METHODOLOGY

STUDY PLACE

The study was carried out in the dept of Diabetology, All India Institute of Diabetes and Research & Yash Diabetes Specialities Centre (Swasthya), Ahmedabad. The hospital provides all speciality services related to diabetes under one roof. The hospital is having a consortium for under graduate & postgraduate students with B.J. Medical College, Ahmedabad and Smt. NHL Municipal Medical College, Ahmedabad for research & other collaborative activities. The hospital has approximately 7500 patients registered in last 3 years.

Diabetic patients visiting the hospital for the first time undergo a battery of investigations after which they consult diabetologist. Patients undergo a detailed clinical assessment by the diabetologist with the results of the blood test, imaging techniques and other investigations. They are then given advice regarding various treatment modalities and the diet pattern. Figure 38 shows the flow chart of work at Swasthya.

Swasthya provides high quality and efficient laboratory services. The quality control is ensured in two ways i.e. Internal and External Quality control. The latter is done in collaboration with ACBI/CMC External Quality Assessment Scheme, CMC, Vellore, India. As a part of the Quality control project, Swasthya has been undertaking standardization of the HbA1c assays to international standards. To achieve the above goal, Swasthya has been utilizing the state of the
art equipment for HbA1c assays and uses National glycohaemoglobin standardization program (NGSP) approved kit.

To provide complete diabetes care, Swasthya has a diabetes management team, which includes Diabetologist, Ophthalmologist, Cardiologist, Nephrologist, Podiatrist, other specialists, Nurses, Dietitians, Educators, and others as shown in the figure 39.

Every diabetic patient who visits Swasthya has a routine retinal screening by an ophthalmologist to detect early diabetic retinopathy and progression of retinopathy is graded and documented.

Swasthya has set up a unique diabetes education program. A team of efficient patient educators is involved in taking lectures everyday at the centre with the help of various audio-visual aids. The education program covers the causes and the symptoms of diabetes, demonstration of self-monitoring blood glucose equipments, insulin injections, foot care etc.
Figure 38 The flow chart of work at Swasthya

**Front Desk**
Appointments, Registration

**History**
Personal History, Family History, Anthropometry, Physical Activity

**Consultants**
Medical History, Physical Examination, Foot examination, Test prescription

**Billing**

**Laboratory**
General, Biochemistry

**Special tests**
ECG/ Echocardiography/ TMT, Fundoscopy/ Eye check, Biothesiometry, ANS testing, X-Ray, USG, Doppler, Foot scan

**Consultants**
Overview, Treatment adjustment, Prescription

**Dietitian/ Educator**
Diet recall & advise, Education, Yoga/ Exercise advise

**Diabetic supply Centre**
Figure 39 The diabetes management team at Swasthya

REFERENCE POPULATION:
The reference population for the study is people living in the western Indian state of Gujarat as per the update census 2001
STUDY GROUPS:

People with diabetes attending the diabetes clinics (known or newly diagnosed) and/or admitted in the hospital with or without complications.

STUDY PERIOD:

The data for the study was collected for a period of 30 months and included all cases of any type of diabetes mellitus who are attending diabetic clinic or admitted in wards in the period from 1st August 2006 to 31st January 2009.

STUDY DESIGN:

Cross sectional study.

SAMPLE SIZE AND SAMPLING METHODOLOGY:

Simple random technique was utilized to collect a desired sample of around 660 patients, during the course of study period. Sample size is decided on the fact so as to study at least 20% of newly diagnosed case based on the data review of the hospital which reveals that at least 100 patients (newly diagnosed) are presented every month, hence during the study period there will be 3000 patients and assuming a drop out of 10% during the study period.
INCLUSION CRITERIA FOR CASE SELECTION

ALL THE NEWLY DIAGNOSED CASES

1. Case definition of New Case: The study group assembled amongst all newly detected people with diabetes (diagnosed within last 6 month) attending the indoor and outdoor patient departments of the hospital for first time.

2. Diagnosis confirmation: The diagnosis of diabetes mellitus was made as per ADA guidelines.

EXCLUSION CRITERIA

1. Old cases of diabetes.
2. Cases not willing to participate in the study.

DATA COLLECTION

The case history was recorded on a semi structured, close-ended protocol.

709 subjects were enrolled in the study after satisfying the inclusion and exclusion criteria. Included patients were explained in detail about the study pattern.

