

Materials and Methods



What does this section answer?

I keep six honest serving-men

(They taught me all I knew);

Their names are **What** and **Why** and **When**

And **How** and **Where** and **Who**.

The Elephant's Child

Rudyard Kipling

Where, When

- Study setting
 - The study will be carried out on patients attending the Diabetes Clinic of the Department of Medicine at PGIMER and Dr R M L Hospital, New Delhi from _____ to _____.
- Specify exactly where the patients will be recruited from
 - OPD
 - Clinic
 - Ward

Who

- Eligibility criteria

Inclusion criteria – Who will be included in the study

- Age
- Gender
- Diagnosis – define
- Disease duration
- Newly diagnosed / treated

Who

- Eligibility criteria

Exclusion criteria – Who will **not** be included in the study

- Disease characteristics
 - Treatment related
 - Co-morbidities
- Failing to give consent is **not** an exclusion criterion
(such patients are not even considered for the study)

Who – An example of eligibility criteria

Serum 25 (OH) vitamin D levels in patients with type 2 DM

- Inclusion criteria

- Age 30 – 65 years
- Type 2 DM diagnosed by ADA 2012 criteria
- Disease duration from diagnosis > 2 years

- Exclusion criteria

- Insulin therapy
- Intake of vitamin D supplements
- Intake of anti-epileptic drugs
- Diabetic nephropathy - define

What, How

STUDY DESIGN

- Observational
 - **Cross – sectional**
 - Case – control
 - Cohort
 - Retrospective
 - Prospective

- Experimental / Interventional
 - Randomized controlled trial
 - Cohort - prospective

What, How

What will be done to the study participants?

- Written, informed consent will be obtained
- History
 - How was diabetes mellitus initially diagnosed?
 - Is there a family history of DM?
 - What treatment has been given?
 - Is there a history of hypertension / coronary artery disease?

What, How

What will be done to the study participants?

- Examination
 - General physical examination – specific points
 - Blood pressure – how will it be measured?
 - How will hypertension be defined? JNC 7 - quote
 - Height – technique of measurement
 - Weight – least count, zero error
 - Systemic examination – specific points

What, How

What will be done to the study participants?

- Investigations
 - Hemogram – Hemoglobin, TLC, platelet count
 - Liver function tests – Bilirubin, AST, ALT, SAP
 - Kidney function tests – Blood urea, serum creatinine
- Specific test
 - 25 (OH) vitamin D – describe technique since this is the main test in this project – Radio immuno assay

What, How

- Define outcome beforehand:
 - Patients will be classified into three groups on the basis of their serum 25 (OH) vitamin D levels
 - Normal >30 ng/ml
 - Insufficient 20 – 30 ng/ml
 - Deficient < 20 ng/ml

What, How – Sample size

- Sample size of convenience
 - Based on
 - Experience
 - Availability of patients
 - Availability of resources
 - Time available for the study
 - Example: 20 patients / clinic /week ----- 5 eligible
250 / year --- Take 150 – 200 patients
- A small sample size decreases the power of the study

What, How – Sample size

- Calculated using statistical methods
- **CONSULT BIostatistician**
- Provide the following information:
 - Prevalence found in previous studies / pilot project
 - Standard deviation – from previous studies
 - Expected / significant difference between groups

Sample size - Example

- Estimating prevalence in a cross-sectional study
 - What proportion of patients with Type 2 DM have osteoporosis?
 - Known prevalence from previous studies
= $p = 10\% = 0.1$
 - 1-prevalence = $q = 1-p = 90\% = 0.9$
 - Acceptable error in estimate = $d = 20\% \text{ of } 10\% = 0.02$
 - Sample size = $(4 \times p \times q) / d^2$
= $(4 \times 0.1 \times 0.9) / (0.02 \times 0.02)$
= 900

Statistical Methods

- CONSULT BIostatistician
- Continuous data will be presented as mean SD
- Categorical data will be presented as proportions
- Groups will be compared using Student's t test for normally distributed data, Mann Whitney U test for other distributions
- Multivariate logistic regression will be used to assess independent predictors of the outcome, for example osteoporosis.