8)	49(24.3)	202(100)
Presence of chronic disease (%)	30(14.9)	22(10.9)	11(5.4)	63(31.2)
Source: Primary survey, 2008 Udupi				

Thirty one percent of the study subjects were having co morbidities like heart disease, hypertension, diabetes, asthma and other disabilities. Fifteen percent of the TB patients were current smokers who also had co morbidities.

3.1.4 Prevalence of different forms of tobacco use:

Of the 202 study subjects, 178 (88.1%) were ever tobacco users, only 26 (12.9%) had quit tobacco use six months before the diagnosis of TB.

Of the 202 study subjects, 109 (55.1%) were ever chewing tobacco users, 27 (13.6%) had quit chewing tobacco use six months before diagnosis. Thirty five (17.7%) were ever snuff users and, 26 (13.1%) had quit snuff use six months before diagnosis.

Of the 202 study subjects, 153 (75.7%) were ever smokers and 103 (51%) were current smokers 6 months before the diagnosis.

The prevalence of various types of tobacco consumed by the remaining 152 tobacco users at different time points covered by the study is provided in Table 3.4

Table 3.4 Forms of tobacco use among male TB patients at eight time points 2008

Current tobacco use	Any form of tobacco use n=202		Smoking n=202		Chewing n=198		Snuff use n=198	
	n	%	n	%	n	%	N	%
6 months before diagnosis	152	75.2	103	51	82	41.4	9	4.5
1week before diagnosis	137	67.8	79	39.1	78	39.4	8	4.0
1 week after diagnosis	39	19.6	20	9.9	18	9.1	4	2.0
During IP*	35	17.6	16	7.9	18	9.1	4	2.0
During CP**	39	19.6	19	9.4	19	9.6	4	2.0
On completion of treatment	44	22	22	10.9	21	10.6	5	2.5
3 months after treatment	92	45.5	41	20.3	54	27.3	9	4.5
6 months after treatment	106	52.5	46	22.8	63	31.8	11	5.6
*during last week of intensive phase, **during mid period of continuation phase								

Source: Primary survey, 2008 Udupi

3.2 Descriptive analysis on current smokers:

In this part descriptive analysis on current smokers will be based on smoking status at six months after completion of treatment.

3.2.1 Smoking status of male TB patients at each time points:

Of the 103 current smokers, 97 (94.2%) were daily smokers and 6 (5.8%) were non-daily smokers at six months before diagnosis. Eighty nine (86.4%) subjects smoked only bidis, 10 (9.7%) smoked only cigarettes and only four (3.9%) patients were smoking both type.

Table 3.5 Smoking status of male TB patients who had smoked at eight time points 2008 (n=103)

Time points	Persistent Smoker		Relapsed Smoker		Quitter
	Daily n (%)	Non Daily n (%)	Daily n (%)	Non Daily n (%)	n (%)
6 months before diagnosis	97(94.2)	6(5.8)	--	--	---
1week before diagnosis	78(75.7)	1(1.0)	--	--	24(23.3)
1 week after diagnosis	19(18.4)	1(1.0)	--	--	83(80.6)
During IP*	14(13.6)	1(1.0)	1(1.0)	--	87(84.5)
During CP**	13(12.6)	1(1.0)	4(3.9)	1(1.0)	84(81.6)
On completion of treatment	13(12.6)	1(1.0)	6(5.8)	2(1.9)	81(78.6)
3 months after treatment	13(12.6)	1(1.0)	24(23.3)	3(2.9)	62(60.2)
6 months after treatment	13(12.6)	1(1.0)	30(29.1)	3(2.9)	56(54.4)
*during last week of intensive phase, **during mid period of continuation phase					

Source: Primary survey, 2008 Udupi

Table 3.5 highlights the smoking history of the 103 current smokers at eight different time points before, during and after TB treatment. Nearly 24 (23.3%) patients had quit one week before being diagnosed with TB, another 59 (57.3%) had quit within one week of diagnosis and another 5 (4.9%) had quit by the end of Intensive phase and last one patient had quit during continuation phase of treatment. Of 89 patients who initially quit smoking, five (5.6 %) of them relapsed during treatment, three (3.4%) relapsed on

completion of treatment and remaining 25 (28.1%) relapsed within six months after completion of the treatment. During the treatment period, there were only 14 (13.6%) persistent smokers and 89 (86.4%) initial quitters. By the end of the study period, the 89 initial quitters had converted to 33 (37.1%) relapsed smokers and 56 (62.9%) permanent quitters. Six months after completion of treatment, there were 13.6 percent persistent smokers, 32 percent relapsed smokers and 54.4 percent permanent quitters.

3.2.2 Quantity of smoking:

The mean number of sticks smoked daily 6 months before diagnosis by cigarette-only smokers was 7.6±7.1, by bidi-only smokers it was 21.5±13.7 and by smokers of both tobacco products it was 27.5.

Table 3.6 Quantity of smoking of male TB patients at eight time points by smoking status 2008 (n=103)

Time Points	Persistent Smokers n = 14		Relapsed Smokers n = 33		Permanent Quitters n = 56		Total n= 103
	Mean (SD)	Median Sticks	Mean (SD)	Median Sticks	Mean (SD)	Median Sticks	Mean (SD)
6 months before diagnosis	25.9 (15)	25.0	20.9 (16.3)	15.0	17.4 (12.4)	22.5	19.7 (14.3)
1week before diagnosis	21.0 (15.5)	18.5	17.4 (16.9)	10.0	13.2 (10.9)	10.0	16.1 (14.3)
1 week after diagnosis	6.0 (6.1)	5.0	4.3 (1.2)	5.0	6.7 (4.7)	5.0	5.9 (5.3)
During IP*	5.2 (6.4)	3.0	3.0 (2.8)	3.0	__	__	5.0 (6.1)
During CP**	6.3 (8.2)	2.5	2.3 (1.5)	3.0	__	__	5.2 (7.2)
On completion of treatment	6.7 (7.9)	3.5	2.1 (1.4)	2.5	__	__	5.1 (6.7)
3 months after treatment	8.8 (8.2)	5.0	5.2 (6.4)	4.0	__	__	6.5 (7.2)
6 months after treatment	9.3 (8.9)	5.0	6.2 (6.5)	4.0	__	__	7.2 (7.4)
*during last week of intensive phase, **during mid period of continuation phase							

Source: Primary survey, 2008 Udupi

Mean number of sticks per day smoked by 103 current smokers at six months before diagnosis was 19.7. Quantity of smoking decreased significantly one week after the

diagnosis. Overall there was a reduction in the quantity of smoking between pre and post treatment and it showed an increasing trend after completion of treatment.

Quantity smoked by persistent smokers was highest and that of permanent quitters was lowest during six months before diagnosis. All the smokers had reduced quantity of smoking after being diagnosed as having TB. Permanent quitters had stopped smoking totally in the intensive phase. But persistent smokers had increased their quantity of smoking from continuation phase itself compared to relapsed smokers who increased after completion of the treatment.

