Nutrition

Trial Effectiveness of Daily and Flexible Administration of Micronutrient Sprinkles to Control Anaemia in Young Children in Rural Bangladesh

Farhana Haseen
Ziauddin Hyder
Hedy Ip
Mizanur Rahman
Stanley Zlotkin

October 2005

BRAC Research Report

BRAC Research and Evaluation Division
BRAC Centre, 75 Mohakhali, Dhaka 1212, Bangladesh
E-mail: research@brac.net, Fax: 880-2-8823542, 8823614
Telephone: 9881265, 8824051, 8824180-87

Trial Effectiveness of Daily and Flexible Administration of Micronutrient Sprinkles to Control Anaemia in Young Children in Rural Bangladesh

Farhana Haseen
Ziauddin Hyder
Hedy Ip
Mizanur Rahman
Stanley Zlotkin

October 2005

Research and Evaluation Division
BRAC Centre, 75 Mohakhali, Dhaka 1212, Bangladesh
E-mail: research@brac.net, Fax: 880-2-8823542, 8823614
Telephone: 9881265, 8824051, 8824180-87
and
Sprinkles Global Health Initiative
The Hospital for Sick Children
555 University Avenue (8th Floor), Black Wing
Department of GI/Hepatology and Nutrition, MSG 1X8
Toronto, Ontario Canada
Telephone: (416) 813-6171

For more details about the report please contact: fhaseen02@yahoo.com

ACKNOWLEDGEMENT

This research was conducted through an academic collaboration between the SPRINKLES Global Health Initiative at the Hospital for Sick Children, Toronto, Canada and the Research and Evaluation Division of BRAC, Bangladesh. The necessary funding was provided through a generous donation from the H.J. Heinz Company Foundation. Special thanks to the fieldworkers at Kaliganj for their dedication and high quality fieldwork. We also thank and acknowledge Mr. Fazlul Karim, Ms. Nuzhat Choudhury, Late Mr. MG Sattar and Dr. Imran Matin for their support. Editorial support of Mr. Hassan Shareef Ahmed is highly acknowledged. Finally, we thank the mothers and the community at large without whose support and cooperation this research project would not have been successfully completed.

EXECUTIVE SUMMARY

Introduction and rationale

Iron deficiency anaemia is a major public health problem worldwide, especially in developing countries. Infants and young children aged between 6-24 months are one of the most vulnerable groups. Although iron intervention programme, such as iron-folate tablets, have been implemented for pregnant women at the national level in many countries, a suitable effective public health strategy to control childhood anaemia remains to be established. In response to this need, researchers at the Hospital for Sick Children and the University of Toronto in Canada developed "Sprinkles", an innovative 'home-fortification' strategy. Sprinkles consist of microencapsulated iron (as ferrous fumarate) and other essential micronutrients in powder form that are packed into single serve sachets, which are to be mixed into any kind of weaning food right before serving. The efficacy of Sprinkles in improving anaemia status of young children has been tested in several countries around the world. A previous efficacy trial in Bangladesh, testing daily and weekly administration of Sprinkles, revealed in focus group discussions that caregivers preferred more flexible instructions for Sprinkles use. Therefore, in this study, the flexible administration of Sprinkles was examined on the basis that it may increase programme effectiveness by improving adherence.

Subjects and methods

The study was carried out in 16 villages of Kaliganj upazila in Gazipur district, about 40 km north of Dhaka city. Gazipur district has agro-ecological characteristics similar to that of the plains in rural Bangladesh. A total of 362 children aged 6-24 months (haemoglobin concentration (Hb) $\geq$ 70g/L) were selected for the study. Children were randomized by village to receive 60 sachets of Sprinkles (containing 12.5 mg elemental iron) in two months (one sachet per day), or flexibly over three or four months. Under flexible administration, caregivers were able to decide how frequently to give Sprinkles, but were instructed not to give more than one sachet per day. Hb was measured at baseline, end of each intervention period, and six-month post-intervention from capillary blood via a finger prick. Only the children successfully treated for anaemia were followed-up for six months post-intervention. Adherence was assessed monthly by counting the number of sachets used through home visits. Caregiver acceptability was assessed at the end of intervention through interviews and focus group discussions (FGDs).

