METHODOLOGY
Chapter - III

METHODOLOGY

Maternal iron deficiency is thought to have a negative effect on pregnancy outcomes through impaired haemoglobin transport of oxygen to the uterus, placenta and foetus. However, while there is noteworthy consistency among studies demonstrating this negative effect, there is still much data, which is conflicting, not least because only very large study samples can hope to control all the possible sources of variation that can influence pregnancy outcome.

Iron deficiency anaemia in pregnancy is often associated with low socioeconomic status, multiple pregnancies, and extremes of maternal age, and smoking, all of which may independently account for the poor pregnancy outcomes (Scholl and Hediger, 2001).

Most of the studies do not control for these and other factors that may affect birth weight and prematurity making it unclear whether iron deficiency and anaemia have a direct influence on pregnancy outcomes. The more cynical view is that, given how common both iron deficiency and iron supplementation during pregnancy are, the ill effects of the former and the positive effects of the latter should be clear cut (Walker, 1993).

Iron deficiency and subsequent iron deficiency anaemia are the most prevalent nutritional problem afflicting pregnant women. The extent to which maternal iron deficiency affects maternal and neonatal health is still uncertain.

Therefore such a study is very timely one on maternal anaemic status and outcome of pregnancy. Hence this study is undertaken.
The experimental procedures used in the study on “The effect of maternal anaemia on the outcome of pregnancy in Trivandrum” are discussed under the following headings.

1. Selection of the area for the study.
2. Selection of the sample.
3. Selection of Methods
4. Selection of the Tools.
5. Pilot Study.
6. Collection of the data.
7. Analysis and interpretation of the data.

1. Selection of the area: The study was conducted in two hospitals in Thiruvananthapuram city. The hospitals were Medical College hospital, and Sree Uthradam Thirunal hospital.

The reason for selecting these hospitals were,

1) These hospitals had pregnant women coming from different income groups and were accessible to the people living in prime junctions in Thiruvananthapuram. i.e., Medical College and Pattom.
2) These hospitals have a special wing for gynaecology and gave good support in following up with the case history of the patient.
3) The doctors were also keen to know the latest anaemic trends in pregnancy.

And this enabled the investigator to follow up the pregnancy period of the women up to nine months and delivery. Also to take classes of nutritional awareness for experimental group in the sub sample study.
2. Selection of the Sample: A sample is that part of the universe which we select for the purpose of investigation, selected for observation and analysis, this sampling technique, instead of taking the whole universe only part of the universe is studied and the conclusion drawn are considered applicable to the entire universe (Sharma, 1990) (Best and Khan, 1996).

A sample is a small proportion of the population selected for observation and analysis. By observing the characteristics of the sample, one can make certain inferences about the characteristics of the population from which it is drawn (Trochima, 1999).

A good sample of a population is one which restriction imposed by size, will reproduce the characteristic of the population with the greatest possible accuracy, that is to say, a good sample should be free from (1) errors due to bias and (2) random sampling errors (Ghosh, 1995).

The main sample selected were 1000 pregnant women of high income and low-income groups in first trimester of pregnancy. They were between the age group of 20 to 40 years attending antenatal checkups at Medical College and Sree Uthradom Thirunal hospital. A sample of 500 from each hospital was selected by survey method.

According to WHO (Sari et al, 2001), anaemia among pregnant women is considered normal if Hb is greater than 11g/dl, mild anaemia between 9 -11g/dl, Moderate anaemia between 7-9 g/dl and severe anaemia if Hb is below 7g/dl.
In the phase I of the study, based on above criteria, main sample were categorized into anaemic and non-anaemic pregnant women. These samples were studied from the time of attending first trimester pregnancy check-up to delivery and the outcome of pregnancy.

The method used for selecting the anaemic pregnant women sub sample was purposive sampling. According to Bailey (1982) and Trivedi (1991) in purposive sampling the researcher uses his own judgment about which respondent to choose and picks only those who but meet the purpose of the study.

