SUBJECTS AND METHODS

CHAPTER 3 METHODOLOGY

The details of the methodology used for the purpose of present research, the selection of subjects and the experimental design are presented in this chapter under the following heads :

- Selection of area
- Selection of sample
- Plan of the study
- Types of data collected
- Parameters for the study and techniques for data collection
- Statistical analysis

SECTION I

Selection of Area

The study was conducted in two major cities of Gujarat; Baroda and Ahmedabad from May 1991 to January 1994. The under-privileged pregnant women living in the slums in both the cities received health and nutrition services through the Integrated Child Development Services (ICDS) scheme and the Health and Family welfare scheme which included immunization against tetanus, iron supplements, antenatal care, supplementary food and nutrition health education.

Within this scheme, two grass-root level functionaries operated the programme at the field level, the auxiliary nurse mid-wife (ANM) being responsible for immunization, antenatal

care (ANC) and distribution of iron supplements whereas the AWW was responsible for distribution of food supplements and provision of nutrition-health education to pregnant women. However, in practice, iron supplements were distributed by the AWW, while the ANM was held accountable for the overall administration such as procurement of the supplies, record keeping and report. Of a total of 200 ICDS centres in Ahmedabad city and 154 in Baroda city, 15 and 12 centres respectively were selected, the selection in both instances being purposive since the cooperation of the subjects was considered important for the study.

The criteria for selection were :

- The area should be socio-economically backward
- It should be accessible to the investigator
- It should have an anganwadi centre (AWC) with an AWW and a helper having a good rapport with the community.
- The subjects should be willing to participate in the study.

Since the iron supplements routed through the National Nutritional Anaemia Prophylaxis Programme (NNAPP) were administered by the directorate of health services, the cooperation of the joint director of ICDS as well as medical officers in charge was sought and obtained at the beginning of the study. The ICDS authorities at both places were contacted and requested to permit the AWWs to assist in identifying pregnant women for enrolment in the study and also to distribute the tablets as per the suggested alternative delivery system.

Selection of the Sample

Each ICDS centre catered to a population of about 1000 people. All pregnant women between 20 and 24 weeks of gestation were considered eligible for the study. The names of the pregnant women were taken from the list of the AW centres and eligible mothers contacted with the assistance of AWW or helper and enroled. Women who consented to participate in the study and who were not likely to move out during the study period were included in the study. The subjects were enroled on an ongoing basis from May 1991 to Aug 1993 and they were followed-up till delivery. In all 268 women were enroled at or before 24 weeks of gestation.

Plan of the Study

Phase I

A Study of Perceptions of Pregnant Women, Lactating Women, Elderly Women and Functionaries Through the Use of Qualitative Methodology: Focus Group Discussions : Qualitative research provides greater depth of understanding regarding consumer responses and the problem studied. Of the qualitative research methods, focus group discussions capitalise on group dynamics. The interaction of respondents stimulates richer responses and allows valuable thoughts to emerge. They can be completed more quickly and help generate new ideas (Scrimshaw and Hurtado 1987, Debus and Novelli 1989). Hence, they were used as tools for collecting qualitative data regarding beliefs and perception of women regarding pregnancy and consumption of

iron tablets.

Twelve Focus Group Discussions (FGD) were conducted with pregnant women to assess their perceptions about health problems during pregnancy and anaemia, with regard to its causes, symptoms, consequences, prevention and their attitude towards consumption of iron tablets.

Seven of these were conducted in Baroda and five in Ahmedabad. Guidelines for FGDs were designed in such a way that the questions moved from general, non-threatening issues to specific topics of interest according to the objectives and information needs of the research. Open-ended and non-biased questions were used, to minimise the moderator's influence. It was ensured that all the areas relevant to the research objectives were covered (Guidelines for FGDs are shown in Appendix I).

