

**WORKING WITH TRADITIONAL
BIRTH ATTENDANTS TO IMPROVE
IRON TABLET UTILIZATION BY
PREGNANT WOMEN**

Maluku Province, Indonesia

TECHNICAL WORKING PAPER #8

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TABLE OF CONTENTS

EXECUTIVE SUMMARY	7
BACKGROUND	9
INTRODUCTION	10
General Statement of the Project	10
History of Project Implementation.....	10
Project Implementation Methodology	12
<i>Study Design</i>	12
<i>Study Population</i>	13
<i>Procedures</i>	13
<i>Data entry and analysis</i>	15
RESULTS	15
Background and Pregnancy Status.....	15
Iron Tablet Distribution	17
Weekly versus Daily Iron Tablets.....	21
Effect of Anthelmintics on Iron Supplementation	24
CONCLUSION	27
TBA role in iron supplementation	27
Daily versus weekly iron supplementation	28
Effect of anthelmintics on iron supplementation	29
APPENDIX A	31
APPENDIX B	32

TABLES

TABLE 1: STUDY SUBJECT DEMOGRAPHICS	16
TABLE 2: PROPORTIONS WITH PREGNANCY AND INFECTION-RELATED COMPLAINTS	17
TABLE 3: IRON TABLET CONSUMPTION	18
TABLE 4: COMPARISON OF HEMOGLOBIN STATUS BETWEEN TBA AND CONTROL GROUPS	18
TABLE 5: Change in Hemoglobin Level in Relation to Total Intake of Iron (TBA-Daily Group N=191)	19
TABLE 6: IMPROVEMENTS IN KNOWLEDGE ABOUT ANEMIA	21
TABLE 7: KNOWLEDGE ON PREVENTION OF ANEMIA	21
TABLE 8: COMPARISON OF HEMOGLOBIN STATUS BETWEEN TBA-DAILY AND WEEKLY (Compliance >50%)	22
TABLE 9: COMPARISON OF TABLET CONSUMPTION BETWEEN TBA-DAILY AND -WEEKLY REGIMENS	22
TABLE 10A: PAIRED FERRITIN LEVELS IN SUBJECTS BEFORE AND AFTER INTERVENTION	23
TABLE 10B: PAIRED FERRITIN LEVELS IN SUBJECTS BEFORE AND AFTER INTERVENTION	23
TABLE 11: EFFECT OF ANTHELMINTHICS ON HEMOGLOBIN LEVELS OF WOMEN IN TBA-DAILY GROUP	24
TABLE 12: INFLUENCE OF ANTHELMINTHIC TREATMENT ON HEMOGLOBIN LEVELS IN TBA-DAILY SUBJECTS WITH >50% COMPLIANCE	25

TABLE 13: INFLUENCE OF COMPLIANCE ON HEMOGLOBIN LEVELS AMONG TREATED AND PLACEBO SUBJECTS COMBINED FROM THE CONTROL AND TBA-DAILY GROUPS 26

TABLE 14: INFLUENCE OF ANTHELMINTHIC TREATMENT ON HEMOGLOBIN LEVELS IN COMBINED TBA-DAILY AND CONTROL SUBJECTS RECEIVING >75 IRON TABLETS 26

FIGURES

Figure 1. Change in hemoglobin levels over 20 weeks when iron tablets are administered by TBAs daily or in clinic setting (Control)..... 19

Figure 2. Hemoglobin responses in relation to number of iron tablets consumed..... 20

Figure 3. Change in hemoglobin levels in subjects taking mebendazole or placebo in the TBA-Daily group..... 24

Figure 4. Change in hemoglobin levels in subjects on mebendazole or placebo in the TBA-Daily group who had >50% compliance in taking iron supplementation.....25

Figure 5. Egg counts reflecting intensity of hookworm infection in 45 randomly selected stool samples from survey of fertile women in the Maluku Province 30

EXECUTIVE SUMMARY

Anemia in pregnancy affects an estimated 50 to 60 percent of pregnant women in Indonesia. One of the major causes is inadequate intake of iron and folate. Supplementation has been difficult due to lack of knowledge and difficulties with the distribution scheme. **This study was undertaken to test the feasibility of using traditional birth attendants (TBAs) as a conduit for iron/folate tablet distribution with the specific objective of increasing the number of tablets consumed and thus, increasing hemoglobin levels.** A previous MotherCare study in Java with intensive monitoring revealed that TBAs have the potential of improving the distribution scheme. This needed to be further verified under more normal field conditions where "study" effects are minimal. A large number of TBAs (80) in an experimental area in Maluku were trained to provide health education and distribute the tablets to the pregnant mothers they normally service. Tablet consumption and hemoglobin levels were monitored in experimental and control populations. Serum ferritin levels were measured in a randomly selected sub-group.

Out of more than 600 pregnant women enrolled, 580 were followed for 12 to 20 weeks on three different iron supplementation regimens. Group 1 (TBA-Daily) received 60-mg elemental iron and folate tablets daily supplied and monitored by TBAs. Group 2 (TBA-Weekly) mothers received two 60-mg iron tablets once weekly supplied and monitored by TBAs. Group 3 (Control) subjects received their iron supplements at the health center and had no TBA input into supply or health education/monitoring. In order to assess the impact of anthelmintic therapy, each of the three groups was divided equally between mebendazole and placebo treatment in the second trimester in a blinded fashion. Results revealed:

1. TBA-Daily subjects consumed an average of 95 tablets during the 20-week course compared to 65 tablets in the Control group. Compliance in the TBA-Daily subjects (70%) was much better than compliance in the Control group (47%). The difference amounted to a total of 1800 mg more elemental iron consumed by the women in Group 1.
2. TBA-Daily subjects had a net 6.5 g/l rise in hemoglobin level over the 12 to 20 weeks treatment period versus a 6.5 g/l **decrease** for the control women compared to the baseline.
3. Dose-response determinations indicate that ninety 60-mg elemental iron tablets are barely adequate to produce a significant increase in hemoglobin status and iron stores even when compliance is good. Consistent hemoglobin improvement requires 100 or more tablets consumed over 12 to 20 weeks.
4. The TBA-Daily women demonstrated an increase in knowledge regarding the symptoms, risk, and prevention of anemia that, in most cases, surpassed the improvements made by the Control group.
5. Results revealed that the daily dose regimen was far more effective than the once weekly regimen. The daily regimen rose 8.0 g/l versus only 2.4 g/l for the weekly group after twenty weeks of therapy.
6. Ferritin levels decreased in all three groups, reflecting the physiologic iron depletion expected with pregnancy. There was a suggestion that the TBA-Daily group ferritin levels

did not drop as much as the others.

7. The data indicate that mebendazole did not enhance the increase in hemoglobin in TBA-Daily and Control subjects more than the placebo. It is possible this was due to the low intensity of hookworm infection in our subjects.

BACKGROUND

At the 1991 Anemia Expert Meeting in Indonesia, it was estimated that the prevalence of anemia (Hb<11 g/dl) in pregnant women was 50 to 60 percent based on collected studies. In 1997, this represented about 2.8 to 3.2 million pregnant women. There has been a national policy to give every pregnant woman ninety 60-mg elemental iron tablets, but this has yet to be optimally implemented in all areas. There are problems with management and logistics. Tablets are not always available at the points of service (*Posyandu*, health centers, and hospitals). Pregnant women frequently do not seek antenatal care. In the Maluku Province, these problems are compounded by the difficult geographic situation where two million people are spread over 1000 islands. More than 70 percent of the villages are located more than 10 kilometers from a health center and 65 percent of the villages cannot be reached by wheeled vehicles. In addition, many women do not understand the causes, dangers, and prevention of anemia. Many village women do not appreciate their dietary needs. Some mothers refuse to take the tablets because of the smell and metallic taste, upset stomach, or fear that the tablet will make the baby too large for delivery.

