CHAPTER 5: RESULTS AND DISCUSSION

The data was collected from the three different settings (Group 1, 2 and 3) and analysed in each of the three groups; and comparison amongst the three different settings has been made and the detailed result of the study has been described under the following headings:

5.1 Socio-demographic profile and type of antenatal care

- 5.1.1 Socio-demographic profile (SDP)
- 5.1.2 Type of antenatal care

5.2 Obstetric profiles

5.3 Food frequency, food security and dietary intake in pregnant women

- 5.3.1 Food frequency
- 5.3.2 Household food security assessed from the amount of food purchased
- 5.3.3 24-Hour Dietary Recall
  - 5.3.3.1 Household food security assessed from the amount of food cooked in the previous 24-hours
  - 5.3.3.2 Dietary intake of the pregnant women

5.4 Nutritional profile at enrolment

5.5 Haemoglobin status at enrolment

5.6 Current regimen for calcium and vitamin D supplementation in Delhi Hospitals

5.7 Exploring feasibility of providing two tablets of calcium and vitamin D as supplement

5.8 Follow up during pregnancy

5.9 Compliance with the supplementation

- 5.9.1 Group 1
- 5.9.2 Group 2
- 5.9.3 Group 3

5.10 Haemoglobin status during follow up

5.11 Course of pregnancy

5.12 Weight gain during pregnancy

5.13 Pregnancy outcome

5.14 Maternal anthropometric indicators and Birth Weight

5.15 Post-pregnancy weight retention

5.1 Socio-demographic profile and type of antenatal care

5.1.1 Socio-demographic profile (SDP)

A total of 1235 pregnant women were enrolled for the study in the 3 previously defined groups. At the initial visit information on socio-demographic profile (SDP) was collected; the detail of the same is given in Table no 5.1.

Table 5.1: Socio-demographic profile (SDP) of pregnant women

	Group 1 (n=387)	Group 2 (n=400)	Group 3 (n=448)
	n (%)	n (%)	n (%)
Type of family			
Joint	186 (48.1%)	230 (57.5%)	170 (37.9%)
Nuclear	201 (51.9%)	170 (42.5%)	278 (62.1%)
Size of family			
≤3	172 (44.4%)	155 (38.8%)	175 (39.1%)
4 to 8	185 (47.8%)	204 (51.0%)	220 (49.1%)
>8	30 (7.8%)	41 (10.3%)	53 (11.8%)
Woman's education			
No schooling	70 (18.1%)	83 (20.8%)	94 (21.0%)
Had schooling	247 (63.8%)	229 (57.3%)	276 (61.6%)
College	70 (18.1%)	88 (22.0%)	78 (17.4%)
Husband's education			
No schooling	36 (9.3%)	53 (13.3%)	46 (10.3%)
Had schooling	261 (67.4%)	235 (58.8%)	306 (68.3%)
College	90 (23.3%)	112 (28.0%)	96 (21.4%)
Woman's work status			
Home maker	369 (95.3%)	379 (94.8%)	429 (95.8%)
Working outside	18 (4.7%)	21 (5.3%)	19 (4.2%)

Husband's work status			
Unskilled	10 (2.6%)	35 (8.8%)	14 (3.1%)
Semi-skilled	237 (61.2%)	195 (48.8%)	279 (62.3%)
Skilled	138 (35.7%)	167 (41.8%)	147 (32.8%)
Not working	2 (0.5%)	3 (0.8%)	8 (1.8%)
Standard of living			
Low	208 (53.8%)	164 (41.0%)	122 (27.2%)
Middle	178 (46.0%)	236 (59.0%)	315 (70.3%)
High	1 (0.3%)	0 (0.0%)	11 (2.5%)
Comparison amongst the groups			
		ANOVA P-value	**Significance**
Type of family		0.873	NS
Size of family		0.145	NS
Literacy of women		0.317	NS
Literacy of husband		0.592	NS
Work status of women		0.502	NS
Work status of husband		0.685	NS
Standard of living index		0.899	NS
Note: NS-Statistically Non-Significant			

In Group 1, Group 2 and Group 3 a total of 387, 400 and 448 pregnant women who were willing to participate in the study were enrolled.

Majority of the women were from nuclear family except in Group 2 where 42.5% were from nuclear families and more than half of the women were from joint families. About half of the women enrolled had an average family size of 4 to 8 members (Table 5.1).

Majority of women were from low or low-middle-income Group families, about 60% had a school education and 1/5th had a college education. More than 90% of them were homemakers. About 2/3rd of husbands had schooling and little more than 1/5th were college educated. Similarly, about 2/3rd of husbands had a semiskilled or unskilled job and 1/3rd had worked in clerical jobs or had small business (Table 5.1).

The family income was sufficient to meet the basic requirements of food, shelter, health care and education for their children. Due to urban space constraints majority of them lived in one or two-room tenements in overcrowded and unhygienic surroundings. In Group 1 and Group 3, more than 80% were living in Pucca houses but in Group 2 about 2/3rd were living in pucca houses, 30.5% were living in semi-pucca houses and 45 were living in kuchha houses whereas in Group 1 and Group 3 women living in kuchha houses were lower than 1.5% and in Group 1 only one woman was living in kuchha house. More than 50% of the women were living in rented houses, about 40% were sharing their toilets with other tenants and below 1% had no facilities.

The majority of women were from non-vegetarian households (mostly egg eaters). More than 95% of the households had facilities of gas ovens for cooking and 99% were using utensils made of stainless steel.

More than half of the households were dependent on public transport. More than 80% of the households had colour television as a means of entertainment.

There was no statistically significant difference in the sociodemographic profile of the women enrolled under the three settings (Table 5.1).

5.1.2 Type of antenatal care

There were some differences in availability and access to antenatal care between the three settings in which pregnant women were enrolled. Group 1 women were enrolled in South Delhi hospital with better infrastructure, staff and supply of supplements. Pregnant women of Group 2 attended a primary health care institution which had poorer infrastructure, manpower, supply of supplements and services. Group 3 was an urban community setting where all of the pregnant women did not access antenatal care; those who did sought antenatal care from public and private health care service providers; some received home-based antenatal care and supplements from the ANMs. Because of this availability, access, quality and adequacy of antenatal care and supplementation varied in Group 3.

5.2 Obstetric profile

In all three settings majority of the women were in their twenties and having their first or second pregnancies. None had any obstetric problems because those with previous obstetric problems were not enrolled for the study. There were no differences in the sociodemographic, obstetric and nutrition profiles of women who continued the supplements and those who discontinued. The detailed obstetric profile of the enrolled pregnant women is given in Table 5.2. There was no statistically significant difference between the three groups in the obstetric profile (Table 5.2).

Table 5.2: Obstetric Profile of the pregnant women

	Group 1 (n=387)	Group 2 (n=400)	Group 3 (n=448)
	n (%)	n (%)	n (%)
Age (years)			
<20	20 (5.2%)	18 (4.5%)	25 (5.6%)
20-29	327 (84.5%)	347 (86.8%)	356 (79.5%)
≥30	40 (10.3%)	35 (8.8%)	67 (15.0%)
Gravida (No of pregnancies)			
1	163 (42.1%)	189 (47.3%)	150 (33.5%)
2	129 (33.3%)	120 (30.0%)	152 (33.9%)
≥3	95 (24.5%)	91 (22.8%)	146 (32.6%)
Parity (No of deliveries)			
0	186 (48.1%)	190 (47.5%)	171 (38.2%)
1	142 (36.7%)	148 (37.0%)	180 (40.2%)
2	48 (12.4%)	59 (14.8%)	67 (15.0%)
≥3	11 (2.8%)	3 (0.8%)	30 (6.7%)
Abortion			
0	321 (82.9%)	354 (88.5%)	368 (82.1%)
1	56 (14.5%)	41 (10.3%)	56 (12.5%)
≥2	10 (2.6%)	5 (1.3%)	24 (5.4%)
Comparison amongst the groups			
		ANOVA P-value	**Significance**
Age		0.123	NS
Gravida		0.618	NS
Parity		0.311	NS
Abortion		0.296	NS
Note: NS- Statistically Non-Significant			

In both in Group 1 and 2, nearly 2/3rd of the women were enrolled at 14 to 19 weeks of pregnancy. Only around 5.0% were enrolled late in the second trimester. There was no significant difference in the period of pregnancy at the time of enrolment between these two settings.

Unlike the enrolment of women in Group1 and 2 Group 3 pregnant women were enrolled as and when they were identified to be pregnant. The majority (87.3%) were enrolled in their first and second trimester; 12.7% of the pregnant women were enrolled in their third trimester.

The mean gestational age at enrollment was 19.2±2.62 weeks, 18.8±2.90 weeks and 17.3±7.82 weeks in Group 1, Group 2 and Group 3 respectively. There was a statistically significant difference in gestational age at enrollment of Group 3 women with the other two groups because women who were identified in their first trimester and early second trimester were enrolled and followed up even though they received antenatal care and supplements much later; a small number of women who did not receive antenatal care and supplements till early third trimester were also enrolled.

5.3 Food frequency, food security and dietary intake in pregnant women

Majority of the pregnant women were homemakers and cooked and consumed homecooked food. It was therefore possible to collect the data pertaining to dietary intake using the 24-hour dietary recall even in the hospital settings. Collecting information on food security and dietary intake using food frequency, food purchase and 24-hour dietary recall is time-consuming and takes an average of 30 to 45 minutes to complete. Most of the women in any of the three settings were unable to spend such a long time with the research team. As there was no statistically significant difference in the sociodemographic profile of the pregnant women enrolled in the three groups the data on dietary intake from the pregnant women from all three groups were combined and analysed to assess food frequency, food security of the families and dietary intake of non-pregnant and pregnant women.

Food frequency, food purchase and 24-hour dietary recall when done together give a detailed idea of the food consumption pattern in any particular family, the food security status of the family and dietary intake in an individual i.e. pregnant woman. Information on the type and frequency of consumption of different food stuffs was collected to obtain data on the type and frequency of foodstuffs consumed by the family; based on the data it is possible to assess the adequacy of the macro and micronutrient consumption of the family members. From the data on different foodstuffs purchased in a defined period, the food consumption/consumption unit/day of the family were computed and based on the energy consumption/consumption unit/day, the food security status of the family was assessed. Household food security and dietary intake of the women in the family (control group) and pregnant women were assessed using 24-hour dietary recall. Data on food and nutrient intake was calculated for the non-pregnant and pregnant women and compared with the EAR recommended by the ICMR-NIN-2020.

5.3.1 Food frequency

Food frequency data was collected as described in the methodology for the household. Data on the consumption of all foodstuffs belonging to the major food groups were collected as described in the methodology (Table 5.3).