Six to ten participants (pregnant women) were invited for each of the focus groups. Women were informed in advance regarding the time, venue and purpose of the meeting to facilitate their attendance. Most of the FGDs were conducted at the Anaganwadi centres (AWC) after the pre-school education hours or at the place of one of the willing participants who had enough room for all the participants to be seated comfortably. The participants were usually seated in a circular or semi-circular arrangement so that each could see and hear what others said. Willing peer group participants (women of similar age group) were also allowed for the focus group discussion. FGDs were also conducted with lactating

women and older women on similar guidelines as described above (Appendix I and II).

The FGDs were conducted by the moderator, with the help of an observer who recorded the salient features of the discussions. The investigator was the moderator in all instances and a colleague was the observer in a few of the FGDs whereas the AWW was trained to be an observer and to record the relevant details in the others.

Four focus group discussions were also conducted with functionaries chiefly the AWWs to assess their own perceptions regarding anaemia, importance of treating anaemia, the health seeking behaviour of community mothers and the advice the AWWs gave to the mothers regarding anaemia and other health problems. The guidelines for FGDs used with the functionaries were similar to the ones used with the mothers and are given in appendix III.

Soon after completion, the FGDs and interviews which were written in the form of field notes were reviewed by the investigator along with the observer and a detailed draft was prepared for final compilation and analysis.

Phase II

Identifying The Alternative Delivery System And Studying Its Effectiveness : The need for an alternative distribution system has been already pointed out in the introduction. The only feasible alternative that emerged from the various FGDs was to link the distribution of iron tablets to pregnant women

with the child immunization in the community. This called for no major change in the work load of the functionaries or the administrative protocol that was already being followed.

Linking the iron tablet distribution with child immunization was found to be better than linking the distribution with the tetanus toxoid immunization of the pregnant mothers, as they availed of the TT injections in the last two months of pregnancy which left inadequate number of days for full iron supplementation. Further, not all pregnant women availed of TT injections from the ANM at AWC. On the contrary, the child immunization organized once every month in each slum provided an opportunity to contact the pregnant women from 20 to 24 weeks of gestation till delivery and inform them ahead of time about the distribution of iron tablets at this time. This revised system of distribution was expected to overcome the following constraints experienced in the ongoing one.

1) The timing of the distribution of the iron tablets could be made known to the pregnant women, as the community was usually informed ahead of time the dates of child immunization.
2) The AWW and the helper who informed the mothers about the child immunization could inform and request the pregnant women to come and collect the tablets from the centre.
3) The distribution of tablets which was very irregular in the ongoing system, was expected to become regular, once a month.

4) Counselling could be provided by AWW to currently pregnant and prospective mother at the time of collection of tablets.

i) Distribution and administration of the supplements in the alternative delivery system :- When the distribution of the supplements was linked with the child immunization for the present study, the AWW took the responsibility for distribution of the supplements with help from the ANM. The ANM visited the AWCs once each month for immunizing children. All pregnant women were informed about this visit and were asked to collect a month's supply of 30 iron tablets at this time. No change in the packaging was made i.e. they were distributed wrapped in ordinary paper. The AWW instructed the women to consume one tablet daily and come back for the next 30 tablets on the successive immunization day the next month.

(ii) Form of iron used and source of supplements :- Oral iron was provided in the form of ferrous sulphate ($FeSO_4$) tablets manufactured by Eupharma Laboratories. These tablets containing 60 mg of elemental iron and 0.5 mg folic acid were made available for the present study by the Family Welfare Bureau in Ahmedabad and Baroda. In addition, the supplements prescribed by doctors, the amount bought and consumed and its composition were recorded each month by detailed questioning of subjects, scrutiny of the prescription slips and personally verifying the preparation and the amount they had prescribed. The details of these preparations, their composition and the elemental iron content are indicated in Appendix IV.

Phase III

Role Of Private Sector and Government Hospitals in Anaemia Control: Many subjects of the present study availed of routine ANCs from the private physicians for which they had to pay for or from larger government hospitals which were free of charge. During these check-ups, they were prescribed various iron preparations and hence it was necessary to study the contribution of these two sectors to the receipt and consumption of iron tablets by the subjects.