The patient identification number, given as the Case Identification Number by the hospital admitting authority and diabetic clinic outdoor authority, have been recorded on the data collection form for
identification purposes and will be followed up for possible complications.

The **basic data** on age, sex, education, occupation, lifestyle related factors (smoking status, tobacco chewing alcohol consumption, diet and physical activity) were collected from all patients. A detailed medical history was obtained regarding the present complaints with particular reference to cutaneous complain. All patients were interviewed regarding past history of diabetes, hypertension & other co-morbid conditions, type of treatment taken for control of the disease. A general physical examination was done. All anthropometric measurements, including height, weight, waist and hip circumferences and blood pressure were measured using standardized procedures.

These patients under went **various clinical tests** like urinalysis (for evaluation of micro-albuminuria), blood sampling (for complete hemogram, plasma glucose, HbA1c, renal function tests and lipid levels).

The blood samples were collected by venipuncture, after ensuring 8 hours of overnight fasting. Samples were taken in EDTA disodium-coated and plain vials and centrifuged to obtain plasma and serum. Biochemistry analysis was carried by following the manufacturer’s instructions, using an automated, clinical chemistry analyzer; A25 BioSystems (Barcelona, Spain)

**SERUM LIPID ANALYSIS**

Total Cholesterol (TC), triglycerides (TG) and HDL-C levels were estimated in serum, using kits (End Point Assay with Liquid Clearing
LDL-C was calculated using the Friedewald formula
\[ LDL-C + TC - [HDL-C - (TG \text{ in mg/dl}/5)] \]

PLASMA GLUCOSE ANALYSIS

Glucose level was measured in plasma using GOD-POD End Point Assay (Span Diagnostics Ltd. India).

TESTING FOR MICROALBUMINURIA

Testing for Microalbuminuria was done by turbidometry using kit from Biosystems (Barcelona, Spain).
The first morning urine sample was brought to the hospital for measurement of microalbuminuria. Urinary Albumin Excretion >20 µg/min found on several occasions was considered positive.

GLYCOSYLATED HEMOGLOBIN (HBA1C)

Glycosylated hemoglobin (HbA1c) was measured by the High Pressure Liquid chromatography (HPLC) method using the Variant machine (BIORAD, Hercules, California). Reference non diabetic range is 4.0-6.0%.

Control sera were included in each batch of samples analyzed. As a part of external quality assurance, our laboratory is enrolled with the proficiency testing surveys of ACBI/CMC External Quality Assessment Scheme, CMC, Vellore, India.
Fundoscopy and 12 lead electrocardiography (ECG) were also carried out in each patient. These patients had complete neurological examinations of the foot as well as assessments of extremity pulses for determination of the extent and type of lesions.

Several common indicators of diabetic complications were analyzed.

For analysis, the current smokers and ex-smokers were categorized in the "ever smoker" group. Similarly, the current tobacco chewer/snuffing and ex- tobacco chewer/snuffing were categorized in the "ever tobacco chewer" group. Ever smoker group and ever tobacco chewer were considered as tobacco user.

Those who reported to have consumed alcohol at least once in last one-month period were considered as current alcohol users.

Physical activity was categorized as follow:

- **Sedentary**: Sitting, standing, and driving for most of the day. Cooking, light cleaning, light yard work, slow walking, most major activities involve sitting.

- **Moderate**: An occupation that includes lifting, lots of walking, or other activities that keep you moving for several hours qualifies as moderately active.

- **Heavy**: Heavy manual labor, a very active lifestyle, dancer or very active sports played for several hours almost daily. An elite athlete in training, or an extremely active lifestyle - both a work and at play. Sport or activity last for several hours, almost daily.

Anthropometric measurements including weight, height, waist and hip measurements were obtained using standardized techniques as given below.
BODY WEIGHT was measured (to the nearest 0.05 kg) with the subject standing still on the electronic weighing scale, feet about 15 cm apart and weight equally distributed on each leg. Subjects were instructed to wear minimum outerwear (as culturally appropriate) and no footwear while their weight was being measured.

HEIGHT was measured using a non-stretchable tape (to the nearest 0.1 cm) with the subject in an erect position against a vertical surface and the head positioned so that the top of the external auditory meatus was in level with the inferior margin of the bony orbit.

BODY MASS INDEX was calculated by dividing the weight (in kilograms) with the square of height (in meters). Standard classification of obesity was used for the categorization.