Data were analyzed with SPSS/WIN software and differences between and within groups were analyzed by chi-square, ANOVA and paired t-test, when applicable. Ethical clearance for the study was obtained from the appropriate authorities in Canada and Bangladesh. The study was conducted during May to September 2004.

Results

Households in the three intervention groups did not differ in indicators of socioeconomic status and childcare practices at baseline. Baseline mean Hb and anaemia prevalence did not differ among groups. Hb increased significantly from baseline to end of intervention by 11g/L, 13g/L and 17g/L in the daily-2-month, flexible-3-month and flexible-4-month groups, respectively. This increment was higher in the flexible-4-month group as compared to the daily-2-month group (P<0.01). Anaemia prevalence (Hb < 110g/L) was similar between groups at baseline and end, with an overall significant decrease from 77% to 39% (P<0.01). Anaemia resolved in

65% of the children in flexible-4-month group compared to 51% in the daily-2-month and 54% in the flexible-3-month groups (P=0.04). The percent of children who were successfully treated for anaemia and maintained a non-anaemic status at six-month post-intervention was significantly greater in the flexible-4-month (82%) and flexible-3-month (80%) groups compared to the daily-2-month group (53%) (P<0.01). Mean percent adherence was higher in the flexible-4-month group (98%) than the flexible-3-month (93%) and daily-2-month (88%) groups (P<0.01). FGDs suggested that both flexible models were preferred over daily administration by most caregivers because of perceived benefits, including more freedom and time to give Sprinkles, which resulted in less anxiety and psychological pressure associated with following the recommended instructions for use.

Conclusion

Based on the results, it can be concluded that flexible administration of Sprinkles over three and four months yielded better outcomes compared to daily administration with respect to haematological status, adherence and acceptability. It may be recommended that the flexible administration of 60 Sprinkles sachets over a four-month period may be more effective to control childhood anaemia at the population level because of increased adherence).

INTRODUCTION

Despite global nutrition goals and efforts in the past decade, iron deficiency anaemia continues to be the most common and preventable form of malnutrition worldwide. In South Asia alone, 60-75% of children under-5 suffer from anaemia and as high as 64% anaemia prevalence was observed among children aged 6-24 months in Bangladesh (1, 2). Iron deficiency anaemia has been associated with impaired cognitive, motor and language development in children, which may be irreversible (3,4). It has been estimated that a country may lose up to 4.1% of its gross domestic product (GDP) annually from physical productivity and cognitive losses due to iron deficiency (5).

Although there are multiple causes of anaemia, lack of dietary iron is the most common cause (6). Therefore, the World Health Organization (WHO) suggests that starting at six months of age children should be given frequent small complementary meals rich in micronutrients in addition to breast milk (7). However, in many developing countries, the late introduction of weaning food is common and infants are fed predominately cereal-based diets that lack nutrients and bioavailable iron (6). Supplementation with iron drops and syrup has been the primary therapeutic solution for the treatment of iron deficiency anaemia in children for many decades, but has not been effective as a large-scale public health intervention mainly because of poor adherence (8). A new goal for 2010 has been set by UNICEF to significantly reduce the prevalence of anaemia in children by one-third of 2003 levels (9). If this goal is to be achieved, new effective public health strategies must be implemented to control childhood anaemia.