3.2.3 Time points of smoking relapse by type of DOTS provider:

Table 3.7 Time points of smoking relapse by type of DOTS provider 2008

Time points	Type of DOTS provider		
	Health staff (n=16) n (%)	Non health Staff (n=17) n (%)	Total (n=33) n (%)
During Intensive Phase	1 (6.3)	—	1(3)
During Continuation Phase	3 (18.8)	1 (5.9)	4 (12.1)
On Completion of Treatment	2 (12.5)	1 (5.9)	3 (9.1)
3 months After Treatment	7 (43.8)	12 (70.6)	19 (57.6)
6 months After Treatment	3 (18.8)	3 (17.6)	6 (18.2)
Total	16 (100)	17 (100)	33 (100)

Source: Primary survey, 2008 Udupi

Table 3.7 Presents data on when some of the initial quitters relapsed to start smoking again, with respect to type of DOTS provider they had during treatment.

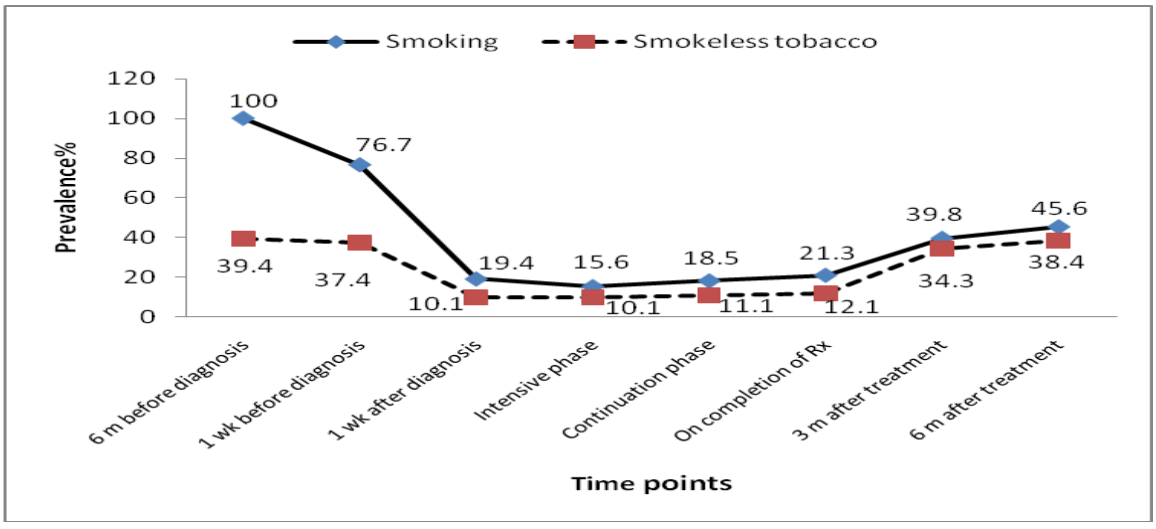
Of the 33 TB patients who relapsed, 16 had health staff DOTS providers and the remaining 17 had non-health staff DOT providers. Almost three fourth (75.8%) of all relapses happened after the completion of the treatment. Only a quarter of relapses occurred during treatment and on completion of treatment.

About 62 percent of the relapses among patients whose DOTS providers were health staffs and 88 percent of relapses among patients whose DOTS providers were non-health staffs occurred after completion of treatment. Nearly 12 percent of the relapses among patients whose DOTS providers were non health staffs and about 38 percent of relapses among patients whose DOTS providers were health staffs occurred during and on completion of the treatment. But these differences were statistically not significant. (P value=0.085)

3.2.4 Smokeless tobacco (SLT) use pattern:

Ever use of smokeless tobacco among TB patients who were current smokers at six months before diagnosis was 57.6 percent. In this part, prevalence of SLT use and smoking among current smokers was compared graphically across eight time points.

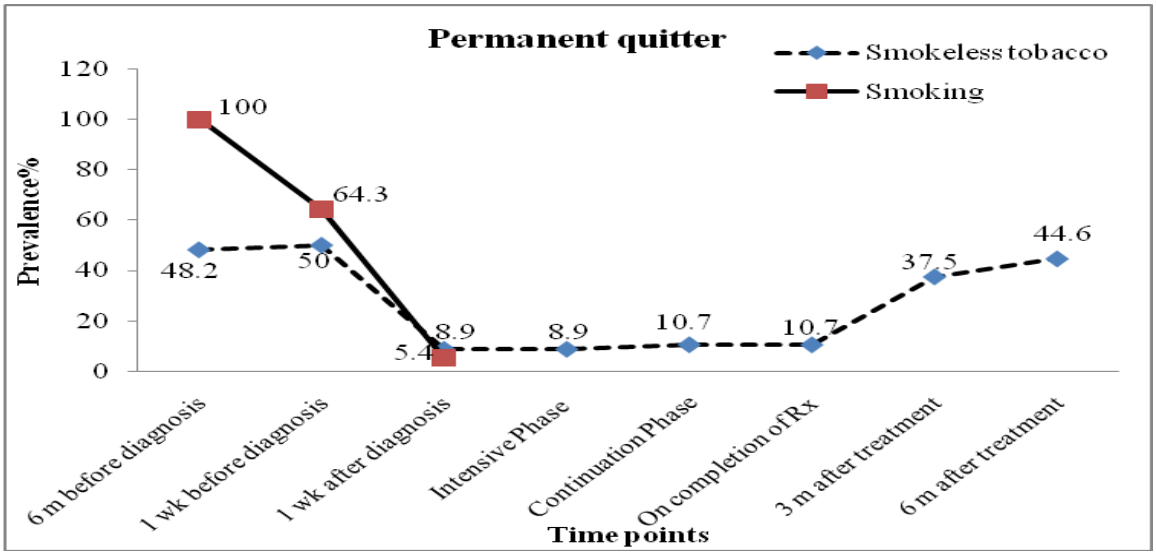
Graph 3.1 Pattern of smokeless tobacco use among current smokers (n=99)



Of 103 current smokers, 39.4 percent were using smokeless tobacco currently at six months before diagnosis. There was a reduction in their consumption after diagnosis, followed by an increase from continuation phase onwards. By the end of study period it reached almost the six months before the diagnosis level.