WAIST AND HIP CIRCUMFERENCE (to the nearest 0.1 cm) was measured using a non-stretchable measuring (tailor's) tape. The subjects were asked to stand erect in a relaxed position with both feet together on a flat surface; one layer of clothing was accepted. Waist girth was measured at a point mid way between tip of iliac crest and lowermost costal margin in the back and at umbilicus in the front at minimal respiration and observer sitting in front of the subject. Hip circumference was measured at the maximum circumference of buttocks at the level of the greater trochanter. Mean of three readings of each circumference will be taken for the calculation of WHR.

BLOOD PRESSURE (BP) was recorded, after the subjects had rested for at least 5 min, in a chair (rather than on an exam table), with feet on the floor, and arm supported at heart level. Caffeine, exercise, and
smoking should be avoided for at least 30 minutes prior to measurement. The auscultatory method of BP measurement was used.807

The operator was trained and regularly retrained in the standardized technique, and the patient was properly prepared and positioned.808-810 The equipment was mercury sphygmomanometer (Diamond Deluxe BP apparatus, Pune India). The machine was regularly inspected and validated. An appropriately sized cuff (cuff bladder encircling at least 80 percent of the arm) was used to ensure accuracy. It was applied on right arm. The stethoscope bell was placed lightly over the brachial artery and the blood pressure was recorded to the nearest 2 mm Hg, reading from the top of the mercury meniscus. Systolic blood pressure (SBP) was recorded at the first appearance of two or more Korotkoff sounds and the disappearance of Korotkoff sound (onset of phase 5) was used to define DBP. Two readings were taken 5 minutes apart and mean of two was taken as the blood pressure.

Classification of blood pressure for adults was done as per the Table 52

### Table 52 Classification of blood pressure for adults

<table>
<thead>
<tr>
<th>Classification</th>
<th>SBP (mmHg)</th>
<th>DBP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>and &lt;80</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120–139</td>
<td>or 80–89</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>140–159</td>
<td>or 90–99</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>&gt;160</td>
<td>or &gt;100</td>
</tr>
</tbody>
</table>
Table 52 provides a classification of BP for adults 18 years and older. The classification is based on the average of two or more properly measured, seated, BP taken 5 minutes apart.

Blood pressure was also measured in the supine and standing position as recommended by JNC811 to rule out postural hypotension. In case of marked postural hypotension, patients were subjected to Cardiovascular Autonomic Function Tests.

**FUNDOSCOPY**

**METHOD**

Dilatation of both eyes was done with one drop of Tropicamide (0.8%) + Phenylephrine eye drops. The patients were asked to keep eyes closed for 20 to 30 minutes.

Ophthalmologist had examined patients after full dilatation of pupil. The examination was done in lying position with direct and indirect ophthalmoscope.

The findings were documented as follow:

1. No diabetic retinopathy / Normal retina
2. Background diabetic retinopathy with out CSME (clinically significant macular oedema)
3. Background diabetic retinopathy with CSME
4. Preproliferative diabetic retinopathy
5. Proliferative diabetic retinopathy
EVALUATION OF FOOT

NEUROPATHY ASSESSMENT

Neuropathy was assessed by clinical examination, by using the simple tuning fork, pin-prick tester, 10-g nylon monofilament and tendon hammer. Biothesiometer is important equipment which measures Vibration Perception Threshold (VPT).

Table 53 Screening for Neuropathy

<table>
<thead>
<tr>
<th>History</th>
<th>Exam</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence/ absence of neuropathic symptoms</td>
<td>Pin – prick test</td>
<td>Disposable instrument, e.g. a disposable dressmaker's pin (Not a hypodermic needle)</td>
</tr>
<tr>
<td>Nature of symptoms (Positive/negative?)</td>
<td>Light touch</td>
<td>Consistent method - Cotton wisp.</td>
</tr>
<tr>
<td>Duration/ progression of symptoms</td>
<td>Vibration test</td>
<td>A 128 - Hz tuning fork, initially on the big toe</td>
</tr>
<tr>
<td>Nocturnal exacerbation?</td>
<td>Ankle reflex</td>
<td>To compare the ankle reflex with the knee reflex</td>
</tr>
<tr>
<td>History of insensitive injury/ulcers?</td>
<td>Pressure perception</td>
<td>Sensation in the foot with a 10g monofilament to assess the risk of foot ulceration.</td>
</tr>
</tbody>
</table>