MICRONUTRIENT SPRINKLES

Sprinkles were developed as an innovative 'home-fortification' strategy to deliver iron and other essential micronutrients to young children. They consist of microencapsulated iron (as ferrous fumarate) in a powder form packaged in single-dose sachets that are easy to use and transport, require no literacy and are to be mixed once daily into any available household complementary food right before serving (10). Microencapsulation of the iron prevents changes in the taste, colour and smell of food. Other important micronutrients such as vitamin C, vitamin A, zinc and folic acid are added to Sprinkles to improve the overall quality of complementary food. The efficacy, bioavailability and safety of Sprinkles have been demonstrated by several community-based trials (11-13). A large field trial in Ghana shows that Sprinkles (80 mg iron dose) are as efficacious as conventional iron drops in treating anaemia, with higher compliance and reported acceptability (11). Recently, a daily iron dose of 12.5 mg from Sprinkles (same dose recommended by WHO for iron supplementation in young children) was found to increase haemoglobin levels significantly and successfully treat anaemia within a two-month period (14). To increase the effectiveness of Sprinkles as a public health intervention, an optimal model of use or administration needs to be established.

RATIONALE

The rationale for this study was based on focus group discussions (FGD) conducted with mothers of children from an earlier Sprinkles efficacy study in Bangladesh (15). FGDs revealed that mothers preferred more flexible instructions for Sprinkles use. Mothers felt that a prescribed dosing regimen, whether daily or weekly, was rigid and strict. As a result, they reported feeling psychological pressure and anxiety. Many mothers reported often worrying about missing a dose, forgetting to give their child Sprinkles and feeling guilty if they did.

Thus, a flexible approach to using Sprinkles may be more convenient, attractive and easier to adhere to. Under a flexible regimen of Sprinkles use, caregivers would be instructed to give a specified number of sachets to their child over a specified period of time. However, caregivers themselves would decide how often to give sachets within this time, as long as no more than one sachet is given per day. Past studies have shown that even in controlled settings, daily compliance to Sprinkles on average ranges from 50-100%, yet significant increases in haemoglobin concentration have been achieved (15, 16). This suggests that flexible administration has the potential to be effective, as daily Sprinkles use may not be necessary for successful treatment outcomes. In this study, the flexible administration of Sprinkles was examined on the basis that it may increase programme effectiveness by improving adherence. The study was therefore designed to test the practicality of a more flexible approach to Sprinkles use in terms of its impact on haematological status, adherence and acceptability.

OBJECTIVES

- To assess the trial effectiveness of daily and flexible administration of Sprinkles to determine which would be most effective and suitable to control childhood anaemia in Bangladesh.

SPECIFIC

- To compare one daily and two flexible models of Sprinkles use on haematological status, adherence and acceptability in a rural community-based setting.

HYPOTHESIS

Haematological status, adherence and acceptability will be higher with flexible instructions to use Sprinkles compared to daily administration.

METHODS

STUDY AREA, POPULATION AND RECRUITMENT

The study was conducted during May to September 2004 in Kaliganj upazila under Gazipur district of Bangladesh. The rural area of Kaliganj has a population of 250,000 and is 40 km north of the capital city, Dhaka. It has similar geo-ecological characteristics to the rest of the plains in the country including high population density and fertile agricultural land. Like most rural parts of the country, villages in Kaliganj have limited access to health care services. Diets mainly consist of rice, vegetables and lentils, with occasional mixing of fish, poultry and meat. Malnutrition is widespread among women and children and the prevalence of malaria and hookworm is low (less than 2% among children under-2) (17). Infant mortality rate and low birth weight prevalence in the study area is comparable to the national averages for Bangladesh of 46 deaths per 1,000 live births and 30%, respectively (18).

For recruitment, children aged 6-24 months in Kaliganj were listed and screened through house-to-house visits. Infants who met the following criteria were enrolled in the study: i) 6-24 months of age at the time of recruitment; ii) consuming at least one regular meal of weaning food in addition to breast milk; iii) had haemoglobin concentration (Hb) $\geq$ 70g/L and no clinical sign of acute or chronic illness as reported by the caregivers; iv) were permanent residents of the village; v) were not receiving any other form of iron supplementation; and vi) parental consent obtained. Children who met the inclusion criteria were recruited until the total sample size was reached. Children with chronic illness or severe anaemia (Hb < 70g/L) were excluded at screening and received treatment free of cost at a local health centre. A total of 362 infants from 16 villages participated in the study.