In addition to increasing the role of information, education, and communication programs, the Ministry of Health (MOH) has identified the need to increase and extend the coverage of the iron supplementation program. Iron distribution effectiveness can be improved by expanding the variety of places and personnel allowed to dispense the tablets. Village midwives and traditional birth attendants (TBAs) have been suggested. In 1992, a trial utilizing TBAs was carried out in Indramayu, W. Java by the University of Indonesia with support from MotherCare. Midwives and thirty-six TBAs were trained to instruct mothers on the importance of iron supplementation. Packets of iron/folate were distributed and their consumption monitored. The average number of tablets consumed during each pregnancy was significantly greater in the experimental area than the control (64 vs. 23 tablets) and the proportion of pregnant mothers taking iron/folate increased as well. Due to technical difficulties, hemoglobin determinations were not done. This study was conducted in conjunction with another larger project that used a comprehensive Sample Registration System (SRS) with intensive follow-up through monthly interviews of the enlisted pregnant mothers. Before the study described in this paper was undertaken, the capability of TBAs to conduct this distribution program under normal field conditions was unknown. This study was the next logical step in assessing the feasibility of turning over iron/folate distribution to TBAs on a larger scale.

Project Concern International (PCI), with the Maluku Ministry of Health, trained 1485 TBAs in 1993. More than six hundred of these TBAs participated in a pilot project to test the feasibility of using TBAs to distribute vitamin A to mothers in the first postpartum month (*ibu nifas*). This pilot was successful in demonstrating an increased knowledge about vitamin A in both mothers and TBAs. This program has been approved by the provincial MOH and a policy has now been established for vitamin A distribution by TBAs in all districts of Maluku. Now, thousands of capsules of vitamin A are reaching *ibu nifas* and benefiting their breastfeeding infants.

TBAs in the PCI/Maluku program have been trained in further duties, including reporting births and maternal/neonatal deaths using a simple pictorial reporting form. This form also provides the capability for community based neonatal tetanus surveillance. TBAs also distribute Road-to-Health cards and Lifetime Tetanus Toxoid cards as a strategy to promote the importance of immunizations and MCH services at the *Posyandu*. This, of course, is all in addition to the usual

tasks of assisting in "clean deliveries" (PCI has provided midwifery kits), identifying and referring high-risk pregnancies and complications, plus providing health education to mothers and the community at large.

The supplemental duties offered to TBAs have been accepted with enthusiasm as they enhance the prestige of the individual TBAs in the community (not to mention the health center staff). Several surveys have clearly demonstrated that TBAs trained in the PCI programs are in greater demand and receive a significantly higher payment for their services.

Recognizing the need to address the issue of the high incidence of anemia in pregnant women and its adverse affect on maternal mortality, this pilot project was conceived to further develop the scheme of iron/folate distribution using TBAs recently trained in Maluku.

As discussed in further detail below, the original project underwent several modifications in order to address several other issues related to iron supplementation in pregnant women. A group was added to investigate the feasibility of weekly versus daily supplementation, and the subject sample size later increased to assess the effects of de-worming on hemoglobin and ferritin levels.

INTRODUCTION

General Statement of the Project

Goal:

Improve the health status of pregnant women by decreasing anemia.

Objectives:

1. Examine the capability and effectiveness of using traditional birth attendants (TBAs) to assist in the implementation of the iron supplementation program for pregnant women in rural villages.
2. Determine whether the administration of two tablets of iron per week in one dose is as effective as a daily dosage of one tablet (120-mg Fe) in satisfying the needs of pregnant women.
3. Determine whether the combined and separate effects of iron supplementation with anthelmintic treatment can improve hemoglobin and iron status in women.

History of Project Implementation

The original project document submitted for funding consideration in September 1994 was funded in September 1995. The original design provided for 200 women in the experimental group receiving daily iron tablets distributed by TBAs and 100 in the control group accessing the usual MOH clinic system. Several months into the study the experimental group was sub-divided into daily and weekly regimens. The weekly regimen (two tablets once weekly) was added to

address the suggestive evidence that iron in tablets is better absorbed when administered every few days rather than daily.

Activities began in November 1995, with the orientation of midwives and TBAs, followed by the development of project training materials and the training of midwives/TBAs in the first few months of 1996 (see **Appendix A** for detailed schedule of activities). Project staff began enrolling pregnant women in April 1996. However, by mid-September after almost 200 mothers were registered, it was determined that the filter-paper method for performing hemoglobin analyses gave results that were clearly too erratic to be trusted. In addition, ferritin analyses as performed by the provincial laboratory were likewise questionable.

At this point it was decided to change the methodologies for hemoglobin and ferritin analyses and modify the project design. HemoCue® machines were purchased and distributed to the health centers to improve hemoglobin determinations. Arrangements were made to send serum samples to the laboratory of the Southeast Asia Tropical Medicine Research Center (SEAMEO) in Jakarta for ferritin analysis.

On consultation with Dr. Werner Schultinck (SEAMEO) and Dr. Ray Yip of UNICEF, it was decided to change the weekly regimen to two tablets (total 120 mg Fe) once weekly instead of one tablet twice a week to conform to the protocols of most of the previous studies that have been undertaken.

Early in the first phase of the original study an intestinal parasite survey of women of child-bearing age in the project area was conducted by a team from the University of Sydney with funding from the Rotary Club of Australia. The study showed a high infection rate with hookworm, whipworm and ascaris. Although the hookworm prevalence was high, the worm load (eggs/gram) was not great. An anthelmintic component was added to the study following an offer by Dr. Lorenzo Savioli, Director of the Schistosomiasis and Intestinal Parasites Unit/WHO/Geneva to provide \$17,000 (\$US) in funding. This decision was made during a visit to Geneva by Dr. Robinson, the principal investigator. The extra funding was needed in order to double the number of subjects needed. This provided for three arms each divided into two sub-groups of placebo and mebendazole for a total target population of 600 pregnant mothers.

The modified and enhanced study design began anew to enroll pregnant mothers in October 1996, following the training of field staff in the use of the HemoCue machines and the administration of the anthelmintic therapy by TBAs and midwives. New consent forms were drafted and field staffs were instructed to avoid giving mebendazole to women until after they entered the second trimester (fourth month).

Two new health centers were added to the geographic area of the study in order to increase the number of subjects available. Two health centers were dropped from the study because health center staff complied poorly with the study protocol and the patients tended to live too proximal to the district capital where antenatal care was likely to be better-developed than in the more rural areas for the other subjects.

Registration of pregnant women was completed in September 1997 with the registration of more than 600 subjects. Some (less than 10%) were dropped because they miscarried before repeat

blood samples were obtained or were lost to follow-up. The final blood samples were obtained in mid-December 1997.

