Summary and Conclusion

CHAPTER 5

SUMMARY AND CONCLUSIONS

The high prevalence of anemia and its hazards during pregnancy have led to several approaches for anemia control, of which supplementation with medicinal iron offers the most appealing alternative as it can be targeted to specific vulnerable groups and can produce rapid improvements in Hb levels. However, iron supplementation as a field level programme has not achieved the desired results as was shown by the NNAPP evaluation (ICMR 1989) due to drawbacks in coverage and compliance. Therefore an attempt was made in the present study to identify and develop an alternate strategy for improving coverage and compliance with iron supplementation by pregnant women.

The effectiveness of different dose levels of iron supplementation during pregnancy in reducing the prevalence of anemia and raising the Hb levels has been investigated in several controlled and supervised therapeutic trials (Sood et al 1975, Reddiah et al 1989, Charoenlarp et al 1988, ICMR 1992). However studies on the impact of different dose levels of iron delivered through unsupervised field supplementation trials are scarce. Further, maternal and infant outcome in anemic pregnant women, in relation to the

level of iron consumed is an area which has received little attention. Thus, in the quest for a universally accessible alternate delivery system and the level of iron that may provide wide ranging benefits, the present study was undertaken in pregnant women. The following objectives were set for the study :

1. To study the efficacy of decentralized home based delivery of iron supplements at different dose levels on coverage, compliance, side effects and beneficial effects in pregnant women.

2. To study longitudinally the effect of different dose levels of iron, 60 mg, 120 mg and 180 mg with 1.5 mg folic acid given during pregnancy on selected parameters of maternal and infant outcome.

The first part of the study focussed on studying the coverage that could be achieved by providing iron supplementation through home delivery, compliance with these supplements by the pregnant women, nature of side effects reported at each dose level of iron and the credibility of a calendar type of device for measuring compliance.

The second part of the study consisted of the effect of different dose levels of iron on prevalence of anemia, rise in Hb, weight gain during 20-36 weeks of gestation,

morbidity profile, gestational duration and birthweight of the infants.

At six months postpartum the weight and Hb of the pregnant women were measured to know if there were any differences in women supplemented with higher level of iron. The impact of iron supplementation during pregnancy on infant of growth, Hb and morbidity profile were also studied at third and six months postpartum.

The study was conducted over a period of two years (1991-93) in the city of Baroda, which has a population of 1.32 million, one-third of whom live in urban slums. The vulnerable sections of the slum population were covered by the ICDS scheme. The sample of pregnant women for the present study was selected from 15 ICDS centres. One hundred and seventy one pregnant women of 20 or 24 weeks of gestation were enrolled from the 15 centres and were randomly alloted to three iron treatment groups as mentioned below:

Group I - 60 mg elemental iron + 1.5 mg folic acid
Group II - 120 mg elemental iron + 1.5 mg folic acid
Group III - 180 mg elemental iron + 1.5 mg folic acid

Supplementation was provided through a decentralized home distribution every month until delivery.

Ninety tablets of iron and folic acid were provided every month in autoseal polythene covers and the women were appropriately instructed to consume three tablets a day (1 tablet after every meal). A calendar type of device was also provided every month to record tablet consumption. Before supplementation commenced, data on socio-economic status, obstetric history, utilization of health services, anthropometry and hemoglobin were collected. Subsequently data was obtained on health services utilization, compliance with iron supplements, anthropometry, morbidity profile and Hb every month till delivery.

After delivery, the mother-child pair were followed up for a period of six months. At 6 months peri-natally, data were obtained on body weight and Hb of the mothers. Data on infant height and weight, diet pattern and morbidity profile were obtained at 3 months and 6 months of age while Hb estimations on infants post-natally were done at 6 months.

Standard methods were utilized for collection of all the data.

Of the 171 women who were enrolled 30% dropped out of the study initially mainly due to migration to other places. Of the 120 women, who were followed up fully till delivery, only 50% of the mother infant pairs were available at 3 months post-partum and 85% at 6 months post-partum.

The major findings of the study are summarized below and is also shown in Table 5.01.

Table 5.01 Summary highlights of the study : Responses to iron supplementation at three dose levels

Parameters	Level of iron supplementation (mg)		
	60	120	180
Coverage	+++	+++	+++
Compliance	+++	+++	+++
Side effects	-	-	---
Beneficial effects	++	+++	+++
Prevalence of anemia	+	+++	+++
Rise in Hb	+	+++	+++
Maternal morbidity	+	+	++
Weight gain	++	+	++
Gestational duration	++	++	++
Premature delivery	++	++	++
Birth weight	++	++	+++
Low birth weight	+	+	++
Mother's Hb postpartum	+	++	++
Mother's weight postpartum	-	+	+
Infant height	+	++	++
Infant weight	+	++	++
Infant morbidity	+	++	+++
Infant Hb	+	++	++

+++ positive beneficial effect highest
--- negative effect highest

Significant and new findings

1. The decentralized home delivery of iron supplementation, made the supplements accessible to 70% of the pregnant women population in the urban slums as against the 11.4% coverage reported in the NNAPP evaluation.