VIBRATION PERCEPTION THRESHOLD: (VPT) assessed with

- 128 Hz tuning fork
- Sensitometer (Biothesiometer)
The sensory examination was done in a quiet and relaxed setting. First the tuning fork was applied on the patient's wrists (or elbow or clavicle) so the patients knows what to expect. The patient was not able to see if and where the examiner applies the tuning fork. The tuning fork was applied on a bony part on the dorsal side of the distal phalanx of the first toe. It was applied perpendicularly with a constant pressure. This application was repeated twice, but alternated it with at least one "sham" application, in which the tuning fork was not vibrating.

The test was considered positive if the patient correctly answered at least two out of three applications and negative (at risk for ulceration) with two out of three incorrect answers.

Neuropathy was considered when patient was unable to perceive vibration sensation with 128 HZ TUNING FORK when applied over the great toe for testing.

Patients were encouraged during testing.

**BIOTHESIOMETRY**

Biothesiometry is a test to measure Sensory Neuropathy (Large Fiber Function). It was assessed using Biothesiometer (Bio Medical Instrument CO, Newbury, Ohio, USA)- a simple to operate easy to use equipment.
Procedure: Biothesiometer works on principle of application of electrical energy to a calibrated vibrator. Vibratory perception threshold (VPT) of the great toes was measured in a standardized fashion by a single observer. The biothesiometer probe was applied perpendicular to the test site with a constant and firm pressure and VPT was measured at the distal plantar surface of the great toe in both legs. The voltage was slowly increased from 0 to 50 v by turning the control switch to the right in a clockwise manner gradually. The VPT was defined as the moment when the subject first felt the vibration. A single reading entered in the mean of 3 readings of both legs, which were nearly the same or less than 10% away.

INTERPRETATION was made on the basis of minimum voltage required for minimal sensation/ vibration.

Impaired Peripheral Sensation – more than 10v
Significant Peripheral Neuropathy – more than 25v
Markedly increased vibratory thresholds indicate sensory Neuropathy and a "HIGH-RISK" of foot ulceration.

MONOFILAMENT TESTING

10g Semmes- Weinstein Nylon monofilament (5.07) was used during study. It carries out the test for the combined sensation of light touch and pressure.
PROCEDURE: Examination was done in a quiet and relaxed setting. First monofilament was applied on the patient's hands (or elbow or forehead) so the patient knows what to expect. The patient was not able to see if and where the examiner applies the filament. The recommended sites to use were the great toe, heel and five metatarsal heads. The monofilament was applied perpendicular to the skin surface. It was applied with sufficient force to cause the filament to bend or buckle. The total duration of the approach, skin contact and removal of the filament was approximately 2 seconds. The filament was not allowed to slide across the skin or make repetitive contact at the test site. The filament was pressed to the skin and the patient was asked, if he can feel the pressure applied (yes/No) and next where they feel the pressure applied (Left / Right foot).

This application was repeated twice at the same site, but alternated this with at least one "sham" application, in which no filament was applied (total three questions) per site.
We defined 1 insensate area on the planter surface of the foot with 10-g Semmes-Weinstein monofilament testing as a positive finding for neuropathy.

Any patients who cannot feel the 10-g monofilament on the planter surface of the foot was considered at a higher risk of foot ulceration.

VASCULAR ASSESSMENT

- Clinical Examination
  Distal pulses in the lower extremity (dorsalis pedis or post tibial aretery) were palpated on clinical examination
- Doppler test

All Doppler studies were done using the Versalab machine (Madras Engineering Services, Chennai, India) A painless, simple and inexpensive measurement to measure Ankle brachial index (ABI). ABI is not an imaging technique. It does not detect early plaque formation or minimal stenosis but detects individuals with more advanced (although often asymptomatic) vascular disease.

It was done by a single observer. Blood pressure recordings were made of the brachial pulses in the upper limb. Similar recordings were made of the dorsalis pedis and posterior tibial pulses in the lower limb by inflating the cuff proximal to the ankle and the mean of these two readings was taken as ankle pressure. The ankle/brachial pressure index (ABI) index ratio was calculated in every subject.
An abnormal ABI is defined as a value <0.90. It has a sensitivity of about 90% and a specificity of about 98% for moderate or greater obstructive peripheral artery disease (PAD) on angiography.