Table 5.3: Frequency of non-perishable food items consumption

	Rice	Wheat	Other Cereals	Pulses	Legumes	Oil	Sugar/ Jaggery
Daily	102 (50.0%)	194 (95.1%)	1 (0.5%)	79 (38.7%)	8 (3.9%)	204 (100.0%)	191 (93.6%)
Alternate Day	28 (13.7%)	3 (1.5%)	1 (0.5%)	35 (17.2%)	9 (4.4%)	-	1 (0.5%)
Twice a Week	34 (16.7%)	1 (0.5%)	-	51 (25.0%)	26 (12.7%)	-	8 (3.9%)
Once a Week	30 (14.7%)	2 (1.0%)	1 (0.5%)	28 (13.7%)	106 (52.0%)	-	2 (1.0%)
Twice a Month	4 (2.0%)	-	2 (1.0%)	2 (1.0%)	15 (7.4%)	-	2 (1.0%)
Once a Month	3 (1.5%)	1 (0.5%)	-	1 (0.5%)	14 (6.9%)	-	-
Rarely/ Never	3 (1.5%)	3 (1.5%)	199 (97.5%)	8 (3.9%)	26 (12.7%)	-	-

Cereals were consumed daily; wheat being the predominant cereals consumed in the region where data has been collected around 95% of the households consumed wheat daily, 50% of the households consumed rice daily and other cereals were consumed rarely/ never (Table 5.3). Other cereals like jowar, bajra were mostly consumed in the winter seasons.

The frequency of consumption of pulses and legumes was lower. Around 39% of the households consumed pulses daily and the majority were consuming pulses either on alternate days or twice a week. Consumption of legumes was even lower, around 50% of the households were consuming legumes once a week. Overall, only 2/5th of the subjects were consuming pulses and/or legumes daily (Table 5.3).

Oil was used for the medium of cooking and therefore all the households used oil for cooking daily, and sometimes some of the households with a better economic condition, either replaced oil with ghee or added a small amount of ghee along with oil (Table 5.3).

Over 90% of the households consumed sugar/ jaggery daily mainly with tea. Sugar was consumed in the summer as well as in the winter seasons mainly with tea; in winter-season, jaggery was used for the preparation of desserts; jaggery was also consumed with chapati/ roti (Table 5.3).

Table 5.4: Frequency of perishable food items consumption

	Roots	Tubers	Other vegetables	GLV	Fruits
Daily	194 (95.1%)	155 (76.0%)	200 (98.0%)	6 (2.9%)	114 (55.9%)
Alternate Day	7 (3.4%)	32 (15.7%)	2 (1.0%)	8 (3.9%)	26 (12.7%)
Twice a Week	1 (0.5%)	13 (6.4%)	1 (0.5%)	35 (17.2%)	25 (12.3%)
Once a Week	2 (1.0%)	3 (1.5%)	-	80 (39.2%)	15 (7.4%)
Twice a Month	-	1 (0.5%)	-	5 (2.5%)	3 (1.5%)
Once a Month	-	-	-	14 (6.9%)	3 (1.5%)
Rarely/ Never	-	-	1 (0.5%)	56 (27.5%)	18 (8.8%)

Along with cereals, roots and tubers were the major source of carbohydrates, as roots and tuber consumption in the study population was high; 95% of the subjects consumed roots daily and approximately 3/4th of the households consumed tubers (mainly potatoes and onions) daily throughout the year. Potato onion curry was a predominant dish in the households of the study population and the reason may be economic as the potato is cheaper than other vegetables and at the same time palatable also. (Table 5.4). During the winter seasons, consumption of carrots, radishes, beetroots etc. increased.

Around 98% of the households consumed other vegetable; tomatoes were included as other vegetables and were consumed regularly; other seasonal vegetables were consumed as and when available; in majority of the households, other vegetables were consumed during one meal of the day (Table 5.4).

The frequency of consumption of green leafy vegetables was relatively low; the majority (39%) of the households were consuming GLV once a week (Table 5.4). The frequency of green leafy vegetable consumption was higher in the winter as fresh GLVs are available at a reasonable price in the winter.

The frequency of consumption of fruit was low, around 50% of the subjects consumed fruits on a daily basis. Bananas are the predominant fruit consumed followed by pomegranate. The predominance of bananas may be attributable to the fact that bananas are easily available at reasonable prices, are palatable and give satiety. Other fruits like apples, pears, guavas were consumed but their consumption was seasonal and not frequent (Table 5.4).

Table 5.5: Frequency of milk and milk product consumption

	Milk	Curd	Butter milk	Milk products
Daily	182 (89.2%)	33 (16.2%)	8 (3.9%)	-
Alternate Day	5 (2.5%)	23 (11.3%)	15 (7.4%)	1 (0.5%)
Twice a Week	3 (1.5%)	18 (8.8%)	16 (7.8%)	11 (5.4%)
Once a Week	2 (1.0%)	36 (17.6%)	20 (9.8%)	31 (15.2%)
Twice a Month	-	9 (4.4%)	3 (1.5%)	28 (13.7%)
Once a Month	-	4 (2.0%)	3 (1.5%)	41 (20.1%)
Rarely/ Never	12 (5.9%)	81 (39.7%)	139 (68.1%)	92 (45.1%)

The major contributors of dietary calcium are milk and milk products. In North Indian households with reasonable purchasing capacity milk is bought regularly though the quantity may be less. Around 89% of the subjects were consuming milk on a daily basis; curd, buttermilk and other milk products were predominantly consumed once a week. Milk is majorly consumed with tea in most of the households, but during pregnancy, women tried to consume whatever quantity available (Table 5.5).

Table 5.6: Frequency of animal food (except milk and milk products) items consumption

	Egg	Flesh food	Fish
Daily	7 (3.4%)	-	-
Alternate Day	14 (6.9%)	6 (2.9%)	-
Twice a Week	14 (6.9%)	8 (3.9%)	4 (2.0%)
Once a Week	55 (27.0%)	57 (27.9%)	24 (11.8%)
Twice a Month	7 (3.4%)	18 (8.8%)	9 (4.4%)
Once a Month	8 (3.9%)	9 (4.4%)	13 (6.4%)
Rarely/ Never	99 (48.5%)	106 (52.0%)	154 (75.5%)

Animal food items like eggs, flesh food and fish were consumed once a week or less frequently. Egg was consumed more than flesh foods and fish; though the majority consumed once a week, 3.4% of the subjects consumed eggs daily. Consumption of flesh food mainly, poultry was higher than fish. Only around 25% of the households were fish eaters. There is not much difference between the food consumption patterns of the pregnant women and their families (Table 5.6).

5.3.2 Household food security assessed from the amount of food purchased

From the information on the amounts of foodstuffs purchased by the family energy consumption/consumption unit/day was computed and compared with the EAR for energy to assess the food security status of the family. The average energy intake/CU/day computed from the food purchased was 2040.9±468.52 Kcal (n=204). EAR of energy requirement recommended by ICMR Expert Group on Nutrient Requirement of the 65 kg reference man; Delhi weight of the average Delhi man was computed [height 163.6cm height (NFHS 4) for their optimal BMI (21)] was to be about 1800 Kcal. The average energy consumption/CU/day of the households of the present study is higher than the EAR calculated suggesting that the majority of the households of the present study were food-secured based on the energy consumption, but data from the food frequency showed micronutrient rich food consumption was low.

5.3.3 24-Hour Dietary Recall

Information collected by using 24-hour dietary recall method provides information on the average energy consumption/CU/day for the household and based on that data household food security can be assessed; 24-hour dietary recall also provides the database for computation of the macro- and micro-nutrient intake of the non-pregnant and pregnant women from these families.

5.3.3.1 Household food security assessed from the amount of food cooked in the previous 24-hours

The food security status of the household was assessed by comparing the energy intake/CU/day computed from the diet survey using 24-hour dietary recall method with the EAR for energy. The mean energy intake /CU/day computed based on the foods cooked and consumed by the family members in the previous 24 hours from the diet survey was 1807.0±544.33 Kcal (n=205); the energy intake meets the computed EAR for the family.

The average energy consumption/CU/day of the households computed from the food amount purchased was 2040.9±468.52 Kcal and from the food amount cooked in the previous 24-hours was 1807.0±544.33 Kcal and. The small difference between energy intake computed by the two methods might be due to the fact that the food cooked in the previous 24-hours provides information only on what was consumed in the previous 24 hours and not on average foods consumed over a period of time from the food purchased. Data from the study clearly indicate that the majority of the families are food secure when energy adequacy is used as the criterion both by household purchase and 24-hour dietary recall method.

5.3.3.2 Dietary intake of the pregnant women

Information on foodstuffs cooked and consumed in the last 24 hours by the family including the non-pregnant and pregnant women was collected using 24-hour dietary recall method (Table 5.7).

In non-pregnant women, intake of cereal and roots and tuber and fat intake were higher than requirements for Delhi women.

There were no differences in the type of foodstuffs consumed by the pregnant and NPNL women from the same household; the quantity of pulses and milk consumed by pregnant women was higher as compared to NPNL women.

In pregnant women

- Consumption of milk and milk products was below the appropriate quantity of foodstuffs needed for the balanced diet (AQFBD)
- Intake of roots and tuber were higher than requirements for Delhi pregnant women
- Pulses/ legumes, GLV and other vegetables consumption was below the appropriate quantity of foodstuffs needed for the balanced diet
- Oil and fat consumption was way more than the appropriate quantity of foodstuffs needed for the balanced diet
- Animal foods were consumed only once or twice a month but, on the day, they were cooked, they were consumed in adequate quantities

Table 5.7: Dietary intake of food stuffs in pregnant and NPNL women (24-hour dietary recall)

Group	Intake of food stuffs (gms/ml)							
	Cereals	Pulse/legume	Roots/Tubers	GLV	Other Vegetables	Oils and Fat	Milk/Milk products	Animal Food
Pregnant women								
All Pregnant women (n=205)	204.3±88.27 (205)	55.7±45.27 (145)	136.4±92.56 (200)	77.4±93.75 (46)	133.2±90.50 (135)	32.4±26.67 (205)	301.0±183.80 (192)	136.5±92.95 (30)
Pregnant women in households with NPNL women (n=71)	208.9±89.26 (71)	48.9±27.59 (45)	106.4±67.67 (69)	43.8±76.10 (23)	127.3±97.37 (49)	30.3±23.07 (71)	300.3±201.73 (66)	151.7±72.63 (10)
AQFBD for Ref Pregnant women (12 Kg weight gain)	325	90	100	100	200	25	400	
AQFBD Delhi Pregnant women (12 Kg weight gain)	300	82	87	87	175	23	362	
AQFBD Delhi pregnant women (8 Kg weight gain)	258	72	87	87	175	20	328	
NPNL Women								
All NPNL women (n=71)	222.2±96.53 (70)	41.2±20.98 (47)	103.0±71.37 (71)	56.7±77.27 (25)	129.4±116.41 (50)	31.1±29.16 (71)	253.7±198.72 (65)	110.2±36.78 (9)
AQFBD for Ref NPNL women	200	60	100	100	200	15	300	
AQFBD Delhi NPNL women	175	52	87	87	175	13	262	

Nutrient intake: Energy and fat intake of pregnant women were higher than the EAR for sedentary Delhi pregnant women with height 151.7cm and optimal bodyweight (BMI of 21 in the non-pregnant state) of 48kg and 8kg pregnancy weight gain. Fats contributed nearly 30% of the energy in the diets consumed by pregnant women. The difference between the EAR for energy for Delhi pregnant women with 8kg pregnancy weight gain and actual intake was only about 65 Kcal/day (Table 5.8).