3.2.4a Pattern of smokeless tobacco use among permanent quitters:

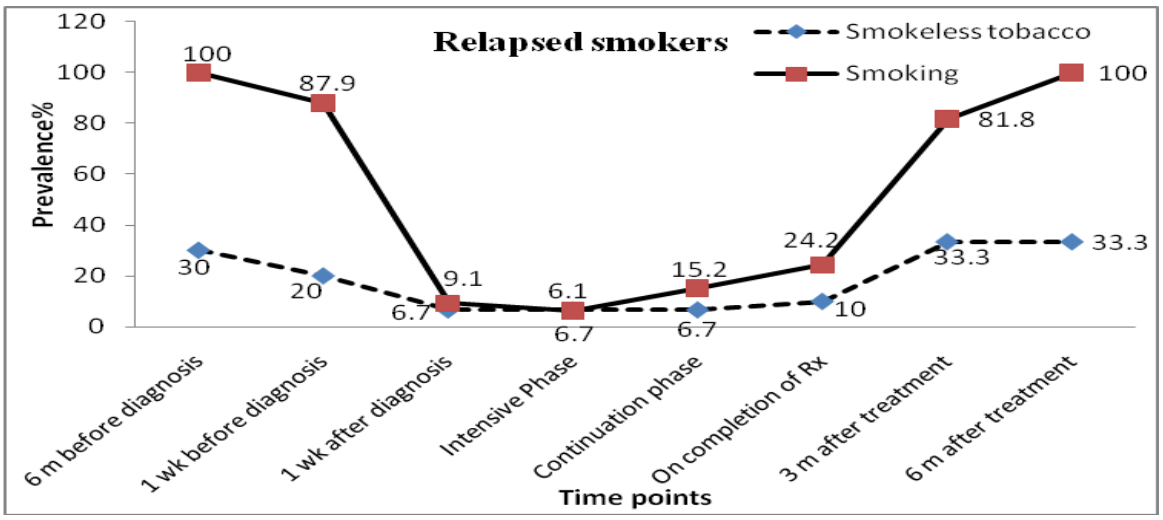
Graph 3.2 Pattern of smokeless tobacco use among permanent quitters (n=56)



Permanent quitters had the prevalence of smokeless tobacco about 48.2 percent which was highest compared to relapsed and persistent smokers. Among permanent quitters (n=56), there was an increase in consumption one week before the diagnosis followed by drastic reduction after diagnosis which started increasing from continuation phase onwards. Half the users among permanent quitters restarted and about 38 percent of non users had newly started the smokeless tobacco use by the end of study period.

3.2.4b Smokeless tobacco use pattern among relapse smokers:

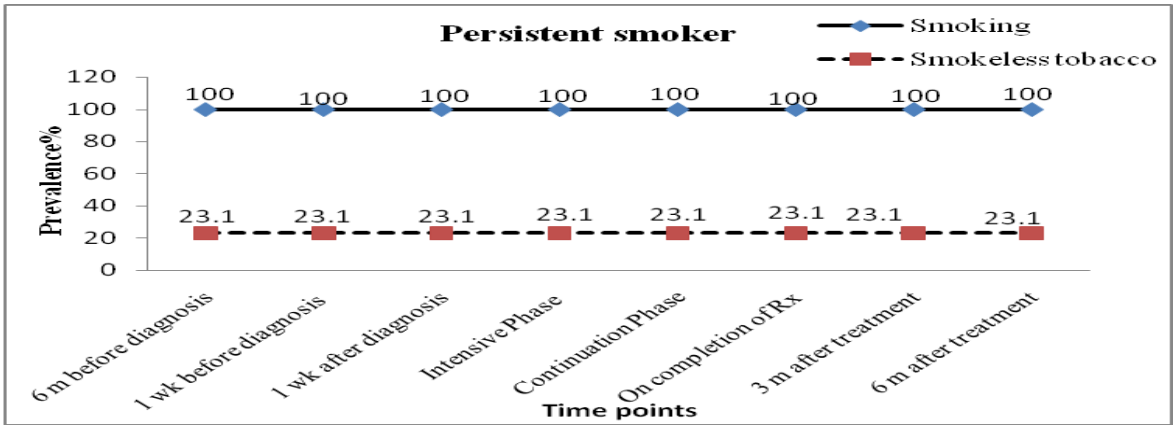
Graph 3.3 Smokeless tobacco use pattern among relapse smokers (n=30)



Among relapsed smokers, the reduction in consumption of smokeless tobacco during treatment was followed by an increasing trend on completion of treatment.

3.2.4c Smokeless tobacco use pattern among persistent smokers:

Graph 3.4 Smokeless tobacco use pattern among persistent smokers (n=13)



Prevalence of smokeless tobacco among persistent smokers remained constant before, during and after completion of the treatment.

3.3 Type and pattern of cessation advice:

Descriptive analysis of types and patterns of smoking cessation messages reported to be received from health professionals and DOTS providers by male TB patients who were current smokers (n=103) at six months before diagnosis are included in this part.

3.3.1 Pattern of cessation advice reported to be received during treatment

Table 3.8 Advice reported to be received at different phases of treatment 2008

Characteristics	Persistent smoker (n=14) n (%)	Relapsed smoker (n=33) n (%)	Permanent quitter (n=56) n (%)	Total (n=103) n (%)
The beginning of treatment	14 (100)	31 (93.9)	54 (96.4)	99 (98.0)
The beginning of CP*	11 (78.6)	27 (81.8)	36 (64.3)	74 (73.3)
During the CP*	11 (78.6)	27 (81.8)	36 (64.3)	74 (73.3)
The end of treatment	11 (78.6)	28 (84.8)	39 (69.6)	78 (77.2)
*Continuation phase of the treatment				

Source: Primary survey, 2008 Udupi

At the beginning of the treatment, all the TB patients who were smokers received advice to quit smoking. In subsequent phases of treatment more than 70 percent of all smokers reported receiving the cessation advices. Throughout the treatment, relapsed smokers were used to get cessation advice more number of times compared to other two groups.

3.3.2 Pattern of cessation advices from different health professionals:

Almost 85.6 percent of rural TB patients reported receiving cessation advice by primary care physicians. Only 56.7 percent of staff nurses and pharmacists of peripheral health institutes gave cessation advices. Overall more than 90 percent of patients reported receiving messages by any physician.

Table 3.9 Advice reported to be received from different health professionals 2008

Characteristics	Persistent smoker (n=14) n (%)	Relapsed smoker (n=33) n (%)	Permanent quitter (n=56) n (%)	Total (n=103) n (%)
Any Physician	12(85.7)	31(93.9)	52(92.9)	95(93.1)
**DH/TH physician	5(35.7)	18(54.5)	26(46.4)	49(48)
PHI physician*	11(78.6)	25(92.6)	41(83.7)	77(85.6)
DH/TH nurse/pharmacist	1(7.1)	5(15.2)	7(12.5)	13(12.7)
PHI nurse/pharmacist*	6(42.9)	15(55.6)	30(61.2)	51(56.7)
Health worker	12(85.7)	25(75.8)	44(78.6)	81(79.4)
TB health worker	9(64.3)	22(68.8)	24(42.9)	55(53.9)
DOTS provider	10(71.4)	25(75.8)	36(64.3)	71(69.6)

*Denomitor is only rural subjects as they get registered for treatment only in corresponding primary health institutes irrespective of their place of diagnosis
** District hospital/Taluk hospital

Source: Primary survey, 2008 Udupi

Half of all patients received advice from physicians working at taluk and district hospitals (most of the patients get diagnosed at peripheral institutions so they need not go to referral hospitals. So only patients who were urban residents and those rural residents who were diagnosed at referral centers got advice from such physicians).