ABI assumes importance because the traditional clinical assessments for PAD (the pulse, palpation and symptom assessment) have low sensitivity, specificity and a low predictive value. ABI can detect subclinical (asymptomatic) cardiovascular disease (CVD), and up to 40% of patients with abnormal ABI test have no symptoms.

ABI shows fair repeatability, with a 95% CI of ±16% for a single measurement, which improves to ±10% when taken as the mean of four measurements.

ABI however is generally poorly suited to serial testing and thus is more commonly used in cross-sectional population screening.

**DEFINITIONS AND PREFERRED CUTOFF VALUES**

**HYPERTENSION:** Hypertension was diagnosed based on drug treatment for hypertension or if the blood pressure was ≥ 140/90 mmHg - Joint National Committee 7 (JNC VII) Criteria.812

**DIABETES:** The diagnosis of DM was done, using criteria established by the American Diabetes Association,813 i.e.: a medical record indicating either a fasting plasma glucose (FPG) level ≥ 7.0 mmol/l or ≥ 126 mg/dl after a minimum 12-h fast, or 2-h post glucose level (oral glucose tolerance test or 2-h OGTT) ≥ 11.1 mmol/l or ≥ 200 mg/dl on more than one occasion, with symptoms of diabetes. Impaired glucose
tolerance (IGT) was defined as an FPG level of 100 mg/dl (5.6 mmol/l) but < 126 mg/dl (7.0 mmol/l) or 2-h OGTT of ≥ 140 mg/dl (7.8 mmol/l) but < 200 mg/dl (11.1 mmol/l). The diagnosis of T2DM was based on clinical records and medication. In the absence of information from medical records, we confirmed a self-reported case by establishing that there is regular treatment with hypoglycaemic medication or by performing a 2-h OGTT.

DYSLIPIDEMIA: National Cholesterol Education Programme (NCEP) guidelines were used for definition of dyslipidemia.

HYPERCHOLESTEROLEMIA: Serum cholesterol levels > 200 mg/dl (> 5.2 mmol/l) or drug treatment for hypercholesterolemia.

HIGH LDL CHOLESTEROL: LDL as >100mg/dl (> 2.59 mmol/l) or drug treatment for high LDL cholesterol

HYPERTRIGLYCERIDEMIA: Serum triglyceride levels were > 150 mg/dl (> 1.7 mmol/l) or drug treatment for hypertriglyceridemia.

LOW HDL CHOLESTEROL: HDL cholesterol levels were < 40 mg/dl (< 1.04 mmol/l) for men and < 50 mg/dl (1.3 mmol/l) for women.

DYSLIPIDEMIA IS DEFINED BY PRESENCE OF ONE OR MORE THAN ONE ABNORMAL SERUM LIPID CONCENTRATION.

OBESITY:
BMI values were defined according to the recent recommendations of ICMR for Indians Generalized obesity was defined as BMI ≥ 25 kg/m² (Table-54)
Table 54

<table>
<thead>
<tr>
<th>Body Mass Index</th>
<th>Graded Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>Under Weight</td>
</tr>
<tr>
<td>18.5 - 22.9</td>
<td>Normal</td>
</tr>
<tr>
<td>23.0 - 24.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>&gt;25</td>
<td>Obesity</td>
</tr>
</tbody>
</table>

Abdominal obesity was defined as waist circumference ≥ 90cm for men and ≥ 80 cm for women and WHR for men was > 0.90 and > 0.85 for women.\(^{816}\)

A patient was considered a case of METABOLIC SYNDROME based on IDF Consensus (2005) as shown in Table 55

Table 55 International Diabetes Federation Metabolic Syndrome Definition (Revised 2005)

