CHAPTER III

MATERIALS AND METHODS

This chapter describes the methodology adopted to assess the prevalence and risk factors of Iron Deficiency Anemia among the tea garden women of selected tea gardens of Sonitpur District Assam.

This chapter deals with research design, settings, study population, sampling techniques, criteria for sample selection, sample size, development of tools, scoring procedures, content validity, pilot study, data collection procedures and plan for statistical analysis.

RESEARCH DESIGN

The research design chosen for the study was Cross sectional community based study.

VARIABLES

The variables of the study are as follows:

Demographic variables - Age, educational qualification, occupation, Marital status, religion, type of family, etc.

Environmental variables - Housing condition, ventilation, lighting, kitchen, water supply, lavatory, refuse disposal, drainage, surrounding, cattle shed, poultry, piggery.

Socio economic status - Family income.

Study variables - Prevalence and causes of Iron Deficiency Anemia.
SETTING

Sonitpur is an administrative district in the state of Assam in India. The district headquarter is located at Tezpur. As of 2011 census report it is the third most populous district of Assam (out of 27 district), after Nagaon and Dhubri.

According to the 2011 census Sonitpur district has a population of 1,925,975. The district has a population density of 365 inhabitants per square kilometer (950 /sq Km). Its population growth rate over the decade 2001-2011 was 15.67%. Sonitpur has a sex ratio of 946 females for every 1000 males, and a literacy rate of 69.96%.

Tezpur is a city and the administrative headquarter and municipal board of Sonitpur district in the state of Assam in Northeastern India. Tezpur is an ancient city on the banks of the river Brahmaputra and is the 2nd largest of the north bank towns with a population exceeding 100,000, after Bongaigaon. It is situated 175 kilometers (109 Km) north east of Guwahati, the fifth largest city of Assam, considered to be the "Cultural Capital of Assam".

The economy of Tezpur is dependent on its Tea Gardens. There are many tea gardens surrounding the town of Tezpur. The surrounding tea gardens and agriculture contribute to the local economy.

Tea gardens under Sonitpur District is divided under four sub divisions. They are namely Tezpur subdivision, Dhekiajuli sub division, Biswanath sub division and Gohpur sub division.
The population of the study composed of tea garden women of Sonitpur District of Assam. The target populations of the study were women aged between 14-45 years under Tezpur sub division of Sonitpur District. The accessible populations were the women aged between 14-45 years, who were tea tribe, working and residing in the tea garden areas on regular basis and women who fulfilled the inclusion criteria were chosen from selected tea gardens as a study sample.

CRITERIA FOR SAMPLE SELECTION

The study subjects were selected in line with inclusion and exclusion criteria stated by the researcher.
Inclusion Criteria

➢ Women who are tea tribe and working in the tea gardens.
➢ Women living in the tea garden areas.
➢ Women aged between 14-45 yrs.

Exclusion Criteria

➢ Women who were on regular medication of antacid, Iron and folic acid.
➢ History of Diabetes Mellitus, Hypertension, Cancer, Chronic Kidney diseases, Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrome.

SAMPLE SIZE

Sample sizes of 202 tea garden women were selected for the main study as a study sample.

SAMPLING TECHNIQUE

According to Polit and Hungler (2004), convenient sampling entails the use of the most conveniently available people as subjects of the study. Convenient sampling technique is a strategy in which the investigator’s knowledge of the population and its elements are used to select sample which are typical to the population.

Assam is one of the states of North Eastern Region of India. Assam has total 27 districts and 21 tea producing districts. Sonitpur district was selected by using purposive sampling technique. Sonitpur district has four sub divisions. They are namely Tezpur subdivision, Dhekiajuli sub division, Biswanath sub division and
Gohpur sub division. The researcher has selected Tezpur sub division by using convenient sampling technique. Sonitpur district has 72 tea gardens and Tezpur subdivision has 18 tea gardens. Simple random sampling technique was used to select the two tea gardens out of 18 tea gardens. Study samples were selected by using non probability convenient sampling technique from two tea gardens of Tezpur subdivision under Sonitpur District. Statistical formula $n = \frac{Pq}{L^2}$ ($P$=Population proportion of positive character, $q=1-P$, $L$=Allowable error) was applied in the present study. G.K Medhi study was taken as population of positive character to draw the subjects from the accessible population.