Nearly 80 percent of patients got advices from health workers (junior and senior health assistants (male and female)). Only 55 (53.9%) patients got advice from TB health workers (senior treatment supervisors) who visit all patients of their TB unit.

3.3.3 Pattern of cessation advices from DOTS Providers:

Overall 50 (48.5%) DOTS providers were health professionals and 53 (51.5%) were non health professionals.

Table 3.10 Distribution of DOTS providers (n=103) 2008

Type of DOTS provider	n (%)
AWW	33 (32.0)
Private Practitioner	1 (1.0)
MPW	15 (14.6)
Pharmacist	2 (1.9)
Staff Nurse	27 (26.2)
Volunteers	20 (19.4)
Family members	—
Others(Lab technician)	5 (4.9)

Source: Primary survey, 2008 Udupi

Overall when the DOTS providers were health staff members, 37 (74%) of the patients received advice and when DOTS providers were non health staffs, 34 (65.4%) reported of receiving cessation advice. (P value-0.344)

3.3.4 Nature of cessation advice received during treatment:

All patients were asked if any health staff had asked about their smoking status during any of their visit to health centre from the time of diagnosis of TB. All of those who smoked at six months before the diagnosis were then asked whether they received any cessation advice from any health professional.

Only two of 103 TB patients reported not receiving cessation advice from any of the health professionals or DOTS providers. Otherwise nature of cessation messages received by majority of the patients was TB specific.

Table 3.11 Nature of cessation advice received during treatment 2008

Characteristics	Persistent smoker (n=14) n (%)	Relapsed smoker (n=33) n (%)	Permanent quitter (n=56) n (%)	Total (n=103) n (%)
None	__	1 (3)	1 (1.8)	2 (2.0)
Advice to quit without any message	1 (7.1)	2 (6.1)	__	3 (2.9)
Advice with general message	__	__	1 (1.8)	1 (1.0)
Advice with TB specific message	13 (92.9)	29 (87.9)	54 (96.4)	96 (94.1)

Source: Primary survey, 2008 Udupi

3.3.5 Content analysis of the messages:

TB specific messages- messages that smoking aggravates TB, reduces effectiveness of TB treatment. These messages were very superficial and not advised systematically. Common most messages reported were 1) while smoking, drugs won't work 2) smoking does not suit with this disease 3) to get cured of TB, you have to stop it 4) at least you stop till the TB gets cured.

General messages to quit- common messages were 1) stop smoking 2) stop smoking completely 3) smoking is not good for your health 4) stop smoking if you want your cough to be reduced.

3.4 Results of bivariate and multivariate analysis:

Results of bivariate analysis to identify predictors of smoking relapse:

Outcome variable was relapse of smoking. Non relapsed smokers were permanent quitters. Total sample in this analysis (89) = Relapsed smokers (33) +Non-relapsed or permanent quitters (56).

3.4.1 Socio-demographic predictors and relapse of smoking:

Table 3.12 Socio-demographic predictors and relapse of smoking 2008

Variables	n	Relapse	Non relapse	p value
Age group				
18-54	45	18 (40)	27 (60)	0.56
>54	44	15 (34.1)	27 (65.9)	
Education				
Literate	60	26 (43.3)	34 (56.7)	0.08
Illiterate	29	7 (24.1)	22 (75.9)	
Occupation				
Unskilled	36	17 (47.2)	19 (52.8)	0.21
Skilled/self employed	29	10 (34.5)	19 (65.5)	
Unemployed	24	6 (25.0)	18 (75.0)	

Source: Primary survey, 2008 Udupi

Prevalence of relapse of smoking was higher among younger age group (18-54) when compared to patients who were above 54 years. But the difference was not statistically different.

From the cross tabulation it looks that literate patients had 43 percent of relapsed smokers compared 24 percent among illiterates. But it was statistically not significant.

Unskilled laborers had higher proportion of relapsed smokers compared skilled/self employed and unemployed patients. But this difference in proportions of relapse between occupation groups was statistically not significant.

3.4.2 Behavioral factors and relapse of smoking:

Among the participants who were ever users of any form of smokeless tobacco had only half the prevalence of relapsed smokers among never users of smokeless tobacco. This difference was statistically different.

Proportion of relapsed smokers among patients who were not using smokeless tobacco one week before diagnosis was more than two times the proportion found among patients who were using smokeless tobacco at that time. This difference in prevalence was statistically significant.

Table 3.13 Behavioral factors and relapse of smoking 2008

Variables	n	Relapse	Non relapse	p value
Ever use of smokeless tobacco (SLT)				
Yes	54	14 (25.9)	40 (74.1)	0.02
No	32	16 (50.0)	16(50.0)	
Use of SLT one week prior to diagnosis				
Yes	34	6 (17.6)	28 (82.4)	0.01
No	52	24 (46.2)	28 (53.8)	
Current Alcohol use				
Yes	33	14(42.4)	19 (57.6)	0.42
No	56	19 (33.9)	37 (66.1)	

Source: Primary survey, 2008 Udupi

Among the users of alcoholic drinks relapse rate of smoking was higher when compared to relapse rate among non users of alcoholic drinks but that difference was not statistically significant.

3.4.3 Other people's influence and relapse of smoking:

Higher proportion (43.2%) of relapse of smoking was observed among patients whose coworkers were smokers compared 36.4 percent among those whose coworkers were not smokers. But this difference was not statistically different**.**

Table 3.14 Other people's influence and relapse of smoking 2008

Variables	n	Relapse	Non relapse	p value
Coworkers smoking status				
Yes	44	19 (43.2)	25 (56.8)	0.59
No	22	8 (36.4)	14 (63.6)	
Family members smoking status				
Yes	8	5 (62.5)	3 (37.5)	0.11
No	80	27 (33.8)	53 (66.3)	

Source: Primary survey, 2008 Udupi

Sixty two percent of patients who had smoking family members (those who were living with patient) were relapsed smokers while compared to 34 percent among those patients who did not had smoking family members. This difference was not statistically different.

3.4.4 Type of DOTS provider, cessation messages and relapse of smoking

Table 3.15 Type of DOTS provider and cessation messages, and relapse of smoking 2008

	n	Relapse	Non relapse	p value
Type of DOTS provider				
Health professional	43	16 (37.2)	27 (62.8)	0.98
Non health professional	46	17 (37.0)	29 (63.0)	
Type of cessation message				
TB specific	83	29 (34.9)	54 (65.1)	0.12
Non TB specific	6	4 (66.7)	2 (33.3)	

Source: Primary survey, 2008 Udupi

Those who had health professionals as a DOTS provider during TB treatment had almost same proportion of relapsed smokers as those who had non health professionals as a DOTS provider.