Further, this also provided an opportunity to assess the relative role of the three sectors viz. the private, large government hospitals and the grass-root level community centres in the distribution of iron tablets and to assess which of these elicited best compliance. Such information, it was expected, would contribute to strengthening the anaemia control programme by routing the iron supplements through the sector that elicited the greatest compliance. A tentative hypothesis was setup that since the subjects had to pay for the iron tablets received from the private sector, it may be valued more and hence, utilized completely.

Thus, data regarding receipt and consumption of iron supplements from the private sector and larger government hospitals by the subjects were obtained using an appropriate pre-tested questionnaire (Appendix IX).

Phase IV

Impact of the Supplements : In order to assess if an impact occurred, weight and Hb were measured each month from enrolment till delivery, within one week of each woman's LMP date. The morbidities experienced by the women for the past one month, its frequency, duration and treatment taken for the same were recorded each month. Birth weight of the infants, complications during delivery and birth date were also recorded in order to assess the impact of consuming iron tablets on birth weight, prematurity, LBW infants and complications during delivery.

Types Of Data Collected

At the beginning of the study, data on socio-demographic information, past obstetric history, women's knowledge regarding anaemia and their health-seeking behaviour, weight, height, haemoglobin, morbidity profile for the past one month and receipt and consumption of iron tablets and utilization of other health services were collected. Knowledge regarding anaemia and attitude towards tablet consumption were also collected from the subjects' mothers-in-law. Data on socio-demographic information and obstetric history, KAP regarding anaemia and height were obtained only once at the beginning of the study. All other data were recorded at monthly intervals from 16/20 week of gestation till delivery.

The birth weights of the infants were obtained from the hospital records.

SECTION II

Details of Parameters and Techniques for Data Collection

The parameters assessed at different points during the study are shown in Table 3.01.

Socio - Demographic Information : Socio - economic characteristics of the subjects were recorded using a pretested interview schedule which included information on family characteristics, family type and size, the educational level of the subject and her spouse, the occupation of the subject and her spouse, total income from all the sources, the type of housing, source of drinking water, toilet facilities available and environmental sanitation. The environmental sanitation was categorised into four classes i.e., excellent, good, fair and poor based on the observations of the cleanliness inside and outside the house. Per capita income of the family was derived later. The interview schedule used for the collection of socio-economic data is shown in Appendix VI.

Obstetric History : Information on age of the subjects, past obstetric history of the subjects like age at menarche, age at marriage, age at first conception were elicited using a pre-tested structured schedule. Sometimes the subject could not recall the age at menarche or at marriage. In such cases, she was questioned about events in some detail and from the information so collected, approximate age was worked out.

Data on parity, previous miscarriages or induced

Table 3.01 : Parameters For The Study

Parameters	Gestational Age (Weeks)				
	16/20	24	28	32	36/40
SES And Obsteteric History	X				
Knowledge Of Mothers	X				
Knowledge Of Mother-in-law	X				
Height	X				
Weight	X	X	X	X	X
Haemoglobin	X	X	X	X	X
Morbidity	X	X	X	X	X
Receipt Of Iron Tablets	X	X	X	X	X
Compliance With Tablets	X	X	X	X	X
Birth Weight And Birth Date Of Infant					X

abortions, incidence of premature deliveries, still births and Low birth weight (LBW) babies were obtained by detailed questioning (Appendix VII). For the purpose of the study, various terms were defined as follows.

Parity was defined as the number of full term birth by the mother. It included all live or dead births and miscarriages after 20 weeks of gestation.

Miscarriage was defined as the termination of pregnancy before 28 weeks of gestation from the first day of the last menstrual period (LMP).

Premature delivery was defined as delivery occurring between 28 to 36 weeks of gestation.

Still birth was defined as a full term infant, who was not alive at birth.

LBW babies were defined as infants with birth weights less than 2.5 kg.

Information on all other parameters was supplied by the mother except for birth weight which was taken from the hospital records.

Utilization of Health Services by Women : A pre-tested interview schedule (Appendix VIII) was used to record information regarding the health services utilized, viz. TT immunization, time of immunization, receipt of iron tablets, antenatal checkups, time of first and subsequent visits for ANC, preventive health checkups by doctors/nurse, receipt of supplementary food and the number of contacts with the AWW.

