THE ECONOMIC BURDEN OF TYPE 2 DIABETES USING THE INCREMENTAL COST OF ILLNESS APPROACH - AN EXPLORATORY STUDY IN MUMBAI

VISHAKHA ANBHORE

**DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT
FOR THE AWARD OF THE DEGREE OF**

Master of Public Health

ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY, TRIVANDRUM

Thiruvananthapuram, Kerala. India - 695011

June 2020

THE ECONOMIC BURDEN OF TYPE 2 DIABETES USING THE INCREMENTAL COST OF ILLNESS APPROACH - AN EXPLORATORY STUDY IN MUMBAI

VISHAKHA ANBHORE

Dissertation submitted in partial fulfillment of the requirements
For the award of

Master of Public Health

ACHUTHA MENON CENTRE FOR HEALTH SCIENCE STUDIES

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY, TRIVANDRUM

Thiruvananthapuram, Kerala. India - 695011

June 2020

ACKNOWLEDGMENT

I would like to express my sincere gratitude to my Research Guide, Dr Raman Kutty, Emeritus Professor, Achutha Menon Centre for Health Sciences Studies (AMCHSS) for his valuable guidance, time and encouragement at every step.

I am grateful to our faculty members at AMCHSS: Dr Dr PS Sarma, Dr Mala Ramanathan, Dr Rakhal Gaitonde, Dr K Srinivasan, Dr Biju Soman, Dr Ravi Prasad Varma, Dr Manju R Nair, Dr.Jeemon P, Dr. Srikant and Ms Jissa VT for providing suggestions to improve this study.

I am also thankful to Dr. Gurpreet Singh and Dr. Antony Stanley for their continuous support and suggestions at all developing stages of this study.

I am also obliged to Dr Prasad Thakurdesai and Dr Shrikant Pawar for supporting the study by providing the Hindi translated version of the MDQ questionnaire.

Lastly, I would like to thank all my friends and family for their constant support in all my endeavors. And to all my respondents for giving their time for participating in this study.

Thank You.

CERTIFICATE

Certified that the dissertation entitled "**The Economic Burden of Type 2 diabetes using the incremental cost of illness approach in Mumbai- An exploratory study**" is a record of original research work undertaken by Vishakha Anbhore, in partial fulfillment of the requirements for the award of the degree of "Masters of Public Health", under my guidance and supervision.

Guide

DR. SHANKAR SARMA P

Professor

DR. RAMAN KUTTY

Emeritus Professor

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

Thiruvananthapuram, Kerala. India - 695011

June, 2020

DECLARATION

I hereby declare that this dissertation titled "**The Economic Burden of Type 2 diabetes using the incremental cost of illness approach in Mumbai- An exploratory study**" is the bonafide record of my original field research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

VISHAKHA ANBHORE

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum

Thiruvananthapuram, Kerala. - 695011

June, 2020

Table of contents

Sl. No		Page no
1.	List of tables/illustrations	7
2.	Abstract	10
3.	Back ground	11
4.	Rationale of the study	13
5.	Literature review	14
6.	Methodology	24
7.	Results	30
8.	Discussion	54
9.	Conclusion	57
10.	References	59
11.	Annexure- MDQ QOL	61
12.	Annexure- Interview Schedule	70
13.	Annexure- Patient information Sheet	86
14.	Annexure- Informed consent	87
15.	I.E.C Clearance certificate	88
16.	Urkund Plagiarism document	90

TABLES AND ILLUSTRATIONS

ILLUSTRATIONS

Figure 1: Sex distribution by diabetes status

Figure 2: Age distribution by diabetes status

Figure 3: Sex distribution by onset of diabetes

Figure 4: Total time invested for consultation

Figure 5: Opportunity time lost while visiting health-care facility

Figure 6: Household coping mechanism

Figure 7: Households opportunity cost's frequency distribution

---

TABLES

Table 1: Number of clusters selected from each ward according to their population

Table 2: Frequency of study population by disease categories

Table 3: Frequency of study population by socioeconomic status

Table 4: Frequency of study population by household characteristics

Table 5: Monthly household income of the study population

Table 6: Monthly consumption expenditure of the study population

Table 7: Income quintile distribution as per diabetes

Table 8: Total annual mean health expenditure (INR) as per diabetes status

Table 9: Type of direct medical and non-medical cost

Table 10: Type of healthcare facility visited for consultation

Table 11: Direct consultation cost (INR) as per disease categories

Table 12: Investigation frequency as per to diabetes status

Table 13: Direct Investigation cost (INR) as per disease categories

Table 14: Direct Hospitalization cost per day (INR) as per disease categories

Table 15: Total drug cost per day (INR) as per source of buying medication

Table 16: Total drug cost per day (INR) as per disease categories

Table 17: Type of income or productivity loss

Table 18: Days of productivity loss of patient as per disease categories

Table 19: Days of productivity loss of accompanier as per disease categories

Table 20: Wage loss of due to hospitalization INR as per diabetes status

Table 21: Coping mechanism with as per diabetes status

Table 22: Coping mechanism as per income quintile

Table 23: Opportunity cost as per diabetes status

Table 24: Effect on consumption of medication as per diabetes status

Table 25: Frequency of subjects who discontinue medication

Table 26: Mean score of diabetic patients as per general perceptions of diabetes and related social support

Table 27: Mean score of diabetic patients as per social incentives related to self-care activities

Table 28: Mean score of diabetic patients as per self-efficacy and outcome expectations

LIST OF ABBREVIATIONS

1. NCD: Non-communicable diseases
2. CABG: Coronary artery bypass graft
3. INR: Indian rupee
4. MDQ-QOL: Multidimensional Questionnaire for Quality of life
5. COI: Cost of illness

ABSTRACT

Background: The rapid growth of non-communicable diseases (NCD's) are not only the leading cause of mortality and morbidity but also causes a greater economic burden on the households of the people suffering with NCD's. This study aims to provide evidence by measuring the cost of illness of type 2 diabetes and its impact on the subjects and their families.

Methodology: A community-based household survey was done using structured interview. The data was collected on demographic characteristics, direct and indirect cost incurred on health in past one year and their coping mechanisms. Quality of life was also calculated to establish psychosocial cost

Results: The study population has 36 percent of diabetic (N-150) and among the diabetic subject's 20 percent exist with other morbidities. The diabetic subjects have an additional expenditure on medication by INR 5909.5 per year and the overall annual mean health expenditure of diabetic subjects was INR 41766.53 with mean loss in productivity as 10 days. Around 60 percent of the population managed through current income and among the diabetic population 13 percent involved in borrowing. The quality of life of diabetic subjects in terms of perception and social support was moderate, with social incentives and self-care was low and with self-efficacy and outcome expectancies was also moderate.

Conclusion: The average annual expenditure of diabetic subjects was 1.45 times higher than those who do not have diabetes. Around 43.60 percent of the total cost was accounted for medications and 41.6 percent of diabetic population are compromising due to their excessive health expenditure on either food or social obligations or both.

BACKGROUND

An epidemiological transition in disease burden and death is observed due to noncommunicable diseases (NCD). This broad group comprises of conditions like diabetes, cardiac conditions, cancers, chronic pulmonary diseases, mental health condition and others, these are slow progression and are conditioned due to behavioural, environmental, physical and physiological factors. (*WHO*, 2014)

Globally, 71 percent of deaths are due to NCD, each year 15 million die between the ages of 30 to 69 years and 1.6 million deaths are related to Diabetes. Low socioeconomic status is linked with NCDs and a rapid rise may obstruct the initiatives to reduce poverty among them, therefore increasing the household costs associated with healthcare. The healthcare costs to treat NCDs are associated to prolong and expensive treatment which may result in loss of breadwinner and also lead to poverty or decrease their socioeconomic status. (*WHO*, 2014)

According to International Diabetes Federation- South-East Asia Region (IDF-SEA), India is one of the seven countries of the IDF SEA region and 463 million people have diabetes in the world and the SEA region has 88 million people and they are estimating that by 2045 the diabetes cases will rise to 153 million. Currently, the prevalence of diabetes in India is 8.9 percent and there are over 77,005,600 cases.(IDF, 2020)

Globally, around 422 million adults were living with diabetes in 2014 as compared 108million in 1980.(*WHO*, 2014) The prevalence of diabetes (measured accordingly as in when the fasting blood glucose is equal or higher than 7mmol/L, or on medication for raised blood glucose or with a history of diagnosis of diabetes) among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014 (Emerging Risk Factors Collaboration et al., 2010).

A study was assessed which shows the trends in the prevalence of diabetes and glucose tolerance in urban South India, 50.1 % of the study subjects with Diabetes Mellitus were in the age group of 40-59 years. (Mohan et al., 2008)

According to the study conducted by India State-Level Disease Burden Initiative Diabetes Collaborators, the age-specific prevalence of diabetes in India has increased with increasing age in both 1990 and 2016. There was a divergence between the prevalence in 1990 and 2016 started in young adults, showing statistically significant results for men at 50–54 years (from 10·1% [95% UI 8·7–11·5] in 1990 to 13·6% [11·8–15·4] in 2016) and for women at 55–59 years (from 10·4% [9·1–11·7] in 1990 to 13·5% [11·9–15·2] in 2016) and remained significant in all older age groups. (Tandon et al., 2018)

RATIONALE OF THE STUDY

Diabetes Mellitus is a serious chronic illness which leads to heavy economic burden and expensive lifestyle. The tremendous economic burden on patients themselves, their families and to the society as a whole in terms of treating diabetes and managing the income losses occurs due to it. This will be an exploratory study looking at cost of illness through an incremental approach and it would enable us to find the overhead burden of type -2 diabetes than other diseases economically. Choosing subjects above 50 years would be a convenient way to analyse the costs as they would exhibit some of kind of ailment.

This would bring forward the economic burden experienced by the households and patients affected by diabetes mellitus as compared to subjects without the disease.

This study could further be explored in a form of multimorbidity in terms of economic burden, hence choosing subjects above 50 years and above subjects was feasible as they would show traits for the same. Moreover, this approach has never been explored in India.

REVIEW OF LITERATURE

The content of this chapter is a result of the systematic literature review that was done through an extensive search on PubMed, Science Direct and Google Scholar using MESH terms and keywords for articles published within the last ten years.

Diabetes Mellitus

Diabetes is a serious chronic disease which affects the body's ability to produce or use the produced insulin. Insulin is a hormone that helps regulate blood sugar. If uncontrolled may lead to raised blood sugar also known as hyperglycaemia and over the time it causes various complication related to nerves and blood vessels.

In Diabetes Mellitus a person has high level of blood sugar which leads to a number of morbidities like cardiac disorders, renal disorders etc.

a. Type -1 Diabetes Mellitus (Insulin dependent diabetes, juvenile or childhood-onset) this condition arises when human body fails to produce insulin for Glucose metabolism in the body and the patient requires daily administration of Insulin. The cause of type 1 diabetes is unknown and it is not preventable.

Symptoms include excessive excretion of urine (polyuria), thirst (polydipsia), constant hunger, weight loss, vision changes, and fatigue.

b. Type-2 Diabetes Mellitus (Non-Insulin dependent diabetes or adult-onset) – this condition arises when body produces insulin but not in sufficient amount or produced insulin is not used because of any resistance in body which leads to the improper metabolism of glucose. Majority of people suffer with diabetes around the globe and is largely consequence of excess body weight and physical inactivity.

Symptoms include constant hunger, weight loss, vision changes and fatigue all of these are similar to type1 diabetes but are often less marked in type 2 diabetes.

Earlier this type of diabetes was occurring in adults only until recently it is also seen in children with increased frequency.

c. Gestational Diabetes- it is a condition where hyperglycaemia with blood glucose values is above normal and recognized first time during pregnancy. Women may have risk of complications during pregnancy as well as the condition may precede to the development of type-2 diabetes mellitus later in life.

It is diagnosed through prenatal screening and with symptomatic approach.

d. Impaired Glucose Tolerance (IGT) and Impaired Fasting Glycaemia. (IGF): Impaired glucose tolerance (IGT) and impaired fasting glycaemia (IFG) are intermediate conditions in the transition between normality and diabetes. People with IGT or IFG are at high risk of progressing to type 2 diabetes, although this is not inevitable.

A person who is affected by Diabetes usually suffers from improper absorption of glucose which consequently increases the levels of the blood glucose. This leads to a condition known as Hyper-glycaemia which causes damage to the different types of body tissues over a period of time. The damage caused to these tissues leads to many complications, commonly known as Diabetic complications, and can prove to be life threatening.(Macdonald, 2008)

Diabetes has over the time complication due to its chronic nature, it can damage the heart and blood vessels, eyes, kidneys and nerves. There is 3 fold increased risk of heart attacks and strokes among the adult population.(Emerging Risk Factors Collaboration et al., 2010).

Cost of illness studies

Cost-of-illness (COI) studies aim to assess the economic burden of health problems on the population overall, and they are conducted for an ever-widening range of health conditions and geographical settings. While they attract much interest from public health advocates and healthcare policymakers, inconsistencies in the way in which they are conducted and a lack of transparency in reporting have made interpretation difficult, and have ostensibly limited their usefulness.(Larg and Moss, 2011).

COI can be studied through various perspectives like societal which will calculate costs including medical, morbidity, mortality, non-medical. Health care system perspective COI will calculate only medical cost but will given an insight about the costs rendered to the government or hospital for treating a particular patient (illness). The most common perspective will be through participants and their families, here the costs will be calculated as out of pocket expenditure, wage loss and household productivity loss.