Those who had reported receiving non TB specific smoking cessation advices had higher proportion of relapsed smokers (66.7%) when compared to the proportion (34.9%) among those who reported receiving TB specific cessation messages.

3.4.5 Tobacco dependency related factors and relapse of smoking:

All the initial quitters asked whether they had suffered craving after quitting smoking. Further questions were asked to those who had craving, to know which part of the treatment did they suffered craving most.

Fifty seven percent of patients relapsed to smoking if they had craving during the end of intensive phase of TB treatment. But only 33.3 percent of patients relapsed to smoking if they didn't have craving and this difference was not statistically different.

Fifty four percent of TB patients relapsed to smoking if they reported having craving during continuation phase of treatment compared to 31.3 percent relapsed smokers among patients who did not face craving during that period but it was statistically not significant.

Table 3.16 Tobacco dependency related factors and relapse of smoking 2008

Predictors	n	Relapse	Non relapse	p value
Craving during end of Intensive phase				
Yes	14	8 (57.1)	6 (42.9)	0.09
No	75	25 (33.3)	50 (66.7)	
Craving during CP				
Yes	22	12 (54.5)	10 (45.5)	0.05
No	67	21 (31.3)	46 (68.7)	
Craving after completion of treatment				
Yes	30	20 (66.7)	10 (33.3)	<0.01
No	59	13(22.0)	46(78.0)	
Withdrawal symptoms at the time of quitting				
Yes	36	18 (50)	18 (50)	0.04
No	53	15 (28.3)	38 (71.7)	

Source: Primary survey, 2008 Udupi

Statistically significant higher proportion (66.7%) of patients relapsed to smoking if they had suffered craving after completion of the treatment compared to 22 percent relapse among patients who did not had craving after completion of the treatment.

Fifty percent of those patients who had withdrawal symptoms at the time of quitting relapsed to smoking and it was higher when compared to 28.3 percent of relapse among patients who did not suffer any withdrawal symptoms after quitting. This difference was statistically different.

3.4.6 Time of quitting and relapse of smoking:

TB patients who had quit smoking before the diagnosis due to aggravation of TB symptoms by smoking had low proportion (16.7%) of relapsed smokers when compared to 44.6 percent of relapsed smokers among patients who had quit after diagnosis.

Table 3.17 Time of quitting smoking and relapse of smoking 2008

	n	Relapse	Non relapse	p value
Time of quitting				
before diagnosis	24	4 (16.7)	20 (83.3)	0.02
after diagnosis	65	29 (44.6)	36 (55.4)	

Source: Primary survey, 2008 Udupi

3.4.7 Comparison of means of predictors among relapsed and non relapsed smokers

Number of sticks per day smoked six months and one week before diagnosis by relapsed smokers was higher (20.9 per day and 17.4 per day respectively) compared to the quantity smoked in those periods (17.4 per day and 13.2 per day respectively) by non relapsed smokers which was statistically not significant.

Table 3.18 Comparison of means of predictors among relapsed and non relapsed smokers 2008

Variables	Relapsed smokers n=33	Non relapsed smokers n=56	p value
The number of sticks per day perceived to cause relapse of TB			
Cigarettes/day (SD)	9.9±6.7	6.3±4.9	0.03
Bidis/day (SD)	22.3±15.3	15.1±9.6	0.03
Number of sticks per day smoked before diagnosis			
6months before (SD)	20.9±16.3	17.4±12.4	0.25
One week before (SD)	17.4±16.9	13.2±10.9	0.23

Source: Primary survey, 2008 Udupi

Quantity of smoking perceived to cause relapse of tuberculosis was significantly different among study population. Perceived number of sticks per day required to cause relapse of TB (number of cigarettes and bidis per day were 9.9 and 22.3 respectively) was significantly higher for relapsed smokers compared to quantity perceived (number of cigarettes and bidis per day were 6.3 and 15.1 respectively) by non relapsed smokers.

3.4.8 Multivariate analysis:

Forward stepwise multiple logistic regression analysis was done. In the final model, use of smokeless tobacco one week before diagnosis and craving after completion of treatment were the two important predictors for relapse of smoking.

Other predictors used in the analysis but found to be insignificant were age, withdrawal symptoms at the time of quitting, time of quitting (before or after diagnosis), education,

and current alcohol use (collinearity was checked and no pair of variables found to be significantly collinear)

Table 3.19 Results of multiple logistic regression analysis 2008

Variable name	Adjusted OR	Confidence interval	p value
Smokeless tobacco use one week before	3.45	1.09-10.89	0.035
Craving after completion of treatment	8.45	2.94-24.29	<0.001

Source: Primary survey, 2008 Udupi

People who only smoked were 3.5 times likely to relapse to smoking compared to those who had used both smoking and smokeless tobacco one week prior to diagnosis.

Those who had craving for smoking after completion of treatment was 8.5 times more likely to relapse than who did not suffer craving during that period.

3.4.9. Results of bivariate analysis to identify predictors of initial quitting:

Bivariate analysis was performed with many important predictors which were mentioned earlier, to indentify the significant predictors of initial quitting.

3.20 Results of bivariate analysis to identify predictors of initial quitting 2008

Variable	n	Initial quitters	Persistent smokers	Odds Ratio	Confidence interval	p value
*Perception						
Can be smoked (1-10sticks per day)	24	16 (66.7)	8 (33.3)	1		
Un safe	64	61 (95.3)	3 (4.7)	8.13	(2.1-32.1)	0.001
Smokeless tobacco						
Never use	42	32 (76.2)	10 (23.8)	1		
Ever use	57	54 (94.7)	3 (5.3)	5.63	(1.4-21.9)	0.013
*Perception about risk of smoking while undergoing treatment						

Source: Primary survey, 2008 Udupi

Patients who perceived that smoking is absolutely unsafe while undergoing treatment were 8.13 times likely to quit initially at the time of diagnosis compared to their counterpart.

Ever users of smokeless tobacco were 5.6 times more likely quit initially at the time of diagnosis compared to smokers only group.