There was a small but statistically non-significant increase in the macronutrient intake of pregnant women as compared to NPNL women. Because of the higher than required amount of macronutrient consumption in non-pregnant women, the small increase in energy intake in pregnant women was adequate to meet the additional energy recommended during pregnancy.

Table 5.8: Macro-nutrient intake in pregnant and NPNL women (24-hr dietary recall)

Group	Macro-nutrient intake			
	Energy (Kcal)	Protein (gms)	Fat (gms)	Carbohydrate (gms)
Pregnant women				
All Pregnant women (n=205)	1765.5±606.68	52.4±20.84	61.5±33.24	273.7±92.63
Pregnant women in households with NPNL women (n=71)	1721.5±556.63	51.5±18.81	58.0±30.61	272.8±91.58
EAR for Ref Pregnant women (12 Kg weight gain)	2010	43.6		
EAR Delhi Pregnant women (12 Kg weight gain)	1800	39		
EAR Delhi Pregnant women 8 Kg weight gain	1700	36.5		-
NPNL women				
All NPNL women (n=71)	1631.4±644.77	47.8±18.10	56.0±40.37	253.3±83.58
EAR for Ref NPNL women	1660	36		
EAR for Delhi NPNL women	1450	31.4		

In NPNL women the selected micronutrient intake met the EAR for their actual computed weight.

In pregnant women dietary intake of calcium and vitamin A met the EAR; whereas iron intakes were lower as compared to EAR (Table 5.9).

Table 5.9: Intake of selected micro-nutrient in pregnant and NPNL women (24-hr dietary recall)

Group	Micro-nutrient intake		
	Calcium (mg)	Iron (mg)	Vitamin A (µg)
Pregnant women			
All Pregnant women (n=205)	845.2±494.18	13.8±6.25	531.1±718.59
Pregnant women in households with NPNL women (n=71)	815.5±471.03	13.7±5.85	454.6±612.46
EAR for Ref Pregnant women (12 Kg weight gain)	800	21	406
EAR Delhi Pregnant women (12 Kg weight gain)	698	19	356
Adjusted for 8 Kg pregnancy weight gain	698	17	351
NPNL women			
All NPNL women (n=71)	701.9±431.70	13.3±5.18	402.5±584.88
EAR for Ref NPNL women	800	15	390
EAR for Delhi NPNL women	698	13	340

5.4 Nutritional profile at enrolment

The mean height of the pregnant women and the initial weight were measured at the enrollment and the detail is given in table no 5.10.

Table 5.10: Nutritional profile of the pregnant women at enrollment

	Group 1	Group 2	Group 3
Mean Height	151.5±5.20 (387)	150.1±5.51 (391)	152.1±5.53 (448)
Mean weight at enrollment	50.3±8.44 (373)	50.1±8.54 (400)	53.9±10.08 (448)
Student's T-test P-values	**Group 1 vs 2**	**Group 1 vs 3**	**Group 2 vs 3**
Height	0.00012	0.1401	1.4E-07
Mean weight at enrollment	0.78652	2.4E-08	3.8E-09

There was a small but statistically significant difference in the height of the pregnant women of Group 2 with both, Group 1 and 3. There were no differences in the height between Group 1 and 3.

There was no statistically significant difference in initial weight at enrollment between Group 1 and Group 2. As enrollment continued across the second and third trimesters in Group 3; there was a statistically significant difference in the initial weight with the other two groups. The height and weight of the pregnant women from Group 2 were lower than the other two groups. This is because as described earlier they might be coming from a slightly lower strata of the society and their access and utilization of the antenatal facilities were lower than the other two groups.

5.5 Haemoglobin status at enrolment

At the time of their initial visit to the antenatal clinic, all pregnant women have the blood drawn from the blood Grouping and VDRL test. In those who agreed to participate in the study in Group 1 and 2 (in PHCIs), an additional 20 µl blood was pipetted and put on a filter paper for haemoglobin estimation by indirect cyanmethaemoglobin method.

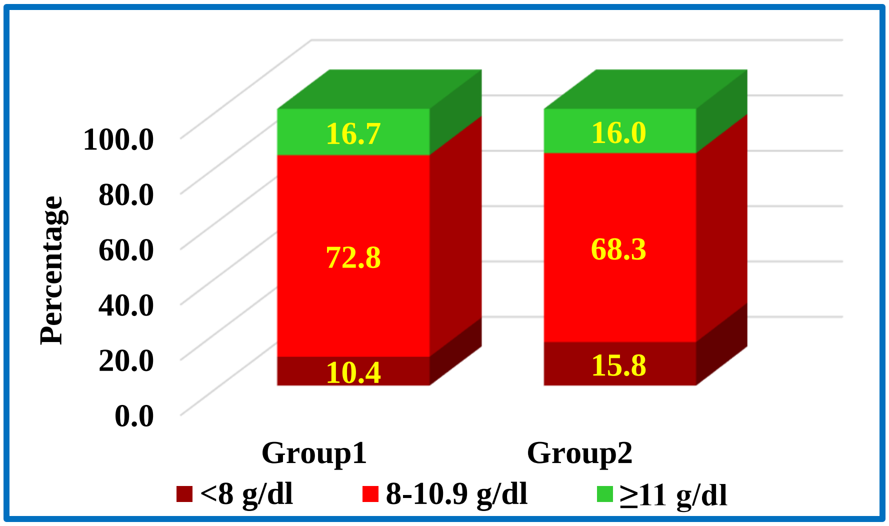

Figure 5.1: Percentage prevalence of anaemia at enrollment

In Group 1, the haemoglobin status was available for 383 women. Mean Hb at recruitment was 9.6±1.44 g/dL. Nearly ¾th of the women had mild anaemia; 10% had Hb levels below 8 g/dL. Only 16.7% were not anaemic at recruitment (Figure 5.1).

In Group 2 mean Hb at recruitment was 9.4±1.53 g/dL. More than 2/3rd of the women had mild anaemia; 15.8% had Hb levels below 8 g/dL. Only 16% were not anaemic at recruitment (Figure 5.1). There was no significant difference in haemoglobin status between Group 1 and Group 2.

5.6 Current regimen for calcium and vitamin D supplementation in Delhi Hospitals

In 2014, when the study commenced, the Government protocol for IFA supplementation (NIPI) recommended that all the anaemic pregnant women were to be supplied with IFA supplements (containing 100mg of elemental iron and 500 mcg of Folic acid), twice daily.

In the traditional Indian three-meal pattern if two IFA tablets were taken after two meals there was only one meal left for the calcium and vitamin D supplements. Adverse consequences of anaemia on mother-child dyad were well known. Therefore, many physicians prescribed 2 IFA and 1 calcium and vitamin D to be taken by pregnant women.

The present study also showed that more than 80% of the pregnant women were anaemic in Group 1 and Group 2 (Figure 5.1). This finding also suggested that two tablets of IFA had to be taken to correct anaemia in order to avoid adverse consequences. The PHCI was already following the protocol of providing two tablets of IFA to be consumed after two separate meals and one tablet of calcium and vitamin D which was to be consumed after the third meal in the habitual three-meal pattern.

For the research component of the study, the hospital regimen of providing one tablet of IFA each with breakfast & dinner and providing 1 tablet of calcium and vitamin D with lunch was followed by the research team. The hospital provided IFA tablets under service conditions. To ensure regular and uninterrupted supply and consistent use, the calcium and vitamin D tablets were purchased by our institution, provided by the research team who monitored the compliance with supplementation.

5.7 Exploring feasibility of providing two tablets of calcium and vitamin D as supplement

In 2018, the guidelines for IFA supplementation were revised to Intensified National Iron Plus Initiative (I-NIPI, MOHFW, 2018). Under the revised recommendations anaemic pregnant women were to receive two tablets of IFA containing (containing 60 mg elemental iron and 500 mcg) after a meal. Because of this modification, it became possible to provide two tablets of Calcium and vitamin D after the remaining two meals.

Nutrition Foundation of India carried out a short-term cross-over study on the side effects of IFA (containing 60 mg elemental iron and 500 mcg) and calcium and vitamin D (containing 500 mg elemental calcium and 250 IU vitamin D) supplementation within the usual three-meal pattern. Data from the study showed that gastro-intestinal side effects were seen after IFA supplementation both with single and two tablets given after a meal. There was no significant increase in the side effects when two tablets of IFA were consumed together after the meal. Side effects with calcium and vitamin D supplementation were uncommon; however, there was a statistically significant increase in the side effects between a single tablet of calcium and vitamin D and two tablets of calcium and vitamin D consumed together (Ramachandran, Pramanik and Kalaivani, 2019). However, the Delhi government continued providing one tablet of calcium and vitamin D after lunch leaving the other two meals for consumption of two tablets of IFA after two meals. In view of this, the study continued to use the same regimen.

5.8 Follow up during pregnancy

In Group 1, Group 2 and Group 3 a total of 387, 400 and 448 pregnant women were enrolled. Efforts were made to follow-up with the pregnant women till delivery. The highest follow-up rate (over 90%) was in Group 3, as the pregnant women in this group were followed up by the research team by home visits. In Group 2, a substantial number of the loss to follow-up was because the pregnant women were referred to other hospitals due to the poorer infrastructure and manpower of the PHCI where Group 2 was undertaken. The follow-up rate was the lowest in Group 2, just above 60% in comparison to the other two groups (Table 5.11).

In both Group 1 and 2, women with high BP pressure and/ or oedema were referred to tertiary care hospitals and these women continued to attend antenatal clinics in the referral hospital; which in turn led to loss of follow-up and absence of data on PIH. In Group 2 due to poorer infrastructure and manpower many of the pregnant women were referred to other PHCIs which led to the loss of follow-up. In all three settings some of the losses to follow up were seen as the family of the pregnant women shifted from the locality, which was also common as many of the families were living on rent as tenants.

In the community i.e. Group 3, much better follow-up of the women was possible; as the research team was reaching the households for follow-up. However, in the community setting data on the course of pregnancy (including data on PIH) was not available as some of the pregnant women did not attend any ANC and when attended they were not routinely checked for PIH and their attendance to the ANC was poor. As a result, in the community setting, information on the course of pregnancy was not available; but data on pregnancy weight gain, birthweight, pre and post pregnancy weight and weight retention after pregnancy was available.

Table 5.11: Follow up status of the pregnant women

	Group 1 (n=387)	Group 2 (n=400)	Group 3 (n=448)
Followed up	299 (77.3%)	248 (62%)	415 (92.6%)
Loss to follow up	88 (22.7%)	152 (38%)	33 (7.4%)

5.9 Compliance with the supplementation

Information on the type and regularity of supplements provided and compliance rates were recorded. Women were given the tablets required for the month either by the research team in Group 1 or by the existing service providers in Group 2 and Group 3. In Group 1 and 2 i.e. in PHCIs when they came to collect the tablets for the next month the compliance was checked and recorded by the research team of NFI. The pregnant women were requested to bring the completed tablet strips; using this compliance was checked and recorded. In all women the address and mobile phone numbers of the husband/ neighbour of the woman were collected; the mobile phones were used to contact them as and when necessary especially when they did not come for follow-up to the centre on the expected date. In the community setting, NFI staff went to the homes of the enrolled willing subjects and collected information about their ANC practice i.e. whether they were attending any ANC clinic or they were getting the required supplements from the ANM/ ASHA workers. The compositions of the supplements were recorded along with the compliance and continuation of the same.