COSTS

Direct costs: All resource costs employed to treat patients with diabetes (care and/or assistance). It includes medical and non-medical costs. Direct costs include expenditures for prevention, detection and treatment. They also include rehabilitation, research, training, and investment in medical facilities. Therefore, direct costs include expenses on hospital, nursing homecare, physicians and other medical services, these include drugs, medical supplies, research and other nonpersonal services.(Rice, 1967)

Indirect costs: All the costs associated with the loss of productivity resulting from morbidity and mortality caused by diabetes.

Intangible costs: They are also known as psychosocial costs because they are associated with all the negative effects caused by the disease leading to deterioration in the quality of life of patients (e.g. isolation, anxiety, pain).

The cost of illness study can be of two types prevalence based and incident based. The prevalence-based method estimates the cost or economic burden for a specific time period, generally for one year and it commonly used method. Conversely, the incidence-based estimates the total life time cost incurred from the onset of the disease.

There can be various approaches to study COI, it can be either prospective or retrospective. The commonly used method is by estimating costs retrospectively from the previous medical record of the patient. The prospective approach, could be expensive and time consuming as the subjects have to followed up for particular years and then estimate the cost incurred to them. The limitation for retrospective approach would be recall bias by the subjects which may or may not estimate the actual cost incurred.

Top down and bottom-up approach can also be used for estimating costs. The top-down approach, also known as the epidemiological or attributable risk approach, measures the proportion of a disease that is due to exposure to the disease or risk factor.

The bottom-up approach estimates costs by calculating the average cost of treatment of the illness and multiplying it by the prevalence of the illness. (Segel, 2006)

The Costs can be calculated using various methods to analyse the study according to Akobundu et al. That study depicted four methods for analysing costs.

1. Sum All Medical: it calculates cost by identifying all patients with a particular diagnosis and summing all the healthcare expenditure irrespective of whether they are directly related to the disease of interest

2. Sum_All Diagnosis: here the subject must not have the primary diagnosis of the disease but only the costs that are directly related to it.

3. Matched Control method: this included studies in which subjects with particular diagnosis are matched on demographic or clinical characteristics to the control group which doesn't have the said diagnosis. This method is useful in calculating cost of illness based on incremental approach wherein you subtract out the average cost of the sample to find incremental costs for treatment; alternatively, subtract out the average cost of a matched cohort instead.

4. Regression: estimates incremental cost of illness from the estimated coefficient on an indicator variable for the diagnosis of the disease. Useful in estimating costs where confounding factors could be modelled directly or by using controls on co-morbidities. In this method identify all patients with a diagnosis, complete a regression analysis and indicate the individual β for each diagnosis. Identify all patients with a diagnosis, find a matched cohort (similar to a clinical trial) and complete a regression analysis to quantify the individual β for each diagnosis – gold standard.(Akobundu et al., 2006).

According to American diabetes association, there was a 26 percent increase in total cost of diabetes over a period of five year. The total costs of diagnosed diabetic patients had risen from $245 billion in 2012 to $327 billion in 2017. The largest components of medical expenditures were inpatient hospital care which contributed 30 percent of the total medical cost, 30 percent were prescription medication and 13 percent were physician office visits. (*Diabetes Care*, 2018)

The indirect costs had also increased over the period with $3.3 billion increased absenteeism, there was productivity loss at work which accounted for $2.69 billion, reduced productivity for non-workers by $2.3 billion and $37.5 billion accounted for inability to work due to diabetes related disability. (*Diabetes Care*, 2018)

In India, “the mean out of pocket expenditure for per in-patient hospital stay for diabetes mellitus increased from 134 USD to 211 USD between 1995 and 2004 and direct total out of pocket spending per year was estimated at 262–280 USD. The percent wise household consumption spent out of pocket ranged between 7.7 and 17.5 % “(Jaspers et al., 2015)

A study which was conducted using the National health Insurance Fund under the Lithuanian Ministry of health with around 762 diabetic patients estimated the ambulatory care cost mean per patient as EUR 156.14 (95% CI, 411.14-165.24). the mean annual cost per patient for hospitalization was EUR 1160.16 (95% CI, 1019.60– 1300.73) and the covered drugs and diabetes supplies for annual direct cost mean per patients was EUR 448.34 (95% CI, 411.14–485.54).(Domeikienė et al., 2014)

A retrospective hospitalized study was conducted among 649 hospitalized patients for type 1 and type 2 diabetes. The average age of diabetes mellitus patients in the study was 57.24 ± 15.79 years old and the average length of stay for these patients was calculated as 9.56 ± 10.35 days. The average amount of service activity invoice was calculated as $714.90 and the costing for diagnosis related group with respect to diabetes mellitus was $1223.40 for 649 inpatients with the diagnosis of diabetes mellitus in 2013. The costs in this study were calculated by the inpatient treatment invoices(bills).(Top et al., 2020)

A study was conducted in 1998 in the Bangalore urban district to estimate the cost of illness due to diabetes. The annual direct cost for routine diabetes treatment, without hospitalization in different settings was 5959 INR. The total consultation fee accounted for 38% of the cost, medicines 32 % of the cost, transportation 23% and 7% was other direct costs. On an average the patient spent 823 INR annually for routine lab test. This study design had limitation as the of indirect costs was not evaluated.(Rayappa et al., 2005)

Another study conducted, in the private hospitals of Chennai indicated that the 24.5% of income was spent on diabetes among poorest strata of patients, as compared to richest strata where they spent only3.5%. It was also reflected in the study that in public hospitals where the median family income was much lower than private hospital, the poorest quartile spent 3.3% of their income on diabetes treatment while the richest quartile spend almost 0% of their income on diabetes treatment.(Shobhana et al., 2000)

A Cost of illness study was done on 50 out patients with diabetes from Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh. Total treatment cost was 7254.05 rupees for the six-month period. It includes 68.4% of the direct cost, 28.76% of indirect cost and 2.8% providers cost. The direct treatment cost was INR 4966.42/-. And the mean indirect treatment cost was INR 2086.74/- and INR 205.55/- contribute for total providers cost for diabetes mellitus.(Grover et al., 2005)

Another subsequent large community-based study was conducted to estimate the cost of illness for diabetes in India. In this study they found that the mean direct annual cost for outpatient care for all patients with diabetes was INR 4724/-, those without complications had an 18% lower cost while those with three or more complications had a 48% higher cost. Indirect cost was estimated to be INR12,756/- of this productivity loss accounted for INR 9166. The mean annual cost for the entire study population was 19914/- INR. (Kapur, 2007)

A population-based COI study was conducted at MV Hospital for diabetes and diabetes Centre, Chennai among 718 diabetes patients. In that study the median annual direct cost associated with diabetes was found to be INR 25,391 and indirect cost was INR 4970. Extrapolating the direct and indirect costs to Indian population, the annual costs for diabetes would be 1541.4 billion INR in 2010.(Tharkar et al., 2010)

A study conducted in 2010, explored the burden of diabetes in 606 individuals in government, private and rural clinics in South India, the annual direct costs were highest among those who attended the private clinic (INR 19 552/-, US$ 425) and lowest among those who attended the government clinic (INR 1204/-, US$ 26.17). It reported absenteeism due to diabetes which was low among the private clinic attendees (2.36 work days/year) while among the patients who attended the government clinic reported maximum absenteeism (7.48 work days/year)(Sharma et al., 2016)

A community based prospective cohort study conducted in 2014, explored the mean direct cost of DM management over 6 months was estimated to be INR 4125 (687.5 per month). 92.5 % of the participants had a direct cost for the management of DM less than INR 10000/-. The mean indirect cost of management of DM for 6 months was INR 2092.5 (INR 348.75 per month). And The out of pocket expenditure towards management of Diabetes was borne by 72.5% (total 120 participants) of the participants (Fernandes and Fernandes, 2017).

A systematic review was conducted for low and lower middle-income countries and around eight eligible studies were found. Those studies in combine represent the annual average cost per person for treating type 2 diabetes ranged from USD29.91 to USD237.38, the direct costs ranged from USD106.53 to USD293.79, and indirect costs ranged from USD1.92 to USD73.4 per person per year. Hospitalization cost was the major contributor among them. (Afroz et al., 2018)

Around 67.3 percent of the cost for diabetes care in the United states of America was provided by the government insurance which included Medicare, Medicaid and the military. The rest were managed by private insurance (30.7 percent). (*Diabetes Care*, 2018)

GAPS IN RESEARCH

Economic evidence is important for making decisions regarding allocation of resources. Most of the studies have been addressed only to estimate the direct cost associated with diabetes and very few with respect to indirect cost.

An overall economic burden and the relation between “the cost rendered”, the way patients cope up with the same and its effect on quality of life has not been established. In India, majority of the cost of illness studies have been conducted in hospital settings and community-based studies are very few.

The literature which are from developed country where the Cost of illness are explored through various methods, one of them being incremental cost approach is conducted via secondary data collected by overall health Insurance of that country. To my knowledge there are no studies exploring the community-based Cost of illness via incremental cost among type 2 diabetic patients above 50 years of age in India.

METHODOLOGY

Objectives

1. To estimate the incremental cost (Direct and Indirect) of Type 2 Diabetes Mellitus in Mumbai among subjects above 50 years of age

2. To assess the Impoverishment effects i.e. on what levels, did type 2 diabetes affect the subjects or their families and how did they cope up with the costs rendered (Coping mechanism)

3. To document the psychosocial cost of Type 2 Diabetic patients by estimating the Quality of life.

Study type: The present study is a community-based household survey focussing on the age group above 50 years

Study design: Exploratory study

Study setting and Sampling strategy:

The study setting and the sample size were selected using multi-stage cluster sampling. Mumbai is divided into 6 zones and these zones are further divided into wards alphabetically.

Step 1: For convenience Zone 4 was selected which is comprised of 5 wards.

Step 2: Probability proportional to size (PPS) cluster Sampling was adopted to determine no of clusters in each ward according to their respective population size. Being an exploratory study, we have selected a sample size of 150 subjects.

Step3: Using the above method 15 clusters were chosen from all the wards. From each ward, a cluster of 10 subjects was chosen. From the main junction of each ward, a random road will be chosen and pen rotation method will be used to determine the direction; in the direction pointed alternate houses on the right side will be approached for the subjects. This process will continue until 10 subjects from each cluster will be found. In the case of multi-storey buildings, alternate floors and alternates houses will be approached for the subjects.

Table 1: Number of clusters selected from each ward according to their population

Ward	Area Name	Population (Census2011)	No of Clusters according to PPS	No of Subjects according to Ward
P North	Malad	941366	5	50
P South	Goregaon	463507	2	20
R Central	Borivali	562162	3	30
R North	Dahisar	431368	2	20
R South	Kandivali	691229	3	30

Study population

All the Subjects who are above 50 years of age and residing for more than a year in zone 4, Mumbai

a. Target population: This study aimed to generalize the study findings to residents of all the households in Zone 4 of Mumbai district.

b. Study population: The study included only those subjects above 50 years who were residents of zone 4 Mumbai district for more than year.

Inclusion Criteria

1. Subjects who are above 50 years of age and have given their informed consent.
2. Subjects should be a resident of Zone 4 for more than a year.

Exclusion Criteria

1. Subjects who have a severe chronic condition (cancer, CABG, paralysed, bedridden, on the wheelchair, etc)
2. Subjects who have been diagnosed with diabetes within one year. (if patient has diabetes)
3. Subjects who did not give informed consent for the study.

Non-responders

Those who were not available or refused to participate were considered as non-responders and the reasons for not participating in the study were noted.

Data Collection

Data collection was done during December'19 -March'20. A face to face interview was conducted to collect the data. Initially, Screening questions were administered which helped to identify the study participants and subjects adhering into the inclusion criteria were administered with the rest of the interview schedule. The interview schedule was developed for this study based on the conceptual framework and reviewed literature.

Data analysis and statistical methods

Data entry was done in Microsoft Excel 201. Data analysis was done using Microsoft Excel 2010 and SPSS. The data related to the costs was collected retrospectively pertaining to one year.

The total costs for type 2 diabetes mellitus will be established from direct costs (medical and non-medical), indirect costs (productivity and wage loss) and psychosocial costs which will calculated as quality of life.

The incremental cost will be calculated from all the direct and indirect costs.

(Incremental cost due to diabetes =mean cost of health care in diabetic – mean cost of health care for non-diabetic for month).

Direct medical and non-medical cost will be calculated by summing the total medication cost, total consultation cost, total laboratory cost, total hospitalization cost, transportation cost and food cost. All of these costs will then be extrapolated to one year.

The consultation cost in this study will be calculated as one-time event and the expenditure incurred will not be extrapolated as the comparison between subjects with and without diabetes needs to be established.

The indirect cost in this study will be represented by wage loss in monetary terms and productivity loss in terms of time (days). The indirect cost for consultation in this study is expressed in terms of opportunity cost.

Coping strategies will be explored by estimating the opportunity cost i.e. what the patient would have done with the money spent on the disease if they would not have got the disease.

Quality of life will be used to estimate psychosocial costs (intangible costs) and MDQ-QOL tool will be used.

LIMITATIONS

This is an exploratory study based on small sample of 150 patients, hence generalising would be difficult. There may be selection bias due to convenience method of sampling.

The costs estimation by incremental approach, is generally applied on secondary data and with the help of matching or propensity score the individuals are compared. However, this study is a community based and with the limited amount of time it was difficult to develop the study in the above said way.

While collecting data the expenditure and income was taken as gross amount because the respondents were either uncomfortable or did not remember the exact number. This may have led to recall bias. The value of household activity or other non-paying activities performed by the patients could not be estimated and hence, the loss of productivity measure has its limitations

Ethical considerations

The proposed study complied with the basic ethical principles of research. The study was conducted only after getting the approval and clearance from the institutional ethics committee (IEC) of Sree Chitra Tirunal Institute of Medical Science and Technology.