CHAPTER 4

Discussion and Conclusion

4.1 Discussion:

In the present study, among 202 former male TB patients surveyed, any form of tobacco use prevalence was 75.2 percent which is similar to the results found in a recent similar study from Kerala by Pradeepkumar et al.[58] Half of the subjects were current smokers at six months before diagnosis. This rate is almost two times higher than that in the general population in Karnataka[3] and it is a point of concern also as tobacco smoking is a potential risk factor for developing pulmonary tuberculosis[33] when two of every five Indian is infected with Mycobacterium tuberculosis.[6] Smoking men were 2.3 times more likely to die from tuberculosis compared to non smokers.[20] In the present study 86 percent of the smokers were predominantly bidi smokers. In a Mumbai cohort study, it was found that mortality rates were 1.78 times higher for bidi smokers compared to non smokers and was concluded that bidi smoking was no less hazardous than cigarette smoking.[43]

Of 103 current smokers at six months before diagnosis, some of them quit even before diagnosis of TB due to aggravation of symptoms by smoking and others had quit as soon as they were diagnosed with TB either due to fear of death or cessation advices by health staffs or physical discomforts. This initial quitting was followed by smoking relapse when they started feeling symptomatically better after 1-2 months treatment. About 37 percent of those who had quit at some point relapsed by six months post treatment. Similar pattern was observed in the study by Pradeepkumar et al.[58] This rate of smoking relapse is really a warning signal as smokers are three times more likely to suffer relapse of TB[46] and also mortality rate from TB is four times higher among smokers compared to non smokers.[19]

Fourteen (13.6%) smokers continued to smoke persistently throughout the study period. This is also a point of concern as smoking was significantly associated with default and failure as compared with success[47] and smokers were more likely to die from any cause during follow-up than ex smokers and never smokers.[38]

A majority of tobacco users significantly reduced the quantity of tobacco they consumed following the detection of TB. Similar pattern was mentioned in another study from Kerala on TB patients.[56] But once they symptomatically became better, the quantity also showed increasing trend though at the end of study period it was much below the pre treatment level.[58]

Many studies have highlighted and advocated for incorporation of tobacco cessation activities in the TB control program.[50,54]

Type and pattern of quit smoking advice received by patients from health professionals in the present study explains why smoking relapse rate was much lower (15%) during treatment compared to post treatment relapse rate (75%). Most of the patients were advised to quit at the beginning of the study and more than 70 percent of smokers received follow up messages at different phases of treatment. During treatment 93percent of patients received advice from any physicians and 89 percent from other health staffs. Almost 94 percent of patients received cessation messages which was TB specific but they have not emphasized smoking as a cause for relapse of TB. Also those advices were not followed up after completion of treatment.

In contrary, the study by Pradeepkumar et al,[58] demonstrated that two third of all smoking relapses occurred during treatment because only half of the patients have received cessation messages during treatment which were TB specific. Messages were mainly received from doctors and such advices were not followed up during subsequent interactions with other health staffs.

Though quantity smoked per day six months before the diagnosis was higher among smokers of present study, the reduction in quantity smoked from pre treatment to post treatment was much higher in present study compared to the study by Pradeepkumar et al.

There was no difference in relapse and quitting rates between the patients who had health staffs or non health staffs as DOTS providers. But the type of DOTS provider was the significant factor found to be associated with smoking relapse in the study by Pradeepkumar et al.[58] Since the TB control program seems to be running well in the present study setting,[6] the involvement of other health staffs as well as DOTS providers was seen more. This may not be true for other settings.

DOTS providers are good resources to give brief cessation interventions as they see TB patients, thrice in a week in intensive phase and once a week during continuation phase of treatment. Capacity building of health staffs to give brief cessation interventions was highlighted by many studies.[22,50,54] Trained DOTS providers are able to give brief cessation intervention during and after completion of treatment up to six months but the ability of non health staff DOTS provider to give cessation interventions should be ascertained by further studies.

In present study, perceptions of risk related to smoking while afflicted with TB significantly varied across different groups of smokers. Persistent smokers perceived less risk of smoking during treatment so they continued to smoke. Perceived quantity of smoking required to cause relapse of TB was much higher for relapsed smokers compared to permanent quitters. Similar other types of perceptions were highlighted in another Kerala study by Thresia et al.[51] Patient's region and culture specific perceptions about smoking and TB are important in brief cessation intervention as reported by the 'Quit tobacco international' which is a tobacco cessation research project, undertaking activities to develop culturally appropriate cessation interventions.[56]

In the present study, craving for smoking was found to be significant factor for smoking relapse as reported earlier. Craving due to conditioning can continue much longer period even after quitting[59] and especially craving after completion of treatment was much more powerful than craving during treatment. Fear of death, cessation advices and aggravation of symptoms by smoking might have reduced craving during treatment. So it is reasonable to opine that if 5 A's approach (Ask, Advise, Assess, Assist, Arrange) by trained health staffs may definitely help patients to cope with craving.[57]

In this study, another important finding emerged was that use of smokeless tobacco was one of the important predictors of different patterns of smoking across different study points. Six months before diagnosis quantity smoked per day from highest to lowest was in the order of persistent smokers, relapsed smokers and permanent quitters, in contrary, prevalence of smokeless tobacco use was in the reverse order. The trend which came out was use of smokeless tobacco as a natural harm reduction or nicotine substitution strategy or as a coping method by many quitters. This trend was seen among permanent quitters who had increased their consumption during one week before diagnosis when their symptoms got aggravated by smoking. Thirty eight percent of permanent quitters and 10 percent of relapsed smokers had newly started using smokeless tobacco after quitting. But all types of smokeless tobacco products contain nicotine, a potent addictive substance and use of it causes variety of cancers in humans.[60]

So all permanent quitters are not really quitters of any form of tobacco use. It was estimated in the present study that only 30 percent (31 of 103 current smokers) were permanent quitters of any form of tobacco use by the end of study period. When prevalence of smoking and smokeless tobacco use was compared between beginning and end of study periods, it was found that there was no reduction in smokeless tobacco use except during treatment. This may be due to less focus on smokeless products by health

staffs while giving cessation advises, patients' perceived relative safeness of smokeless tobacco use while undergoing treatment and also due to shift in consumption pattern for coping craving.

In present study, younger age group and literate patients had more proportion of relapsed smokers. Further analysis revealed that illiterates and higher aged patients were users of both type of tobacco products. So they had a viable coping method to quit smoking permanently by shifting to smokeless tobacco.

In one of the educational series on 'Tobacco and Tuberculosis' it was stated that craving can be very strong, and is very difficult to resist if others in the environment are smoking or if the person is drinking alcohol. So such people can restart smoking.[59] In the present study also smoking relapse was more among alcohol users and those who had smoking co workers or family members. But this observation was statistically not significant may be due to small sample size.

In the present study, it was found that patients who had quit before the diagnosis due to aggravation of symptoms by smoking was more likely to quit permanently than who had quit after diagnosis. This may be because aggravation of symptoms by smoking might have changed the patients' perception about risk of smoking while afflicted with TB and use of smokeless tobacco before diagnosis which did not aggravate the symptoms of TB.

Quantity of smoking was not a significant predictor of smoking relapse in this study. But quantity smoked by persistent smokers was significantly higher compared to permanent quitters at six months before diagnosis.

In this study, withdrawal symptoms at the time of quitting were considered as a proxy for tobacco dependency. It was a significant predictor for smoking relapse only during bivariate analysis. Withdrawal symptoms might have caused craving during early part of treatment period but it does not last longer than 30 days,[59] so we can assume that much of

the craving during continuation phase and post treatment was due to conditioned responses and environmental cues.

