Introduction

CHAPTER 1

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Nutritional anemia is a serious public health hazard affecting over a billion people in the world (WHO 1992). The magnitude of this disorder is much higher in the developing world compared to the industrialized nations (De Maeyer and Adiels Tegman 1985). Current evidence indicates that this disorder is a common feature in all segments of the population in the developing countries but women and children are most affected (De Maeyer 1989). Prevalence estimate of anemia in pregnant women has shown that it is the highest in South (75%) and South East Asian (63%) regions (WHO 1992) of which India ranks the highest (88%).

Several factors play a contributary role in the etiology of anemia in pregnancy but the most predominant one is insufficient dietary intake in the face of increased iron requirements coupled with poor bioavailability of dietary iron (Morck and Cook 1981, Narasinga Rao 1983, Hallberg 1984). Other etiological factors in pregnancy include folic acid deficiency, hookworm infestations and malaria the incidence of which varies according to the geographical locations (Cook et al 1971, Baker and De Maeyer 1979, Simmons and Gurney 1982, Brabin 1983, WHO 1993). Close birth

spacing and high fertility have also been reported to contribute to iron deficiency anemia of pregnancy (Ratten and Beischer 1972, Luwang et al 1980, De Maeyer 1989, Hercberg 1991).

Anemia characterized by decreased levels of circulating hemoglobin (Hb) and tissue iron content is known to lead to several functional abnormalities and adverse health consequences.These include impairment of maximal work capacity, reduced work output, decreased muscle function and impairment in immune function (Gardner et al 1975, INACG 1977, INACG 1981, Prema et al 1982). In addition to these, pregnancy anemia is also associated with increased maternal morbidity and mortality, increased perinatal and neonatal mortalities, and higher incidence of low birth weight babies (Garn et al 1981, Prema et al 1981a, WHO 1993).

Major interventions for the control of anemia include dietary modification, food fortification, control of parasitic infestation and suplementation with iron and folic acid (ACC-SCN 1991).

Changes in dietary pattern involve long range efforts in persuading the population to increase food consumption especially cereal and leafy vegetable consumption, thereby increasing iron intake. Appropriate counselling to modify the dietary habits to reduce the intake of inhibitors of

iron absorption and increase the intake of enhancers is also an important strategy. In industrialised countries like Sweden, UK and USA where the prevalence of anemia is much lower than in the developing countries, fortification of a staple food item such as wheat and bread has been widely advocated and sucessfully implemented (INACG 1977). In India salt has been used as a vehicle for iron fortification (Narasinga Rao 1981) and community trials have shown that consumption of iron fortified salt resulted in a significant improvement in Hb in school children (Food and Nutrition Board and UNICEF 1981) but the amount of iron ingested through this vehicle (about 15 mg) may be insufficient to meet the increased requirements during pregnancy. Public health measures such as improved environmental sanitation are related to socio-economic development and are long term measures. Thus these strategies, important as they are, suffer from the limitation that they cannot bring about rapid improvements in the Hb levels or they provide too little iron to be of any significant value in pregnancy.

Supplementation with medicinal iron on the other hand is potentially powerful as it has the advantage of producing rapid improvements in the iron status and can be targeted to specific population groups. The efficacy of therapeutic supplementation has been demonstrated in reducing the prevalence of anemia and raising the Hb levels in pregnant

women in controlled trials (Nutrition Society of India 1968 and Sood et al 1975). In view of this and in recognition of the high prevalence and serious health implications of anemia in pregnancy, the Government of India launched the National Nutritional Anemia Prophylaxis Program (NNAPP) in 1970, which envisaged the delivery of iron folic acid supplements to underprivileged pregnant women with Hb levels equal to or more than 10 g/dl . During each pregnancy the women were expected to receive 100 tablets , each tablet providing 60 mg elemental iron and 0.5 mg folic acid. The pregnant women with Hb levels less than 10 g/dl were to be put on active anti-anemia treatment.However in actual practice the Hb estimations were not carried out due to lack of facilities and it was decided that Hb estimations be done wherever feasible (Nutrition Society of India 1968).

The National evaluation of the NNAPP in eleven different states (ICMR 1989) 20 years after its inception,revealed several operational constraints which contributed to the lack of impact of this program in reducing the prevalence of anemia in pregnant women. Coverage of pregnant women was woefully inadequate as only 19.4% of the 5779 pregnant women surveyed had been offered the supplement. Of those who received the supplement only 11.4% of the women consumed the stipulated dose of 90 or more tablets thus resulting in a very low compliance. A

subsequent study by the ICMR (ICMR 1992) also reported a relatively low compliance (90 tablets) of 47% when tablets were distributed every month. Therefore an important operational research need is to evolve and test strategies that can increase coverage and promote compliance.Currently the distribution of the supplements is mostly at the subcenters, public health clinics or hospitals (ICMR 1989). As pregnant women do not visit the clinics regularly for various reasons (Gopaldas et al 1975) a decentralised delivery system like home based delivery could result in wider coverage, the efficacy of which has not been tested so far.