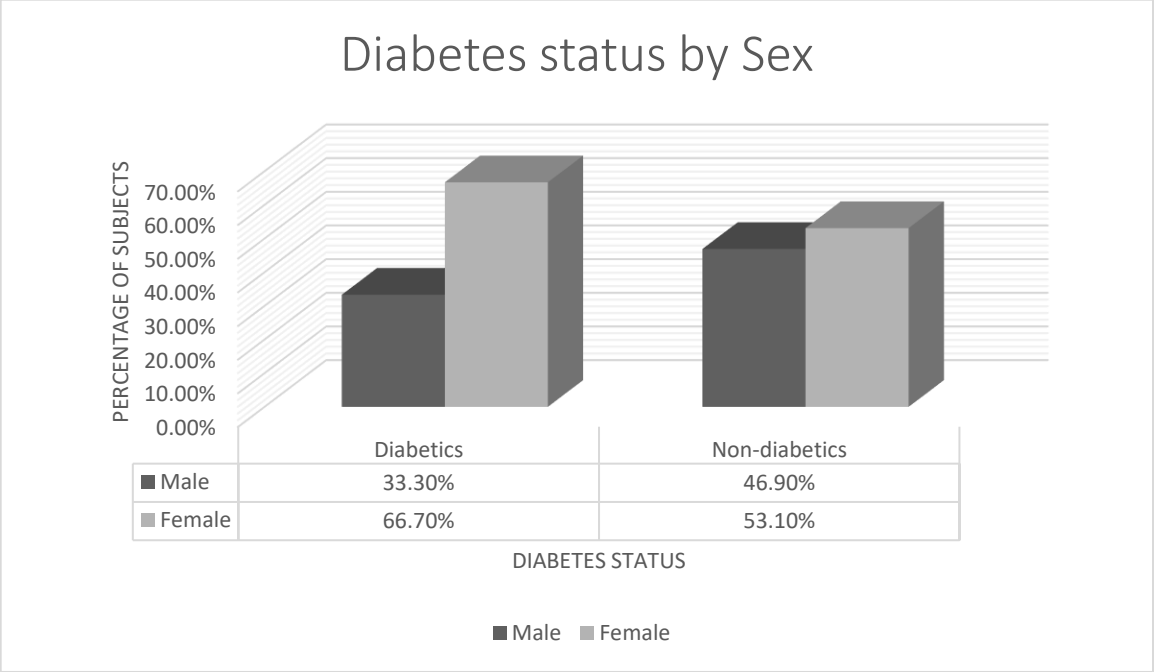
Written informed consent was taken from all respondents after providing them with necessary information. Subjects were explained how valuable their response was going to be to complete the research. Privacy was maintained during the interview and confidentiality of the subject and information will be provided.

All the project documents and records will be kept under lock and key or computers with passwords under the supervision of principal investigator. After the completion of the project the documents will be sealed and stored at secured place for 5 years.

RESULTS

The sample population of 150 represents 58.7 percent of subjects have NCD and 41.3 percent subjects have other acute illnesses (non-chronic). The overall sample consists of 36 percent of subjects with Diabetes and 64 percent with Non-diabetes.

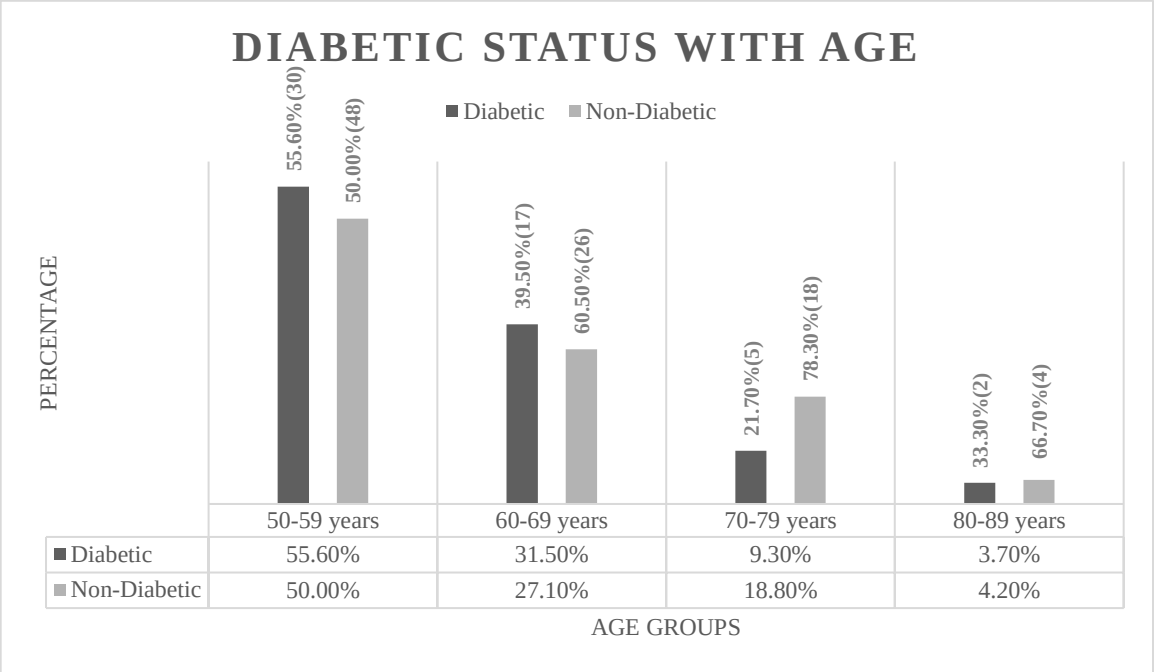
Figure: 1 Sex distribution by diabetes status



The overall percentage of male subjects in the sample population is 42 percent and there are 58 percent females.

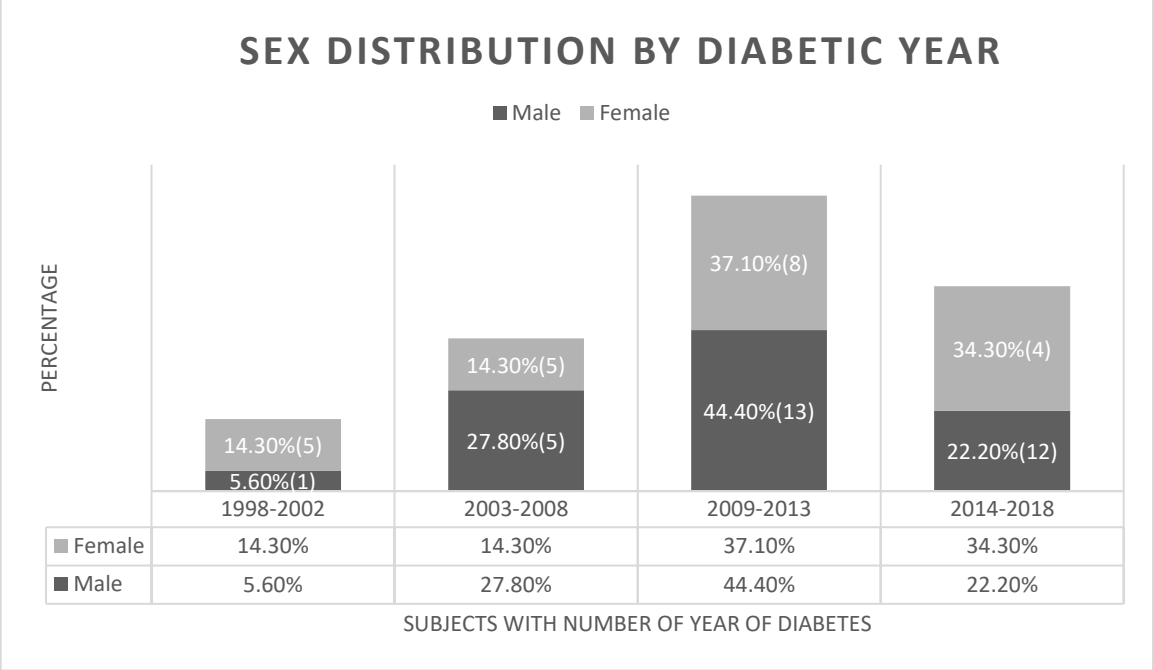
Table 1 explains that the percentage difference between male and female with among diabetic and non-diabetic population. The sex difference is more prominent in the diabetic group with 33 percent and only 3.2 percent in non-diabetic group.

Figure: 2 Age distribution by diabetes status



Maximum subjects belong to 50-59 years age group and percentage of non-diabetics is more among 70-79 years age group.

Figure: 3 Sex distribution by onset of diabetes



Majority of the diabetic subjects had the onset of diabetes between 2009 to 2013 as well as 2014-2018

Socioeconomic Status

Table 3: Frequency of study population by socioeconomic status

Variable	Category	Frequency (%) N=150
Age	50-59 years	78 (52.0)
	60-69 years	43 (28.7)
	70-79 years	23 (15.3)
	80-89 years	6 (4.0)
Gender	Male	63 (42.0)
	Female	87 (58.0)
Education	No formal Education	45 (30.0)
	Less than Primary School	3 (2.0)
	Primary School	9 (6.0)
	Middle School	19 (12.7)
	High School	58 (38.7)
	Degree and above	16 (10.7)
Occupation	Non-worker	12 (8.0)
	Self-employed	25 (16.7
	Employed	16 (10.7)
	Labourer	17 (11.3)
	Retired	19 (12.7)
	Pensioner	15 (10.0)
	Homemaker	46 (30.7)

Majority of the subjects fall under 50-59 years of age group and 87 percent are females. About 38.7 percent have studied till high school and only 16 percent have done degree. As majority of the population are females, the prominent occupation is of a Homemaker (30 percent), approximately 39 percent of the population are working, 8 percent are non-worker and only 10 percent receive pension. Among the female population 12.6 percent are self-employed, only 4.6 percent are employed, 13.8 percent are in Labour jobs, 9.2 percent are either pensioner or retired and 52.9 percent are homemaker.

Household Characteristics

Table 4: Frequency of study population by household characteristics

Variable	Category	Frequency (%) N=150	
		Diabetic (54)	Non- Diabetic (96)
Type of house	Kuccha	0	1 (1.0%)
	Semi Pukka	1 (1%)	3 (3.1%)
	One Room Kitchen	36 (66.7%)	59 (61.5%)
	One BHK	16 (32.6%)	30 (31.3%)
	Two BHK or more	1 (1.9%)	3 (3.1%)
Ownership of House	Rented	9 (16.7%)	11 (11.5%)
	Own House	45 (83.3%)	85 (88.5%)
Number of people residing in one Household	3 and below	27 (50%)	56 (58.3%)
	4-6	23 (42.63%)	30 (31.3%)
	7 and above	4 (7.37%)	10 (10.3%)

The study population shows that majority of the subjects reside in one room kitchen and have their own houses. The number of people residing in each household ranges from 2-14 and 42.63 percent of diabetic population have more than 3 members within the household.

Household Income and Expenditure

The monthly household income represents the spending capability of the households. The monthly consumption expenditure represents the amount of spending a household does on food items and non-food items. Therefore, both these variables are important to understand the economic status of the household.

Table 5: Monthly household income of the study population

Monthly Household Income (N-150)	INR
Mean	33402.67
Standard Deviation	24684.05
Standard Error of Mean	2015.44
Minimum	5000
Maximum	150000
Sum	5010400

The average monthly household income is INR 33,402.67 with minimum earning of INR 5000 and maximum of INR 1,50,000. The total sum of monthly income of households was INR 50,10,400.

Table 6: Monthly consumption expenditure of the study population

Monthly Household Consumption Expenditure (N-150)	INR
Mean	15728.00
Standard Deviation	7225
Standard Error of Mean	589.951
Minimum	4000
Maximum	40000
Sum	2359200

The average monthly consumption expenditure is INR 15728.00 with minimum earning of INR 4000 and maximum of INR 40,000. The total sum of monthly consumption expenditure of households was INR 23,59,200.

We have further divided the monthly household income into Quintiles to understand the economic status of the household.

Table 7: Income quintile distribution among diabetics and non-diabetics

Income Quintiles	**Frequency (%) N=150**		
	Diabetic	Non-Diabetic	Total
Q1 Highest	11 (20.4%)	18 (18.8%)	29 (19.3%)
Q2	11 (20.4%)	18 (18.8%)	29 (19.3%)
Q3	17 (31.5%)	15 (15.6%)	32 (21.3%)
Q4	4 (7.4%)	15(15.6%)	19 (12.75)
Q5 Lowest	11 (20.4%)	30 (31.3%)	41 (27.3%)

The first quintile is of higher Income group with incomes between INR 45,001– 1,50,000, second quintile group is the Middle Upper Income group Middle Lower Income group with incomes between INR 35,001 – 45,000, the third income group is the Middle income group with incomes between INR 20,401 – INR 35,000, the fourth quintile is the lower middle Income group with incomes between INR 15,001 – 20,400 and the fifth quintiles is the lowest income group with incomes between INR 5,000-15,000.

Our sample population majorly lies either in lowest income group 27.3 percent or the middle-income group which is 21.3 percent. When compared with diabetic and non-diabetics we can see that 31.3 percent among non-diabetic lie in lowest quintile and approximately 15-18 percent in rest quintiles. Whereas the diabetic are maximum in middle income group with 31.5 percent among the diabetics and were least among the lower middle income group.

Disease Categories

As the methodology suggests, the subject population were anyone above the age group of 50 years and all the illnesses they have during the interview were recorded excluding the Subjects who have had an encounter with severe chronic conditions (cancer, CABG, paralysed, bedridden, on the wheelchair, etc).