The purposive sampling method is used as it selects a particular group or category from the population to constitute the sample because this category is considered to mirror the whole with reference to the characteristics in question. In this type of sampling, the sample is restricted and is typical of the population.

In the phase II of the study, out of the anaemic pregnant women group, 250 sub samples were selected by purposive sampling method for intensive study.

A simple random sampling is one in which every unit of the population has an equal chance of being selected (Sukia, 1989) (Sidhu, 1997).

And in the third phase of the study the 250 sub samples were categorised into 125 experimental and 125 control group based on random sampling method.
3. Selection of the Method:

In this study the data was collected by the survey method. Survey method was selected because it helps in obtaining the desired data in the limited set of conditions and also survey method information’s are accurate within the sampling error ranges. It has been recorded that many excellent individual surveys give good assessment of the nutritional status (Singh, 1985).

Survey is that method of investigation, which attempts to describe and interpret, which exist at present, in the form of conditions, practices, processes, trends, effects, attitudes and beliefs. It gathers data regarding current conditions (Davidson and Passmore, 1986) (Fowler, 2001).

The present study is designed in three phases. In the first phase a general survey was conducted for which 1000 confirmed pregnant women in first trimester in the two hospitals that is Medical College Hospital and Sree Uthradom Thirunal Hospital were included.

A questionnaire was implemented to get an in depth follow up data of the first trimester and third trimester of pregnancy till outcome.

In the second phase of the study, the main data was categorized into anaemic and non-anaemic pregnant women in the identified population. And from the anaemic pregnant women a sub sample of 250 confirmed anaemic pregnant women in the age group of 20 to 40 years were selected for the third phase.
In the third phase for the sub sample size of 250 anaemic pregnant women a detailed questionnaire cum interview schedule was implemented for all the three trimesters. Along with the schedule follow up data on biochemical analysis of blood by cyanmethahemoglobin method for all three trimester, stool analysis by smear technique, food weighment for two consecutive days and an attitude scale on nutritional awareness was also collected systematically and attached to the schedule.

The sub sample were further categorized into experimental (intervention group) and control group (non intervention group) of 125 anaemic pregnant women. For the 125 experimental groups a nutrition awareness class was taken “Nutrition for Anaemic Pregnant Women” and a booklet on “Combating Nutritional Anaemia during Pregnancy” was developed by the researcher in regional language and handed out to them. The lesson plan of the class taken is given in appendix VII and a copy of the booklet translated in English is attached in appendix VIII.

4. Selection of the Tools: For collecting new data required for the study of any problem one may use various devices. Certain instruments are required to gather new facts. The instruments thus employed as means are called tools (Sukhia.1989).

To carry out any research investigation, data are gathered on the basis of which hypothesis may be tested. A great variety of research tools have developed to aid in the acquisition of data. These tools are of many kinds and employ distinctive ways of describing and qualifying the data. Each tool is appropriate for certain source of data, yielding information’s of the kind and in the form that would be most effectively used. Tools are
certain instruments, which are used in the research for gathering new facts. Selection of a suitable tool is vital.

Questionnaire is a systematic compilation of questions by using a form that the respondent fills in himself (Good and Hatt, 1981).

The main tool for data collection of large sample was a questionnaire with two-day food recall schedule. The tool applied on the sub sample was a questionnaire cum interview schedule, a attitude scale, 24 hour food weighment schedule along with clinical, biochemical and stool analysis.

The well-formulated and standardized questionnaire was used to elicit information's of 1000 sample regarding following aspects.

- Part I, consisted of socio economic background, educational status of the pregnant women and husband, income of the family, order of pregnancy, type of last delivery, age of first delivery, total number of pregnancies, complication in previous delivery, disorders during present pregnancy, medical supplementation taken during pregnancy, special foods taken and foods avoided.

- The part II of schedule consisted anthropometric details like weight before pregnancy, weight at pregnancy, weight in third trimester, height of the sample, birth weight of baby, birth length of baby, and question regarding feeding of colostrum.