Compliance with Iron Supplements Provided Under the Alternative Delivery System : Information regarding receipt and consumption of iron supplements from all sources and the dosages received till enrolment were recorded using a pre-tested questionnaire (Appendix IX). The receipt and consumption of tablets after enrolment were recorded once every month. Since the women received prescriptions from private doctors for various types of iron preparations in addition to those received from AWCs, the information on total number of tablets received after the investigator's previous visit, their source and consumption, whether any other medicine was prescribed or obtained from other sources, was recorded. The subject was requested to provide detailed information regarding the consumption of iron tablets, and whether she had taken the tablets as per the instructions provided, if she was regular or irregular in consuming the iron tablets, if tablets were spoiled, lost or shared by other family members. The information provided by the subject on compliance was verified by counting the remaining number of tablets. The past month's balance was recorded and carried forward to the next month. The subject was also questioned in detail regarding the consumption of the tablets left over at the time of previous visit and the tablets received thereafter. The total quantity of iron consumed was calculated from the amount of iron contained in each tablets (Appendix IV) obtained by calculating the amount of iron present in various iron compounds as indicated in Appendix V. This was

then multiplied by number of tablets received.

Iron consumed from all sources was calculated by adding the compliance of the total doses received from the three sectors.

Morbidity Profile of the Subjects : After some preliminary information, a list of common morbidities experienced during pregnancy was prepared, in consultation with a professor of gynaecology of the local medical college and a schedule was prepared to record various morbidities, their duration, severity and type of treatment taken by the pregnant women. This was pre-tested before use (Appendix X).

The proforma for recording the morbidities consisted of three categories : 1. Pregnancy related morbidities, 2. Anaemia and work related morbidities and 3. Infectious episodic morbidities.

The infectious or episodic morbidities were defined as follows:

Morbidity	Defined As
Diarrhoea	Passing of >=3 loose stools in a day
Cold	Running or blocked nose
Cough	Frequent coughing, recorded on basis of subject's history.
Fever	Based on subject's history of high body temperature.
Malaria	High fever, shivering or pain in the abdomen, may also be diagnosed by doctor
Typhoid	Prolonged high fever,diagnosed by doctor.
Pain in throat/ear	Based on subject's history
Conjunctivitis	Subject's history, may also be observed

Validation of reference period :- Many studies indicate recording of morbidities at various periods, ranging from daily to once a week, in 3 months or even once in 12 months. However, long periods of recall are considered less valid, especially for minor health problems, since the individual tends to forget the morbidity and the number of episodes due to long time gap. Since it was not feasible, in the present study, to make weekly visits to all the women, a reference period of one month was selected. This was validated against a weekly recall of morbidity data on a sub-sample of 15 women. Morbidity was collected from them using the pre-tested schedule once a week. At the end of 4 weeks, the women were requested to recall the morbidity for the whole month. When both the data were compared, it was observed that the average of the episodes of morbidities and the number of days of the morbidity experienced over the reference period of one month and one week did not vary as is shown below.

Validation of morbidity recall

Time Period	Mean No Of Episodes	Mean No of Days
Weekly record	0.43	0.24
Monthly record	0.45	0.20

Knowledge Regarding Anaemia : Knowledge regarding anaemia and tablet consumption and attitude towards tablet consumption were elicited on a sub-sample of subjects and their mothers-in-law before and after the study. This was done by individual interviews using a pretested questionnaire. Knowledge regarding anaemia was also elicited from the

functionaries chiefly AWW (Appendix XI, XII, XIII).

Anthropometry

Assessment of Height : Height is a linear measurement made up of the sum of four components : legs, pelvis, spine and skull (Jelliffe, 1966). For assessment of height, subjects were made to stand erect, bare-footed with heels together, parallel to the wall; with head, shoulders, buttocks and heels in alignment and touching the wall. A flat board was placed on the head so as to slightly press the hair. Height was marked on the wall and read off from a fibre glass tape on the wall to the nearest 0.1 cm as described by Jelliffe (1966).