The majority of the subjects had more than one illness and for the ease of the situation those were further categorized into five disease categories.

Table 2: Frequency of study population by disease categories

Disease Category	Frequency
Only Diabetes	24 (16%)
Diabetes and Chronic conditions	22 (14.7%)
Diabetes and Non-chronic conditions	8 (5.3%)
Chronic conditions	34 (22.7%)
Only Non-chronic conditions	62 (41.3%)
Total	150

The sample population as represented in the table has 22.7 percent subjects with NCD's other than diabetes like hypertension, arthritis, thyroid, hypercholesteremia etcetera and 41.3 percent have non-chronic conditions like hypothermia, cold, seasonal flu, joint pains and other kinds inflammations etcetera.

HEALTH EXPENDITURE

The total health expenditure is the sum of direct and indirect costs incurred due to Diabetes. In this study, the direct costs consist of consultation costs, investigation costs, hospitalization costs, drugs costs, transportation, food and accommodation while visiting the health facility, accompanier's costs and any other costs related to treatment and health

in the past one year. The indirect costs consist of loss of wages of the patient and the accompanier.

The diabetic subjects have an additional expenditure on medication by INR 5909.5 per year and the overall annual mean health expenditure of diabetic subjects was INR 41766.53.

The mean annual indirect cost (wage loss) was high among the non-diabetic subjects INR 2303.92. The mean wage loss experienced by non-diabetic subject annually as compared to diabetic subject was INR 555.44.

Table 8: Total annual mean health expenditure (INR) as per diabetes status and the total annual mean increment cost (INR)

Health Expenditure	**Total Annual Mean Cost (Diabetics) INR**	**Total Annual Mean Cost (Non-Diabetics) INR**	**Total annual mean increment cost of Diabetics INR**
Consultation	932 (+/-1374)	693 (+/- 860)	239
Investigation	2965.93 (+/- 6497.53)	208.33 (+/- 1006.97)	2757.59
Hospitalization	12888.89 (+/- 32963.48)	11020.83 (+/- 43168.94)	1868.06
Drugs	**16989.50** (+/- 12332.64)	11080 (+/- 11574.84)	5909.5
Non-medical	641.74	464.52	177.22
Others	2800	1500	1300
Total Direct Cost	37218.05	24966.68	12251.37
Wage loss: Indirect Cost	1748.48 (+/- 3667.91)	2303.92 (+/- 2476.78)	-555.44
Total Annual Health Expenditure	41766.53	28770.6	**12995.93**

DIRECT COSTS

As per the table: Direct costs can be divided into direct medical cost which are the costs related to medical expenses or healthcare and direct non-medical costs which are incurred due to medical expenses but are not related to healthcare.

Table 9: Type of Direct medical and non-medical cost

DIRECT MEDICAL COST	DIRECT NON-MEDICAL COST
Cost of consultation	Cost of transportation
Cost of drugs	Cost of transportation in case of accompanier
Cost of hospitalization	Cost of accommodation in case of accompanier (hospitalization)
Cost of investigations	Investment in care-giver for past one year
One-time investment in any health-related item	Cost of food applicable during consultation or hospitalization

Consultation cost

Consultation costs are experienced when the subject visits the particular service provider as regular check-up or as one-time event. Here we are considering consultation costs as one-time event occurred to the patient in one year.

Table 10: Type of Healthcare facility visited for consultation

Type of Healthcare Facility	Frequency
Acupuncture clinic	1 (0.6%)
Ayurvedic	2 (1.3%)
Government Hospital	15 (10%)
Homeopathy	3 (2%)
Private	111 (74%)
Public (Mobile Van)	6 (4%)

Out of 150 households, only 92 percent have gone for consultation within three months (December to February). For consultation, only 14 percent have visited public facility that is either government hospital (10 percent) or Mobile Van (four percent). About 3.9 percent have visited AYUSH facilities for consultation and maximum households have visited private facility.

Table 11: Direct consultation cost (INR) as per disease categories

Disease category	Frequency	Mean	Std. Deviation	Minimum	Maximum
Only Diabetes	24	536.11	741.11	0.00	3300.00
Diabetes and Chronic conditions	22	769.70	1142.56	50.00	5600.00
Diabetes and Non chronic conditions	8	2020.83	2662.58	150.00	8300.00
Chronic conditions	32	687.39	1219.19	0.00	5500.00
Only Non-chronic conditions	62	621.04	746.63	0.00	2950.00

Direct Consultation costs consists of expense due to service provider, expense for drugs if given, transportation and food costs as well as expenses related to accompanier. As consultation costs are taken as one-time event they will not be extrapolated to a year.

The trend shows that the costs are higher among subjects of diseased group diabetic with non-chronic condition followed by diabetic with chronic condition even though the frequency of subjects is higher among the latter. Subjects with only diabetes have lesser cost as compared to subjects with chronic conditions and non-chronic conditions.

Investigation costs

Investigation expenses are experienced when the subject undergoes some diagnostic tests. These are calculated with the expenditure incurred that is for diagnosis, transportation and accompanier and are extrapolated to one year according to the subject's frequency of investigations.

Table 12: Investigation frequency as per diabetes status

Disease category	Once a year	Twice a year	Quarterly	Once every two months	Monthly
Diabetes	21 (38.9%)	10 (18.5%)	13 (24.1%)	7(13.0%)	3(5.6%)
Non-Diabetes	94 (97.9%)	1 (1.0%)	1 (1.0%)	0`	0

Frequency of investigations was observed in diabetic subjects more than 60 percent subjects have frequency for investigations, done more than once a year whereas in case of non-diabetic subjects the frequency for investigations was maximum for once a year which could be inferred as one-time event with respect to illness

Table 13: Direct Investigation cost (INR) as per disease categories

Disease category	Frequency	Mean	Standard Deviation	Minimum	Maximum
Only Diabetes	24	696.67	1216.38	.00	4750.00
Diabetes and Chronic conditions	22	742.55	1149.69	.00	3900.00
Diabetes and Non chronic conditions	8	500.00	963.62	.00	2500.00
Chronic conditions	34	269.12	1322.30	.00	7600.00
Only Non-chronic conditions	62	99.19	333.33	.00	1650.00

The annual investigations costs are highest among the Diabetic and chronic condition group with Rs 742.55 as the mean value and the lowest among non-chronic conditions which is only 99.19 Rs with minimum being 0 which could indicate that the tests are done in government hospital.

Hospitalization Costs

Only 18 percent subjects were hospitalized and the expenditure calculated is summation of hospitalization charges which includes investigation conducted during hospitalization, drugs used, transportation of the subject, accommodation, transportation and food expenditure of the accompanier. The summation was then divided by the number of days an individual was hospitalized. Hospitalization costs are shown on per day basis to attend linearity.

Table 14: Direct Hospitalization cost per day (INR) as per disease categories

Disease category	Count	Mean	Standard Deviation	Minimum	Maximum
Only Diabetes	5	13030.95	5842.33	3904.76	18750.00
Diabetes and Chronic conditions	4	9184.52	6300.61	1250.00	16666.67
Diabetes and Non chronic conditions	2	24583.33	11195.86	16666.67	32500.00
Chronic conditions	9	13002.80	12800.55	00	35714.29
Only Non-chronic conditions	8	4938.10	3948.63	166.67	10000.00

As the trend continues, we can see that maximum per day cost for complete hospitalization is among Diabetes with Non-chronic conditions and the least among Non-chronic condition. Subjects with only diabetes have higher hospitalization cost INR 13030.95 than subjects having diabetes with chronic conditions INR 9184.52. The minimum costs that is INR 0 and INR 166.67 for hospitalization was due to admission in government hospitals.

Drugs Cost

The Drug cost was also expressed as per day cost because the medication for the non-chronic conditions was prescribed for either a week or 15 days.

Table 15: Total drug cost per day (INR) as per source of buying medication

Drugs/ Injectables Source	Count	Mean	Standard Deviation	Minimum	Maximum
Ayurvedic	5	27.43	19.24	6.67	57.14
Government Hospital Pharmacy	16	8.66	7.61	1.67	30.00
Homeopathy	2	14.17	12.96	5.00	23.33
NGO	1	0	0	0	0
Private	122	48.80	35.30	.00	200.00

Table 16: Total Drug cost per day (INR) as per disease categories

Disease category	Count	Mean	Standard Deviation	Minimum	Maximum
Only Diabetes	24	34.54	30.16	.00	116.67
Diabetes and Chronic conditions	22	**60.15**	33.52	16.67	116.67
Diabetes and Non chronic conditions	8	**42.50**	36.11	3.33	116.67
Chronic conditions	34	36.07	24.77	2.67	100.00
Only Non-chronic conditions	62	40.96	41.38	.00	200.00

Majority of the spending is among Diabetics with Chronic conditions followed by diabetics with non-chronic conditions and least spending is done among only diabetic groups.

INDIRECT COSTS

Indirect costs as defined can be calculated either by wage loss of the subject and the accompanier or by calculating the productivity lost due to engagement in activities related to decrease in health (illnesses).

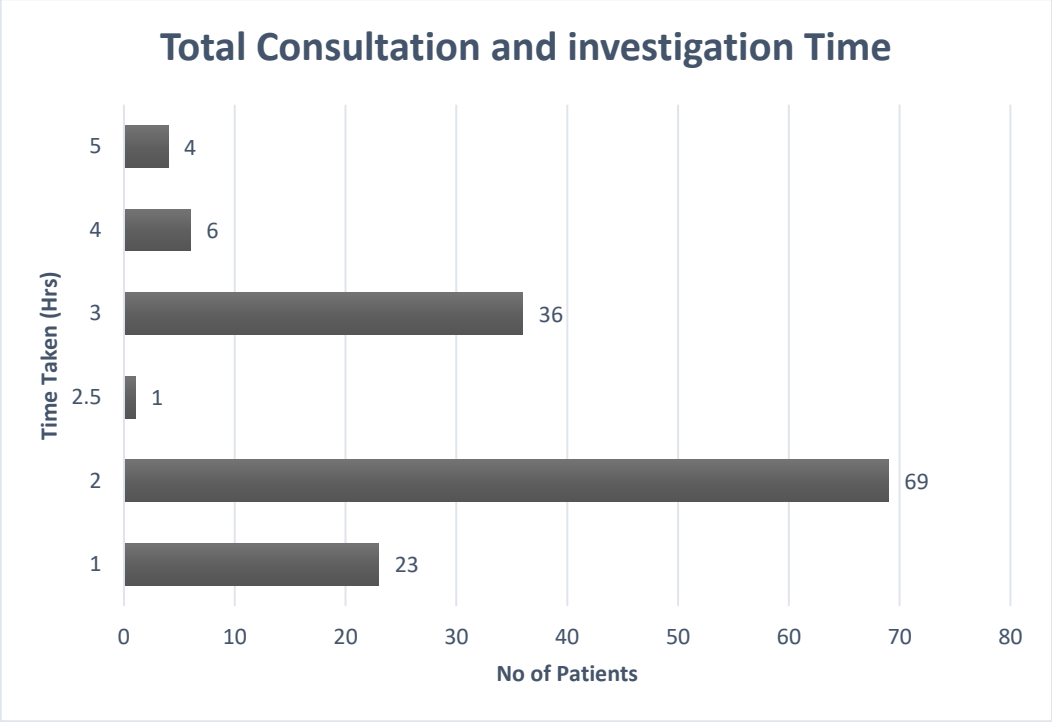
Table 17: Type of income or productivity loss

INCOME LOSS/PRODUCTIVITY LOSS
Hours invested in consultation (patient and accompanier)
How would the subject/accompanier otherwise utilise the hours invested in health-care facility
Days lost during hospitalization (patient and accompanier)
Income loss of accompanier during hospitalization

Consultation and Investigation

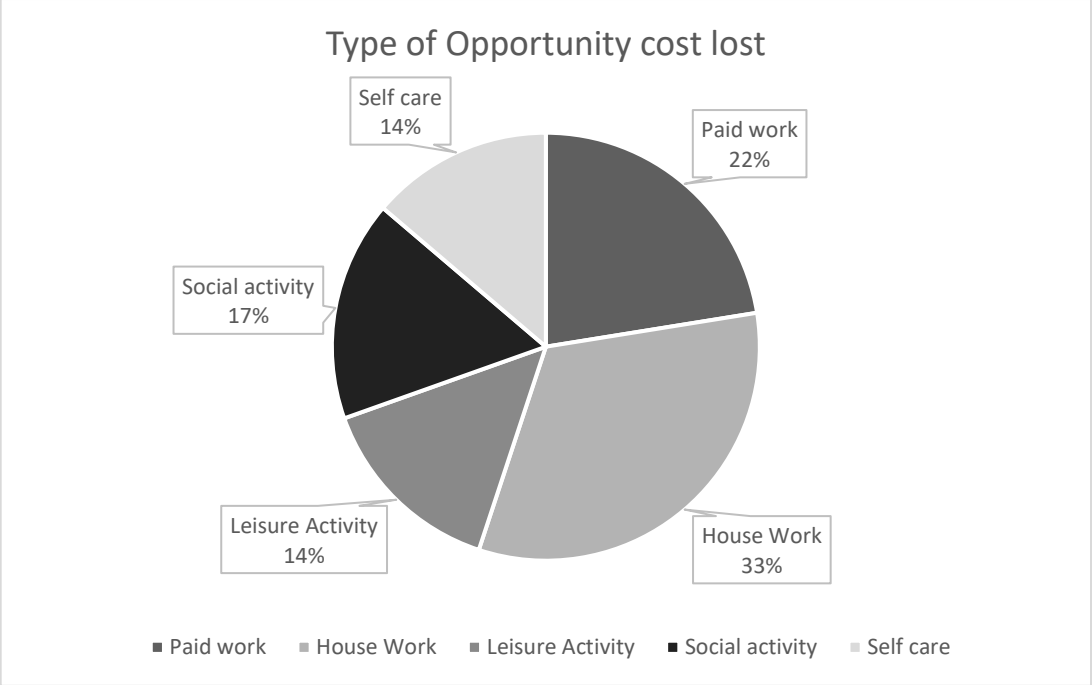
As the time invested by the subject and their accompanier in consultations and investigations are either few hours, if working, visited during breaks or they took half day off. It was observed that there wasn't any loss of wage related to the time taken for these two activities but there was productivity loss, here we are showing the productivity loss in terms of opportunity cost lost. Opportunity cost lost would mean that if the person was not involved in the above two activities what would they be doing for those hours?