Another important finding of the NNAPP evaluation (ICMR 1989) was that the mean Hb levels of pregnant women who received 90 or more doses of the 60mg tablets was not significantly different from those who received less than 90 doses thus raising questions concerning the adequacy of the level of iron recommended in the NNAPP. This finding highlights the need for initiating more unsupervised field supplementation trials with different dose levels of iron in Indian pregnant women, and studying the impact in terms of Hb levels and prevalence of anemia so that dose levels consistent with the highest reduction in prevalence of anemia can be advocated.

While compliance with the preventive or treatment regimen is mandatory for a positive impact,currently the only method for measuring compliance is the subject's recall. Investigators of the multicentric study by ICMR (1992) reported that compliance as obtained by the mothers recall may be in error as 37.8% of those with a reported consumption of 90 or more tablets had a mean Hb of 10 g/dl, and 19.4% had a mean Hb of 9 g/dl. Stool examinations provide an objective measure of recent iron consumption (Macdougall 1970) but are not feasible in the field conditions. A mother retained card has been shown to provide a reliable estimate of compliance in Thailand (Charoenlarp et al 1988) but has not been tested under the Indian conditions.

With increasing levels of iron supplementation non compliance due to side effects may emerge as a major operational constraint resulting in a high drop out rate. This has been observed in several controlled iron supplementation trials at different dose levels (Kuizon et al 1983, Charoenlarp et al 1988, Reddiah et al 1989, ICMR 1992). However, no convincing data are available from field level supplementation trials to show that the high drop out rate is due to side effects. In the NNAPP evaluation in India (ICMR 1989) only 3 % reported that iron supplements were discontinued due to side effects. The coverage in this

study was too low to make any further analysis of this aspect. It is therefore important to undertake further studies to investigate the side effects profile at different dose levels of iron and their role in non compliance and drop out in unsupervised field supplementation trials.

A relatively neglected area is also the range of beneficial effects experienced by pregnant women who consume the iron supplements regularly. Far too much of emphasis has been laid on side effects, perhaps with enough justification but it is necessary to identify the beneficial effects experienced so that educational messages with positive reinforcement can be prepared.

Impact evaluation studies of iron supplementation at different dose levels in pregnant women have focussed chiefly on the changes occurring in the hematological indices (Sood et al 1975, Jackson and Latham 1982, Kuizon et al 1983, Charoenlarp et al 1988, Reddiah et al 1989, ICMR 1992) with little information available on other parameters of maternal and infant outcome such as weight gain during pregnancy, gestational duration, and birthweight of the infants.

Although anemia is reported to be associated with depressed immunocompetance (Prema et al 1982), few studies have addressed the effect of anemia on morbidity profile of

pregnant women. Further what effects iron supplements have on the morbidity profile of underpriviledged pregnant women exposed to a heavy load of infections is an area that has received little attention. This is an important issue as high levels of iron are suspected to increase susceptibility to infections (Hercberg 1991).

Iron supplementation during pregnancy may not only raise the Hb levels prenatally but may also help to maintain better Hb levels in the postpartum period. The opportunity for antenatal care and iron supplementation can be used to best advantage if information is available on the level of iron that will prevent women from lapsing into anemia after delivery. This calls for a longitudinal study on the effects of different levels of iron administration during pregnancy on the Hb levels at varying periods after delivery.

Recently iron transfer to the infant has been shown to be dependent on the maternal iron status (Singla et al 1978, Agarwal et al 1983) thus postulating that improving maternal iron stores may lead to better iron endowment at birth and delayed development of anemia in infancy. In view of this and the accelerated growth velocity reported in anemic school children provided with iron supplementation (Chawang Leh Chii et al 1988, Bhatia and Seshadri 1993) it may be postulated that iron supplementation during pregnancy may

have a favourable effect on the Hb levels and growth of the infant postnatally. Empirical studies to support this postulate are not available.

Against this background and the questions that have been raised the present study was undertaken with the following goals :

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.

To study longitudinally the effect of different dose levels of iron i.e. 60 mg, 120 mg and 180 mg of iron and 1.5 mg of folic acid per day given during pregnancy for 12-16 weeks on selected parameters of maternal and infant outcome.

The study comprised of four major parts with the following specific objectives :

Part 1

To study the efficacy of home based delivery of iron supplements at different dose levels (60 mg, 120 mg and 180 mg/day) during pregnancy on coverage, compliance, side effects and beneficial effects,and to study the credibility of a mother retained card as a compliance measure.

Part 2

To investigate the effect of three different dose levels of iron (60 mg, 120 mg and 180 mg/day) given during pregnancy for 10-16 weeks on the following maternal parameters : prevalence of anemia and rise in hemoglobin at different gestational ages, weight gain per month, morbidity profile during 20-36 weeks of gestation, percent of preterm delivery, and incidence of low birth weight infants.

Part 3

To study the effect of the above different levels of iron supplementation during pregnancy on maternal weight and hemoglobin at six months post partum.

Part 4

To determine the effects of the above three different levels of iron supplementation during pregnancy on growth (in terms of height and weight), morbidity profile and Hb of the infants at 3 months and 6 months of age.