Chapter IV
MATERIALS AND METHODS

The present work is based on the field investigation conducted from September, 2007 to August, 2010, among the people of Ballary district of Karnataka. Ballary district is under hot condition with normal temperature of around 40°C throughout the year. Therefore, the investigator had to face lot of difficulty in reaching the hospitals and village PHC’s.

It is needless to emphasize that the researcher was conscious of the importance of having a thorough knowledge of the methods and principles, which are involved in the present study. Therefore, all precautions were taken while collecting and analyzing the data. The researcher has also taken the assistance of qualified physician and laboratory technician wherever required. Genetic and Socio-cultural factors were also recorded as per the schedule made for the purpose of this research. Socio-cultural factors and Socio-demographic study includes Occupation, dietary intake, age, sex, birthplace, marriage and number of individuals in the family were recorded with the help of some pedigree charts drawn for the purpose. (Schedule attached at the end of the thesis). In the absence of any written record about age or date of birth one has to estimate the age in relation to some important local events. Cross checking with more knowledgeable persons is also essential for minimizing error. In the present investigation though
most of them were able to tell their age in terms of years even then, the
above method was followed in order to be more precise in the case of
individuals, who were above the age of 20 years. In most of the cases
elderly men and women were the most suitable informers.

Before conducting the research Hospital based survey was
carried out in the district to gather the information about number of
patients attend for the purpose.

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<thead>
<tr>
<th>Sl.No</th>
<th>Name of the Institution</th>
<th>Number</th>
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<tbody>
<tr>
<td>1</td>
<td>Primary Health Centres</td>
<td>54</td>
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<tr>
<td>2</td>
<td>General Hospitals</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Community Health Centres</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>GAD’s</td>
<td>11</td>
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<td>5</td>
<td>Primary Health Unit</td>
<td>6</td>
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<td>6</td>
<td>Urban Family Welfare Centre</td>
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<td>7</td>
<td>M.L.C.U. Centres</td>
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<td>8</td>
<td>National Leprosy Centres</td>
<td>1</td>
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<td>9</td>
<td>Taluk Health Offices</td>
<td>7</td>
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<tr>
<td>10</td>
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<tr>
<td>11</td>
<td>Mobile Medical Units</td>
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<tr>
<td>12</td>
<td>Mobile Ophthalmic Unit</td>
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<td><strong>Total</strong></td>
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**Primary health centres:** There are 54 Primary Health Centers sanctioned to Bellary District with six bedded capacity each. Out of which 7 P.H.C’s have been upgraded to Community Health Centers. Out of upgraded PHC’s one is fully functioning. Out of 54 Primary Health
Centers 53 have own buildings, 2 buildings are constructed under I.P.P.-IX and 3 are under Z.P. Sector. For each Primary Health Center 4 to 5 Health Sub-Centers are attached. The total Sub-Centers existing in Bellary District are 293. Out of 293 Sub-Centers 267 Sub-Centers have got own buildings. 26 Sub-Centers are under construction.

**General hospitals:** In Bellary District there are 6 General Hospitals. All the General Hospitals are equipped with 50 beds, except one 100 beded hospital at Hospet, for the treatment of inpatients. The ambulance facilities are provided at General Hospitals. All the General Hospitals have got their own buildings except Hagari Bommanahalli.

**Community health centers:** Four Community Health centers are already sanctioned in the previous years, they are C.J.Halli, Kurugodu, Kottour and Ittigi. Ambulance facilities are provided in these four centers. In the current year recently 3 PHCs, Hampasagara, Ujjini, and Thekkalakote have been Upgraded as CHC’s.

**Programmes:** The department is implementing a number of programmes and taking preventive measures against all types of communicable diseases. The following Programme Officers are designated for implementing these programmes.
Data were collected on the following aspects, which formed the bases of the present work.