- And part III of schedule consisted of dietary a 24-hour recall of three consecutive day's diet, biochemical analysis of blood in first trimester and clinical examination.
Interviewing almost all segments of the population with the help of schedules can collect data. The interview schedule is used for collecting data by interviewing the informant. These contain standard questions that are asked by the interviewer and blank tables, which are filled up after getting information from the respondent. The interview schedule forms the best sources of information as far as illiterates are concerned (Sidhu, 1997).

The sub sample were given a separate interview schedule with a detailed clinical assessment for the three trimester, food weighment sheet which the investigator collected personally from each individual for three days. For the sub sample weight in the second trimester was also taken.

The approximate quantity of food consumed by the subject was measured with the help of a standardized cup prior to their meals. The number of cups of cooked food consumed was noted and the raw weight of ingredients used in food was calculated with the help of “Calorie counter” (Gopalan et al., 1996).

From the individual consumption, the raw equivalent were calculated using the formula below:

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\text{Individual intake in terms of equivalent (g)} = \frac{\text{Total raw amount of each ingredient (g) X individual intake of cooked amount (g)}}{\text{Total cooked amount (g)}}
\]

The nutritive value of each ingredient was calculated by using the nutritive value of Indian foods (Gopalan et al., 1996).
The quantity of each food item as well as the computed nutritive value was then compared with the recommended daily allowance of food and nutrients for pregnant women by ICMR (2009).

An attitude schedule to test the nutritional awareness of anaemic pregnant women regarding nutrition, pregnancy and anaemia was implemented with the interview schedule.

Nutritional status of the women was assessed through anthropometric and biochemical studies in the sub sample.

The height of an individual is made up to the sum of four components: legs, pelvis, sphere and skull. In field nutritional anthropometry is only total height is measured (Jelliffe, 1989).

To determine height fibreglass tape was used. The subject was asked to stand erect without slippers with the heels, buttocks, shoulder and occiput against the wall.

Weighing is the key anthropometric measurement (Chumlea, 1984). Weight was determined using a bathroom balance, which was checked by calibration with standard heights.

Haemoglobin estimation of the pregnant women was conducted by cyanmethaemoglobin method as per NIN procedure. In this method, 20 μl of blood was collected from a figure prick, into a haemoglobin pipette and delivered on to a Whatman No.1 filter paper disc. The blood samples collected in this manner were then diluted using Drabkin’s solution and read color metrically at 540 nm in the photo colorimeter against a blank. Procedure is given in appendix III. And a standard curve was constructed.
by preparing six reference standard curves (Morris et al., 1999) (Mohanram et al., 2002).

Smear technique was done to find hookworm infestation in stool. Procedure is given in appendix IV.

The knowledge and attitude of the anaemic pregnant women regarding food and health were assessed. Attitude is the state of readiness for motivates arousal. In attitude measurement the subject is confronted with a closed question in which not only the focal object and dimension of appraisal, but also a set of categories from which to choose her reply (DeVeilis 2003).

In accordance item analysis was done with many statements e formulated. Selected fifteen statements were finalized and care was taken to see that the statements were worded to express positive and negative responses. The responses to the statements were obtained on a five point continuum ranging from strongly agree to strongly disagree.

The score pattern was as follows:

- **Strongly agree**: 2
- **Agree**: 1
- **Undecided**: 0
- **Disagree**: -1
- **Strongly disagree**: -2

A copy of the questionnaire cum interview schedule is presented in appendix I and schedule for attitude scale in appendix II. Item analysis is given in appendix V.
5. **Conduct of the Pilot Study:** A pilot study was conducted among 30 pregnant women to find out the adequacy of the prepared tool.

A pilot study is a step preliminary to the formulation of a schedule.

Bajpai (1974) defines pilot study as a miniature of some part of the actual study in which the intended instrument is administered to subjects drawn from the same population as sample, but subjects who are not in the sample.