STUDY DESIGN AND RANDOMIZATION

The study was a community-based, cluster-randomized trial that involved three intervention groups. Placebo control group was not used in the study due to ethical considerations. Field supervisors randomly assigned study villages to one of three intervention groups. Thus, children recruited from the same village (cluster) would be assigned to the same group. Since it was not possible to double blind mothers to administration, randomization by village was used to decrease bias by preventing 'contamination' or group crossover. Children were assigned to receive 60 sachets of Sprinkles (each containing 12.5 mg of elemental iron) either for two months on daily dose (daily-2-month group), or flexibly over three months (flexible-3-month group) or 4 months (flexible-4-month group). Caregivers whose children were randomized into the flexible-3-month and flexible-4-month groups were able to decide how frequently to give sachets to their child during the specified intervention period. However, they were instructed not to give more than one sachet a day. The study was designed to assess differences between the groups at the end of their intervention period and at six-month post-intervention (follow-up). In this study, blood was sampled at baseline, end of two, three, or four months, depending on the group's duration of intervention, and then again six months after intervention on eligible children. The rationale for delivering 60 sachets to all children was based on the demonstrated efficacy of a two-month supply of Sprinkles (14, 15).

COMPOSITION OF SPRINKLES

Each Sprinkles sachet was identical in content for all intervention groups and contained 12.5 mg of elemental iron (as microencapsulated ferrous fumarate), 300 μg of vitamin A (retinol

acetate USP), 5 mg of zinc (zinc gluconate USP), 50 mg of vitamin C (ascorbic acid USP-FCC) and 160 μg of folic acid (folic acid USP).

SPRINKLES DISTRIBUTION

The study was carried out in a community-based setting within an existing primary healthcare framework. In Bangladesh, over 40,000 community health workers (CHW) are trained by BRAC, the country's largest non-governmental organization (NGO), to address the basic health needs of the rural poor by delivering a variety of essential items at a low cost. Such items are oral rehydration saline (ORS), sanitary napkins, folic acid supplements and iodized salt. The CHWs are known as *Shastho Shebikas* (SS). In this study, SS from the 16 study villages distributed Sprinkles to participants as part of their regular programme activities. Since each community health worker visits every household in her village once a month, a monthly distribution of sachets was implemented to further facilitate real-life community conditions. The 60 sachets provided to each child in the study were divided by supplying the first 30 sachets at the start of the first month of intervention and the remaining 30 sachets in the second month for all groups.

Shortly after recruitment, mothers and children from each study village attended a group education and feeding session. The session was conducted by the local SS, who was trained by field supervisors to deliver information, education and communication (IEC) package on Sprinkles. Mothers were educated regarding iron deficiency anaemia, healthy weaning practices, and the proper use of Sprinkles and expected side effects. Moreover, a demonstration was given whereby each child was provided with a bowl of complementary food (a mixture of lentils, rice and spices) and mothers were instructed together to open one Sprinkles sachet, mix the powder contents into the food and feed the entire bowl of food to their child. The first monthly supply of sachets was given to caregivers at this time.

OUTCOME MEASURES AND DATA COLLECTION

Both quantitative and qualitative data collection methods were used in this study and field-based researchers of the Research and Evaluation Division of BRAC conducted all field activities. A group of five trained interviewers were responsible for data collection and two field supervisors managed the field operations. Demographic, socioeconomic and dietary practice information was collected for each child during a baseline interview using a structured questionnaire. Anthropometric assessment of length and weight was performed at baseline, end of intervention and six-month post-intervention using a standard technique (19). Child's weight was measured using the electronic bathroom scale (UNISCALE) to the nearest 100 g and length was measured using a wooden length board to the nearest 1 cm. Two fieldworkers completed anthropometric measurements in duplicate using the standard technique.