Clinical assessments were recorded as per protocols:

1. Blood Pressure
   a. SBP (systolic blood pressure)
   b. DBP (diastolic blood pressure)

2. Blood Sugar Sample:
   a. FBS (fasting blood sugar)
   b. RBS (Random Blood sugar)
   c. PPBS (Post Parandial Blood Sugar)

3. Lipid Profile:
   a. Cholesterol
   b. HDL (High density lipoproteins)
   c. LDL (Low Density Lipoprotein)
   d. TG (triglyceride)

4. Anthropometry measurements:
   a. Circumferences (Measuring Tape)
      i. Abdomen      iii. Upper arm
      ii. Chest        iv. Calf
   b. Skin fold (Skin Fold Caliper)
      i. Triceps      iii. Abdomen
      ii. Biceps      iv. Scapular
Biochemical Indicators:

Biochemical observations represent the most objective assessment of nutritional status and also provide sub clinical information. During the development of any deficiency disease, biochemical changes precede clinical symptoms hence; biochemical tests help to prognosis the disease at the sub clinical stage. These tests are also used to confirm the clinical diagnosis (Lakshmi et al. 2003).

**Blood Pressure (BP)** is the pressure exerted by circulating blood upon the walls of blood vessels, and is one of the principal vital signs. When used without further specification, "blood pressure" usually refers to the arterial pressure of the systemic circulation. During each heartbeat, BP varies between a maximum (systolic) and a minimum (diastolic) pressure. The mean BP, due to pumping by the heart and resistance to flow in blood vessels, decreases as the circulating blood moves away from the heart through arteries. Blood pressure drops most rapidly along the small arteries and arterioles, and continues to decrease as the blood moves through the capillaries and back to the heart through veins. Gravity, valves in veins, and pumping from contraction of skeletal muscles are some other influences on BP at various places in the body. The measurement of blood pressure without further specification usually refers to the systemic arterial pressure measured at a person’s upper arm. It is measured on the inside of an elbow at the brachial artery,
which is the upper arm's major blood vessel that carries blood away from the heart. A person's BP is usually expressed in terms of the systolic pressure over diastolic pressure (mmHg), for example 140/90.

**Blood Sugar Sample:** The blood sugar concentration or blood glucose level is the amount of glucose (sugar) present in the blood of a human or animal. Normally in mammals, the body maintains the blood glucose level at a reference range between about 3.6 and 5.8 mM, or 64.8 and 104.4 mg/dL. The human body naturally tightly regulates blood glucose levels as a part of metabolic homeostasis. Glucose is the primary source of energy for the body's cells, and blood lipids (in the form of fats and oils) are primarily a compact energy store. Glucose is transported from the intestines or liver to body cells via the bloodstream, and is made available for cell absorption via the hormone insulin, produced by the body primarily in the pancreas. The mean normal blood glucose level in humans is about 4 mM however; this level fluctuates throughout the day. Glucose levels are usually lowest in the morning, before the first meal of the day (termed "the fasting level"), and rise after meals for an hour or two by a few milliMolar. Blood sugar levels outside the normal range may be an indicator of a medical condition. A persistently high level is referred to as hyperglycemia; low levels are referred to as hypoglycemia. Diabetes mellitus is characterized by persistent hyperglycemia from any of several causes, and is the most prominent disease related to failure of
blood sugar regulation. A temporarily elevated blood sugar level may also result from severe stress, such as trauma, stroke, myocardial infarction, surgery, or illness. Intake of alcohol causes an initial surge in blood sugar, and later tends to cause levels to fall. Also, certain drugs can increase or decrease glucose levels.