Figure 4: Total time invested for Consultation



The total consultation and investigation time were calculated by taking the average time for each subject and accompanier, the time taken for subject and accompanier would be the same hence represented as no of subjects.

Figure 4: Opportunity cost lost while visiting health-care facility



From fig 4 and fig 5 we could infer that the average time invested in consultation and investigation was 2.27 hours and the maximum time taken is five hours. Around 33 percent reported that if they were not involved in visiting a healthcare facility, they would be spending time doing housework. Similarly, 22 percent subjects would have invested in their paid work, 17 percent would have been involved in some social activities and 28 percent would not have lost their leisure and self-care time.

Hospitalization

The indirect cost calculated for hospitalization would be by wage loss and productivity loss. Here wage loss will be represented in terms of cost and productivity loss will represented in terms of time.

Table 18: Days of productivity loss of patient as per disease categories

Disease category	Days of Productivity loss due to Hospitalization (Patient)			
	Mean	Standard Deviation	Minimum	Maximum
Only Diabetes	10	6	5	20
Diabetes and Chronic conditions	9	4	5	15
Diabetes and Non chronic conditions	10	7	5	15
Chronic conditions	10	6	2	20
Only Non-chronic conditions	19	20	3	60

The days for productivity lost among subjects who were hospitalized was highest among the non-chronic diseased group with 19 days where as the other groups have almost same mean days lost that is 10 days. The maximum days of productivity lost among diabetic subjects was 20 days.

Table 19: Days of productivity loss of accompanier as per disease categories

Disease category	Days of Productivity loss due to Hospitalization (Accompanier)			
	Mean	Standard Deviation	Minimum	Maximum
Only Diabetes	**5**	**3**	**2**	**8**
Diabetes and Chronic conditions	**7**	**2**	**3**	**8**
Diabetes and Non chronic conditions	**6**	**5**	**2**	**9**
Chronic conditions	**6**	**5**	**2**	**17**
Only Non-chronic conditions	**10**	**10**	**2**	**30**

The accompanier days of productivity loss among the NCD group is higher in diabetes with chronic conditions and the overall productivity loss is higher in Non-chronic conditions with 10 days lost in taking care of the subject.

Wage loss

Wage loss was calculated by adding the loss in income of the subject hospitalized and the accompanier who also incurred loss of income due to the subject.

Table 20: Wage loss of due to hospitalization INR as per diabetes status

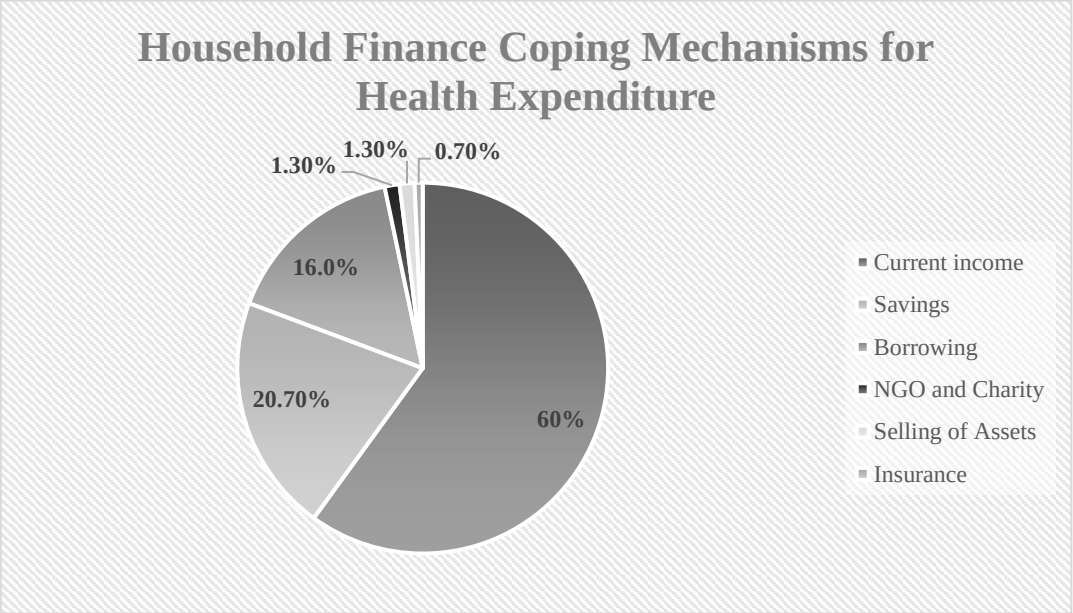
	Frequency	Mean	Standard Deviation	Minimum	Maximum
Diabetes	11 (39.28%)	1748.48	3667.91	0	12500
Non-diabetes	17 (60.71%)	2303.92	2476.78	0	8000

The wage loss among non-diabetic and diabetic subjects was INR 2303.92 and INR 1748.48 respectively.

Coping Mechanism

Coping Mechanism refers to the way in which households are able to manage their health expenditure. These expenses could be covered in the form of current income, savings, borrowing with or without interest, selling of assets like land or gold or managing it with the help of NGO, Insurance or Charity.

Figure 6: Household coping mechanism



Around, 60 percent of the households are managing their expenses through current income, 20.70 percent through savings and 17.3% by either borrowing or selling their assets. Only 0.7 percent manage through insurance and 1.3 percent are helped by charity or any NGO.

Table 21: Coping mechanism with as per diabetes status

	Savings	**Current income**	**Borrowing**	**NGO and Charity**	**Selling of Assets**	**Insurance**	**Total**
Diabetes Yes	16 (29.6%)	29 (53.7%)	7 (13%)	1 (1.9%)	1 (1.9%)	0	54
No	15 (48.4%)	61 (63.5%)	17 (17.7%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	96

Diabetes doesn't play a part in households with respect to managing their expenses, subjects with or without diabetes rely on current income to fulfil their health needs and only 20.70 percent subjects having savings.

Table 22: Coping mechanism as per income quintile

Income Quintile	Coping Mechanism						Total
	Savings	Current income	Borrowing	NGO and Charity	Selling of Assets	Insurance	
Q1_Highest	10	17	0	1	0	1	29
Q2	3	21	4	0	1	0	29
Q3	9	17	5	0	1	0	32
Q4	3	13	3	0	0	0	19
Q5_Lowest	6	22	12	1	0	0	41
Total	31	90	24	2	2	1	150

From the above table we can understand that subjects falling under highest quintiles have some savings from which they manage their health expenditure. All the quintile groups majorly manage through current income. The subjects under lowest quintile are the one who majorly involved in borrowing.

Effect of Health expenditure on household spending

Only 24 percent of households had effect on their non-health expenses due to health expenditure. The opportunity cost lost on non-health expenses were categorised as explained by the households, 47.20 percent households compromised on food and social obligation, 16.70 percent on food consumption only, 22.20 percent mentioned about

compromising on child's education and 14 percent compromised on household's other members treatment, food as well as child's education.

Figure 7: Households Opportunity cost's frequency distribution

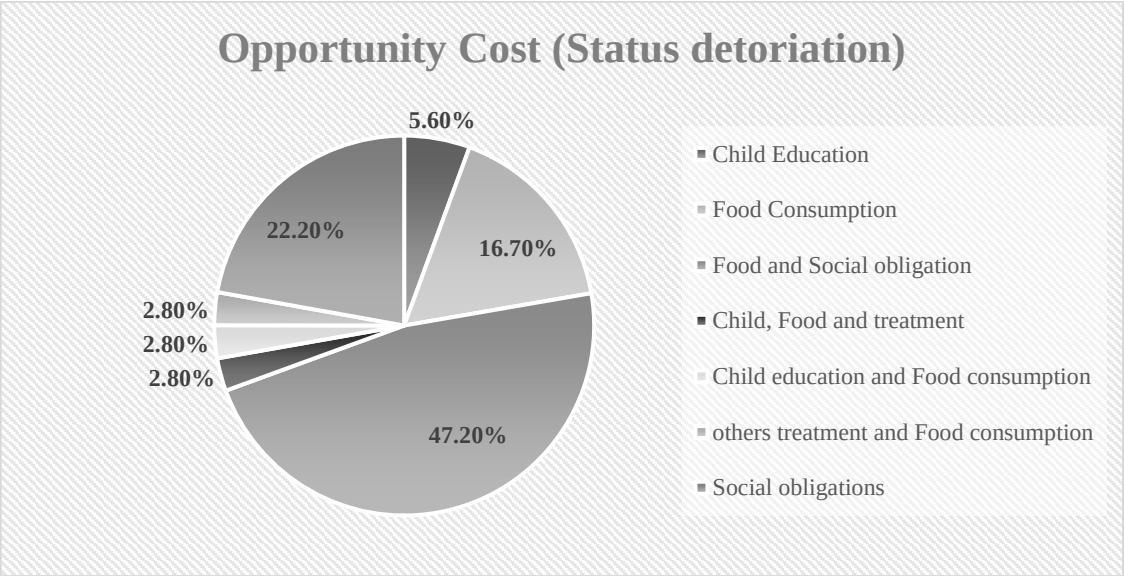


Table 23: Opportunity cost as per diabetes status

	Child Education	Food Consumption	Food and social obligation	Child education, Food and treatment of other member	Child education and Food consumption	Others treatment and Food consumption	Social obligation	TOTAL
Yes	**1**	**0**	**7**	**1**	**0**	**1**	**5**	**15**
No	**1**	**6**	**10**	**0**	**1**	**0**	**3**	**21**

Only 24 percent of the overall sample population had to compromise on various aspects, among them 41.6 percent were diabetic population and they majorly compromised on food and social obligations or only social obligations. The non-diabetic population has also majorly compromised on food and social obligations. Only one subject which belongs in the diabetic group has compromised on all the aspects that is child education, food and treatment of other member in the household.

Effect of health expenditure on consumption of medication

Table 24: Effect on consumption of medication as per diabetes status

	Effect on consumption of medication	
	YES	**NO**
DIABETES Yes (54)	14 (25.9%)	40 (74.1%)
No (96)	17 (17.7%)	79 (82.3%)

Overall 20.67 percent of subjects have effect of their medication consumption. 25.9 percent of subject who have diabetes compromise on medication. The maximum frequency overall to discontinue the medication due to financial reason was twice a month. Around 6.4 percent subjects do not consume medication at all.

Table 25: Frequency of subjects who discontinue medication

Medication Discontinued due to Financial Reason	**Frequency**
once or twice a week	**4**
thrice a week	**1**
2 weeks or more	**3**
twice a month	**13**
5 times in a month	**3**
thrice a month	**3**
One Whole Month	**1**
Doesn't eat medication	**2**
Sometimes	**1**

Intangible costs

Quality of life was calculated using MDQ-QOL tool, it contains three sections and are targeted on understanding Quality of life with respect to interference, severity, social support, positive reinforcing behaviours, misguided reinforcing behaviour, self-efficacy and outcome expectancies of diabetes as a disease on subject's life.

Section I: General perceptions of diabetes and related social support

It consists of Interference, Severity and Social support, the scale here ranges from zero to six where zero means "not at all" and six means "extremely".

Table 26: Mean score of diabetic subjects as per general perceptions of diabetes and related social support

Section I	Mean Score	Standard deviation	Median
Interference	3.01	1.55	3
Severity	3.58	1.93	4
Social support	3.18	1.34	3

The mean score of interference, severity and social support are in the range of 3 which means that majority of the subjects are neutral or moderate with respect to general perceptions of diabetes which could also mean that they do not understand about the disease and are also neutral about the social support which could be inferred as that they would not be getting proper support

Only 7.4 percent subjects consider that diabetes does not interfere (not at all) in their lives and 9.4 percent subject consider it extremely affects. Only 7.4 percent subjects consider that diabetes is not serious or not at all severe, where as 38.9 percent consider it extremely severe. There are only 16.8 percent subjects who have extreme social support and there

no subjects who are not at all supported, although 14.8 percent subjects have social support score as 2.3.

Section II: Social incentives related to self-care activities

It consists of positive reinforcing behaviours like congratulating or reminds the subject when they do something positive to help with their disease and misguided reinforcing behaviours are like hassling about the disease to the subject, the scale here ranges from zero to six where zero means "never" and six means "very often".

Table 27: Mean score of diabetic subjects as per social incentives related to self-care activities

Section II	Mean	Standard deviation	Median
Positive reinforcing behaviours	1.43	1.55	1
Misguided reinforcing behaviours	1.66	1.66	1.37

The mean score for positive reinforcing behaviours and misguided reinforcing behaviours are 1.43 and 1.66 respectively, infers that majority of the subjects do not experience or have very little experience of the above behaviours in their life.

There are 33.3 percent subjects who never have positive reinforcing behaviours and none of the subjects have often or very often positive reinforcing behaviour. For misguided reinforcing behaviours 33.3 percent subjects have never experienced that and none of them have experienced it very often, which conveys a positive direction towards quality of life.