Project Implementation Methodology

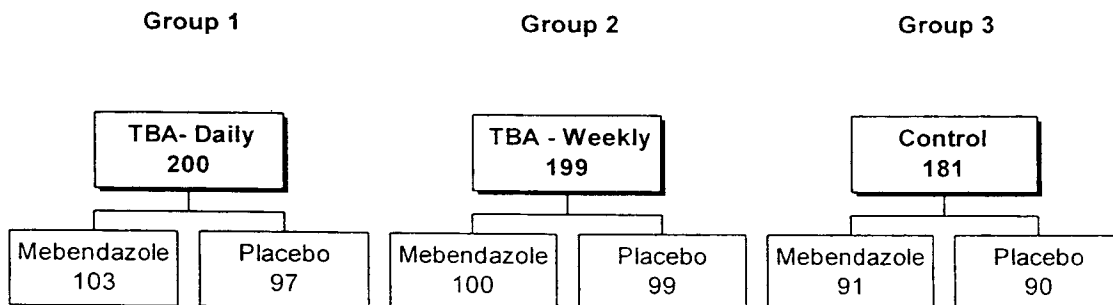
Study Design

The study examined three distinct issues in the management of anemia in pregnant women:

- 1) The feasibility of using TBAs to improve the availability of iron tablets and improve compliance in taking the supplement;
- 2) The efficacy of a once weekly regimen of iron tablets (120-mg elemental Fe) versus daily consumption of 60-mg elemental Fe; and
- 3) The efficacy of an anthelmintic in enhancing hemoglobin and iron levels.

The subjects were divided into three groups (see design scheme below). Groups 1 and 2 comprised of pregnant women who were administered iron supplementation by TBAs. The TBAs were kept a stock of tablets at their home and administered the tablets to the mothers as needed according to the dosage regimen. Group 1 pregnant women were administered 60-mg iron tablets daily while Group 2 women were maintained on a once weekly schedule of two tablets. The TBAs visited the subjects weekly and replenished the iron tablets as needed. In the case of the daily dose group, the TBA left seven tablets during her visit and checked on the number of tablets taken the previous week. The TBAs in the weekly regimen gave their two iron tablets to the mothers during their weekly visit and directly observed their consumption.

IRON SUPPLEMENT STUDY DESIGN



Study design scheme

In Groups 1 and 2, the TBAs were instructed and charged to provide health education to the mothers on anemia and the importance of iron supplementation.

Group 3 was the Control group. This group of subjects obtained their iron tablets in the usual manner at the health center during a visit for prenatal care. During the prenatal visit, women are usually given a packet of iron tablets to take home and consume as per instructions by the midwife. No special provision is made for health education other than what is given at the health center during the mother's routine visit. TBAs were not involved in distributing iron tablets.

Each of the three groups was further divided into two equal sub-groups that were administered mebendazole or a placebo in a blinded fashion.

Study Population

The study community comprised five sub-districts on or near the western end of the island of Seram in the Province of Maluku, Eastern Indonesia (**see map in Appendix B**). The local population of about 100,000 is primarily rural and village-based with incomes from farming and fishing. The demographic status of the population is known to be homogeneous in this area with regard to culture, education, ethnic backgrounds, religion, and occupation. Accessibility to health and other services (transport and communication) was similar. An average of 65 to 70 percent of the pregnant women in this area are delivered with only the assistance of a TBA. Village midwives are stationed in a few of the villages, but were not included in this program.

The population is served by eleven health centers. There has been no previous role for TBAs in iron tablet distribution prior to this study. Many of the TBAs, however, have received refresher training in improved delivery techniques over the past three years through PCI programs.

Procedures

TBA role in iron tablet distribution

Health center midwives were trained in the process of training TBAs to provide health education to pregnant women on the importance of iron supplementation. The midwives were also trained in the use of the HemoCue® apparatus, the drawing of blood, and storage of serum samples for ferritin determinations.

The midwives then trained 80 TBAs on how to manage the iron tablet distribution and provide health education to mothers. A handbook with information in pictorial form was provided to all TBAs as a reference guide.

Pregnant mothers were identified by local TBAs and escorted to the health center where the midwife enrolled the mother in the study if she consented. Enrollment entailed interviewing the mother for information on pregnancy history, knowledge of anemia and iron supplementation, recent illnesses (malaria, worms), and drawing a baseline hemoglobin and ferritin. The TBA then took responsibility for the distribution of iron tablets to the mother under her care. Calendars were given to the mother in the experimental groups.

The TBA then visited the mother weekly to administer new iron supplements and ensure that she was taking her iron supplements. Compliance determination is described below. After about 12 weeks on the supplements, the pregnant woman was escorted to the health center for a follow-up

hemoglobin and ferritin sample and another interview. The mothers were then requested to continue taking the supplements for another eight weeks and return for another hemoglobin determination. Serum ferritin samples were not taken for the 20-week visit.

For the Control group, no TBAs were trained or involved in the iron tablet distribution. Pregnant women coming to the health center were enrolled by the midwife with consent, were interviewed and had their blood drawn as in the experimental group. However, they were then given a packet of 30 tablets of iron by the midwife and sent home. Additional tablets were available by request at subsequent visits. The mother only benefited from health education if the midwife provided it before departing. As per the clinic routine the mother was usually requested to come back for interim prenatal exams, but certainly by 12 weeks (and later at 20 weeks) to have further blood samples checked. No home visit was made to ascertain how many tablets were actually taken (nor a calendar given) as in the experimental groups since this would have disturbed the conditions for a field "control." Compliance was measured by the number of packets (or tablets) of iron distributed (confirmed by the midwife) and then reported by the pregnant mother during the follow-up interview at 12 and 20 weeks. These follow-up interviews were always conducted by project staff (not health center staff). It is assumed that the number of tablets actually consumed was less than that reported.

All hemoglobin readings were recorded by the midwife at the time of the sampling. Duplicate samples were performed for the first several months until the project staff could confirm that the midwives were able to perform the test with good precision.

Blood drawn for ferritin (5 cc) was allowed to clot and serum separated within several hours. Serum samples were then stored in the health center refrigerators at 2 to 8 degrees Celsius for no longer than ten days before being picked up by project staff. Samples were then kept frozen at -20 degrees Celsius until analysis. Samples packed in dry ice were shipped by air to the Southeast Asia Tropical Medicine Research Laboratory at the University of Indonesia. In order to diminish variability, paired (pre- and post-test) samples were analyzed in the same lot. Ferritin concentration in serum was analyzed using the enzyme immunoassay method.¹

Daily versus weekly iron supplementation

All the procedures described in Section 1 were followed in these the Daily and Weekly groups. However, in the case of the Daily group, the mothers were given seven tablets each week and the stock replenished. The TBA could directly confirm the number of tablets consumed from the calendar and the number of remaining tablets actually visualized. In the weekly group, the TBAs directly observed the pregnant mothers consuming the two tablets. No extra tablets were provided as the mothers and TBAs understood the regimen required only two tablets per week. Both these experimental groups were followed-up after about 12 and 20 weeks of therapy with hemoglobin analysis. Ferritin blood sampling was performed only at baseline and at 12 weeks on randomly selected samples.

Effect of anthelmintic treatment on hemoglobin levels

¹ International Nutritional Anemia Consultative Group. Measures of iron status. Washington, D.C.: Nutrition Foundation, 1982.