As Goode and Hatt (1981) have observed, no amount of thinking, however logical or brilliant or insightful can substitute for the careful empirical, situation based thinking which is initiated by a pilot study.

The pre testing of the schedules showed certain repetitions, which was modified. The questionnaire cum interview schedule was again implemented among the pilot study group of 30 pregnant women.

Reliability analysis was done for validity of the questionnaire cum interview schedule before the final collection of the data.

$$Reliability\ coefficient\ alpha\ \alpha = 0.7981$$

Reliability and item analysis of the attitude scale was done among twenty-five statements. And finally, fifteen statements were selected.

$$Reliability\ coefficient\ alpha\ \alpha = 0.7991$$

6. **Collection of the Data:** Collection of data is the most important step in any research study. The questions were based on the general health of the pregnant women, her nutritional status and also the diet of the pregnant women.
The socio-economic and health profile of the 1000 pregnant women sample were collected after obtaining prior permission. The dietary survey was carried out by three-day food recall method. The clinical assessment was recorded from the hospital case history. This gave the base line data for the study.

The haemoglobin values were recorded after collecting 20ul of blood from a finger prick, into a haemoglobin pipette and delivered on to a Whatman No.1 filter paper disc. The blood samples collected in this manner were then diluted using Drabkin’s solution and read colour metrically at 540 nm in the photo colorimeter against a blank and the anaemic sample was select from the main sample group.

Smear technique was used for stool analysis to find out cases of hookworm infestation among the sub sample.

The anaemic pregnant women selected were closely followed up using an interview Schedule. Weighment of foods was done in all the 250 houses. The Investigator went to their houses and weighed the raw food item and cooked weight of the preparation.

According to Rao (1991) any single day or two day weighment method would be effective a tool as that of seven days. In this study a two-day food weighment survey was carried out for the sub-sample.

Their case history was followed up with hospital records after each check-up until delivery.
7. **Analysis of the Data:** After the data collection, data was entered in SPSS master sheet. Statistical tables were constructed in order to interpret the data and to compare the experimental and control group.

Statistical constants like percentage, mean, standard deviation, 't' test and Chi Square were computed.

The statistical hypothesis formulated was tested using Chi-square to find association between variables, student's t-test was done to compare the difference in various variables in experimental and control group. Diagrams and graphs were drawn wherever necessary to substantiate the important findings. Details of statistical formula applied are given in appendix VI.

For presenting the nutritional intake results of the study, comparison of the consumption pattern, nutrient intake and food items between experimental anaemic pregnant women and control group anaemic pregnant women in the sub sample and deviation from the RDA was found out.

Awareness of the sample on nutrition, pregnancy and anaemia was analysed from the attitude scale. A total of 15 statements on different aspects of nutrition, pregnancy and anaemia were included in attitude scale. The scores for the positive statement were given as 2, 1, 0, -1, -2 and that for negative statement as -2, -1, 0, 1, 2. The highest possible score for a statement answered favourably was '2'. A respondent would get a maximum score of 30 (total statement x 2) of all the statements are answered favourably.
SLIDES SHOWING HOOK WORM INFESTATION
MICROSCOPIC VIEW OF ASCARIS INFESTATION

Fertile egg with protein coat

Fertile egg without protein coat

Infertile egg

Infertile egg
FOOD WEIGHMENT OF THE SUB SAMPLE

Fig. 16

RECORDING THE LENGTH AND WEIGHT OF THE BABY
RECORDING THE LENGTH AND WEIGHT OF THE BABY
VISUALS FOR NUTRITIONAL AWARENES SESSION

FOOD PYRAMID

- Fats, oil, and sweets
- Meat, fish, chicken, and eggs
- Fruits group
- Vegetable group
- Milk, yogurt, and cheese group
- Cereal and pulse group

(Davidson and Passmore, 1986)
RICH SOURCES OF IRON

RICH SOURCES OF VITAMIN C