Assessment of Weight : Weight measures the body mass. It indicates short term changes in nutritional status. Maternal weight gain during pregnancy is a sensitive indicator of nutritional stresses and foetal growth and is a critical determinant of its outcome.

The subjects were weighed barefooted on a standardized portable bathroom scale. The subject wearing minimum clothes was made to stand on the platform of the scale without touching any thing. Scale was set to zero before and after each measurement and weight was recorded to the nearest 0.5 Kg. No correction was made for the clothing. Weight was recorded within $\pm$ 1 week of the subject's LMP date every month.

Haemoglobin : The Cyanmethaemoglobin method with the modified filter paper technique as described by NIN (1974) was used for

haemoglobin estimation.

Principle : When a sample of blood is mixed with solution containing potassium ferricynide (K4Fe(CN)6) and potassium cyanide (KCN), ferricynide oxidizes the haemoglobin to methaemoglobin which then reacts with cyanide ion to form cyanmethaemoglobin which absorbs light at 540 millimicrons and its concentration can be read colorimetrically.

Procedure for standardization :- The initial standardization of the method was done by collecting blood samples in duplicate. The middle finger of the left hand of the subject was wiped with alcohol and then with a clean tissue paper. A sharp prick was given using a sterile disposable blood lancet to achieve free flowing blood. Then, 0.02 ml of this blood was carefully pipette using a micropipette. Care was taken to avoid air bubbles. The tip of the pipette was wiped with tissue paper and then blood was blown out into a test tube containing 5 ml Drabkins reagent. The contents were mixed by gradually whirling the test tube and allowed to stand for 30 minutes. The colour developed was read on a spectrophotometer Spectronic-20 at a wave length of 540 nm. The instrument was set at zero using 5 ml of Drabkins reagent.

A series of standards were run using standard cyanmethaemoglobin (HiCN) reference solutions obtained from Span Diagnostics (Baroda).

A series of dilutions were made as follows :

Tube	Dilution
1	10 ml standard
2	5 ml drabkins + 5 ml standard from tube 1
3	5 ml drabkins + 5 ml standard from tube 2
4	5 ml drabkins + 5 ml standard from tube 3
5	5 ml drabkins (reagent blank)

The standard were read in the spectrophotometer against Drabkins reagent as a blank at 540 nm. A calibration curve (Appendix XIV) was made from which Hb values of the sample were calculated. After this standardization the method was modified for use according to the modified filter paper technique by NIN (1974).

Modified filter paper technique :- 0.02 ml of blood was carefully pipette in a calibrated Hb pipette and the blood was blown out in concentric circles on Whatmann grade 1 filter paper of 1.5 X 1.5 cm, labelled with the subject's code number in pencil. The sample was dried and stored between butter papers. The blood stained portion was later cut and eluted in 5.0 ml of Drabkins solution in a labelled test tube for 30 to 45 minutes and was read in a spectrophotometer at wavelength of 540 millimicrons against the reagent blank and the standards. The readings were multiplied with the factor obtained from the calibration curve to obtain the Hb value (g/dl), after making correction (4%) for the difference between the two methods.

Data Analysis

The following procedures were used for analysis of data :

1) Qualitative evaluation of the focus group discussion was done to assess the perception of different groups of people regarding women's health problems, especially regarding anaemia and to suggest strategies to improve compliance.

2) The total amount of iron received and the quantity consumed were computed to have a measure of the receipt and compliance from different sources.

3) Compliance was estimated as percent of the recommended and received dose from each source.

4) Percentages and frequency distribution were calculated for all parameters.

5) Means and SE or SD were calculated for all the quantitative data that were expressed numerically.

6) Independent 't' test was done to compare the difference in quantitative parameters before and after the study.

7) Chi-square tests were carried out to test the difference in percentage and frequencies of various parameters before and after the study.

8) Correlation coefficient was computed between the level of iron intake and rise in haemoglobin.

9) Multiple regression analysis was carried out to determine various factors that affect birth weight and compliance.