Each of the three groups was divided into two sub-groups. One received 500 mg of mebendazole and the other a placebo supplied by WHO/Geneva. Mothers were assigned to anthelmintic or placebo group depending on whether they had an odd or even registration number. The type of medication was blinded to the midwife at the time the mother registered for the study. All mothers had to sign a consent form agreeing to take the medication, but at no time did they know for sure whether it was placebo or mebendazole. Mothers who had not yet entered their second trimester (as determined by the midwife's fundal exam) were not given the medication until later. After determination of the date for entering the second semester these mothers were administered one tablet (anthelmintic/placebo) either by the visiting TBA for the experimental group or at the closest mobile clinic visit by the midwife for the Control group.

The code (placebo vs. anthelmintic) was never broken for the TBAs or midwives. The project field staff knew the code but they did not participate in the analysis of the data. The project director was blinded to the code until the study had been completed and analysis was started.

Data entry and analysis

All data from survey interviews (baseline and 12 weeks) plus Hb and ferritin determinations were entered into the computer using the *Epi Info 6.04* software. Baseline and post-intervention data were combined into one record for each woman to facilitate analysis. Women with missing or bizarre data were not included in the analysis. In addition, women who did not carry their pregnancy for the whole study period (minimum 12 weeks) were not included.

RESULTS

Background and Pregnancy Status

Pregnant women were registered and followed between October 1996 and December 1997. Out of 680 women registered, 580 (85%) completed the primary protocol. Most of the dropouts occurred due to miscarriage or the subject moving out of the study area. Out of the 580 subjects 490 (84%) continued with additional four to eight weeks of iron therapy for a third hemoglobin assay.

Eleven health centers were involved in the study. As seen in **Table 1** the average age of the enrolled subjects was 26.6 years (range 16 to 44 years old). The women were on average 3.5 months gestation on entry into the study. There were 147 (26%) primiparous subjects the rest having had a median average of two previous pregnancies (range=1-9).

Amongst the multiparous women (433), there had been 973 total pregnancies with a miscarriage rate of 4.9% and a stillborn rate of 10.7%. The birth intervals were relatively short with 34.7% (140) having delivered within 24 months of the current conception and 9.4% (38) within the previous 12 months.

As seen in **Table 1** there were no significant differences between groups in any of the above factors. Moreover, there were no differences in average weights, heights, arm circumference, and

weight gain after 12 weeks. The average weight gain of 1.73 kilograms/month did not differ significantly among the three study groups (P=. 065).

TABLE 1: STUDY SUBJECT DEMOGRAPHICS

PARAMETER	STUDY GROUPS			P value
	TBA-DAILY (N = 200)	TBA-WEEKLY (N = 199)	CONTROL (N = 181)	
Health Centers	4	3	4	
Age of Mothers (years)	26.6 ± 0.2	26.1 ± 0.4	27.1 ± 0.4	NS
Gestational Age (months)	3.4 ± 0.1	3.5 ± 0.1	3.5 ± 0.1	NS
Total Pregnancies	3.0 ± 0.1	3.0 ± 0.1	2.8 ± 0.1	NS
% Primiparous	23 %	26 %	28 %	NS
Avg. Deliveries ⁽¹⁾	2.2 ± 0.1	2.3 ± 0.1	2.2 ± 0.1	NS
Avg. Birth Interval (months)	44 ± 3	39 ± 3	43 ± 3	NS
Height (cm)	154.3 ± 0.4	154.1 ± 0.4	154.0 ± 0.4	0.79
Weight (kg)	49.7 ± 0.5	49.2 ± 0.5	49.9 ± 0.5	0.63
Wgt. gain/mo. (kg)	1.70 ± .08	1.61 ± .07	1.89 ± 0.10	0.65
Arm circumf. (cm)	23.6 ± 0.1	23.6 ± 0.1	23.6 ± 0.1	NS
% MUAC < 23 cm	33 %	30 %	34 %	NS

(1) Multiparous women only

Table 2 delineates the frequency of common pregnancy-related complaints in enrolled subjects. Most common were fatigue (71%), dizziness (59%), and nausea (51%). Five percent complained of some vaginal bleeding and four percent mentioned swelling of the feet. There were no statistically significant differences between the three groups for these complaints.

TABLE 2: PROPORTIONS WITH PREGNANCY AND INFECTION-RELATED COMPLAINTS

PARAMETER	STUDY GROUPS			P value
	TBA-DAILY (N = 200)	TBA-WEEKLY (N = 199)	CONTROL (N = 181)	
Fatigue	65 %	76 %	71 %	.058
Dizziness	57 %	65 %	55 %	.104
Nausea	52 %	53 %	49 %	.746
Fever past week	20 %	10 %	15 %	.029
Malaria past year	24 %	12 %	11 %	.0002
Worms in family member	47 %	52 %	38 %	.018

However, more women in Group 1 complained of fever in the previous two weeks compared to Group 2 ($\chi^2=7.07$; $P= .008$) and expectedly more women in Group 1 admitted to having malaria in the previous year compared to the other two groups ($\chi^2=11.45$; $P < .001$). When queried about a history of worm infestation in any family member, there was a greater tendency for women living in the Group 1 and 2 areas to have answered positively. It is known from a previous study of fertile women (March 1996) that the Control area had somewhat lower worm infestation prevalence than the experimental area (64% versus 81%).

Iron Tablet Distribution

This part of the study assessed the effectiveness of village TBAs in improving iron tablet distribution and consumption (during weekly home visits) compared to the usual system of distribution through the health center (monthly visits to the clinic). Out of the 40 TBAs trained for the study, 25 actively participated in the protocol throughout the study period.

Table 3 compares the data on tablet consumption (compliance). In order to fairly compare the two groups, only women who were followed for 12 to 20 weeks and had three hemoglobin measurements were included.

TABLE 3: IRON TABLET CONSUMPTION

	GROUP 1 TBAs-DAILY (N=192)	GROUP 3 CONTROL (N=115)
AVG NO. TABLETS CONSUMED	95.0 ± 1.6	64.9 ± 2.5
AVG DURATION (days)	138.7 ± 1.4	142.3 ± 2.9
COMPLIANCE	69.6 %	46.9 %

It is clear that more tablets were consumed in the TBA experimental group, resulting in Group 1 subjects consuming an average of 30 tablets (1800 mg elemental iron) more than the Control group. The control value is the estimated maximum based on reports of the number of tablets distributed (not necessarily consumed), according to a report by the health center data. It is certain that the number of tablets actually consumed is less than that distributed. Hence, the Control "compliance" rate of 46.9% is likely much greater than reality.

An examination of TBA Group 2, where the mothers received two iron tablets once weekly, reveals that, once again, the TBAs were effective in their duties. An average of 38.1 tablets were given over 19.8 weeks. Based on two tablets per week, the compliance is calculated as 96.2 percent.

Table 4 shows the comparison of hematologic parameters between the experimental daily dose schedule (Group 1) and the Control (Group 3). There is an increase of 6.5 g/l over the 20-week period compared to a **decrease** (7.5 g/l) in the average hemoglobin levels of the Control group. In addition, there is a decrease in the proportion of anemic women (Hb<110 g/l) in the TBA group and an increase in the Control group from 13 % to 30 %.