Haemoglobin

Haemoglobin was measured in the field setting from capillary blood via a finger prick using the portable HEMOCUE B-haemoglobin photometer (HemoCue®, Angelholm, Sweden) and standard techniques (20). Hb was measured at baseline, end of intervention and six-month post-intervention. Only children who were successfully treated for anaemia were included in the six-month follow-up. Children found anaemic at the end of intervention were excluded from follow-up and treated at a local health centre. In this study, anaemia was defined using the WHO cut-off for Hb (Hb<110g/L) (7).

Adherence

Adherence was assessed by calculating the percent of recommended sachets given to children throughout the intervention period. At the end of each month, fieldworkers counted the number of used (empty) and unused (full) Sprinkles sachets remaining and recorded the numbers on a pre-tested semi-structured questionnaire. Mothers were instructed at the beginning of the study not to discard any used sachets and to keep sachets in a zip lock polyethylene bag provided. Easy to use calendars were provided at the beginning of each month for mothers to mark and track the days when Sprinkles were given to the child. The number of Sprinkles sachets consumed, as calculated from used and unused sachets recorded, was crosschecked to calendar markings for consistency. In cases where inconsistencies appeared, fieldworkers probed mothers to clarify the actual number of sachets given to the child. Fieldworkers also verified with mothers whether sachets reported shared or lost were consumed by their child. During monthly assessment of adherence for the daily-2-month group, fieldworkers took back all sachets remaining at the end of each month (both used and unused). For the flexible-3-month and flexible-4-month groups, fieldworkers only collected empty sachets at the end of each month, thus allowing any remaining unused sachets to be available for use throughout the rest of the intervention period.

ACCEPTABILITY

Caregiver's attitudes about Sprinkles and the different administration models were examined at the end of intervention using qualitative assessment tools that included an in-depth interview using a pre-tested semi-structured questionnaire and FGDs. Interviews on acceptability were conducted on all caregivers by five trained and experienced interviewers. Only a sub-group of mothers were invited to participate in FGDs. A total of six FGDs were conducted, two sessions at the end of each group's intervention period (Appendix A). The first session involved six mothers, all from the same administration group. The second session was conducted shortly after the first one and included nine mothers (three from each administration group). A different set of participants was selected for each FGD. Mothers were selected by the field supervisors based on their ability to express a range of views. FGDs were facilitated by two field supervisors who acted as moderators. A note taker was responsible for detailed hand-written notes, which were then translated from the local language to English. As illustrated in Appendix B, transcribed notes were coded and organized into topics and themes using an Excel spreadsheet, and summarized (21).

Sample size and power

The total sample size needed for the study was based on Hb. It was determined that 73 children per intervention group were required in order to detect at least a 5 g/L difference in mean Hb between groups with a standard deviation (SD) of 17 g/L (adjusted for a cluster design effect) within these groups. The sample size calculation was based on using the one-way ANOVA multiple comparison test with type I error $\alpha = 0.05$ and power of at least 0.80. In estimating the dropout rate, we considered children who would be excluded from the six-month follow-up due to anaemia at the end of intervention. Thus, we estimated the proportion of children who would remain anaemic at the end of intervention to be 24% based on a previous study and assumed an additional 15% (for a total loss to follow up of 39%) for non-biological reasons such as emigration, acute sickness and withdrawal of parental consent (15). A total of 362 children were enrolled in the study to meet the final estimated sample size of at least 120 children per group.

Statistical analysis of data

All data collection forms were manually checked for completeness, consistency and range. Forms were then coded and data were processed and analyzed using SPSSWIN (version 11.0) statistical software. Data entry and cleaning was completed at the BRAC research field office at Kaliganj so that any queries could be resolved by rechecking original data forms or through repeat visit if required.