2. Compliance defined as the consumption of atleast 100 tablets of 60 mg elemental iron was above 90% only for the 120 mg and 180 mg dose levels. This level of compliance could not be achieved with 60 mg dose level per day, as the duration for which the pregnant women were available varied from 60 days to 120 days. Compliance defined as the consumption of at least 250 doses of 60 mg could be achieved only at the 180 mg dose level in 60% of the subjects.

3. Although side effects were experienced by larger percent of women at higher level of iron (180 mg), these disappeared as gestation advanced. More importantly no correlation was seen between average number of side effects and the level of iron consumed.

4. Those reporting side effects had a mean tablet consumption and a Hb response similar to the ones with

no side effects which indicated that despite side effects, absorption of iron must have been similar.

5. Several beneficial effects (decreased tiredness, weakness, pain in lower limbs and improved work capacity) were reported by the women and there was a significant correlation between the mean number of beneficial effects experienced by the women and the level of iron consumed. There is a great potential for using this information in the program situation to promote iron consumption.

6. A simple, inexpensive mother retained card was found to be effective both as a compliance measure and as a memory device. Although only 50-60% of the women utilized the calendar at each contact, where recall information is unreliable this device can be used for recording compliance. Additional merits such as using it as a persuasive device to promote iron consumption and general health can be built into it (for example, recording the weight of the mother at each contact).

7. Reduction of anemia prevalence to one-third the level at entry (from 88% initially to 30% finally) could be achieved only with 120 mg or 180 mg iron daily but not with 60 mg iron.

8. Rise in Hb per month was twice as high with 120 mg and 180 mg iron compared to 60 mg iron and twice as many subjects in the 120/180 mg groups had a Hb response in excess of 1 g/dl. A rise of ≥ 2 g/dl was seen in 49% of the women given 180 mg, 40% in 120 mg and only 15% in the 60 mg group.

9. The level of iron consumed did not produce any significant difference in the total weight gain of the mothers between 20-36 weeks or the rate of weight gain per month or per week. Gestational duration was also unaffected by the level of iron provided. However, mean birth weights were influenced by the level of iron provided being highest in the 180 mg group followed by 120 mg. Percent of infants with low birthweight was also substantially lower in the group supplemented with 180 mg iron compared to those supplemented with 60 or 120 mg iron during pregnancy.

10. The morbidity data showed no evidence of higher levels of iron predisposing to greater morbidity. On the contrary there was a trend towards decreased episodes and duration of morbidity with higher level of iron supplementation, but only in the last month of supplementation.

11. The effect of higher levels of iron supplementation had a pronounced effect on maternal outcome at 6 months postpartum. Mean Hb levels were higher and there was a larger percent of women with normal Hb in the 120 and 180 mg group compared to the 60 mg group. Body weight of the women in the 60 mg group showed a decline while the women in 120 and 180 mg group maintained the same weight as at entry.

12. At 3 months and 6 months postnatally, infants of 120 and 180 mg group were taller and heavier than those in the 60 mg group. Morbidity profile of the infants showed a trend towards a decline in the incidence of infectious morbidity at third and six months in the 120 and 180 mg groups, compared to the 60 mg group. Mean number of days of morbidity was also found to be the lower in the 120 mg and 180 mg group compared to 60 mg group.

13. Although the mean Hb of the infants at 6 months did not differ statistically, the levels were higher in 120 and 180 mg group, and the prevalence of anemia was also found to be the lower in these groups in comparison to the 60 mg group. There was no incidence of severe anemia in any of these groups.

Reconfirmation of documented findings

1. The anthropometric measurements at entry indicated one-third of the women were at risk of obstetric outcome by the weight criterion of 40 kg at 20 weeks of gestation and height criterion of 140 cm.

2. As reported in other studies higher incidence of side effects were reported in the 180 mg group when the study was initiated.

3. Duration of stay in the program influenced the level of tablet consumption, lower duration resulting in higher rise in Hb, confirming the findings of other investigators.

4. Weight of the pregnant women at entry was found to be a significant predictor of birthweight, followed by sex of the infant as shown in other regression analysis on factors affecting birthweights in controlled studies. Similarly gestational duration was affected by weight gain and parity as reported in other studies.

Implications of the findings of the present study for anemia control program in India

The present study addressed some of the shortcomings that have been identified with respect to the anemia control

program in India. Home delivery of iron supplements once a month with appropriate counselling and packaging can improve coverage and compliance remarkably and can be effectively implemented in the anemia control program. As evidenced in the present study the 60 mg dose level of iron was insufficient to reduce the prevalence of anemia to one-third the baseline levels as women stay in the program for only 3-4 months but 120 and 180 mg iron per day could achieve this target. The side effects profile of these subjects indicated that initially side effects experienced in the 120 mg level are much lower than 180 mg level and as no major differences were found between the level of beneficial effects experienced in these two groups, 120 mg iron can be recommended for pregnant women.

Post-partum Hb of the subjects at 6 months and Hb of the infants at 6 months indicated that effect of 120 mg and 180 mg iron supplementation produced similar effects and were higher than the 60 mg group. This has significant implications as it can prevent women lapsing into anemia at a later stage due to close birth spacing which is a common feature in India.

Therefore dose levels of iron should be increased to 120 mg/day and should be provided through home delivery with

improved packaging and counselling in the current programme to achieve the targets set for the reduction of the prevalence of anemia in pregnant women.