TABLE 4: COMPARISON OF HEMOGLOBIN STATUS BETWEEN TBA AND CONTROL GROUPS

Parameters	Baseline	12 weeks	20 weeks
Group 1 TBAs (N=192)			
Hb (g/l ± SE)	114.4 ± 0.7	117.2 ± 0.9	120.9 ± 0.9
% Hb <110 g/l	29.2 %	22.9 %	14.6 %
Group 3 Control (N=114)			
Hb (g/l ± SE)	120.5 ± 0.9	116.6 ± 1.0	113.0 ± 1.1
% Hb <110 g/l	13.2 %	24.6 %	29.8 %

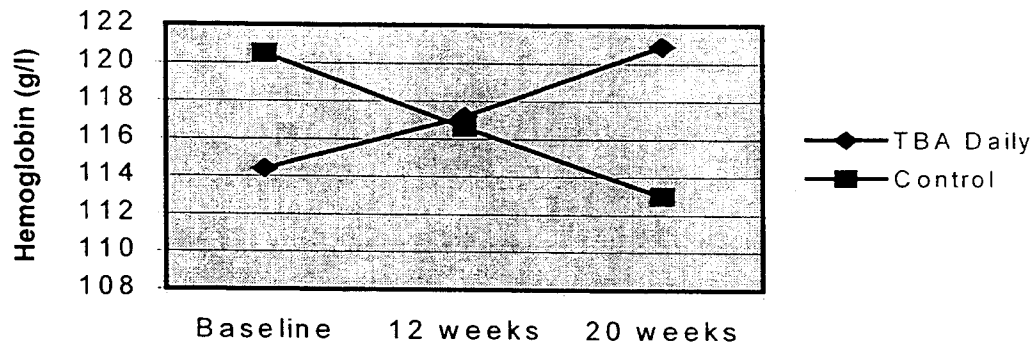


Figure 1. Change in hemoglobin levels over 20 weeks when iron tablets are administered by TBAs daily or in clinic setting (Control)

The hemoglobin response to iron supplementation is dose-dependent (see **Table 5** and **Figure 2** for dose-dependency illustration). From the data from Group 1, it is evident that women must take more than 80 tablets before there is an evident rise in hemoglobin. The higher the compliance (or the more tablets taken) the higher the rise.

TABLE 5: CHANGE IN HEMOGLOBIN LEVEL IN RELATION TO TOTAL INTAKE OF IRON (TBA-DAILY GROUP N=191)

No. of Tablets Consumed	Hemoglobin level (g/l)			Total Hb increase (g/l)
	Baseline	12 weeks	20 weeks	
<60 tabs (N=10)	110.2 ± 3.1	110.2 ± 2.6	110.6 ± 3.0	0.4 ± 4.0
60–79 tabs (N=27)	115.9 ± 1.9	114.3 ± 1.5	114.2 ± 2.2	-1.7 ± 2.2
80–99 tabs (N=70)	113.1 ± 1.1	115.2 ± 1.5	119.2 ± 1.3	6.1 ± 1.1‡
100–119 (N=47)	116.4 ± 1.1	120.6 ± 1.8	124.6 ± 1.3	8.2 ± 0.9‡
≥120 tabs (N=37)	114.1 ± 1.9	120.8 ± 2.4	126.7 ± 2.3	12.6 ± 2.2‡

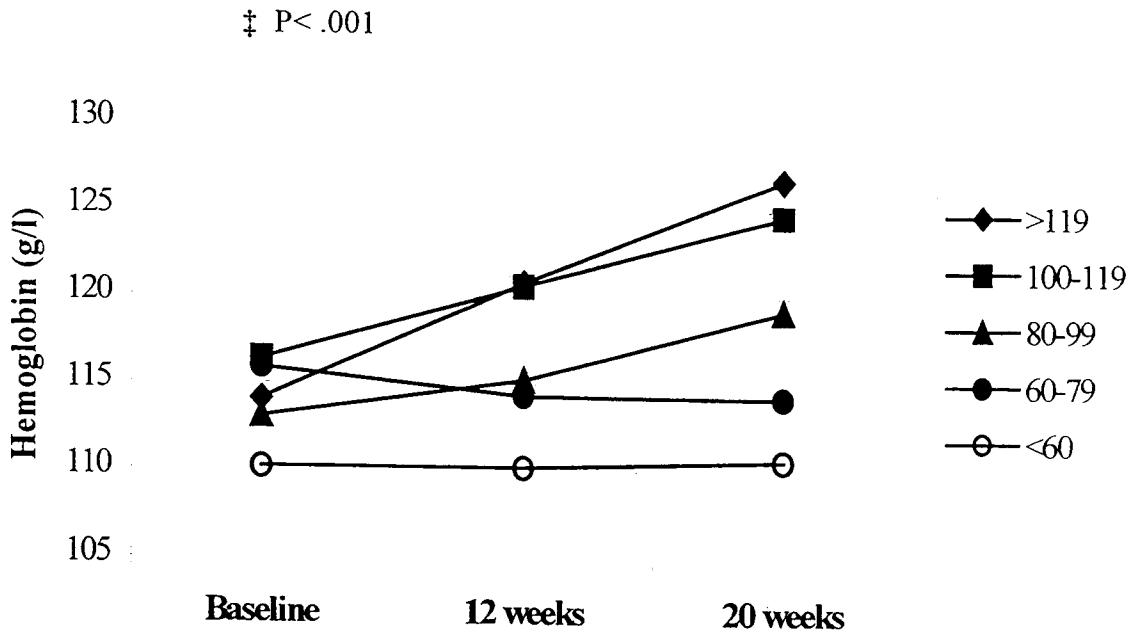


Figure 2. Hemoglobin responses in relation to number of iron tablets consumed

The women in the TBA groups (Groups 1 and 2) had weekly contact with the TBAs who were responsible for administering the tablets plus providing health education on the causes of anemia and the importance of iron supplementation.

Comparison of pre- and post-therapy (12 weeks) symptom data for Groups 1 and 3 reveal that although there were differences in hemoglobin improvement, there was similar improvement in perceived symptoms of fatigue, dizziness, and nausea. Group 1 did not see a greater decrease in anemia symptomatology than the Control.

Knowledge about the proper iron-rich or absorption-enhancing foods to consume improved in both groups. The only difference lay with fruit consumption, where it was seen that consumption by the TBA-Daily women increased whereas in the Control group it remained about the same.

Knowledge about the symptoms and risks of anemia improved in both groups but to a greater extent in the TBA-Daily group (see Table 6).

TABLE 6: IMPROVEMENTS IN KNOWLEDGE ABOUT ANEMIA

	Group	Percentage Knowing		P value
		Pre-test	Post-test	
Symptoms of anemia				
Dizziness	TBA	59	93	<.001
	Control	52	74	
Paleness	TBA	48	82	.051
	Control	42	67	
Did not know	TBA	34	0	.108
	Control	47	5	
Risks of anemia				
Abortion	TBA	5	23	<.001
	Control	15	14	
Stillbirth	TBA	16	53	<.001
	Control	19	36	
Delivery complications	TBA	6	18	<.001
	Control	12	10	
Did not know	TBA	72	8	<.001
	Control	68	34	

In addition, except for the consumption of green leafy vegetables, knowledge about the prevention of anemia improved more in the TBA-Daily group (Table 7) than in the Weekly and Control groups.

TABLE 7: KNOWLEDGE ON PREVENTION OF ANEMIA

	Group	Percentage knowing		P value
		Pre-test	Post-test	
Prevention of anemia				
Green leafy vegetables	TBA	59	86	.394
	Control	45	68	
Meats/other proteins	TBA	22	65	<.001
	Control	24	42	
Iron tablets	TBA	26	83	<.001
	Control	36	67	

Weekly versus Daily Iron Tablets

The second part of the study involved assessing the effectiveness of weekly (two iron tablets) versus daily (one iron tablet) administration. Once again, TBAs were used for the distribution of the iron tablets according to the two regimens. In order to control for variations in compliance,

only women in the two groups who had more than 50 percent compliance were compared. In the case of the Daily group, this totaled 161 subjects (took >70 tablets) and in the Weekly group 184 subjects (took >20 tablets). **Table 8** displays the results of hemoglobin measurements taken at baseline, 12 weeks, and 20 weeks, as well as the proportion of women with hemoglobin values below 110 grams/liter.