5.9.1 Group 1

Calcium and vitamin D supplements were made available to the enrolled pregnant women by the research team in Group 1. IFA tablets were provided by the hospital as per their protocol. Nutrition education was provided by the research team as a part of the research study. The National Guideline on calcium supplementation in pregnancy and lactation recommends two tablets of calcium (500 mg elemental) and vitamin D (250 IU) to be consumed daily after two meals and the IFA supplements and the calcium and vitamin D supplements are not be consumed simultaneously as it will hinder the absorption of the supplements. During the time of data collection in Group 1 where the research team provided the calcium and vitamin D supplementation the national programme recommended that the anaemic pregnant women were to be provided with two IFA tablets (containing 100 mg elemental iron and 500 µg folic acid) which they had to consume after two separate meals daily. As the majority of the pregnant women were anaemic, the obstetrician of the PHCI where the study had been undertaken adhered to the anaemia control programme and recommended two tablets of IFA and one tablet of calcium and vitamin D to the pregnant women to be consumed each after separate meal to accommodate in the habitual pattern of three meal a day. Thus, the research team also followed the hospital protocol and provided a single tablet of calcium and vitamin D to the pregnant women to be consumed daily.

Table 5.12: Availability and consumption of Calcium and Vitamin D supplementation in Group 1

	Tablets available	Tablets taken
Between two blood samples (n=214)	87±10.8	80±11.8
Between enrolment & delivery (n=299)	134±26.2	124±25.9

In Group 1, between the enrollment and the second blood sample collection after12 weeks of supplementation, the pregnant women received a mean of 87 tablets and consumed 80 of them; and between the enrollment and delivery, the pregnant women received a mean of 134 tablets and consumed 124 out of it. These data suggest that these women did consume the tablets regularly. This fact indicates that when the calcium and vitamin D supplements are made available to pregnant women with nutrition and health education, and counselling for the need of the supplements, the pregnant women accept and consume the supplements regularly (Table 5. 12).

5.9.2 Group 2

In Group 2, when the calcium and vitamin D tablets were provided to them from the hospital most of the tablets provided were consumed. Hospital supply of calcium and vitamin D supplements was erratic in the PHCI where the data collection for Group 2 was carried out; when there was no supply of the same in the PHCI, the obstetricians provided prescriptions for the same to the pregnant women and they were asked to buy the supplements form outside pharmacy. There were 32 (12.9%) pregnant women who did not consume calcium and vitamin D supplements at all, as they did not get hospital supplies and they were not able to buy the same; many women were unable to buy all tablets needed for taking the supplements regularly from the time of enrolment till delivery.

Single tablets of calcium and vitamin D tablets were consumed by 199 pregnant women and the details are given in Table 5.13.

Table 5.13: Availability and consumption of single tablets of Calcium and Vitamin D supplementation in Group 2

	Tablets available	Tablets taken
Govt. supply (33)	82±30.7	74±27.8
Bought (150)	62±34.1	58±32.1
Both (16)	92±30.9	84±29.2

Two tablets of calcium and vitamin D were consumed by 15 pregnant women. A mean of 156±70.3 tablets were available out of which the pregnant women consumed 147±71.1 tablets. Two pregnant women consumed sometimes single, sometimes double as per availability and purchasing power and consumed 122±44.5 tablets out of 128±53.0 available tablets.

Regularity of attendance even in the routine antenatal clinic, was lower as compared to Group 1. These data suggest that when the supplements were regularly provided and intake was monitored compliance rate was higher; when the supply gaps occurred and women were requested to buy and consume the tablets consumption rate was lower. But in all the cases the available supplements (provided by the hospital or purchased) were consumed regularly by the pregnant women. This indicates that they were aware of the importance of taking the supplements but because lack of hospital supply and inability to buy the supplements due to cost were unable to take them regularly.

5.9.3 Group 3

In Group 3, 448 pregnant women were enrolled 415 pregnant women continued participating in the study.

Table 5.14: Availability and consumption of Calcium and Vitamin D supplementation in Group 3

	Tablets available	Tablets taken
Calcium and vitamin D between enrolment & delivery		
Govt. supply (51)	120±64.3	111±66.2
Bought (78)	116±71.6	114±70.3
Both (4)	191±127.4	191±127.4
Calcium only between enrolment & delivery		
Govt. supply (189)	138±82.7	126±79.8
Bought (11)	114±64.1	112±63.3
Both (1)	210	160

Out of 415 continued cases 70 pregnant women did not receive or buy calcium and vitamin D tablets and 11 pregnant women did not consume them even after receiving the same. Therefore, a total of 81 (19.5%) pregnant women out of 415 continued cases did not consume calcium and vitamin D supplements.

The majority of the pregnant women went to a Government ANC clinic. Government PHCIs prescribed and supplied calcium and vitamin D as well as only calcium tablets to pregnant women as per the availability. Private practitioners also prescribed calcium and vitamin D tablets as well as only calcium tablets and most of the families tried to purchase the supplements and the women consumed most of the tablets. There is no difference in the consumption rate of calcium and vitamin D tablets and only calcium tablets. Out of the 334 pregnant women, 133 pregnant women consumed calcium and vitamin D tablets and the remaining 201 pregnant women consumed only calcium tablets without vitamin D (Table 5.14).

Thus, it may be inferred that if the supplements are made available to pregnant women, most of the supplements are consumed by most of the pregnant women.

5.10. Haemoglobin status during follow up

Accurate Hb estimation was not carried out in all women for diagnosis of anaemia. When Hb was not available the hospital policy was to provide 60 mg elemental iron to all pregnant women; when women were anaemic two tablets of IFA were provided. The supply of iron tablets was sometimes erratic. Side effects were reported with IFA supplements in about a third of the women and because of this compliance with IFA supplementation was lower than that of calcium and vitamin D supplementation. Haemoglobin was measured in the indirect cyanmethaemoglobin method by the research team at NFI in both Group 1 and Group 2 at enrollment and after 12 weeks of supplementation.

Table 5.15: Haemoglobin status after 12 weeks of supplementation

	Group 1 (n=213)	Group 2 (n=221)
Initial Hb (g/dL)	9.4±1.33	9.4±1.50
Final Hb after 12 wks (g/dL)	10.1±1.41	9.6±1.54
Paired t test P value	<0.001 (9.45E-11)	<0.05 (0.049)

In Group 1, both initial and after 12 weeks haemoglobin was available in 213 pregnant women; mean haemoglobin level at enrollment was 9.4±1.33 and 12 weeks after supplementation was 10.1±1.41g/dL (Table 5.15).

In Group 2, both, the initial and after 12 weeks haemoglobin was available in 221 pregnant women; the mean haemoglobin level was 9.4±1.50g/dL at enrollment and 9.6±1.54g/dL (n=221) at 12 weeks after supplementation (Table 5.15).

Accurate Hb estimation was not carried out in all women for diagnosis of anaemia in either of the hospitals. When Hb was not available, the hospital policy was to provide 60 mg elemental iron to all pregnant women; when women were anaemic two tablets of IFA were provided. The supply of iron tablets was sometimes erratic. Side effects with iron were common. As a result of all these problems the rise in the mean Hb levels in Group 1 and Group 2 over a 12 week period was 0.7 g/dL and 0.2 g/dL in respectively (comparing the paired samples). The increase in haemoglobin is statistically significantly higher in Group 1 as compared to Group 2. This might be due to differences in screening for anaemia by Hb estimation, availability of IFA tablets and compliance between the two hospitals. It is likely both availability and compliance were lower in Group 2.

Unlike calcium and vitamin D the research team did not monitor the supply or compliance of the IFA supplements, it was provided only by the PHCI as and when available. Therefore, it is likely both availability and compliance were lower in Group 2.

5.11 Course of pregnancy

The primary health care institution, where the study was undertaken, referred subjects with a rise in blood pressure and/ or oedema to secondary or tertiary care centres. These women continued to attend antenatal clinics in the referral hospital. As they did not come back to the antenatal clinic the details of the course of pregnancy were not available.

In the community i.e. Group 3, much better follow-up of the women was possible; as the research team was physically checking. But in the community setting women did not get antenatal checkups done regularly, so there was no data regarding PIH. Thus, in the community setting also, information on PIH was not available. In community settings there was excellent data on pregnancy weight gain and also some data on pre- and post-pregnancy weight and weight retention after pregnancy.

5.12 Weight gain during pregnancy

The current study recorded the weight of the pregnant women in the follow-up visits and from that weight gain during pregnancy was calculated.

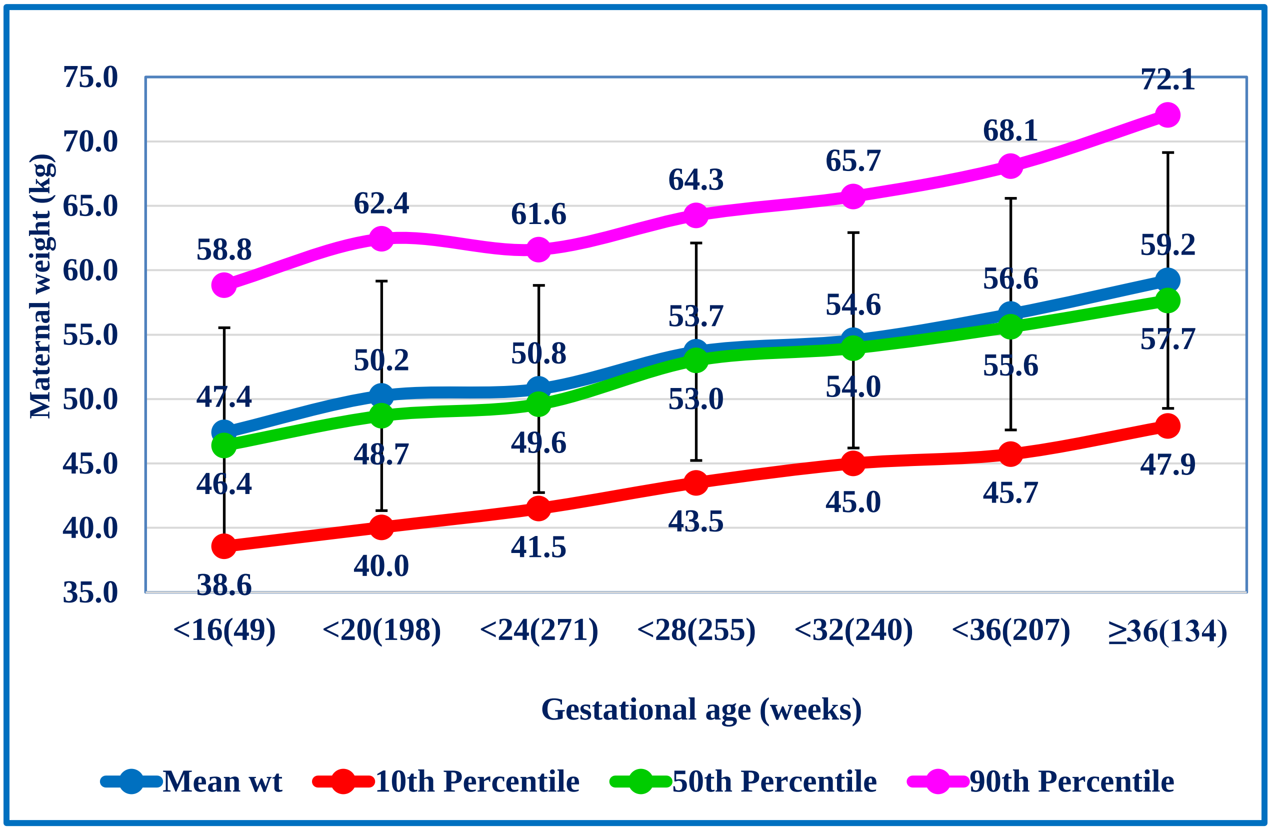

Figure 5.2: Weight gain during pregnancy (Group 1)

The mean weight gain in the second trimester and third trimester was 11.8 kg in Group 1, 7.4 kg in the Group 2 and 7.6 kg in Group 3 (Figure 5.2, 5.3, 5.4).