**Lipid profile** or lipid panel, is the collective term given to the estimation of, typically, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides. An extended lipid profile may include very low-density lipoprotein. This is used to identify hyperlipidemia (various disturbances of cholesterol and triglyceride levels), many forms of which are recognized risk factors for cardiovascular disease and sometimes pancreatitis. It is recommended that healthy adults with no other risk factors for heart disease be tested with a fasting lipid profile once every five years. Individuals may also be screened using only a cholesterol test and not a full lipid profile. However, if the cholesterol test result is high, there may be the need to have follow-up testing with a lipid profile. If there are other risk factors or the individual has had a high cholesterol level in the past, regular testing is needed and the individual should have a full lipid profile. For children and adolescents at low risk, lipid testing is usually not ordered routinely. However, screening with a lipid profile is recommended for children and youths who are at an increased risk of developing heart disease as adults. Some of the risk factors are
similar to those in adults and include a family history of heart disease or health problems such as diabetes, high blood pressure (hypertension), or being overweight. High-risk children should have their first lipid profile between 2 and 10 years old, according to the American Academy of Pediatrics. Children younger than 2 years old are too young to be tested. A total cholesterol reading can be used to assess an individual's risk for heart disease; however, it should not be relied upon as the only indicator. The individual components that make up total cholesterol reading — LDL, HDL, and VLDL — are also important in measuring risk. For instance, one's total cholesterol may be high, but this may be due to very high good (HDL) cholesterol levels — which can actually help prevent heart disease. So, while a high total cholesterol level may help give an indication that there is a problem with cholesterol levels, the components that make up total cholesterol should also be measured. A lipid profile may also be ordered at regular intervals to evaluate the success of lipid-lowering lifestyle changes such as diet and exercise or to determine the effectiveness of drug therapy such as statins.

**Anthropometry measurements:** is the measurement of man refers to the measurement of the human individual. An early tool of physical anthropology, it has been used for identification, for the purposes of understanding human physical variation, in paleoanthropology and in various attempts to correlate physical with racial and psychological
traits. Craniometry is a section of anthropometry that exclusively studies craniums. Today, anthropometry plays an important role in industrial design, clothing design, ergonomics and architecture where statistical data about the distribution of body dimensions in the population are used to optimize products. Changes in life styles, nutrition and ethnic composition of populations lead to changes in the distribution of body dimensions (e.g. the obesity epidemic), and require regular updating of anthropometric data collections.

Figure 2 Different Anthropometric Measurements
In 1883, Frenchman Alphonse Bertillon introduced a system of identification that was named after him. The "Bertillonage" system was based on the finding that several measures of physical features, such as the dimensions of bony structures in the body, remain fairly constant throughout adult life. Bertillon concluded that when these measurements were made and recorded systematically, every individual would be distinguishable. Bertillon's goal was a way of identifying recidivists ("repeat offenders"). Previously police could only record general descriptions. Photography of criminals had become commonplace but there was no easy way to sort the many thousands of photographs except by name. Bertillon’s hope was that, through the use of measurements, a set of identifying numbers could be entered into a filing system installed in one single cabinet. The system involved ten measurements; height, stretch (distance from left shoulder to middle finger of raised right arm), bust (torso from head to seat when seated), head length crown to forehead and width temple to temple, width of cheeks and length of the right ear and the left foot, middle finger and cubit (elbow to tip of middle finger). It was possible, by exhaustion, to sort the cards on which these details were recorded (together with a photograph) until a small number produced the measurements of the individual sought, independently of names. The system was adapted to police methods: it prevented impersonation and could demonstrate wrongdoing. Bertillonage was before long represented in Paris by a collection of some 100,000 cards.
and became popular in several other countries' justice systems. England followed suit when in 1894 a committee was sent to Paris to investigate the methods and its results, reporting favorably on the use of measurements for primary classification but also recommending the partial adoption of the system of fingerprints suggested by Francis Galton and currently in use in Bengal, where measurements were abandoned in 1897 after the fingerprint system was adopted throughout British India. Three years later England followed suit and, as the result of a fresh inquiry ordered by the Home Office, relied upon fingerprints alone. Bertillonage exhibited certain defects and was gradually supplanted by the system of fingerprints and, latterly, genetics. Bertillon originally measured variables he thought were independent - such as forearm length and leg length - but Galton had realized that both were the result of a single causal variable (in this case, stature) and developed the statistical concept of correlation. It was also difficult to tell whether individuals arrested were first-time offenders. Instruments employed were costly and liable to break down, skilled measurers were needed, errors were frequent and all but irremediable and it was necessary to repeat measurements three times to arrive at a mean result.