TABLE 8: COMPARISON OF HEMOGLOBIN STATUS BETWEEN TBA-DAILY AND WEEKLY (Compliance >50%)

Parameters	Baseline	12 weeks	20 weeks
Group 1 TBA-Daily (N=161)			
Hb (g/l ± SE)	114.5 ± 0.8	118.2 ± 1.0	122.5 ± 0.9
% Hb <110 g/l	29.2 %	19.9 %	10.6 %
Avg. Tabs consumed	-	65.4 ± 1.5	101.7 ± 1.3
Group 2 TBA-Weekly (N=184)			
Hb (g/l ± SE)	113.5 ± 1.1	113.1 ± 0.9	115.9 ± 0.9
% Hb <110 g/l	25.0 %	37.0 %	24.5 %
Avg. Tabs consumed	-	24.4 ± 0.3	38.3 ± 0.5

It is evident that in the Weekly group there is no significant rise in hemoglobin during the first 12 weeks. The approximate 2.4 g/l rise above baseline achieved by the 20-week assessment is trivial compared to the results of the daily regimen (8.0 g/l increase) (P< .001 by Kruskal-Wilcoxon test).

If one compares all the data (without adjusting for >50% compliance), the results are almost the same. This would be the case under actual field circumstances where one must accept the compliance achieved.

TABLE 9: COMPARISON OF TABLET CONSUMPTION BETWEEN TBA-DAILY AND -WEEKLY REGIMENS

REGIMEN	IRON TABLETS CONSUMED		
	12 WEEKS	12-20 WEEKS	TOTAL THERAPY
TBA-Daily (N=191)	60.0 ± 1.5	34.7 ± 1.0	95.0 ± 1.6
TBA-Weekly (N=186)	24.4 ± 0.3	13.8 ± 0.4	38.1 ± 0.6

The Weekly group of subjects received an average of 36 tablets less over a 12-week period and 57 tablets less over 20 weeks. Thus, the Daily subjects were receiving an average of 2160 mg more elemental iron than the Weekly in the first 12 weeks and 3420 mg more if administered for 20 weeks.

These results do not support the contention that weekly iron supplementation (even two tablets) has the same efficacy as daily iron supplementation. Although the weekly regimen does not give impressive results, the hemoglobin values did not decrease like in the Control group.

Ferritin Analyses: Paired pre- and post-therapy sera were available for analysis of ferritin levels in randomly selected subjects from each of the three groups. **Table 10A** below shows the results from the three groups.

TABLE 10A: PAIRED FERRITIN LEVELS IN SUBJECTS BEFORE AND AFTER INTERVENTION

GROUP	No.	Mean Ferritin level (mcg/l ± SE)		
		Baseline	12 weeks	Difference ⁽¹⁾
TBA-Daily	78	36.5 ± 3.6	23.0 ± 2.3	
TBA-Weekly	85	29.0 ± 3.1	14.1 ± 1.2	
Control	81	26.3 ± 2.6	14.0 ± 0.9	

⁽¹⁾ Mean difference

Ferritin, a measure of iron stores, dropped significantly ($P < .0005$) in all groups. Those with a ferritin level of < 10 mcg/l are considered iron depleted.

Table 10B shows the proportion of the women in each group who were iron depleted before and after the intervention. Since the ferritin data are not normally distributed, the comparison is expressed in median ferritin values rather than mean levels. Here it seems that depletion is less severe in the TBA-Daily group.

TABLE 10B: PAIRED FERRITIN LEVELS IN SUBJECTS BEFORE AND AFTER INTERVENTION

GROUP	No.	Median (mcg/l)			Proportion < 10 mcg/l	
		Baseline	12 Weeks	Change	Baseline	12 Weeks
TBA-Daily	78	27.8	23.0		14.1%	17.9%
TBA-Weekly	85	21.8	14.1		20.0%	36.5%
Control	81	18.0	14.0		23.5%	33.3%

Effect of Anthelmintics on Iron Supplementation

The goal of the original study was to test the efficacy of TBAs in improving the distribution and compliance of iron supplementation. An additional leg was added to test the effectiveness of anthelmintics in enhancing the response to iron supplementation. Each of the three groups noted above was divided equally into a) mebendazole treatment or b) placebo groups.

As the TBA-Daily group had the best response to iron supplementation, any effect of the anthelmintic would be most easily demonstrated here (**Table 11 and Figure 3**). It can be seen that the initial rise in the 12-week period was greater in the treated group than in the placebo, but then it became the same by 20 weeks. The 20-week differences are not significant. The data for the Weekly and the Control groups also do not show a difference between placebo and treated subjects.

TABLE 11: EFFECT OF ANTHELMINTHICS ON HEMOGLOBIN LEVELS OF WOMEN IN TBA-DAILY GROUP

		Baseline	12 weeks	20 weeks
Treated	Hgb (g/l)	N=103 113.4 ± 1.1	N=103 117.7 ± 1.3	N=98 121.2 ± 1.2
	%<110 g/l	33%	20%	15%
Placebo	Hgb (g/l)	N=97 114.9 ± 0.9	N=97 116.2 ± 1.2	N=94 120.4 ± 1.0
	%<110 g/l	26%	26%	15%

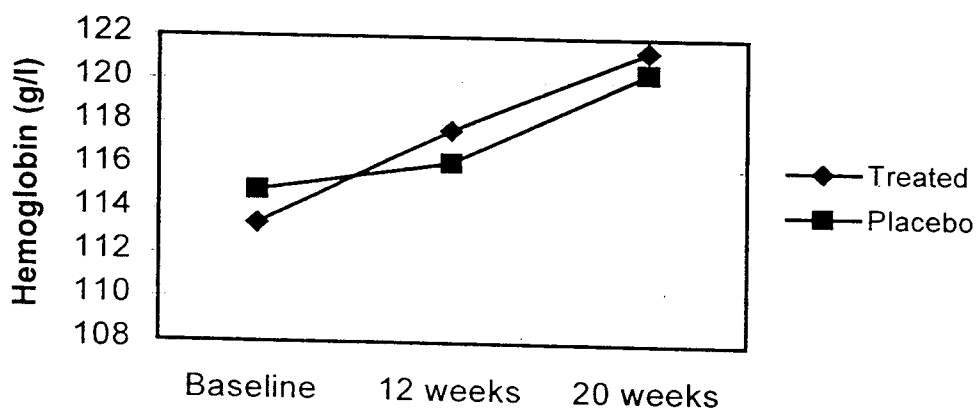


Figure 3. Change in hemoglobin levels in subjects taking mebendazole or placebo in the TBA-Daily group.