During this calculation of weight gain, all the weights available from the pregnant women in the three groups were considered as cross-sectional data.

In Group 1, a total of 1354 weights were available throughout the second and third trimesters; these weights were measured by ANM in the PHCI with the help of a digital weighing balance.

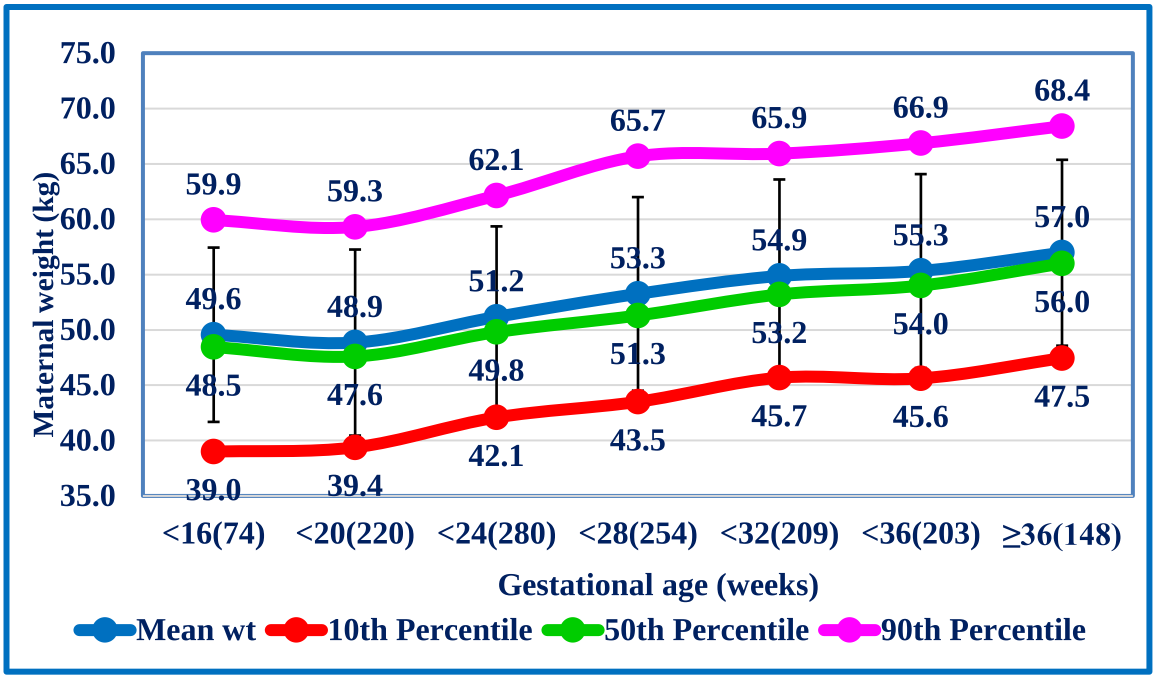

Figure 5.3: Weight gain during pregnancy (Group 2)

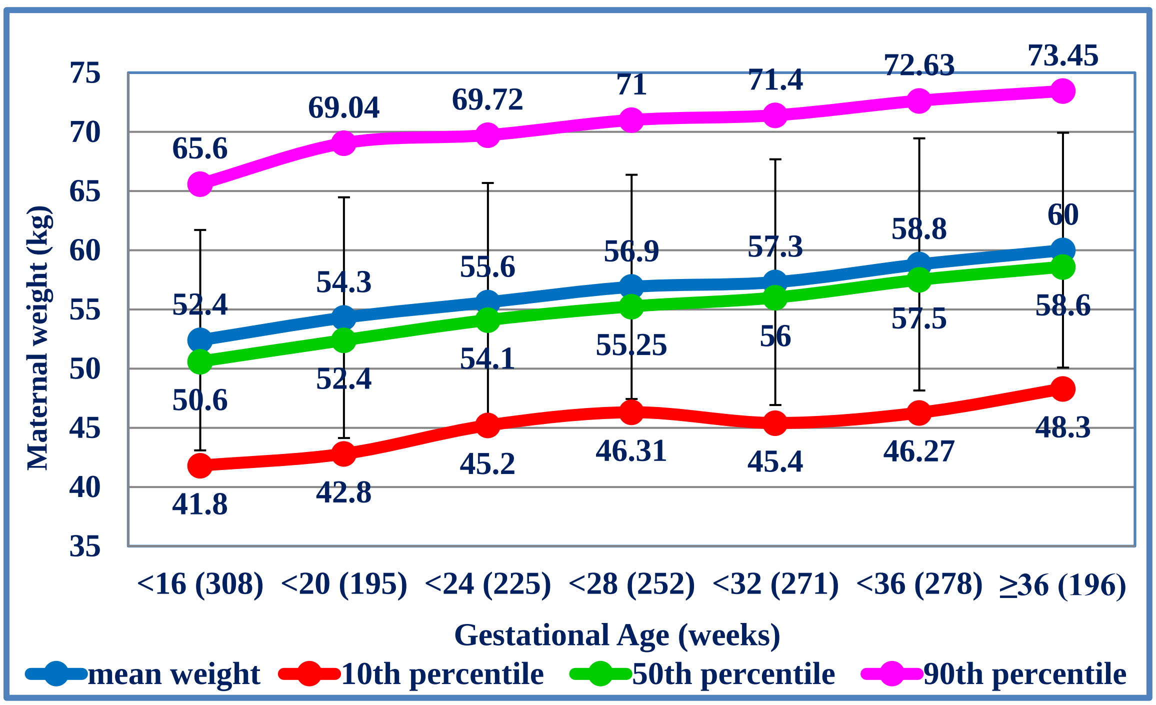

Figure 5.4: Weight gain during pregnancy (Group 3)

In Group 2 and 3 a total of 1388 and 1725 weights of the pregnant women throughout the trimesters were available and the weights were measured by the research team with the help of a digital weighing balance.

5.13 Pregnancy outcome

Efforts were made to collect the delivery details from the enrolled pregnant women.

The mean birth weight in Group 1, 2 and 3 were 2.8, 2.6 and 2.8 respectively. These differences came out to be statistically significant (Student's T-test p values for Group 1 vs. 2 and Group 2 vs 3 were 0.00026 and 0.00088 respectively) except between Group 1 and Group 3 (Student's T-test P value 0.803) (Table 5.16).

Table 5.16: Pregnancy outcome of the three groups

	Group 1 (285)	**Group 2 (223)**	**Group 3 (345)**
Mean BW	2.8±0.41	2.6±0.51	2.8±0.49
<2.5 %	13.0	31.8	21.4
≥2.5 %	87.0	68.2	78.6
	Group 1 (n=298)	**Group2 (n=243)**	**Group 3 (n=415)**
Term %	83.6	78.6	81.9
Preterm %	16.4	21.4	18.1
	Group 1 vs 2	**Group 1 vs 3**	**Group 2 vs 3**
Birth weight (T-test P-value)	0.0003 (SS)	0.8031 (NS)	0.0009 (SS)
LBW (Chi-square P-value)	2.538E-07 (SS)	0.0055 (SS)	0.0056 (SS)
Preterm (Chi-square P-value)	0.1411 (NS)	0.5713 (NS)	0.2967 (NS)
Note: SS-Statistically significant, NS- Statistically non-significant			

In Group 1 and 2, more than 90.0% and in Group 3, 87.3%. had institutional deliveries. Preterm rates were 16.4%, 21.4% & 18.1% and low birth weight rates were 13.0%, 31.8% & 21.4% in the primary health care institution in Group 1, 2 and 3 respectively. The mean birthweight of the neonates born to women in the Group 2 were the lowest amongst the three groups and the same is statistically different from that of Group 1 and 3. There was no statistical or otherwise difference in the birthweight of the neonates born to women of Group 1 and 3. The low birth weight rate was lowest in Group 1 and highest in Group 2 and the differences in low birth weight rate were statistically different between the three groups. The preterm delivery rate followed a similar trend though the differences were not statistically significant between the groups. As previously mentioned in other parameters, the outcome of pregnancy also showed that Group 2 is the weakest group amongst all the three (Table 5.16).

5.14 Maternal anthropometric indicators and Birth Weight

To assess the impact of maternal height on weight in the early second and late third trimester of pregnancy and birthweight, the mean height, weight at 16 weeks and 36 weeks and birthweight were computed in three tertiles of maternal weight taking all three settings together to get a substantial number of pregnant women when divided into sub-groups (Table 5.17).

Women whose height was in the lowest tertile had the lowest mean height and lowest mean weight both at 16 (40.7kg) and 36 weeks of pregnancy(50.0kg) and lower mean birth weights (2.7kg). In contrast, women in the highest height tertiles had the highest mean weight at 16 weeks (60.4kg) and 36 weeks (69.7kg) and highest mean birthweights (3.0kg). The differences in each of these parameters between tertiles were statistically significant ($p<0.01$) (Table 5.17).