4.2 Limitations of this study:

1. Participants were only those former male TB patients who were cured under RNTCP. So patients who were treated at private facilities not included in this study.

2. During data collection, health workers were accompanied to trace the subjects. Though privacy was ensured to all the patients, sometimes patients might have understated the quantity of tobacco use or might have overstated with regard to antismoking message received from the health staff due to their visit.

3. Since this study is primarily a cross-sectional descriptive study, we cannot know the direction of the association.

4. This study excludes female TB patients from participation. Though smoking prevalence among women is very low in Karnataka, it may be higher among female TB patients.

5. Quantity of smokeless tobacco use was not estimated. So patterns of smoking could only be compared with prevalence of smokeless tobacco use

4.3 Strengths of the study:

1. Principal investigator himself conducted all interviews. This eliminated inter-observer variability.

2. This study was community based.

4.4 Conclusions:

1.Current practice of smoking cessation activities in the present study setting has significantly reduced smoking relapse during treatment but much of the relapse occurred within three months post treatment due to lack of follow up cessation messages.

2. Craving for smoking particularly after completion of the treatment was an important cause for smoking relapse among initial quitters.

3. Compared to those who used smoking and smokeless tobacco one week prior to diagnosis of TB the smokers only group was more likely to relapse to smoking.

4. Perception of risk of smoking when affected with TB varied among smokers and played a significant role for persistent smoking and smoking relapse.

4.5 Recommendations:

1. DOTS providers and health staffs should be trained to give effective brief smoking cessation interventions to help patients to cope with craving and to change their harmful perceptions.

2. Since much of the relapse have occurred in first few months of post treatment, all the patients should be given strong quit messages emphasizing the need to remain abstinent to prevent relapse of TB.

3. It was demonstrated in the study that after initial quitting both quantity and prevalence of smoking started increasing once the patient enters continuation phase of treatment. So at this point all the patients can be given a strong cessation intervention by physician apart from intervention by DOTS providers.

4. Additional efforts can be considered in the DOTS program to tackle the shift in the consumption pattern from smoking to smokeless tobacco.

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Annexure - I

Semi-structured interview schedule to assess the smoking status of TB patients at different time points

Treatment Unit Code : ☐ **1= KUNDAPURA; 2= UDULPI ; 3= KARKALA**

Interview Schedule No : ☐

Researcher's Name : ☐

Date: / / **Time:** ☐

SECTION I

1. Name and address : _____

_____

2. Age (in completed years): ☐☐

3. Marital status : ☐

1-Never married 2-Currently married 3 -Widower 4-Divorced

5-Separated 6- Others (please specify)_____

4. Total number of members in the household ☐☐

5. What was your household expenditure on food items in the last month? (in Rupees) ☐☐☐☐☐

6. What was your household expenditure on non- food items in the last month? (in Rupees) ☐☐☐☐☐

7. Residence: 1. Urban 2. Rural ☐

8. How many years of schooling you have completed? (in completed years) ☐☐

9. Occupation ☐☐

1. Government 2. Private Formal 3. Private Informal 4. Professional
5. Business 6 Skilled worker 7. Laborer 8. Farmer
9. Homemaker 10. Student 11. Others (please specify)_____

10. Type of Family: 1. Nuclear 2. Joint /Extended ☐

SECTION II

11. Details of TB treatment: All defined as per the RNTCP guidelines (Transferred out are excluded)

Type of disease	Type of patient	Sputum status at the time of diagnosis	Treatment regimen	Duration of +ve sputum (months)	Treatment		Duration of treatment	Outcome of treatment
					Onset date	Ending date		
Pulmonary	New	Positive	CAT I					Cure
Extra pulmonary	Relapse	Negative	CAT II					Treatment completed
	Failure		CAT III					Failure
	Treatment after default							Defaulted
	Others							Died
								Transferred out

12. Do you have any of the following diseases? If yes, can you give the duration of it?

Sl. No.	Disease Name	Yes = 1 No = 2	Duration
1	Diabetes		
2	High BP		
3	Heart disease		
4	Asthma		
5	Mental illness		
6	Any other disease(specify)_____		

SECTION III

13. Have you ever consumed alcoholic drinks such as beer, whisky, rum , gin, brandy, toddy or arrack in the last one month? 1. Yes 2. No ☐

14. Have you used / using any of the following at any level of use? Tick the appropriate boxes

Type of Tobacco use	Ever used	6 months Before diagnosis	1 week before diagnosis	1 week after diagnosis	During IP	During CP	On completion of treatment	3 months after treatment	6 months after treatment
Smoking									
Chewing									
Snuff									

During IP- During the last week of Intensive phase; During CP- During the mid period of Continuation phase.

15. If smoked at any time, mention the number of sticks used (Cigerette+bidi)

	Daily users		Non-daily users		
	Number per day		Number per day on days of smoking		Number of days of smoking in a week
	Cig	Bidi	Cig	Bidi	
Within 6 months before diagnosis					
1 week before diagnosis					
1 week after diagnosis					
During Intensive phase					
During Continuation phase					
On completion of treatment					
3 months after completion					
6 months after completion					

16. Do the following people smoke?

1. Yes 2. No

a) Family members (those living with you) ☐

b) Friends ☐

c) Co-workers ☐

SECTION IV ☐

17. Who was your DOTS provider?

1. AWW 2. Private practitioner 3.Multi Purpose Worker 4. Pharmacist
5. Staff nurse 6.Volunteers 7.Family member 8.Others (specify)_____

18. Did they give you health education about TB**?** 1. Yes 2 .No ☐

19. When you were diagnosed with TB or during any of your clinic visits to get medicine or sputum test, did anybody ask you whether you smoke or not? ☐

1. Yes 2 .No

- **If non smoker skip all questions upto Q.NO. 27**. **Go to Q.No.28**

20. Did anybody tell you, you should quit smoking? 1. Yes 2 .No ☐

- **If No, go to question no.25**

21. If yes, mention the duration for which you are asked to quit? ☐

1.Life long 2. Till the completion of treatment 3. Duration not mentioned
4.Others(specify in years)_____

22. If yes, when did they tell you? Tick all those applicable

1. At the beginning of Intensive phase ☐ 2. At the beginning of Continuation phase ☐

3. During Continuation phase ☐ 4. At the end of treatment ☐

23. If yes, who told you? and mention number of times you got the message from them?

Tick all those who told you to quit smoking 1. Yes 2. No		Mention number of times you got the message
1. Doctor in DH/TH		
2. Doctor in PHC/CHC/PHU		
3. Doctor in other facility (specify)_____		
4. Nurse in DH/TH		
5. Nurse in PHC		
6.Pharmacist in DH/TH		
7. Pharmacist in PHC		
8. Male health worker		
9. Female Health worker		
10. TB health worker		
11.DOTS provider		
12. Others (mention)…….		