It is obvious that compliance is an issue that needs to be examined more closely. The compliance for this whole TBA-supplemented group averaged 70 percent with women taking an average 95 tablets over 139 days. If we look at the TBA group data only for subjects with compliance >50 percent (see Table 12 and Figure 4), we see the following:

TABLE 12: INFLUENCE OF ANTHELMINTHIC TREATMENT ON HEMOGLOBIN LEVELS IN TBA-DAILY SUBJECTS WITH >50% COMPLIANCE

Treatment	No.	Hemoglobin levels (g/l) \pm SE		
		Baseline	12 weeks	20 weeks
Mebendazole	84	114.1 \pm 1.1	119.1 \pm 1.4	122.8 \pm 1.4
Placebo	74	114.8 \pm 1.0	117.2 \pm 1.5	122.1 \pm 1.3

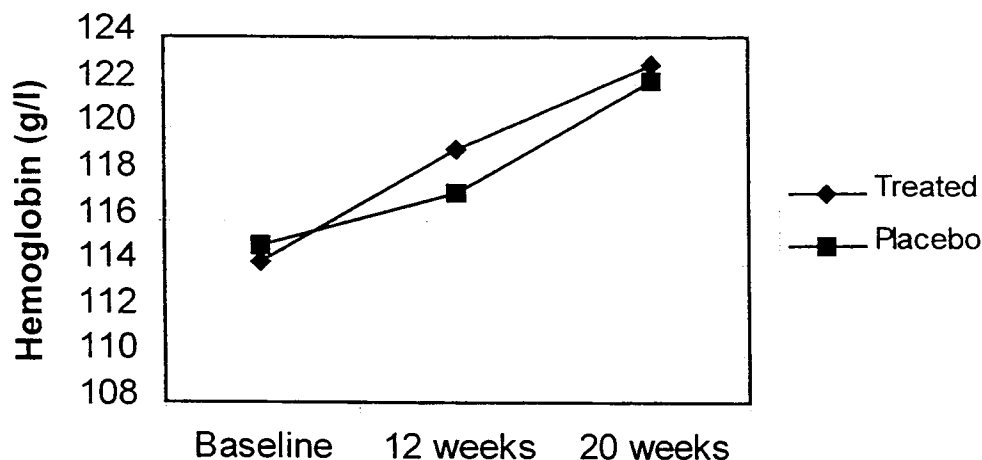


Figure 4. Change in hemoglobin levels in subjects on mebendazole or placebo in the TBA-Daily group who had >50% compliance in taking iron supplementation.

Once again, it appears there is no significant difference in the rise of hemoglobin levels between mebendazole-treated and placebo patients.

If both the Control and TBA-Daily groups are combined to get a larger sample (N=305) and the analysis performed once again only on subjects who had \geq 50% compliance, there is still no significant difference (Table 12).

TABLE 13: INFLUENCE OF COMPLIANCE ON HEMOGLOBIN LEVELS AMONG TREATED AND PLACEBO SUBJECTS COMBINED FROM THE CONTROL AND TBA-DAILY GROUPS

Compliance	Treatment	No.	Baseline	12 weeks	20 weeks
≥50%	Mebendazole	109	115.5 ± 1.0	119.2 ± 1.1	121.2 ± 1.1
	Placebo	99	116.0 ± 0.9	118.2 ± 1.1	120.5 ± 1.1
<50%	Mebendazole	46	117.8 ± 1.7	113.9 ± 1.9	112.4 ± 1.5
	Placebo	51	119.0 ± 1.5	112.4 ± 1.5	112.0 ± 1.5

These data do not seem to indicate that de-worming has an effect on hemoglobin levels when the compliance is at least 50 percent. Even for a higher compliance (60% and 70%), the results are the same—no difference.

If the analysis is done examining the effect of the number of tablets taken instead of compliance, the results are the same. See **Table 14** for those who have taken 75 or more tablets in the combined TBA and Control.

TABLE 14: INFLUENCE OF ANTHELMINTHIC TREATMENT ON HEMOGLOBIN LEVELS IN COMBINED TBA-DAILY AND CONTROL SUBJECTS RECEIVING >75 IRON TABLETS

Treatment	No.	Hemoglobin levels (g/l) ± SE		
		Baseline	12 weeks	20 weeks
Mebendazole	99	114.6 ± 1.0	118.9 ± 1.3	121.5 ± 1.2
Placebo	90	115.2 ± 1.0	117.6 ± 1.3	120.5 ± 1.2

Once again, there is no difference between de-wormed and placebo.

Examining the effect of the onset of treatment, it is seen that comparing those who started iron before four months compared to those who started at four months or later, there is no significant difference between placebo and treated. Moreover, analyzing by initial hemoglobin values (<110 g/l versus ≥110 g/l) also reveals no difference between de-wormed and placebo patients.

CONCLUSION

This study began as a straightforward assessment of the feasibility of TBAs participating in the distribution of iron/folate tablets in rural areas, where it has been seen that compliance is usually poor. The compliance issue is a combination of pregnant women's lack of knowledge on the importance of iron supplementation and the breakdown in the distribution system.

This operational research provided an opportune setting in which to examine the issues of daily versus weekly supplementation and the effects of de-worming on the hemoglobin response to supplementation.

TBA role in iron supplementation

The three study groups were similar and homogeneous in regard to health demographics. The only exception was the greater preponderance of malaria infection (historically) in the daily TBA group. Thus, this group began with somewhat of a disadvantage in raising hemoglobin levels during the course of pregnancy, as malaria chemoprophylaxis was not routinely offered in the project area.

Despite this burden, the TBA-Daily group demonstrated superior gains in hemoglobin during the study. It was shown that compliance was significantly greater in the TBA-Daily group when compared to the Control group where women were responsible for taking their medications *ad libitum* at home and obtaining the medication monthly from the health center. The village TBAs were able to visit their pregnant patients weekly and ensure the stock of tablets. In addition, they provided health education and motivation to the mothers to encourage consumption.

The compliance rate observed in the Control group was an estimate of the maximum since consumption could not be corroborated, and it relied on the number of tablets dispensed and reported by the mother herself. It is likely that the actual compliance was much less than the calculated 47 percent.

The additional iron consumption enjoyed by the TBA-Daily group made a significant difference in hemoglobin levels by 20 weeks while the levels dropped in the control group.

Ferritin levels dropped in all three groups, but without significant inter-group differences. Scatter plots of improvement in hemoglobin levels with changes in ferritin revealed no significant correlation. It was interesting that even when women took 60 or more tablets in the first 12 weeks with a rise of 8.5 g/l Hb, the ferritin level still decreased (from 32.3 to 24.1 mcg/l). The drop in ferritin level appears difficult to overcome despite good iron supplementation.

The original design of the study was to collect data for only 12 weeks of supplementation. However, it was observed that hemoglobin levels were only marginally affected, even when the compliance was good. Hence, it was decided to prolong the therapy for an additional eight weeks in as many cases as possible. Almost half (46.1%) of the subjects were able to continue the therapy for more than 140 days. The data revealed a clear dose-related response to the iron/folate tablets in that it was necessary to consume more than 80 tablets to obtain any

measurable rise in hemoglobin. Under the usual conditions in which women obtain their iron tablets from the health center or *Posyandu* and compliance runs less than 50 percent, one can safely conclude that the current ninety-day iron supplementation program is inadequate. Women need more than ninety tablets during their pregnancy. The current policy is barely effective if compliance is 100 percent, which is never the case.