Table 5.17: Initial pregnancy weight and late pregnancy weight and birthweight

	Initial pregnancy (14-16 weeks)			Late pregnancy (≥36 weeks)		
	Height (cm)	**Maternal Weight (kg)**	**Birthweight (kg)**	**Height (cm)**	**Maternal Weight (kg)**	**Birthweight (kg)**
First tertile	147.4±5.50 (78)	40.7±3.40 (79)	2.6±0.45 (79)	149.8±5.27 (120)	50.0±3.34 (123)	2.7±0.46 (123)
Second tertile	151.3±4.29 (78)	49.2±2.10 (79)	2.7±0.46 (79)	151.6±4.87(121)	58.2±1.96 (121)	2.8±0.44 (121)
Third tertile	153.7±5.62 (81)	60.4±6.04 (81)	2.8±0.53 (81)	153.9±5.04(124)	69.7±6.24 (124)	3.0±0.44 (124)
Student's T-test P values						
First tertile Vs. Second tertile	<0.001 ESS (1.97E-06)	<0.001 ESS (3.93E-39)	NS (0.14)	<0.01 SVS (0.005)	<0.001 ESS (6.70E-59)	<0.01 SVS (0.002)
Second tertile Vs. Third tertile	<0.01 SVS (0.003)	<0.001 ESS (1.38E-28)	NS (0.27)	<0.001 ESS (0.0004)	<0.001 ESS (6.92E-43)	<0.05 SS (0.02)
First tertile Vs. Third tertile	<0.001 ESS (3.35E-11)	<0.001 ESS (1.36E-51)	<0.05 SS (0.013)	<0.001 ESS (1.99E-09)	<0.001 ESS (6.82E-76)	<0.001 ESS (1.75E-07)
Note: SVS- Statistically Very Significant; ESS- Extremely Statistically Significant; SS- Statistically significant; NS- Non-Significant						

These data suggest that maternal height is a major determinant of maternal weight during pregnancy and birth weight. However, the differences in the weight gain during pregnancy between women in the three height tertiles were small and not statistically significant.

For this purpose, all the anthropometric parameters from 1235 pregnant women and the birth weight of the newborn were calculated together. Mean height was available from 1226 pregnant women and the mean height was 151.3±5.48. The mean height at the 10th, 50th, and 90th centile was calculated similarly to the weight gain and the mean height was 144.3cm, 151.2cm and 158.4cm respectively at the mentioned percentile. Weights were available from 4467 visits from all the 3 groups and taking all the weights collectively the mean weight gain from the beginning of the second trimester (<16 weeks) till the third trimester (≥36 weeks) was 7.5 kgs (Figure 5.5).

Birth weight was available from 853 newborns and the mean birth weight was 2.7±0.48 kg.

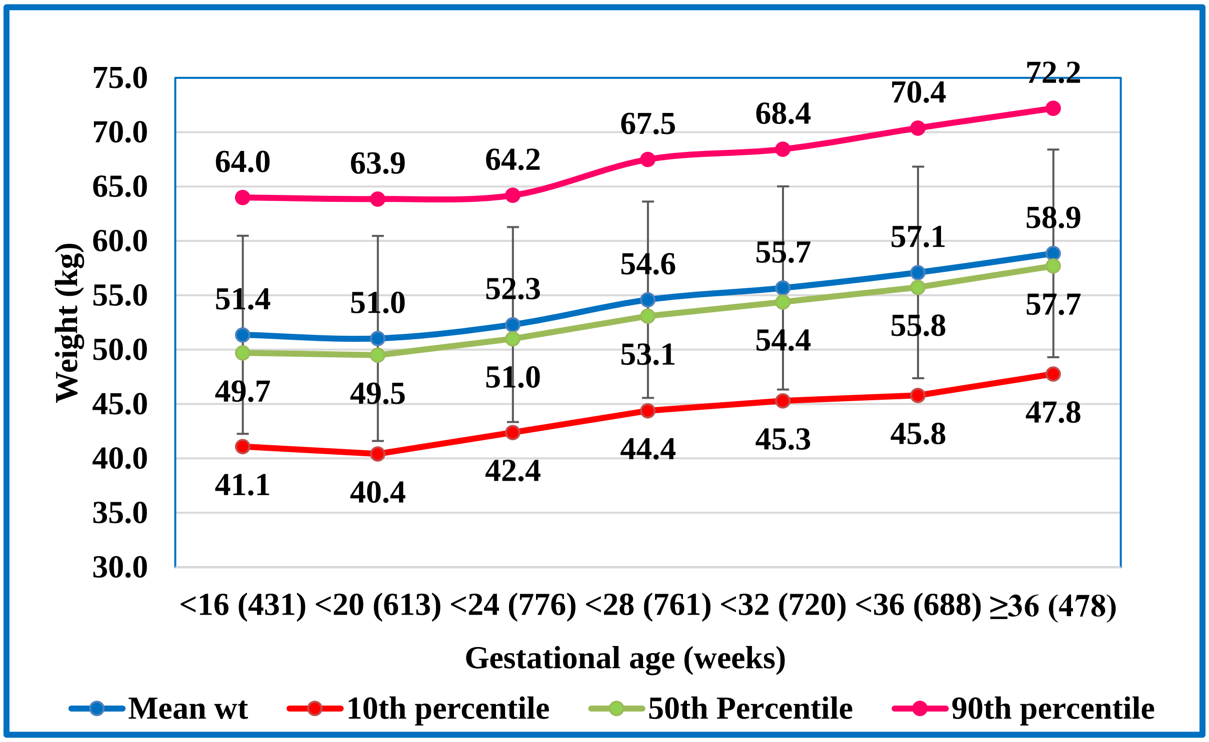

Figure 5.5: Weight gain during pregnancy (all three groups)

In the present study, women were from food-secure families and were eating to appetite; given these conditions, it is possible that optimal weight gain in these short-statured women delivering neonates with a mean birth weight of 2.7 kg is below 8 kg.

5.15 Post-pregnancy weight retention

In the community setting i.e. Group 3, records of prepregnant weight was available in 145 pregnant women. Efforts were made to collect weight in these women between three to six months after delivery.

The mean height of these 145 pregnant women was 152.3±5.49 cm. The mean post-pregnancy weight (55.8±10.33) was higher as compared to the mean pre-pregnancy weight (53.9±10.06 kg).

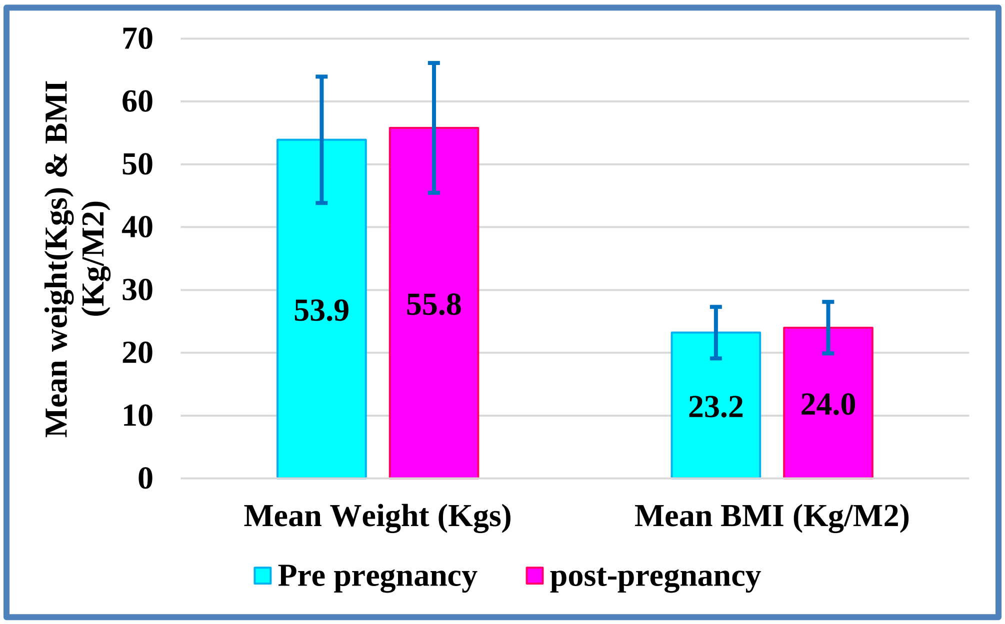

Figure 5.6: Residual weight retention after pregnancy

The mean post-pregnancy BMI (24.0±4.10) was higher as compared to the pre-pregnancy BMI (23.2±4.10) (Figure 5.6). Even when weight gain during pregnancy was less than 8 kg (Group 3), there was a significant residual weight gain of 1.9 kg in the post-pregnancy period. Both the residual weight retention (1.09E-07) and gain in BMI (1.73E-07) were statistically significant (p-value of <0.001 in paired t-test).

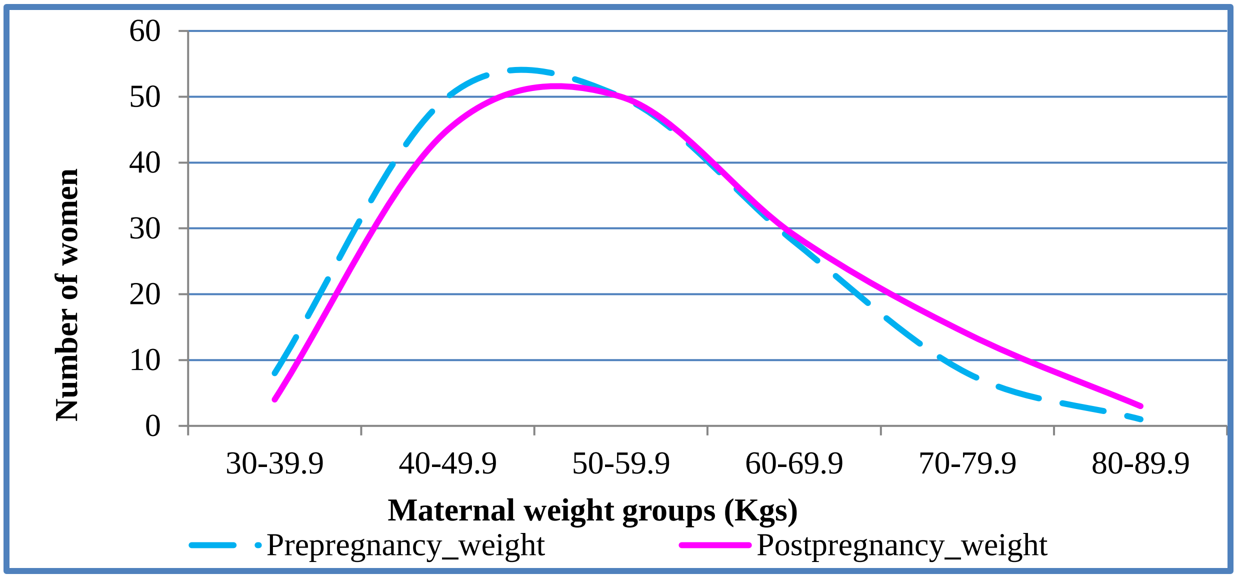

Figure 5.7: Frequency distribution of residual weight

Residual weight retention after pregnancy was evident in all the maternal weight Groups (Figure 5.7). The nutritional status of the under-nourished women improved due to this weight retention but aggravated over-nutrition in overweight women.

DISCUSSION

Poverty and food insecurity were widespread in India four decades ago, therefore in households from lower income groups, the dietary intake of the women was low and their physical activity level was moderate or high as the household chores demanded physical labour. Low dietary intake combined with higher physical activity resulted in over 70% of the nonpregnant, nonlactating women being undernourished; continued low dietary intake during pregnancy was associated with low pregnancy weight gain and low birth weight in India (Ramachandran, 1989 and Ramachandran, 2002).