Section III: Self-Efficacy and Outcome expectancies

It consists of self-efficacy and outcome expectancies; the scale here ranges from zero to 100 where zero means “not at all important” and 100 means “very important”.

Table 28: Mean score of diabetic subjects as per self-efficacy and outcome expectations

Section III	Mean	Standard deviation	Median
Self-Efficacy	59.25	22.83	67.14
Outcome expectancies	64.16	20.37	69.16

The mean score for self-efficacy and outcome expectancies are 59.25 and 64.16 respectively which means that majority of the subjects are confident by only 59.25 about their diet, treatment and everyday routine with respect to diabetes.

Only six percent subjects consider self-efficacy very important and nobody considers it not at all important. Around 11.1 percent subjects have self-efficacy as 67.1 and 9.3 percent subjects have self-efficacy as 18.6. Only 5.6 percent subjects think that the outcome expectancies like following of proper diet, exercising on regular basis and following proper treatment will help in controlling diabetes are very important and none of them think that they are not at all important.

Discussion

This study is a community based with an exploratory methodology to determine the economic burden adhered to type II diabetes. The incremental approach to this cost of illness study gave it an edge as to how much extra does person suffering through diabetes has to pay to receive the same amount of healthcare needs when compared to a non-diabetic subject.

There are only 36 percent diabetic subjects in this study population and the ratio for diabetic to non-diabetic subjects was 2:3, that is for every 2 diabetic subjects this population has 3 non-diabetics. As per literature review the incremental cost of illness studies are generally conducted on secondary data and proceeded through a matching or regression method of the two groups on basis of residence, age and sex or diagnosis respectively (Akobundu et al., 2006). In this study we haven't matched the subjects but we can assume as our population comes from the same zone, both categories have maximum subjects under the age group of 50-59years.

As diabetics and non-diabetics were two broad groups, for the ease of understanding as well as to explore multi morbidity we had further divided them into five categories. 41 percent subjects were non-chronic and only 16 percent subjects had diabetics without any chronic or non-chronic ailments. Although 22.7 percent had other chronic illness but they were existing in co-morbid way, for example a subject suffering from hypertension was also taking medication for arthritis or a subject consuming cancer medication for more than 10 years was also a thyroid patient. 20 percent of the population were having diabetes and other morbidities.

Only 5.3 percent subjects are diabetics with non-chronic ailments but the cost of consultation was highest INR 2020.83 (SD+/- 2662.58) among them and the average

direct cost of their hospitalization was INR 24583.33 (SD+/- 11195.86) as compared to diabetics who have chronic conditions (14.7 percent) with cost of consultation as INR 769.70 (SD+/- 1142.56) and cost of hospitalization INR 9184.52 ((SD+/- 6300.61) The total drug cost per day was highest among diabetics with chronic conditions INR 60.15 (SD+/- 33.52) and least among subjects having only diabetes INR 34.54 (SD+/- 30.16).

People with diagnosed diabetes, on average, have medical expenditures ~2.3 times higher than what expenditures would be in the absence of diabetes (*Diabetes Care*, 2018). In this study population the average expenditure of diabetic subjects was 1.45 times higher than subjects who do not have diabetes.

This study shows that average annual direct cost is higher among those who attended private clinic INR 20,260 and lowest among those who attended government clinics INR 658. A study conducted in south India in 2010 showed similar trend where the annual direct cost of diabetes among 606 individuals was highest among those who attended the private clinic (INR 19 552/-, US$ 425) and lowest among those who attended the government clinic (INR 1204/-, US$ 26.17). (Sharma et al., 2016).

This study shows that the annual average direct cost for routine diabetes treatment without hospitalization was INR 20886.93. The total consultation fee accounted for 2.3 percent of the total cost, medicines were 43.60 percent and 7.6 percent was accounted for investigations. A study conducted in 1998 to estimate the cost of illness due to diabetes accounted for annual average direct cost without hospitalization as INR 5959 and the total consultation fee accounted for 38% of the cost, medicines 32 % of the cost, transportation 23% and 7% was other direct costs. (Rayappa et al., 2005).

In India, where 21.2 % of the population live under 1.90 USD per day (Poverty & Equity Data Portal, 2020), this population are almost on the verge of entering into a vicious cycle

of impoverishment along with poverty while seeking for healthcare majorly for NCD's. (Rijal et al., 2018) In this study the impoverishment effect affects around 17.7 percent of the population as they are involved in selling of assets or borrowing.

Conclusion

The average annual cost of illness calculated for type 2 diabetic subjects was found to be INR 41766.53 with mean loss in productivity as 10 days.

This study shows that an individual with diabetes above 50 years of age will have an average burden of INR **12995.93**/annually.

The impoverishment effects as per the study is not related to the disease burden but relates to the household income. 53.7 percent of diabetic population in the study relies on current income as their only source for managing the health expenditure incurred. 29.6 percent are managing via savings and 13 percent subjects are involved in borrowing money. Apart from managing, 41.6 percent of diabetic population are compromising due to their health expenditure on either food or social obligations or both.

The quality of life of diabetic subjects with respect to General perceptions of diabetes and related social support, the mean score for the same was around 3 which means that the subjects have moderate understanding about the perceptions of diabetes and have moderate social support

The quality of life of diabetic subjects with respect to social incentives and self-care.

The mean score for Positive reinforcing behaviours is 1.43 which means they hardly experience any positive or encouraging behaviour from their surroundings.

The mean score for misguided reinforcing behaviours is 1.66 which means majority of them do not experience negative behaviour from their spouse or caregiver or family which means they are having positive quality of life.

Quality life with respect to self-efficacy and outcome expectancies, the mean score for them 59.25 and 64.16 respectively which means that majority of the subjects are confident by only 59.25 about their diet, treatment and everyday routine with respect to diabetes and the extend was 64.14 for outcome expectancies like following of proper diet, exercising on regular basis and following proper treatment will help them in controlling diabetes.

REFERENCES

Afroz A, Alramadan MJ, Hossain MN, et al. (2018) Cost-of-illness of type 2 diabetes mellitus in low and lower-middle income countries: a systematic review. *BMC health services research* 18(1): 972. DOI: 10.1186/s12913-018-3772-8.

Akobundu E, Ju J, Blatt L, et al. (2006) Cost-of-illness studies : a review of current methods. *PharmacoEconomics* 24(9): 869–890.

Diabetes Care (2018) Economic Costs of Diabetes in the U.S. in 2017.: dci180007. DOI: 10.2337/dci18-0007.

Domeikienė A, Vaivadaitė J, Ivanauskienė R, et al. (2014) Direct cost of patients with type 2 diabetes mellitus healthcare and its complications in Lithuania. *Medicina* 50(1): 54–60. DOI: 10.1016/j.medici.2014.05.007.

Emerging Risk Factors Collaboration, Sarwar N, Gao P, et al. (2010) Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease: a collaborative meta-analysis of 102 prospective studies. *Lancet (London, England)* 375(9733): 2215–2222. DOI: 10.1016/S0140-6736(10)60484-9.

Fernandes SD and Fernandes SDA (2017) Economic burden of diabetes mellitus and its socio-economic impact on household expenditure in an urban slum area. In: 2017. DOI: 10.18203/2320-6012.ijrms20171585.

Grover S, Avasthi A, Bhansali A, et al. (2005) Cost of ambulatory care of diabetes mellitus: a study from north India. *Postgraduate Medical Journal* 81(956): 391–395. DOI: 10.1136/pgmj.2004.024299.

IDF (2020). Available at: https://idf.org/our-network/regions-members/south-east-asia/members/94-india.html (accessed 18 May 2020).

Jaspers L, Colpani V, Chaker L, et al. (2015) The global impact of non-communicable diseases on households and impoverishment: a systematic review. *European Journal of Epidemiology* 30(3): 163–188. DOI: 10.1007/s10654-014-9983-3.

Kapur A (2007) Economic analysis of diabetes care. *The Indian Journal of Medical Research* 125(3): 473–482.

Larg A and Moss JR (2011) Cost-of-Illness Studies. *PharmacoEconomics* 29(8): 653–671. DOI: 10.2165/11588380-000000000-00000.

Macdonald G (2008) Harrison's Internal Medicine, 17th edition. - by A. S. Fauci, D. L. Kasper, D. L. Longo, E. Braunwald, S. L. Hauser, J. L. Jameson and J. Loscalzo. *Internal Medicine Journal* 38(12): 932–932. DOI: 10.1111/j.1445-5994.2008.01837.x.

Mohan V, Mathur P, Deepa R, et al. (2008) Urban rural differences in prevalence of self-reported diabetes in India—The WHO–ICMR Indian NCD risk factor

surveillance. *Diabetes Research and Clinical Practice* 80(1): 159–168. DOI: 10.1016/j.diabres.2007.11.018.

Poverty & Equity Data Portal (n.d.). Available at: http://povertydata.worldbank.org/poverty/country/IND (accessed 21 May 2020).

Rayappa PH, Raju K, Kapur A, et al. (2005) ECONOMIC COST OF DIABETES CARE THE BANGALORE URBAN DISTRICT DIABETES STUDY. In: 2005.

Rice DP (1967) Estimating the cost of illness. *American Journal of Public Health and the Nations Health* 57(3): 424–440. DOI: 10.2105/AJPH.57.3.424.

Rijal A, Adhikari TB, Khan JAM, et al. (2018) The economic impact of non-communicable diseases among households in South Asia and their coping strategy: A systematic review. *PLOS ONE* 13(11). Public Library of Science: e0205745. DOI: 10.1371/journal.pone.0205745.

Segel J (2006) Cost-of-Illness Studies — A Primer January 2006. In: 2006.

Sharma KM, Ranjani H, Zabetian A, et al. (2016) Excess cost burden of diabetes in Southern India: a clinic-based, comparative cost-of-illness study. *Global Health, Epidemiology and Genomics* 1. DOI: 10.1017/gheg.2016.2.

Shobhana R, Rao PR, Lavanya A, et al. (2000) Cost burden to diabetic patients with foot complications--a study from southern India. *The Journal of the Association of Physicians of India* 48(12): 1147–1150.

Tandon N, Anjana RM, Mohan V, et al. (2018) The increasing burden of diabetes and variations among the states of India: the Global Burden of Disease Study 1990–2016. *The Lancet Global Health* 6(12): e1352–e1362. DOI: 10.1016/S2214-109X(18)30387-5.

Tharkar S, Devarajan A, Kumpatla S, et al. (2010) The socioeconomics of diabetes from a developing country: a population based cost of illness study. *Diabetes Research and Clinical Practice* 89(3): 334–340. DOI: 10.1016/j.diabres.2010.05.009.

Top M, Aslan H, Akyürek ÇE, et al. (2020) Costs analysis of diabetes mellitus: A study based on hospital invoices and diagnosis related groups. *Health Policy and Technology* 9(1): 23–31. DOI: 10.1016/j.hlpt.2020.01.005.

WHO (2014) WHO | Noncommunicable diseases country profiles 2014. Available at: http://www.who.int/nmh/publications/ncd-profiles-2014/en/ (accessed 23 September 2019).

ANNEXURE I: MDQ-QOL

Name: _____ Date: _____

Multidimensional Diabetes Questionnaire

Section I

We are interested to learn more about your diabetes and the way it affects your life. For each question, circle the number that corresponds best to your situation.

1. To what extent does your diabetes interfere with your daily activities?

0	1	2	3	4	5	6
Not at all						Extremely

2. To what extent does your spouse (or significant other) support you with your diabetes?

(____ Check here if you live alone)

0	1	2	3	4	5	6
Not at all						Extremely

3. To what extent do you consider your diabetes to be a severe health problem?

0	1	2	3	4	5	6
Not at all						Extremely

4. To what extent does your diabetes decrease your satisfaction or pleasure from social or recreational activities?

0	1	2	3	4	5	6
Not at all						Extremely

5. To what extent do your family and friends support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

6. To what extent do you worry about long-term complications of diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

7. To what extent does your diabetes interfere your effectiveness at work?

0	1	2	3	4	5	6
Not at all						Extremely

8. To what extent does your diabetes interfere with your relationship with your spouse (or significant other)?

(____ Check here if you live alone)

0	1	2	3	4	5	6
Not at all						Extremely

9. To what extent do you worry about your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

10. To what extent does your spouse (or significant other) pay attention to you because of your diabetes?

(____ Check here if you live alone)

0	1	2	3	4	5	6
Not at all						Extremely

11. To what extent does your diabetes prevent you from traveling as much as you would like?

0	1	2	3	4	5	6
Not at all						Extremely

12. To what extent does your doctor or health care team support you or help you with your diabetes?

0	1	2	3	4	5	6
Not at all						Extremely

13. To what extent does your diabetes interfere with your ability to participate in social or recreational activities?

0 1 2 3 4 5 6

Not at all Extremely

14. To what extent does your diabetes interfere with your ability to plan your activities?

0 1 2 3 4 5 6

Not at all Extremely

15. To what extent does your diabetes prevent you from being as active as you would like?

0 1 2 3 4 5 6

Not at all Extremely

16. To what extent does your diabetes prevent you from having a schedule that you like (e.g., to sleep late)?

0 1 2 3 4 5 6

Not at all Extremely

Section II

We are interested to learn about the way your spouse (or significant other) responds to you concerning your self-care program. On the scale listed below each question, circle the number that best indicates how often he or she responds to you in that particular way.