TOOLS AND TECHNIQUES

Based on the research problem and objectives of the study, the following steps were undertaken to select and develop the data collection tool.

DEVELOPMENT OF THE TOOLS

The tools were developed

- After reviewing the related literature
- Based on the experience of the investigator
- Based on the consultation with the guide and subject experts

A diagnostic check list and an inventory check list were prepared to collect the data from the study samples to assess the prevalence of iron deficiency anemia and to find out the risk factors of iron deficiency anemia.

DESCRIPTION OF THE TOOLS
The instrument of data collection consisted of two tools. The first tool consisted of two sections.

**Section – A:** dealt with demographic variables such as age, education, religion, marital status, occupation, average family income, type of family, personal habits like – alcohol consumption, smoking, betel nut and tobacco chewing, tea, environmental sanitation like – housing condition, ventilation, lighting, kitchen, water supply, lavatory, refuse disposal, drainage, surrounding, cattle shed, poultry, piggery.

**Section – B:** dealt with diagnostic check list on general sign and symptoms of Iron deficiency Anemia and report of blood investigation- Hb%, serum iron and report of stool sample.

The second tool – an inventory check list, to find out the risk factors of Iron deficiency anemia comprised of two sections.

**Section A:** Comprised of history of the tea garden women like – personal, menstrual, pregnancy, lactation, abortion, illness, medication history.

**Section B:** Comprised of Dietary history like – 24 hrs dietary recall and dietary habit.

The Hb% of study subjects were detected by World Health Organization color scale. The color scale comprises a small card with six shades of red that represent hemoglobin levels at 4, 6, 8, 10, 12, and 14 g/dL, respectively. The color standards are printed in a continuous row without any separation and are
mounted on a rigid white polyvinyl chloride or polypropylene sheet or thick card with a neutral pale-grey matt background. Estimation of the hemoglobin is done by matching the blood sample with the color standards through circular apertures which are placed in the center of each color standard. The WHO color scale was primarily designed for anemia screening in obstetrical management, pediatric clinics, malaria and hookworm control programs, blood transfusion donor selection, and epidemiological surveys. WHO color scale is a semi qualitative method and over the years it has been a useful tool in identifying anemia in field studies. Efficiency in terms of cost, accuracy, and time makes it an important resource in primary health care settings in developing countries. At present WHO color scale is the most widely used method for detecting anemia in settings where there is no laboratory. It performs better than clinical diagnosis alone in detecting mild to moderate anemia.

To diagnose iron deficiency anemia the following tests need to be performed:

- Hemoglobin and hematocrit
- Mean cellular volume
- Ferrritin
- Serum iron
- Total iron binding capacity
- Iron saturation
Present study is a community based cross sectional study. The researcher decided to perform only one lab test – serum iron test to diagnose iron deficiency anemia after considering cost and sample size of the one man study.

Serum iron is a medical laboratory test that measures the amount of circulating iron that is bound to transferrin. This laboratory test is performed to detect iron deficiency, which can cause anemia and other problems.

A **serum iron test** measures how much iron is in the serum. **Serum** is the liquid that is left over from blood plasma when the red blood cells and the clotting elements have been removed. Especially low iron levels can cause a variety of vague symptoms, such as fatigue, weakness, difficulty in concentrating, and moodiness. The serum iron test can reveal both unusually low and abnormally high blood iron levels. 65% of the iron in the body is bound up in hemoglobin molecules in red blood cells. About 4% is bound up in myoglobin molecules. A laboratory technician inserts a needle into a vein of a study subject’s *arm* or *hand* and draws a small sample of blood. This sample will then be tested in a laboratory. Serum iron is not a routine test. It is usually ordered as a follow-up after an abnormal result on a more common test, such as a complete blood count or hemoglobin test. Normal values of Serum Iron (SI): Women: 50 to 170 μg/dL.