Pregnant women are considered vulnerable from the nutritional point of view as the dietary intakes of the pregnant women not only provide macro- and micro-nutrients for her normal functioning and physiological changes during pregnancy but also for the growing foetus.

Women were undernourished, had limited nutritional intake, and had short statures (NNMB 1975-79 and Krishnaswamy et al., 1997). The mean height of the short-statured women was 150 cm and the mean weight was around 42 kg. The mean pregnancy weight gain was about 5 kg with a mean birth weight of 2.7 kg (Ramachandran, 1989; Ramachandran, 2002).

Inadequate dietary intake was thought to be the major cause behind the low pre-pregnancy weight of the women, lower pregnancy weight gain and low birth weight (Ramachandran, 1989; Ramachandran, 2002). Therefore, nutrition and health education always focused on the need for additional requirements of energy, nutrients and increased dietary intake during pregnancy in India.

In view of the high undernutrition rate the Expert Committees on Recommended Dietary Allowances (RDA), earlier recommended intake of energy and other nutrients at mean + 2SD level. To improve the nutritional status of the pregnant women and optimal weight gain during pregnancy food supplementation programme under Integrated Child Development Services (ICDS) provided 500 Kcal per day through supplementary feeding. ICDS provided food supplements to pregnant women in order to bridge the gap between RDA and the actual dietary intake in pregnant women; though the coverage of the food supplementation to pregnant women was inadequate, the contents of the supplements were suboptimal and the continuation of intake of the supplemented food as an addition to the home food was uncommon. To improve household food security; two-third of the Indians were provided with highly subsidized food grains under the National Food Security Act as a legal entitlement; in addition, food grains for food supplementation to vulnerable groups including pregnant women were provided under this act (National Food Security Bill, 2013).

Over the last four decades per capita income has improved substantially, so has household food security. Employment guarantee programmes and the Public Distribution System improved the purchasing power and access to subsidized food grains respectively. As a result, energy intake was improved in the low-socioeconomic families (Ramachandran & Kalaivani, 2018).

In the last three decade, there has been a progressive decline in physical activity due to mechanization in the household, occupational and transport domains. This mechanization in the household domain, improvement in the access to water in the vicinity and changes in cooking fuel have led to a reduction of physical activity in women (Ramachandran & Kalaivani, 2018).

In comparison to the data reported in the study carried out in the 1980s (Ramachandran, 1989; Ramachandran, 2002), recent data showed increased maternal weight by about 10 kg whereas the increase in maternal height is below 2 cm (Goel et al.,2020). Currently, the mean height of women (18-29 years) from low-middle-income group family in Delhi is 151.7 cm and their weight are 54 kg; with a steep fall in under-nutrition rate, from over 30% four decades ago to 12% currently and increased prevalence of the overnutrition (over one-third of the women in the 18 to 29 years of age group) (Goel et al.,2020). Several national surveys have shown that over time poverty has reduced and household food security has improved. NNMB surveys (NNMB technical report No 27) and NSSO (Consumer expenditure surveys) surveys have shown despite ready availability of subsidised food grains, over the last three decades there has been a slow but progressive reduction in energy intake. These surveys also indicated a reduction in physical activity especially in the urban population. NNMB surveys show a decline in under-nutrition over time from the 1970s to 2000 (NNMB, Technical Report No: 26 and 27). Data from NFHS (IIPS-NFHS-1,2,3,4 and 5), DLHS (IIPS-DLHS-2 and 4) and AHS CAB (RGI-AHS-CAB, 2011) shows a decline in under-nutrition and an increase in over-nutrition rates in women both in urban and rural areas. The major factor responsible for the emergence of overnutrition in adults especially in women was the steep reduction in the physical activity level due to mechanization of all domains of activity.

Taking into account the increasing overnutrition rate and its consequences like the emerging problem of NCDs the recent recommendation by the Expert Group on Nutrient Requirements of Indians has emphasised that the intake of energy and other nutrients should be based on the Estimated Average Requirement (EAR) of the population. The Expert Group has defined the Reference man and women using mean + 2 SD in height and recommended that for computing EAR for any given population group in adults' optimal weight of the current height should be used to attain the optimal BMI i.e. 21(NIN-ICMR, 2020). Due to increasing Basal Metabolic Rate (BMR), pregnancy weight gain and maternal placental and foetal tissue formation, pregnant women require additional calories and nutrients. Expert Group on Nutrient Requirements recommended 350 Kcal of additional energy for pregnant women using the factorial approach. The report by the Expert Group on Nutrient Requirements has recommended the EAR of nutrients for women with a pre-pregnancy weight of 55 kgs and pregnancy weight gain of 10 to 12 kgs.

An increase in obesity indicates a positive energy balance which in turn suggests that the majority of the population was energy secure. In the current dual nutrition burden era, therefore, the present study looked into food security at the family level. Household food security had been assessed in the present study as energy security essentially; it did not include micronutrients including calcium. The energy consumption/CU/day assessed by both food purchased and food cooked in the previous 24-hours showed that the average energy intake of the population met the required EAR. Therefore, these families were food secure considering the energy intake /CU/day. The food frequency data showed a lower frequency of micronutrient-rich foods like green leafy vegetables, fruits etc. The frequency of animal food consumption is low. Therefore, it is more appropriate to say that the families of the present study were energy secure but micronutrient deficiency is there.

The nausea and vomiting of the first trimester usually subside in the second trimester and the discomfort of a fully growing baby in the late third trimester is not present in the second trimester; both of these situations of the first and last trimesters, impact food consumption. However, these problems do not exist in the second trimester and therefore, efforts were made to collect the data using 24-hour dietary recall, essentially in the second trimester. The data on dietary intake by 24-hour dietary recall method showed that energy intake was either adequate or exceeded EAR in short-statured sedentary pregnant women.

The finding of the food frequency regarding the lower frequency of intake of micronutrient-rich food is again validated by the data from 24-hour dietary recall which showed consumption of pulses/ legumes, GLV and other vegetables which are the source of micronutrients was below EAR. The data on dietary intake by 24-hour dietary recall method showed that the calcium intake of the pregnant women met the EAR recommended by the NIN-ICMR. However, the iron intake was way below the EAR for pregnant women.

The present study showed more than 80% of the pregnant women were anaemic; the food frequency data showed less micronutrient-rich food consumption and the data from 24-hour dietary recall showed the iron intake was below the recommended level. Haemoglobin estimation is a part of routine antenatal checkups; though the observation of the present study showed that accurate Hb estimation was not carried out in all the pregnant women for diagnosis of anaemia. The biochemical assessment of vitamin D is expensive and is not a part of antenatal care along with the fact that estimation of vitamin D intake through diet is difficult as vitamin D content of animal foods varies with the diets and breeds of animals; estimation of endogenously synthesized vitamin D is not possible. This makes it difficult to identify the pregnant women with calcium and vitamin D deficiency. In view of these micronutrient deficiencies, the supplementation programmes in pregnancy were envisaged aimed at correcting the same to avoid the adverse consequences on the mother-child dyad. IFA supplementation in pregnancy is well established and whenever the supply was there the pregnant women were provided with the IFA supplements.

Several studies from all over India reported widespread vitamin D deficiency during pregnancy (Goswami et al., 2000, Bhalala et al., 2007, Sahu et al.,2009, Marwaha et al.,2011, Dasgupta et al., 2012, Jani et al., 2014, Kumar et al., 2015, Ajmani et al.,2016, Kumari et al., 2017, Arora et al.,2018, Sharma, Nath & Mohammad, 2019, Sharma, Minhas & Shrama, 2021, Christy, Perumal & Sumathy, 2021 and Ravinder et al., 2022). Low calcium intake in pregnant women has also been documented by several studies (Goswami et al., 2000, Bhalala et al., 2007, Sahu et al.,2009, Marwaha et al.,2011, Dasgupta et al., 2012, Jani et al., 2014, Kumar et al., 2015, Ajmani et al.,2016, Kumari et al., 2017, Arora et al.,2018, Sharma, Nath & Mohammad, 2019, Sharma, Minhas & Shrama, 2021, Christy, Perumal & Sumathy, 2021 and Ravinder et al., 2022). NNMB reports on rural, tribal and urban populations along with other epidemiological studies (Goswami et al., 2000, Sachan et al., 2005, Ganpule et al., 2006, Sahu et al., 2009, Darwish et al., 2009, Jani et al., 2014, Ghosh-Jerath et al., 2015, Sahu et al., 2015, Gupta et al., 2016 and Sharma et al., 2020) had shown low calcium intake in the Indian population including pregnant women.

There are reports available on the consequences of calcium and vitamin D deficiency during pregnancy on the mother-child dyad and the beneficial impact of the calcium and vitamin D supplementation during pregnancy. Studies from UK had a reported reduction in neonatal tetany following calcium and vitamin D supplementation during pregnancy (Brook et al., 1980). A supplementation study conducted by WHO on pregnant women with low calcium intake (<600mg/day) reported that calcium supplementation reduced the relative risk of severe gestational hypertension and eclampsia (Villar et al., 2006).

In view of the high prevalence of biochemical vitamin D deficiency, low calcium intake (Harinarayan, Akhila and Shanthisree, 2021), and known adverse consequences of poor vitamin D status on the mother-child dyad Maternal Health Division, Ministry of Health & Family Welfare, Government of India envisaged the National Guidelines for "Calcium Supplementation During Pregnancy and Lactation", In December 2014, which recommended calcium 500mg (as calcium carbonate salt) and 250 IU vitamin D are to be taken twice daily just after meal calcium and vitamin D supplementation starting from second trimester of pregnancy till six months postpartum.

There is a paucity of published data on coverage, acceptability and compliance (the number of supplements the pregnant women received and, consumed) or the impact of calcium and vitamin D supplements in hospital and community settings. It is essential to obtain data on coverage and compliance with calcium and vitamin D supplementation in the hospital under research and service conditions and in the community settings and therefore the present study was undertaken to assess the acceptance, coverage and compliance of the calcium and vitamin D supplementation during pregnancy in three groups i.e. in government hospitals with inputs from ongoing research studies in terms of research staff providing the calcium and vitamin D supplements to pregnant women enrolled in the study, government hospitals where supplementation was being carried out under the existing service conditions, community settings under existing service conditions.

The National Guideline for calcium and vitamin D supplementation in pregnancy has recommended that all pregnant women from the second trimester onwards till 6 months postpartum should take one oral swallowable calcium and vitamin D tablet containing 500 mg of elemental calcium and 250 IU vitamin D twice daily after meal (MOHFW, 2014). The National Iron Plus Initiative recommend that all anaemic pregnant women should take one IFA tablet containing 100 mg of elemental iron with 500 µg of folic acid, twice daily after meal (NIPI-MOHFW, 2013). As taking IFA and calcium and vitamin D tablets together interferes with iron absorption both the guidelines have stated not to consume them together.