My spouse (or significant other):

1. Congratulates me when I follow my diet.

0 1 2 3 4 5 6

Never Very often

2. Hassles me about my diabetes medication (pills, insulin).

(___ Check here if you do not take medication for your diabetes)

0 1 2 3 4 5 6

Never Very often

3. Congratulates me for regularly measuring my blood glucose level.

(___ Check here if self-monitoring of blood sugar levels has **not** been recommended)

0 1 2 3 4 5 6

Never Very often

4. Hassles me about exercise.

(___ Check here if you have been advised **not** to exercise)

0 1 2 3 4 5 6

Never Very often

5. Reminds me to take care of my feet.

(___ Check here if foot care has **not** been recommended)

0 1 2 3 4 5 6

Never Very often

6. Congratulates me when I follow my meal schedule (meals and snacks).

0 1 2 3 4 5 6

Never Very often

7. Reminds me to take my diabetes medication (pills, insulin).

(___ Check here if you do **not** take medication for your diabetes)

0 1 2 3 4 5 6

Never Very often

8. Helps me to adjust my food intake when I exercise.

(___ Check here if you have been advised **not** to exercise)

0 1 2 3 4 5 6

Never Very often

9. Hassles me about my diet.

0 1 2 3 4 5 6

Never Very often

10. Plans family activities in a way that allows me to take my medication at the right time.

(___ Check here if you do **not** take medication for your diabetes)

0 1 2 3 4 5 6

Never Very often

11. Hassles me about measuring my blood sugar.

(___ Check here if self-monitoring of blood sugar levels has **not** been recommended)

0 1 2 3 4 5 6

Never Very often

12. Encourages me to exercise.

(___ Check here if you have been advised **not** to exercise)

0 1 2 3 4 5 6

Never Very often

Section III

Treatment of diabetes involves several self-care activities (e.g. diet, exercise etc.). People sometimes find it difficult, or do not see the importance of following one or more of these self-care activities. We like to know how this applies to you. Read each question carefully and circle the number that corresponds best to your situation.

1. How confident are you in your ability to follow your diet?

/ / / / / / / / / / /

0 10 20 30 40 50 60 70 80 90 100

Not at all confident Very confident

2. How confident are you in your ability to test your blood sugar at the recommended frequency?

(___ Check here if measuring of blood sugar levels has **not** been recommended)

/ / / / / / / / / / /

0 10 20 30 40 50 60 70 80 90 100

Not at all confident Very confident

3. How confident are you in your ability to exercise regularly?

(____ Check here if you have been advised **not** to exercise)

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

4. How confident are you in your ability to keep your weight under control?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

5. How confident are you in your ability to keep your blood sugar level under control?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

6. How confident are you in your ability to resist food temptations?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities)?

0	10	20	30	40	50	60	70	80	90	100
Not at all confident										Very confident

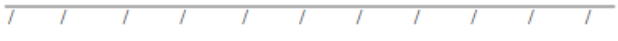
8. To what extent do you think that following your diet is important for controlling your diabetes?

0 10 20 30 40 50 60 70 80 90 100

Not at all important — Very important

9. To what extent do you think that taking your medication as recommended (pills, insulin) is important for controlling your diabetes?

(____ Check here if you do **not** take medication for your diabetes)

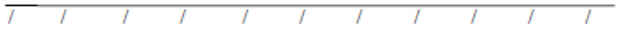


0 10 20 30 40 50 60 70 80 90 100

Not at all important — Very important

10. To what extent do you think that exercise is important for controlling your diabetes?

(____ Check here if you have been advised **not** to exercise)

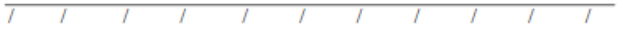


0 10 20 30 40 50 60 70 80 90 100

Not at all important — Very important

11. To what extent do you think that measuring your blood sugar is important for controlling your diabetes?

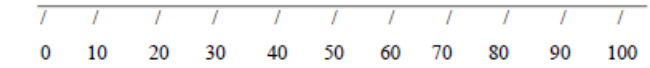
(____ Check here if self-monitoring of blood sugar levels has **not** been recommended)



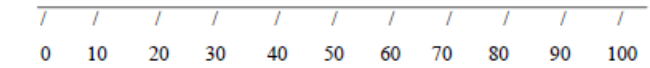
0 10 20 30 40 50 60 70 80 90 100

Not at all important — Very important

12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?



13. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long-term diabetes complications (problems related to eyes, kidneys, heart or feet)?



Scoring of the MDQ:

Section I: general perceptions of diabetes and related social support

Interference: items (1 + 4 + 7 + 8 + 11 + 13 + 14 + 15 + 16) / 9[a]

Severity: items (3 + 6 + 9) / 3

Social support: items (2 + 5 + 10 + 12) / 4

Section II : social incentives related to self-care activities

Positive reinforcing behaviors: items (1 + 3 + 5 + 6 + 7 + 8 + 10 + 12) / 8

Misguided reinforcing behaviors: items nos. (2 + 4 + 9 + 11) / 4

Section III: self-efficacy and outcome expectancies

Self-efficacy: items (1 + 2 + 3 + 4 + 5 + 6 + 7) / 7

Outcome expectancies: items (8 + 9 + 10 + 11 + 12 + 13) / 6

[a] The denominator, which reflects the number of items in that scale, will need to be adjusted if there are missing values for the summed items in a particular scale (i.e. the numerator). For example, if a patient indicated that question 1 in Section I was not applicable or left this item blank, then the denominator of the interference scale would be 8 rather than 9, and only 8 items would be summed to form the numerator. This type of adjustment should be made for each scale that contains missing values so that a patient's score can be compared to scale norms.

ANNEXURE II

INTERVIEW SCHEDULE

Interview Schedule

Title: **The Economic Burden of Type 2 diabetes using the incremental cost of illness approach- An exploratory study in Mumbai**

FORM NO:

Participant Identification No:

Listing Questions/ Screening tool		
1.	Is there anyone in your household above 50 years of age	Y/N
2.	Do you have type 2 diabetes?	Y/N
3.	Are you willing to participate in the study? If no Why?	

Extra Question

1.	How long ago was type 2 diabetes diagnosed? Can you tell me approx. date i.e. how many years ago or months ago?	

DEMOGRAPHIC AND SOCIO-ECONOMIC DETAILS		
1.	What is your Date of Birth?	
2.	Which sex do you address yourself	1. Male 2. Female 3. Transgender
3.	What is your Educational Status?	1. No formal education 2. Less than Primary School 3. Primary school (Class 1- 4) 4. Middle school (class 5-7) 5. High school (class 8-10) 6. Degree and above other(specify)
4.	What is your current Occupational status?	1. Nonworker 2. Self employed 3. Employed 4. Cultivator 5. Labourer(agricultural) 6. Labourer(others) 7. Retried (not on pension) 8. Pensioner 9. Homemaker 10. Others
5.	If, earning Can you please disclose your monthly income	
6.	How many members are there in your household?	
7.	Ownership of the house:	1. Rented 2. Own house 3. Others (specify)
7.	Type of house:	1. Kuccha 2. Semi Pukka 3. 1 room kitchen 4. 1 bedroom flat 5. 2 bedroom flat and more

7.	Relationship of the subject with household member	Date of Birth	Sex	Education (in completed years)	Occupation	Monthly income
1						
2						
3						
4						
5						
6						
7	Income from any other sources:					
8	Total Income:					
9	Monthly household consumption expenditure: Expenditure on Food items Expenditure on Non-Food items					

Consultation		
1.	When was the last time you had gone for physician consultation?	
2.	Date of consultation (if you don't remember exact date let me know the month or the weeks)	
3.	Who was the service provider	1. Private clinic 2. Public clinic 3. Others
4.	What was the reason for consultation?	
5.	Cost of Consultation (in rupees)	
6.	Any Investigations done during or before this visit? (If Yes, Details will be written on the investigations page)	Y/N
7.	Drugs/ Injectables given after consultation (Details will be written on drugs page)	
8.	How did you commute to the provider(auto/taxi/bus/rickshaw/walk)	
9.	What was the cost of transportation (in rupees)	
10.	Do you generally use this mode of transportation for all your consultation visits?	Y/N
11.	If not, then which mode do you use and how much does is cost you? (did you use this mode last to last consultation?)	
12.	How much time did you spend during your consultation (waiting time, transportation time and time with physician)	
13.	Do you go for consultation during your work time?	Y/N

14.	If yes, how much time off work do you take	1. Full day 2. Half day 3. During breaks 4. Specific hours 5. Others specify
15.	If full day/ half day	1. Sick leaves 2. Unpaid leaves
16.	How much does it cost you for one/half day unpaid leave/ one day/ half day wage.	
17.	If self-employed??	
18.	While going for consultation do you indulge in any food refreshments or lunch from outside?	Y/N
19.	If Yes, How much did it cost you	
	<u>ACCOMPAINER QUESTIONS</u>	
20.	Who accompanies you during your visit?	
21.	What is the date of birth and sex of the accompanier?	
22.	What is the accompanier's occupation?	
23.	Monthly income of the accompanier?	
24.	Does the accompanier need to take time off work to help you for consultation visit?	Y/N

25.	If yes, how much time off work do they take	1. Full day 2. Half day 3. During breaks 4. Specific Hours 5. Others specify
26.	If full day/ half day	1. Sick leaves 2. Unpaid leaves
27.	How much does it cost the accompanier for one/half day unpaid leave/ one day/ half day wage.	
28.	Expenditure on Transportation in relation with consultation?	
29.	If applicable food and refreshment costs of accompanier??	
30.	Do you visit any other doctor apart from this provider?	Y/N
31.	If Yes, the reason for visit? When was the last time you had visited?	
32.	Cost of Consultation (in rupees)	
33.	Any Investigations done during or before this visit? (If Yes, Details will be written on the investigations page)	Y/N
34.	Drugs/ Injectables given after consultation (Details will be written on drugs page)	
35.	How did you commute to the provider(auto/taxi/bus/rickshaw/walk)	
36.	What was the cost of transportation (in rupees)	
37.	Do you generally use this mode of transportation for all your consultation visits?	Y/N

38.	If not, then which mode do you use and how much does is cost you? (did you use this mode last to last consultation?)	
39.	How much time did you spend during your consultation (waiting time, transportation time and time with physician)	
40.	Do you go for consultation during your work time?	Y/N
41.	If yes, how much time off work do you take	1. Full day 2. Half day 3. During breaks 4. Specific hours 5. Others specify
42.	If full day/ half day	1. Sick leaves 2. Unpaid leaves
43.	How much does it cost you for one/half day unpaid leave/ one day/ half day wage.	
44.	While going for consultation do you indulge in any food refreshments or lunch from outside?	Y/N
45.	If Yes, How much does it cost you	
	<u>ACCOMPAINER QUESTIONS</u>	
46.	Who accompanies you during your visit?	
47.	What is the date of birth and sex of the accompanier?	
48.	What is the accompanier's occupation?	
49.	Monthly income of the accompanier?	
50.	Does the accompanier need to take time off work to help you for consultation visit?	Y/N

51.	If yes, how much time off work do they take	1. Full day 2. Half day 3. During breaks 4. Specific hours 5. Others specify
52.	If full day/ half day	1. Sick leaves 2. Unpaid leaves
53.	How much does it cost the accompanier for one/half day unpaid leave/ one day/ half day wage.	
54.	If self-employed??	
55.	Expenditure on Transport during consultation?	
56.	If applicable food and refreshment cost of accompanier??	
57.	If not for consultation what you would have done during the time spent on consultation	1. Paid Work 2. House Work 3. Leisure activity 4. Attending social activity 5. Child care 6. Self-care
58.	How many times have you visited same /any other physician in past 3 months? (again ask the consultation questions)	

Hospitalization		
1.	Did you encounter any emergency/ surgical procedure leading to hospitalization in past one year?	Y/N
2.	Date of Hospitalization (if you don't remember exact date let me know the month or the weeks)	
3.	Where did you get hospitalized?	1. Private Hospital 2. Public/ government hospital 3. Others
4.	For how many days you were hospitalised?	
5.	What was the reason?	
6.	Total expenditure incurred during hospitalization (in rupees)	
7.	Any Investigations done during or before? (If Yes, Details will be written on the investigations page)	Y/N
8.	Drugs/ Injectables given after hospitalization (Details will be written on drugs page)	
9.	How did you commute to the hospital (auto/taxi/bus/rickshaw/walk/self(car))	
10.	What was the cost of transportation (in rupees)	
11.	Days of productivity/ work lost Cost of one day (if employed sick leaves or unpaid/ if not formal employee then cost of one day loss)	
	<u>ACCOMPAINER QUESTIONS</u>	
12.	How many people accompanied you during your visit? (extra sheet will be attached if more than one accompanier)	
13.	What is the date of birth and sex of the accompaniers?	

14.	What is the accompaniers' occupation?	
15.	Monthly income of the accompaniers'?	
16.	Does the accompanier need to take time off work to help you for consultation visit?	Y/N
17.	If yes, how much time off work do they take	1. Full day 2. Half day 3. During breaks 4. Specific Hours 5. Others specify
18.	If full day/ half day	1. Sick leaves 2. Unpaid leaves
19.	How much does it cost the accompanier for one/half day unpaid leave/ one day/ half day wage.	
20.	If self-employed ??	
21.	Expenditure on Transport during consultation?	
22.	If applicable food and refreshment cost of accompanier??	
23.	Where did the accompaniers' stay? Was there any expenditure involved?	
24.	How many hospitalizations encounters you had in past one year? (if more than one, repeat the hospitalization questions)	

DRUGS					
1.	Do you take any prescribed/ OTC medication? If, Yes What kind of medication do you take? List them please Oral Injectables				
	Drugs	Reason	Dose	Frequency	Cost of one strip
2.	From where do you obtain these drugs/ Injectables?				1. Government hospital pharmacy 2. Jan aushadi clinic 3. Private pharmacy 4. Others specify
3	Any change of drugs from past 3 months?				
4.	Do you have Glucometer?				Y/N
5.	If Yes, how did you acquire it?				1. Given by NGO 2. Given by Friend 3. Bought 4. Rent
6.	If bought or on rent, how much did it cost? For rent per month charges?				
7.	From the time you have the glucometer how many times have you bought the strips and lancet (to know the frequency).				
8.	Cost of strips?				
9.	Cost of lancet?				