In the present study some of the anthropometric measurements were adopted to compare with the diabetes mellitus scanario they were: Stature, Weight, Circumferences (Measured by measuring tape)
Abdomen, Chest, Upper arm and Calf and some Skin fold (Harpenden skin fold measuring calipers) Triceps, Abdomen, Biceps and Scapular.

**Height or Stature:** This measurement was taken with the help of anthropometer. The subject was asked to stand barefoot as erect as possible, the arms hanging at the sides, the heels together and the eyes were directed upon horizon. The eye ear plane was maintained. Holding anthropometer with one hand, taking care that it is absolutely vertical, the sliding sleeve was lowered till it made a slight contact with the vertex. The maximum measurement was recorded from ground to vertex. The measurement was taken from the front of the subject.

**Weight:** The subject was asked to stand erect and bare footed on the portable weighing machine, which was placed on the flat ground. The weight was recorded in kilograms, after deducting approximate weight of the clothes. The weighing scale was adjusted to zero before each measurement.

**Skin Fold Thickness:** Skin fold measurement provides a mean of estimating the amount of fat content in the body. They are important in the study of body composition and the calorie aspects of nutritional status.

The subject was asked to stand as erect as possible, hanging his hands freely. From the right side of the subject at the centre point which is already marked is carried to posterior side of the upper arm (triceps). At one inch above the mark the skin fold is grasped by using
the thumb and forefinger of the left hand. The fold is extended up to one inch below the mark gradually. The thumb and forefinger which are holding the upper fold are gradually brought to the centre. At this point leaving the lower fold the measurement was recorded by lifting about 1cms longitudinal fold of the skin with thumb and index finger. Immediately with the help of the Harpenden skin fold measuring calipers, the measurement was recorded. Precaution was taken not to compress the skin fold too much. The mid upper arm circumference and the skin fold at triceps are used to calculate the mid arm muscle circumference, which co-relate well with the general manifestations of protein calorie malnutrition.

All the variables were coded and entered into SPSS for Windows version 9.0. Appropriate statistical analyses were performed using the same software. Statistical tests used included analysis of variance by one way ANOVA and Tukeys multiple post hoc procedures to predict diabetes mellitus status among Bellary district. The significance level was preset at 0.05. Informed consent was obtained from all the persons with diabetes. The statistics calculated for every variable normally include the mean with its standard error, the standard deviation with its standard error. These values provide the ranges within which the respective estimates occur with the corresponding degree of confidence.

In the present study Mean, Standard deviation (S.D.) and Standard error (S.E.) were calculated by using the following formulae.
The most popular and widely used measure for representing the entire data by one value is what most laymen call on average and what the statisticians call the arithmetic mean.

\[
M = \frac{\sum fx}{N}
\]

where, 
M = Arithmetic Mean Value
fx = Total of all Values
N = Number of Values

**Standard deviation**

The standard deviation measures the absolute dispersion or variability of a distribution, and is extremely useful in judging the representatives of the mean.

Standard Deviation (S.D.) = \( \sigma = \sqrt{\frac{\sum fd^2}{n}} \)

where, 
f = Frequency
d = (x-m) available from frequency table
n = Number of observations (sample size)

**Standard Error**

It is the error in drawing the sample from the population. It is an estimate of the standard deviation of the means of many samples which might have taken from the same population. The Standard Error gives an indication of the visual magnitude of the sampling error. It depends on the size of the sample.
Standard Error (S.E.) = \frac{\sigma}{\sqrt{n}}

where,

\sigma = \text{Standard deviation}

n = \text{Number of observations (sample size)}

\textbf{t test}

The test of significance of difference namely, \textit{t test} is calculated by using the following formula,

\[ t = \frac{M_1 - M_2}{\sqrt{(SE_1)^2 - (SE_2)^2}} \]

where, \( M_1 \) and \( M_2 \) are the mean, and \( SE_1 \) and \( SE_2 \) are the standard errors of the two groups.