<table>
<thead>
<tr>
<th>Central obesity according to the waist circumference Plus any two of following four risk factors.</th>
<th>Ethnic specific</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>South Asians: Men ≥ 90 cm; Women ≥ 80 cm</td>
</tr>
<tr>
<td></td>
<td>Europids: Men ≥ 94 cm; Women ≥ 80 cm</td>
</tr>
<tr>
<td></td>
<td>Chinese: Men ≥ 90 cm; Women ≥ 80 cm</td>
</tr>
<tr>
<td></td>
<td>Japanese: Men ≥ 85 cm; Women ≥ 90 cm</td>
</tr>
<tr>
<td></td>
<td>South and central Americans: as south Asians</td>
</tr>
<tr>
<td>Raised triglycerides</td>
<td>&gt;150 mg/dl</td>
</tr>
<tr>
<td>Reduced HDL cholesterol</td>
<td>&lt; 40 mg/dl in men</td>
</tr>
<tr>
<td></td>
<td>&lt; 50 mg/dl in women</td>
</tr>
<tr>
<td>Raised blood pressure</td>
<td>Systolic ≥ 130 mm Hg</td>
</tr>
<tr>
<td></td>
<td>Diastolic ≥ 85 mm Hg</td>
</tr>
<tr>
<td></td>
<td>Treatment of previously diagnosed hypertension</td>
</tr>
<tr>
<td>Raised fasting plasma glucose</td>
<td>≥ 100 mg/dl</td>
</tr>
<tr>
<td></td>
<td>Previously diagnosed type 2 diabetes</td>
</tr>
</tbody>
</table>
MODIFICATION OF IDF DEFINITION OF METABOLIC SYNDROME

CONSENSUS STATEMENT:

It includes abdominal obesity [ethnic specific cut-offs of WC, and WC as a non-obligatory criterion (indifference to the IDF definition)], high triglycerides, low-HDL, dysglycemia (impaired fasting glucose/impaired glucose tolerance) and hypertension should be used. Three out of the five criteria have to be abnormal for diagnosing the metabolic syndrome.\textsuperscript{815}

A patient was considered a case of CORONARY ARTERY DISEASE (CAD) based on a past history of documented myocardial infarction and/or medical therapy (aspirin or nitrates) or revascularization for CAD and/or electrocardiographic changes of Q wave changes using appropriate Minnesota codes.

A patient was considered a case of CEREBROVASCULAR COMPLICATION based on a past history of documented stroke or developing a stroke or cerebral ischaemia.

A patient was considered a case of NEPHROPATHY based on a spot Urinary Albumin Excretion >20 μg / min, representing at least microalbuminuria. An increased microalbuminuria found on several occasions gives good evidence for abnormal albuminuria, which was further confirmed by measuring overnight urine collection.

RETINOPATHY was considered on the basis of presence of background diabetic retinopathy or preproliferative diabetic retinopathy or proliferative diabetic retinopathy with or without clinically significant macular oedema (CSME) on direct and indirect Fundoscopy.
NEUROPATHY was considered when:
- at least one insensate area on the toes, dorsum or planter surface of the foot with 10-g Semmes-Weinstein monofilament testing
- inability to percept vibration sensation with 128 Hz tuning fork was applied over the great toe for testing
- vibratory thresholds more than 10v on Biothesiometry testing
- presenting with an episode of cranial neuropathy

PERIPHERAL VASCULAR DISEASE was considered when the distal pulses in the lower extremity (dorsalis pedis or post tibial aretery) were absent on clinical examination and or an Ankle brachial index (ABI) < 0.9.

DIABETIC KETOACIDOSIS (DKA)

DKA consists of biochemical triad of hyperglycemia, ketonemia and acidemia.
Diagnosis of ketoacidosis is based on the characteristic clinical features and following biochemical abnormality.
- Hyperglycemia: (Plasma glucose > 300 g/dl)

- Acidosis: arterial/capillary Ph < 7.3 (venous pH < 7.25 ) and/or Serum Bicarbonate: < 15meq/l)

- Ketonuria and Ketonemia
DATA ENTRY & STATISTICAL ANALYSIS:

The collected data was entered in SPSS, version 16. Descriptive statistics was used to report demographic characteristics of the groups. Data are presented as mean ± SD. The adjusted odds ratios with 95% confidence intervals (CIs) were calculated as an estimate of the relative risks where a statistically significant difference was found using logistic regression. A p value <0.05 was considered significant.

LIMITATION OF STUDY:

Some of limitations were observed due to design of the study as it is based on urban set up hence such studies has its own limitation of non representation of true population.

ETHICAL CONSIDERATIONS:

The study protocol was reviewed and approved by the local institutional review board (IRB). Participants were explained with the purpose and protocol of the study. Written informed consent for the study visit was obtained according to the local IRB requirements from patients aged 18 years or from a participant's parent or guardian if the age was <18 years. It was the discretion of the patient whether to or not to participate in the study. The information was kept confidential.