INVESTIGATIONS		
	When was the last time you had done (if done) the investigations?	

	Were they? (for diabetes patient) 1. Urine test 2. HbA1c 3. FBS 4. PPBS 5. GTT 6. Lipid analysis 7. Renal function test 8. Eye test 9. Any investigation for Foot 10. Any other test apart from these		 Y/N Y/N Y/N Y/N Y/N Y/N Y/N Y/N Y/N Y/N
	Are any of these your routine investigation?		
	Investigation	Frequency within 3 months?	Cost
	Where do you usually go for investigations?		
	Do you separately go for investigations? Or they are accompanied during consultation visits?		
	If Separately, then is it during work/ productivity hours?		
	What is the cost if wage lost? (if possible, for per day)		
	How many hours of your daily routine is spent on investigations?		
	Do you have any accompanier??		Y/N
	What is the date of birth and sex of the accompanier?		
	What is the accompanier's occupation?		
	Monthly income of the accompanier?		
	Does the accompanier need to take time off work to help you for consultation visit?		Y/N
	If yes, how much time off work do they take		1. Full day 2. Half day 3. During breaks

		4. Specific hours 5. Others specify
	If full day/ half day	1. Sick leaves 2. Unpaid leaves
	How much does it cost the accompanier for one/half day unpaid leave/ one day/ half day wage.	
	If self-employed??	
	Expenditure on Transport during consultation?	
	If applicable food and refreshment cost of accompanier??	

Complications (applicable only for diabetic patients)		
21.	Do you have any of the below stated complications? If yes, the date of diagnosis Proof of Diagnosis (if possible)	1. Diabetic Retinopathy 2. Diabetic Nephropathy 3. Diabetic Neuropathy 4. Foot Ulcers 5. Cardiovascular disease 6. Peripheral vascular disease 7. Cerebrovascular disease
	If Retinopathy, Neuropathy Questions about Consultation, Investigations and Drugs	
22.	Due to Retinopathy have you ever undergone any surgery like Laser, if yes Where was the surgery performed (Public/ Private)	
23.	Cost of the surgery	
24.	Were you hospitalized for the same?	
25.	How many days were you hospitalized? (Questions on hospitalization and drugs will attached)	
26.	Days of productivity lost?	

27.	Were you accompanied? If yes (Accompanier question will be attached?)	

28.	- Have you undergone Dialysis?
	  o If Yes, Cost of one session
	  o No of session in One month
	- Time required for one session?
	- Days of productivity lost?
	- If accompanied?
	- (question based on accompanier will be attached)	

29.	- Any macro-complication?? - Were you subjected to hospitalization due to the complication like stroke CAD etc - If yes (Hospitalization questions with drugs and investigations will be attached)	

Other Questions		
	Due to your health conditions do you ever feel not going/ doing your work?	Y/N
	If Yes, how many days in a month do you take off?? Is it paid, unpaid, wages lost	
	Or have you ever taken half day if you are not feeling well because of your diabetes?? (half/ hours taken off), Is it paid, unpaid or wages lost	
	Have you taken Premature retirement??	
	If yes How many work years were left? If I may ask, what was your per annum salary??	

	Have you done any change in your dietary elements? If yes, how much did you spend for this dietary change (per month)?	Yes/No
	Did you join any gym center/yoga classes? If yes how much did you pay for gym/yoga classes (per month)?	Yes/No
	Due to diabetes have you encountered any huge loss in past one year	
	Have employed any care-giver or maid after your diabetes?? If Yes, What are their monthly charges?	

	COPING MECHANISMS	
1	HOW DID YOU MANAGE THE EXPENDITURE INCURRED?	A) CURRENT INCOME B) SAVINGS C) BORROWING WITH INTEREST D) BORROWING WITHOUT INTEREST I) HOW MUCH DID YOU BORROW? II) HOW MUCH DID IT TAKE TO REPAY THE DEBT? E) INSURANCE F) SELLING OF ASSETS (SPECIFY.....)
2	If insurance I) WHICH TYPE OF SCHEME: (CGHS/ESIS/PVT INSURANCE/INSURANCE BY EMPLOYED COMPANY) II) HOW MUCH DID YOU PAY FOR PREMIUM? III) WHAT IS THE TOTAL COVERAGE?	

3	DID YOU EXPERIENCE ANY STATUS DETERIORATION DUE TO INCURRING MEDICAL EXPENDITURE?	Y/N
4	IF YES, THEN ASK THE MEDICAL EXPENDITURE IMPACTED ON Probes I) SACRIFICE OF CHILD'S EDUCATION II) SACRIFICE OF FOOD CONSUMPTION III) SACRIFICE OF OTHER MEMBERS TREATMENT IV) SACRIFICE OF SOCIAL OBLIGATIONS.(FESTIVALS/PURCHASE OF LUXURY GOODS/HOUSE OR EXPANSION OF PROPERTY)	
5	DID YOU EVER DISCONTINUE MEDICATION DUE TO FINANCIAL CONSTRAINTS	Y/N
6	If yes, how many times in 1 months	
7	Any other expenditure related to the disease?	
8	Discontinuation of any Leisure Activities If Yes, What	Y/N
9	Discontinuation of any physical activity If Yes, What	Y/N

ANNEXURE III PATIENT INFORMATION SHEET

PATIENT INFORMATION SHEET

I, Vishakha Anbhore, Masters of Public Health student from Achutha Menon Center for health Science Studies (AMCHSS), Sree Chitra Tirunal Institute of Medical Sciences & Technology, Trivandrum. I am conducting a study The Economic Burden of Type 2 diabetes using the incremental cost of illness approach- An exploratory study in Mumbai. The study requires information on the costs incurred by subjects above 50 years of age on treatment, income losses due to absence from work, both of caretaker and patient and details of socio-economic background of households. This study will enable me understand the increment cost associated with type 2 Diabetes

I would really appreciate your participation in the study, which requires you to give an interview. The interview would last for about 40 minutes. Your decision to participate is purely voluntary. During the interview, if you wish to skip any particular question or like to stop the interview you are free to do so. You would not get any direct benefits or compensation by participating in this study, however your views are crucial to understand economic burden that households with this disease have to bear which might help in bringing about a change to address this issue.

I assure you that information provided by you would be strictly kept confidential and your identity would not be disclosed. The information collected by you would be used solely for academic purposes.

Your participation in the study is completely voluntary and non-participation will not harm you in any way. The information given by you will be kept safely with me and won't be shared with anyone who is not a part of the research. If you have any doubts or need any clarifications regarding the research, you can contact me or the Member Secretary of Institutional Ethics Committee,

Vishakha Anbhore
MPH- student
AMCHSS, Trivandrum
9137819778

Dr Mala Ramanathan
Member Secretary,
SCTIMST, Trivandrum
0471-2524234

Thank you.

ANNEXURE IV INFORMED CONSENT

Informed Consent form

Participant no. ……

I, _____, resident of _____,

aged _____ years, declare that

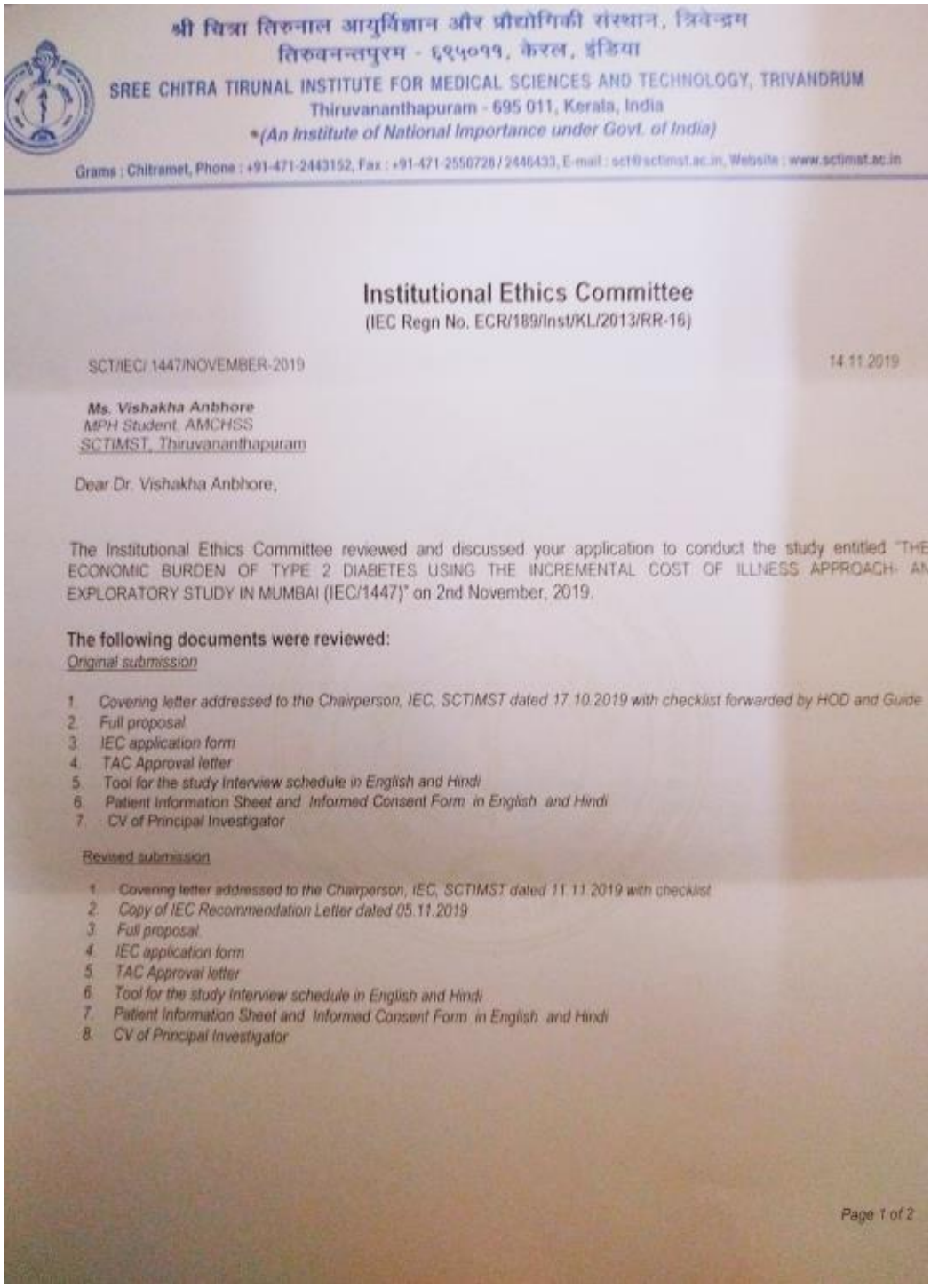
1. I have read about this study in the information form/ have been explained the content of the information form in a language I understand, and I have clarified all the doubts that I had.
2. I also understand that my participation in the study is voluntary and that I can, at any time, discontinue my participation in the study or choose to not answer any uncomfortable question.
3. I understand that my identity won't be revealed in any published or released information from this study.
4. I am voluntarily agreeing to be a part of this study.

Signature/ Thumb imprint

Date:

Place:

IEC CLEARANCE CERTIFICATE



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
*(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/ 1447/NOVEMBER-2019 14.11.2019

Ms. Vishakha Anbhore
MPH Student, AMCHSS
SCTIMST, Thiruvananthapuram

Dear Dr. Vishakha Anbhore,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "THE ECONOMIC BURDEN OF TYPE 2 DIABETES USING THE INCREMENTAL COST OF ILLNESS APPROACH- AN EXPLORATORY STUDY IN MUMBAI (IEC/1447)" on 2nd November, 2019.

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 17.10.2019 with checklist forwarded by HOD and Guide
2. Full proposal
3. IEC application form
4. TAC Approval letter
5. Tool for the study Interview schedule in English and Hindi
6. Patient Information Sheet and Informed Consent Form in English and Hindi
7. CV of Principal Investigator

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 11.11.2019 with checklist
2. Copy of IEC Recommendation Letter dated 05.11.2019
3. Full proposal
4. IEC application form
5. TAC Approval letter
6. Tool for the study Interview schedule in English and Hindi
7. Patient Information Sheet and Informed Consent Form in English and Hindi
8. CV of Principal Investigator

Page 1 of 2

The following members of the Ethics Committee were present at the meeting held on 2nd November, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
2.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
5.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team / Guide who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

Page 2 of 2

URKUND PLAGIARISM CHECK DOCUMENT

URKUND

Document Information

Analyzed document	7284_thesis plagiarism check.docx (D72219139)
Submitted	5/21/2020 8:41:00 AM
Submitted by	Sankara Sarma
Submitter email	sarma@sctimst.ac.in
Similarity	2%
Analysis address	rasma.sctims@analysis.urkund.com

Sources included in the report

SA	URL: Thesis_plagiarism_check.docx Fetched: 5/16/2020 8:10:00 AM	2
W	URL: https://www.diabetes.org/resources/statistics/cost-diabetes Fetched: 5/21/2020 8:44:00 AM	1
W	URL: https://www.researchgate.net/publication/6336330_Economic_analysis_of_diabetes_Care Fetched: 2/13/2020 7:18:00 AM	2
SA	URL: report.pdf Fetched: 11/27/2018 5:24:00 AM	1
W	URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5911784/ Fetched: 5/21/2020 8:44:00 AM	1