**CONTENT VALIDITY OF THE TOOLS**
The content validity of the tools was established on the basis of opinion of three medical experts from the field of medicine and two experts in community health nursing and the guide. Suggestion provided by the experts on demographic section, diagnostic check list and inventory check list on Iron Deficiency Anemia was incorporated in the instrument and the tools were finalized for the main study.

ETHICAL CONSIDERATIONS

Participants were informed about the study purpose and oral consent was obtained from each study subject prior to intervention. Permission for data collection in the tea garden areas were first obtained from the District Nodal officer of National Rural Health Mission. After Nodal officer’s permission, the second permission was obtained from the Senior Medical officers of respected tea gardens.

RELIABILITY OF THE TOOLS

Reliability of the tools to determine the prevalence of and risk factors of IDA were established using Inter Rater method. Inter rater reliability was obtained by the investigator and Accredited Social Health Activist of the tea garden (Rater 2) on the same day. The reliability score was $r = 0.82$. The score obtained indicated the highly positive correlation hence the tool was considered reliable to proceed with the main study.

PILOT STUDY

A written permission was obtained from the Manager of Durung Tea Estate of Sonitpur district. The researcher conducted the pilot study during 4th week of December 2011, for a period of 5 days. The total 35 tea garden women from Durung Tea Estate who fulfilled the selection criteria were selected by non probability
convenient sampling technique. A brief introduction about the self and study was given and data were collected.

The confidentiality of the response was assured. Data were obtained collectively from all the women through interview schedule by using diagnostic check list and inventory check list to assess the prevalence and risk factors of Iron Deficiency Anemia. Interview schedule took approximately 20 - 25 minutes for each tea garden woman. Following this the workers were brought to tea garden hospital for 2 days for diagnostic evaluation after their duty hours. The pilot study result shows that the study was feasible to conduct in the tea garden areas in terms of money, man power and materials. Hence the researcher proceeded for the main study with the objectives to achieve it.

PROCEDURE FOR DATA COLLECTION

The formal written permission was obtained from the District Nodal Officer, National Rural Health Mission (NRHM) of Sonitpur District Assam, in the month of November 2011. The researcher collected data from 202 study subjects of Durung and Shingrijan Tea Estate by using non probability convenient sampling technique. The researcher collected the data of the tea garden women through interview schedule. An inventory check list was used to find out the risk factors of Iron deficiency anemia and diagnostic checklist was used to assess the prevalence of iron deficiency anemia. Assurance regarding confidentiality was provided to all the study subjects. After collecting the data, the Hb% was tested for every sampled person using WHO Color scale and the value was recorded in the format. A sterile container was provided to study samples to give their stool sample to diagnose the presence of worm in the stool.
The blood samples for testing of serum iron were collected by certified laboratory technician of a reputed laboratory of Tezpur. Sterile containers of the stool samples were collected from the study subjects and it was handed over to the laboratory technician for laboratory test to find out presence of worm in the stool. Thus the prevalence and risk factors of Iron deficiency anemia was assessed on the basis of laboratory test reports, and data collected by using inventory and diagnostic check list.
PLAN FOR DATA ANALYSIS

Both descriptive and inferential statistics were used for data analysis. Descriptive statistics were used to analyze the demographic variables of the study subjects and frequency distribution, mean, standard deviation were used to compute the prevalence and risk factors of the women. Inferential statistics chi-square ($\chi^2$) was used to associate the risk factors and prevalence of Iron Deficiency Anemia with selected demographic variables.

- Frequency and percentage distribution was used to compute the socio demographic data.
- Frequency and percentage distribution was used to compute the data of risk factors of Iron deficiency anemia.
- Mean and standard deviation was used to compute the data of prevalence of anemia and iron deficiency anemia.
• Confidence interval was used to compute the data of prevalence of anemia and iron deficiency anemia.

• Karl Pearson’s Correlation coefficient test was performed between hemoglobin result of WHO color scale and serum iron result.

• Chi-Square test was used to find out the association between prevalence of iron deficiency anemia with selected demographic variables.

• Chi-Square test was used to find out the association between prevalence and risk factors of iron deficiency anemia among the tea garden women.

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