Adhering to the National Iron Plus Initiative (NIPI) guidelines, appeared to be more important in view of the well-known adverse impact of the anaemia on mother-child-dyad. More than 80% of the pregnant women in the current study have been found to be anaemic (Figure 5.1) and thus required two tablets of IFA daily. It is not possible in the Indian habitual three-meal-a-day pattern to consume both IFA and calcium and vitamin D supplements separately after meal (4 tablets one each to be taken after one meal). Therefore, obstetricians advised pregnant women to take two tablets of IFA after two separate meals and one tablet of calcium and vitamin D after the third meal. The current study has found that this regimen was followed both in the hospital and community settings.

Available data from the current study shows compliance with calcium and vitamin D supplementation was high (Table 5.12, 5.13 and 5.14) which may be due to the calcium and vitamin D supplements are associated with negligible side effects.

The National Guideline for calcium and vitamin D supplements was laid by MOHFW in the year of 2014, even after so many years calcium tablets without vitamin D were being distributed in the community setting; sometimes private practitioners also prescribed only calcium tablets without vitamin D. It is important to update the programme officers and the clinicians about the importance of providing calcium and vitamin D together.

There are no published data on coverage, compliance and impact of this regimen providing only one tablet of calcium and vitamin D daily to pregnant women in hospital and community settings. A recent study on maternal nutrition practices in a rural area of Uttar Pradesh reported that 20.8% of the study population received or purchased calcium tablets (Nguyen et al., 2019). The present study reports a higher number of pregnant women who received/ bought calcium and vitamin D supplements, in Delhi's urban hospital and community. The study carried out by Nguyen et al., (2019), had not specified the composition or the number of calcium and vitamin D tablets consumed by pregnant women daily. The study also did not report the pregnancy outcome of the subjects. Therefore, the current study cannot be compared and is the first study to report data on coverage, compliance and impact of this regimen providing only one tablet of calcium and vitamin D /day to pregnant women in urban hospital and community settings.

In Group 1, the pregnant women received calcium and vitamin D supplements regularly without interruption, free of cost by the research staff. Most of the tablets provided were consumed by the majority of the pregnant women perhaps due to the absence of side effects (Table 5.12). The major reason for providing only one tablet of calcium and vitamin D per day was to follow the NIPI guidelines. For the anaemic subjects (more than 80%) of the study two tablets of IFA tablets containing 100 mg of elemental iron and 500µg of folic acid and 2 tablets of calcium and vitamin D recommended by the calcium and vitamin D supplementation guidelines could not be accommodated in the habitual three meal pattern of these families. The Nutrition Foundation of India undertook an experimental study to fit all four tablets (2 tablets of IFA and 2 tablets of calcium and vitamin D) of the IFA and calcium and vitamin D supplements in the habitual three-meal-a-day pattern and found that two tablets of vitamin D when consumed together increased the side effects which was statistically significant (Ramachandran, Pramanik & Kalaivani, 2019). Therefore, the research component in Group 1 followed the hospital protocol and provided one tablet of calcium and vitamin D. The current study is part of a larger project under the ICMR-Advanced Centre for Nutrition at the Nutrition Foundation of India. As a component of the ICMR-funded study vitamin D assays were carried out from blood samples collected at enrollment and after 12 weeks of calcium and vitamin D supplementation in Group 1. The data on biochemical analysis of vitamin D had shown that 80% of the pregnant women of Group 1 were vitamin D deficient at enrollment. Given the magnitude of vitamin D deficiency, it is important to ensure improvement in coverage under the calcium vitamin D supplementation programme. After 12 weeks of supplementation with one tablet of calcium and vitamin D supplementation there was an improvement in the mean vitamin D values and a reduction in the prevalence of vitamin D deficiency (<20ng); both these were statistically significant. However, the majority of pregnant women had vitamin D deficiency even after three months of supplementation (data under publication). These data suggest that there is a need to provide two tablets of calcium and vitamin D daily as envisaged in the national guidelines, to pregnant women. With the modification regarding IFA supplementation during pregnancy envisaged in INIPI guidelines, it is possible to fit two tablets of calcium and vitamin D supplementation to pregnant women in the habitual three-meal pattern. Studies have to be undertaken to assess the impact of the supplementation with two tablets of calcium and vitamin D on vitamin D levels in pregnancy to confirm that the dosage provided is adequate.

The supply of calcium and vitamin D tablets in hospital and community settings was not regular. Calcium and vitamin D tablets are expensive in contrast to the IFA tablets, therefore many women reported it was economically not feasible to buy those tablets. Economic constraint was a factor responsible for the relatively lower number of total available calcium and vitamin D supplements in Group 2 (Table 5.13) in comparison to Group 1 where research staff provided the calcium and vitamin D supplements without interruption to the pregnant women. Efforts have to be made to maintain a regular supply of calcium and vitamin D supplements free of cost to the pregnant women as the data on compliance from all three groups shows better compliance. The majority of the pregnant women consumed most of the available tablets. This high consumption rate may be attributable to the fact that calcium and vitamin D supplements were not associated with any troublesome side effects.

This indicates that pregnant women are aware of the importance of taking the supplements but the erratic supply of the supplements in the Government health care system and the high cost of purchasing calcium and vitamin D supplements reduce the consumption of calcium and vitamin D supplements. Once the supply of calcium and vitamin D supplements is optimised, it is likely that the pregnant women will comply with the supplementation.

The study design envisaged that the pregnant women enrolled in the three groups would be followed throughout pregnancy to collect data on the course and outcome of pregnancy, birthweight of the offspring and to compare between those who complied with supplements and those who did not to assess the impact if any of the supplementation on course and outcome of pregnancy. The primary health care institution, where the study was undertaken, referred subjects with the rise in blood pressure and/ or oedema. These women continued to attend antenatal clinics in the referral hospital; hence, we do not have any data on PIH. In the community i.e. Group 3, much better follow-up of the women was possible; as the research team was physically checking, the research team had better access thus outcome-wise the data available in the community setting was better. But in the community setting, we have no data regarding PIH as they were not routinely checked for PIH in clinic settings and their attendance to the ANC was poor. Thus, in the community setting also, information on PIH was not available. As the women enrolled for the study, from the ANC clinic or community were referred to secondary and tertiary hospitals for various obstetric problems including the management of anaemia and thereafter continued to get antenatal care in the referral hospital it is not possible to comment on the impact of the calcium and vitamin D supplementation on pregnancy-induced hypertension.

Data on birthweight was available and the mean birth weight, LBW and preterm birth rate of the three groups were similar but Group 2 was the weakest amongst all three.

The height and weight measurement during pregnancy is done on a regular basis in antenatal visits. Birth weight is recorded in institutional deliveries. Pregnancy weight gain has widely been used to assess the maternal nutritional status and the birth weight reflects the impact of the maternal nutritional status and the weight gain during pregnancy (Ramachandran, 1989, Ramachandran, 2002, Sharma et al., 2008, Darby et al., 1953, Billewicz & Thomson, 1957, Thomson & Hytten, 1961, Venkatachalam, 1962 and Bagchi & Bose, 1962).

Maternal stature, pre-pregnancy weight and pregnancy weight gain determine the birth weight of the offspring (Kramer, 1987). To assess the impact of maternal height on weight in the early second and late third trimester of pregnancy and birthweight, the mean height, weight at 16 weeks and 36 weeks and birthweight were computed for the current study population in three tertiles of maternal height. The data suggest that maternal height is a major determinant of maternal weight during pregnancy and birth weight. (Table 5.17).

The findings of the current study show the actual energy intake by urban pregnant women from low and low-middle-income group families meet the EAR. The mean weight gain during pregnancy in the current study population is around 8 kg (Figure 5.5). Taking this into account the additional requirement during pregnancy is only 250 Kcal and the total energy requirement is 1700 Kcal. The mean energy intake of the pregnant women in the study group was 1765 Kcal which is about 65 Kcal more than the requirement (Table 5.8). Weight gain in the second and third trimesters in the pregnant women from the urban community i.e. Group 3 was 7.6 kg. In the present study pre-pregnancy and post-pregnancy weight is available in a subsample of 145 women enrolled in Group 3 (Figure 5.6). The higher-than-required intake of energy during pregnancy appears to have resulted in post-pregnancy weight retention of 1.9 kg post-pregnancy weight retention. In hospital and community setting it is not possible to undertake a diet survey using 24-hour recall method to assess the adequacy of dietary intake in all the women as it takes an average of 40 minutes per subject and majority of the women were not willing to spare such a long time thus the dietary data is available only from a fraction of the study population.

In the current dual nutrition burden era, it is important to identify the pregnant women who are undernourished by using weighing which is already a routine part of antenatal care and provide with food supplementation continuously during pregnancy using the ICDS system to bridge the gap between the energy requirement and the actual energy consumption by the pregnant women. This when coupled with effective antenatal care for prevention, early detection and management of anaemia and obstetric problems may result in an improvement in the birth weight of the newborn. Untargeted and poorly monitored food supplementation to pregnant women may not lead to improvement in pregnancy weight gain in undernourished women and may aggravate overnutrition in overweight women.

The present study population were food secure as assessed by energy consumption, however, from the food frequency data it was evident that the micro-nutrient intake was low in the same population. Therefore, it was important to focus on nutrition education on improving dietary diversity and vegetable intake. Iron requirements in pregnancy cannot be met by dietary diversity; it is therefore essential that IFA supplementation is provided and IFA compliance monitored.

Calcium and vitamin D supplementation in pregnancy had been introduced only in 2014. There is paucity of data regarding the access, acceptance and the compliance in terms of consumption of the available calcium and vitamin D tablets. The current study was undertaken to obtain these data. Data from the present study suggests that as of now availability and access to calcium and vitamin D supplementation is low both in hospital and community settings. The data on compliance had shown majority of the pregnant women consumed most of the available calcium and vitamin D tablets. The higher compliance of the calcium and vitamin D tablet consumption might be due to the fact that calcium and vitamin D supplements were not associated with troublesome side effects. However, unlike IFA tablets calcium and vitamin D tablets are expensive and many of the pregnant women from the present study who were provided with a prescription of the same to buy from an outside pharmacy had reported that due to economic constraints they were unable to buy the calcium and vitamin D tablets. It is, therefore, important to ensure adequate availability of calcium and vitamin D tablets to pregnant women across the antenatal care system, from tertiary care hospitals to the community setting.

The Intensified National Iron Plus Initiative (I-NIPI, MOHFW, 2018) has revised and recommended that anaemic pregnant women should be provided with two tablets of IFA each containing 60 mg of elemental iron and 500 µg of folic acid after one meal. The IFA supplementation programme for pregnant women is currently getting reorganized and henceforth it will be possible to take two IFA tablets given together after one meal and two tablets of calcium and vitamin D after the remaining two meals. A small-scale study also demonstrated the feasibility of providing two IFA tablets taken together after one meal and two tablets of calcium and vitamin D taken after the remaining two meals (Ramachandran, Pramanik & Kalaivani, 2019).

After reorganization of the supplementation programme for IFA and calcium and vitamin D supplementation to pregnant women, the impact of supplementing two tablets of IFA together after one meal and two tablets of calcium and vitamin D after two remaining meals on haemoglobin status along with biomarkers for assessing iron status and plasma vitamin D levels will have to be investigated and documented.