Hence, the MOH needs to consider altering the iron supplementation policy to provide more tablets for a longer period of time or supporting a mechanism to drastically increase compliance. Given the current economic crisis in Indonesia, it is not realistic to hope that the MOH could financially support the increased distribution of iron/folate tablets. Thus, the best alternative is for the MOH to consider developing a policy and program for local village distribution of iron tablets by village midwives (where active) or through TBAs in areas still lacking a village midwife. This study has demonstrated that TBAs are capable of undertaking this task and providing health education. Knowledge on anemia symptoms, risks, and prevention increased.

A conjunctive qualitative study implemented under a sub-grant to Helen Keller International (HKI) concluded that TBAs were acceptable and likely candidates for "social marketing" and selling iron tablets in the village. The results of this study confirm the conclusions regarding their capability to distribute the tablets. What remains is a trial of "selling" the tablets since the TBAs in this study distributed the supplements free of charge and without personal compensation. Their motivation was primarily social and pursuant to increased prestige in the community, as was found in PCI's previous experience with enhancing the role of the village TBA discussed at the beginning of this paper.

Daily versus weekly iron supplementation

A controversy has raged over the issue of whether weekly or intermittent iron supplementation is as (or more) effective than the daily dose regime.^{2,3,4} This study provided a good opportunity to assess the effect of weekly iron supplementation on a well-monitored group of pregnant women under "field" conditions.

The results revealed that the daily dose regimen was far more effective than the once weekly regimen with two tablets. The daily regimen rose 8.0 g/l versus only 2.4 g/l for the weekly over twenty weeks of therapy. As presented in **Table 5** relating iron dose and response, the total amount of iron consumed plays a large role in the hemoglobin status. Proponents of the weekly regimen defend the strategy on the grounds of superior absorption. It is suggestive from these results that total dose has a greater impact on hemoglobin status than the advantages of improved absorption in the pregnant woman.

² Angeles-Agdeppa I, Schultink W, Sastroamidjojo S, Gross R, Karyadi D. Weekly micro-nutrient supplementation to build iron stores in female Indonesian adolescents. *American Journal of Clinical Nutrition* **66**: 77-183 (1997).

³ Ridwan E, Schultink W, Dillon D, Gross R. Effects of weekly iron supplementation in pregnant Indonesian women are similar to those of daily supplementation. *American Journal of Clinical Nutrition* **63**: 884-890 (1996).

⁴ Yip R. *American Journal of Clinical Nutrition* **63**: 1-3 (1996).

In the first twelve weeks of the regimen, the hemoglobin did not change in the Weekly group and actually dropped in the Control group. In this regard, the weekly regimen gave better results than the Control, but this is not enough to warrant advocating a major shift in supplementation policy. The weekly hemoglobin levels rose only marginally in the additional eight weeks of therapy.

In addition, although mean serum ferritin levels dropped in both groups, the median level was less, and the proportion that dropped below 10 mcg/l was less for the TBA group.

Effect of anthelmintics on iron supplementation

Recent work in Sri Lanka^{5,6} by WHO/Geneva (Dr. Savioli reference) suggests that decreasing the hookworm load would enhance the impact of iron supplementation in pregnant women. Although experimental, we are grateful to the Ministry of Health for giving their approval to the use of mebendazole in pregnant women entering their second trimester. Adding this study leg to the investigation required doubling the number of subjects in order to obtain the statistical power to measure an effect.

Results showed, however, that there was no appreciable benefit from the worm treatment in our subjects over twenty weeks. It is interesting that if the study had stopped at twelve weeks therapy as originally planned the conclusion would have been different. Indeed, it appears that there is an enhancement in the first twelve weeks, especially when controlled for good compliance. Hemoglobin rises 5.0 g/l in the mebendazole-treated mothers versus on 2.4 g/l in the placebo (see **Table 11 and Figure 4**). However, this small difference evaporates by the fifth month of iron therapy, even when desegregating for the trimester the medication was started.

Perhaps the factor here is that the worm loads in our Indonesian patients were not great enough to demonstrate an effect. Indeed, the survey conducted in 1996, on 209 women of childbearing age in the project area revealed that a high proportion of women were infected with ascaris (75.1%), trichuris (55.5%), and hookworm (average 72.7%). However, only 16 percent of those who were hookworm positive had a worm load greater than 1000 eggs/gram (see **Figure 5**). It is possible that with heavier hookworm loads, the effect of hookworm treatment on hemoglobin levels will be more noticeable.

⁵ De Silva H J, De Silva N R, Sirisena J L G J, Gunasekera D P S and Ismail M M. Effect of mebendazole therapy during pregnancy on birth outcome. *The Lancet* **353**: 1145-1149 (April 3, 1999)

⁶ Atukorala Sunethra TM, De C Dassenaeike Stanley T, Dechering Wim HJC, De Silva Dilip R L, Perera Rajitha S. Evaluation of effectiveness of iron-folate supplementation and anthelmintic therapy against anemia in pregnancy- a study in the plantation sector of Sri Lanka. *American Journal of Clinical Nutrition* **60**: 286-92 (1994)

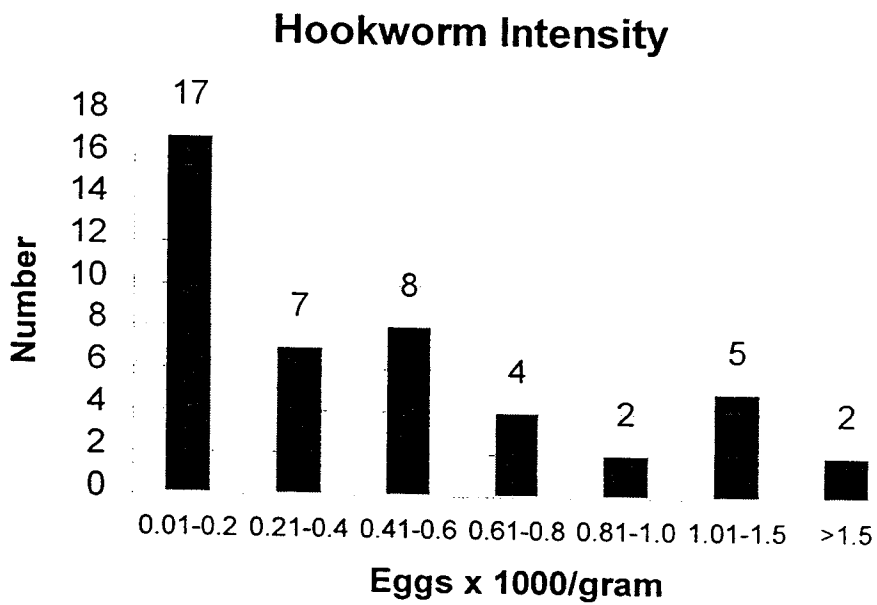


Figure 5. Egg counts reflecting intensity of hookworm infection in 45 randomly selected stool samples from survey of fertile women in the Maluku Province

APPENDIX A

DATE	ACTIVITY
September 1994	Submitted proposal to MotherCare
September 1995	Obtained approved funding
November 1995	Project activities begun MOU with MOH Develop training materials/curricula Focus Group Discussions
April 1996	Training of TBAs began Enrollment of subjects began
August 1996	Review of ferritin & hemoglobin data Project discontinued temporarily
September 1996	Purchase of HemoCue machines Arranged ferritin analyses at SEAMEO
October 1996	Trained midwives in HemoCue usage Refresher training for TBAs Begin enrolling new subjects
December 1997	Complete study Data entry and cleaning started
February 1998	Analysis of data started
March 1998	Report writing started

APPENDIX B

MALUKU PROVINCE