24. What was the anti smoking message told to you?

1. Advice to quit without any message ☐ 2. Advice to quit with general health message ☐

3. Advice to quit with TB specific message ☐ 4.Others (specify)_____ ☐

25. Did you visit the doctor after completion of the TB treatment for follow up or for any reason related to subsequent health problem?

1. Yes 2. No ☐

26. If yes, did the doctor give any anti smoking message? 1. Yes 2. No ☐

27. Did any of your family members ask you to quit smoking during treatment? ☐

1. Yes 2. No

SECTION V

28. Do you think tobacco use is associated with any disease? ☐

1. Yes 2. No 3. Don't know

29. If yes, what are those diseases? ☐
1.Heart diseases 2.Cancers 3. TB 4. Other(specify)_____

30. Do you now feel that you are healthy enough to smoke that you have completed treatment? (not applicable for non smokers) ☐
1.Yes 2.No 3.Don't know 4.Not applicable

31. Do you feel TB has effected your lungs for life? ☐
1. Yes 2. No 3. Don't know

32. Do you think smoking can cause relapse of tuberculosis? ☐
1. Yes 2. No 3. Don't know

33. If Yes, how many cigarettes/bidis per day can cause relapse of TB?
a) Bidis_____/Don't know (99) b) Cigarettes_____/Don't know (99)

34. How many cig/bidi per day is safe to smoke before causing much harm for health? (Don't know = 99)

Healthy person		TB patients on treatment (who is symptomatically better)		Former TB patients after completing treatment	
Cigarettes	Bidis	Cigarettes	Bidis	Cigarettes	Bidis
☐☐	☐☐	☐☐	☐☐	☐☐	☐☐

35. Are there types of tobacco products that can be used in moderation during treatment of TB? Tick all those applicable.

1. Filter cigarettes ☐ 2. Foreign cigarettes ☐ 3. Bidi ☐ 4. Pan chewing ☐

5. Madhu (Khaini) ☐ 6. Ghutka ☐ 7. Nasal snuff ☐ 8. Nothing ☐

9. Don't know ☐

36. What are the potential benefits of stopping smoking?

1. Health ☐ 2.Money savings ☐ 3. Good for my family ☐

4. Good for society ☐ 5. Others ☐ (specify)_____

- **If respondent is never smoker, skip all the questions**

SECTION VI

Question No. 37 - 41 for permanent quitters and relapsed smokers

37. If you gave up smoking during treatment, did you intend to smoke after completion of treatment? 1. Yes 2. No ☐

38. While on TB treatment, did you ever get craving for smoking after you quit? ☐
1. Yes 2. No

39. If yes, when did you get craving for smoking?

1. Beginning of Intensive phase ☐ 2. End of Intensive phase ☐
3. During continuation phase ☐ 4. After completion of treatment ☐
5. Throughout entire treatment period ☐

40. Which of these symptoms have you had when you've tried to stop smoking? (Check all that apply)

1. Cravings for smoking ☐ 2. Anxiety ☐ 3.Restlessness ☐ 4. Eating more ☐
5.Trouble concentrating ☐ 6. Depression ☐ 7. Frustration ☐
8. Trouble sleeping ☐ 9.Grouchiness/irritability ☐ 10. Indigestion ☐
11.Constipation ☐ 12. None of these ☐ 13.Others ☐ (specify)____

- **Q.no.42-43 only for permanent quitters**

41. What were the most important factors that prompted you to quit smoking?

_____

_____

42 .Do you think, you will restart smoking again? 1.Yes 2. No 3. Don't know ☐

43.If Yes, when you may start smoking again? ☐
1.within one month 2. within three months 3.within six months 4.within one year
5. Never 6. Don't know

- **If the respondent is permanent quitter, skip all the questions**

Q.No.44, only for relapsed smokers.

44.Why did you start smoking again ?

1. I enjoy smoking too much ☐
2. Way to deal with my unhappiness ☐
3. Many of my friends /colleagues around me smoke ☐
4. Friends/ colleagues offer cigarettes/bidis ☐
5. I couldn't resist the craving for a cigarettes/bidis ☐
6. The withdrawal symptoms were too unpleasant ☐
7. Helps while at work ☐
8. I didn't really want to stop in the first place ☐
9. Others (specify)_____ ☐

If respondent is persistent or relapsed smoker answer Q.No.45-48

45. How interested are you in stopping smoking ? (Please check one.) ☐
    1. Very 2. Somewhat 3. Not at all

46. If you were to decide to quit smoking completely, during the next two weeks, how confident are you that you will succeed? (Please check one.) ☐
    1. Very 2. Somewhat 3. Not at all

47. Who do you think will be supportive for your quitting efforts? (check all that apply)

    1. Family members ☐ 2. Spouse ☐ 3.Friends ☐ 4. Workmates ☐

    5.DOT provider ☐ 6.Hospital staff ☐ 7.Children ☐ 8.Others ☐ (specify)____

If Q.No 45 answer is 3, then skip Q. No. 48

48. What would be your main reasons for wanting to stop smoking? *(*Check all that apply)

    1. Health reasons ☐ 2. To save money ☐ 3.To be a positive role model ☐

    4. Live longer ☐ 5.Protect the health of others ☐ 6.Other ☐ (specify):____

Annexure II

WRITTEN INFORMED CONSENT

I am Dr. Deepak K G, a post graduate student in Public Health studying at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology in Trivandrum, Kerala. For my thesis I am conducting a study on the 'Smoking patterns and predictors of smoking relapse among male Tuberculosis patients' in this district. For this research, I am conducting interviews with people like you to get some of the information regarding you and your health problems and habits. This is a part of my course requirement. I would like to ask you some questions about you and your illnesses and habits, which will take 30- 45 minutes time. This is a routine procedure to obtain written informed consent from the participant in a study.

While there is no direct benefit for you individually, it is possible that the findings of the study will enhance scientific knowledge and enable us to develop better health policies to help people like you. I therefore, request you to participate in this interview.

The information given by you will not be disclosed to anyone under any circumstances anywhere in the public at any time and kept confidential and will be used only for research purposes. Participation in this study is purely of voluntary nature. If at any time you want to stop answering questions or not to answer some of the questions you may refuse to do so.

If you have any queries or doubt please feel free to clarify those. I will try my level best to answer to any of your queries right now or in the future as well. My contact number is 09961498574. In case you need any clarifications about my credentials or the study you can also contact Dr. Anoop Kumar Thekkuveettil, Member-Secretary of the Institutional Ethical Committee at SCTIMST, Trivandrum-695011 and his contact number is 0471-2520256

Are you willing to participate in this study?

Yes: No:

As a part of the requirement, I need your signature/thumb impression which indicates your willingness to participate. Will you be able to sign below?

_____ _____

Signature of the participant: Thumb impression

If you are unwilling to sign/give thumb impression, but willing to be interviewed, signature of independent witness to consent being taken:

_____

Signature of witness Date:

_____ Time:

Signature of the interviewer: Place:

**********  **********