A one-sample Kolmogorov-Smirnov test was used to determine whether Hb and anthropometric measurements were normally distributed. The effect of the three administration models on the study outcomes was analyzed on an intent-to-treat basis. Differences were considered significant at $P<0.05$. Change in Hb from baseline to end of intervention within group was assessed using the Student's paired t-test. Mean Hb, background characteristics (age, length, weight) and mean adherence were compared among groups using the one-way ANOVA multiple comparison test with Bonferroni correction for differences. ANCOVA was used to control for possible confounding variables on Hb at the end of intervention. Similarly, Hb at 6-months follow-up was examined after controlling for possible confounders. The prevalence of anaemia and anaemia cure rate at baseline and end of intervention were compared between groups using chi-square analysis. Change in anaemia prevalence from baseline to end within group was assessed using McNemar's test. Z scores for length-for-age, weight-for-age and weight-for-height were calculated using the NCHS (National Centre for Health Statistics, Atlanta, USA) reference standard using EpiInfo.

Ethics and consent

Before initiating the study, meetings were held with some parents and community members in the study area to inform them about the study and seek community consent. All caregivers of children in the study gave written informed consent for their child's participation by signing or fingerprinting a consent form. Ethical clearance for this study was obtained from the Research Ethics Board at the Sick Kids Hospital (Canada) and the Bangladesh Medical Research Council (BMRC).

RESULTS

A total of 371 children were selected for the study. Of them, 362 were recruited from 16 villages and were randomly assigned by village to one of the three administration groups. Figure 1 shows a trial profile of the study. Reasons for exclusion from the study were: absence at the time of screening, severe anaemia, not consuming semi-solid foods, refusal of consent or illness. The age and sex distribution of children excluded and included in the study did not differ significantly. At baseline, the daily-2-month group consisted of 120 children from 5 villages and the flexible-3-month and flexible-4-month groups included 120 children from 6 villages and 122 children from 5 villages, respectively (Appendix C). Complete data were obtained for Hb at the end of intervention for 108/120 (90%), 115/120 (96%), 116/122 (95%) children in the daily-2-month, flexible-3-month and flexible-4- month groups, respectively. Dropout rates did not significantly differ among groups. At the end of their intervention period, 61/362 (16%) children could not be assessed because of absence due to illness, migration, withdrawal of parental consent and absence due to flooding and they were not significantly different among groups. Of the 339 children who completed the intervention, 148 became non-anaemic and were therefore eligible for follow-up at six-month post-intervention. At the six-month follow-up, 8 children were unavailable for reassessment due to long-term absence from the household. This loss was similar among groups and no differences in baseline characteristics were observed between these children and those who completed the post-intervention reassessment.

BASELINE CHARACTERISTICS

Mean Hb at baseline was similar among the three groups, with a combined value of 99 ± 14 g/L ($P = 0.52$) (Table 1). Overall 278/362 (77%) children were anaemic (Hb < 110g/L). The proportion of anaemic and non-anaemic children was similar among the three intervention groups ($P = 0.6$). Groups did not significantly differ in demographic variables, socioeconomic variables and mean Hb at baseline, but some differences were found in mean age, length and weight (Table 1). Age and weight were controlled for in the analysis to assess the effect on final Hb. Length was not controlled for since it was found to be highly correlated with weight. The nutritional status of the study children was poor, as indicated by the overall prevalence of stunting (29%), underweight (41.7%) and wasting (13.8%), (length-for-age, weight-for-age, weight-for-height Z scores < –2.0, respectively). Breastfeeding and dietary practices including age of weaning were also comparable among groups. Almost half of children (172/362) received weaning food starting at six months of age, as recommended by WHO. However, the late introduction of complementary food was observed in 67/362 (19%) of children. Only 22/362 (6%) children were reported to receive milk powder or infant formula (non-iron fortified). *Khichuri*, a rice-based porridge mixed with lentils and spices, was the most common weaning food fed to children in the villages. Literacy rate of mothers was similar among groups and was assessed by the percent of mothers with an education of at least primary school level.

Figure 1. Trial profile

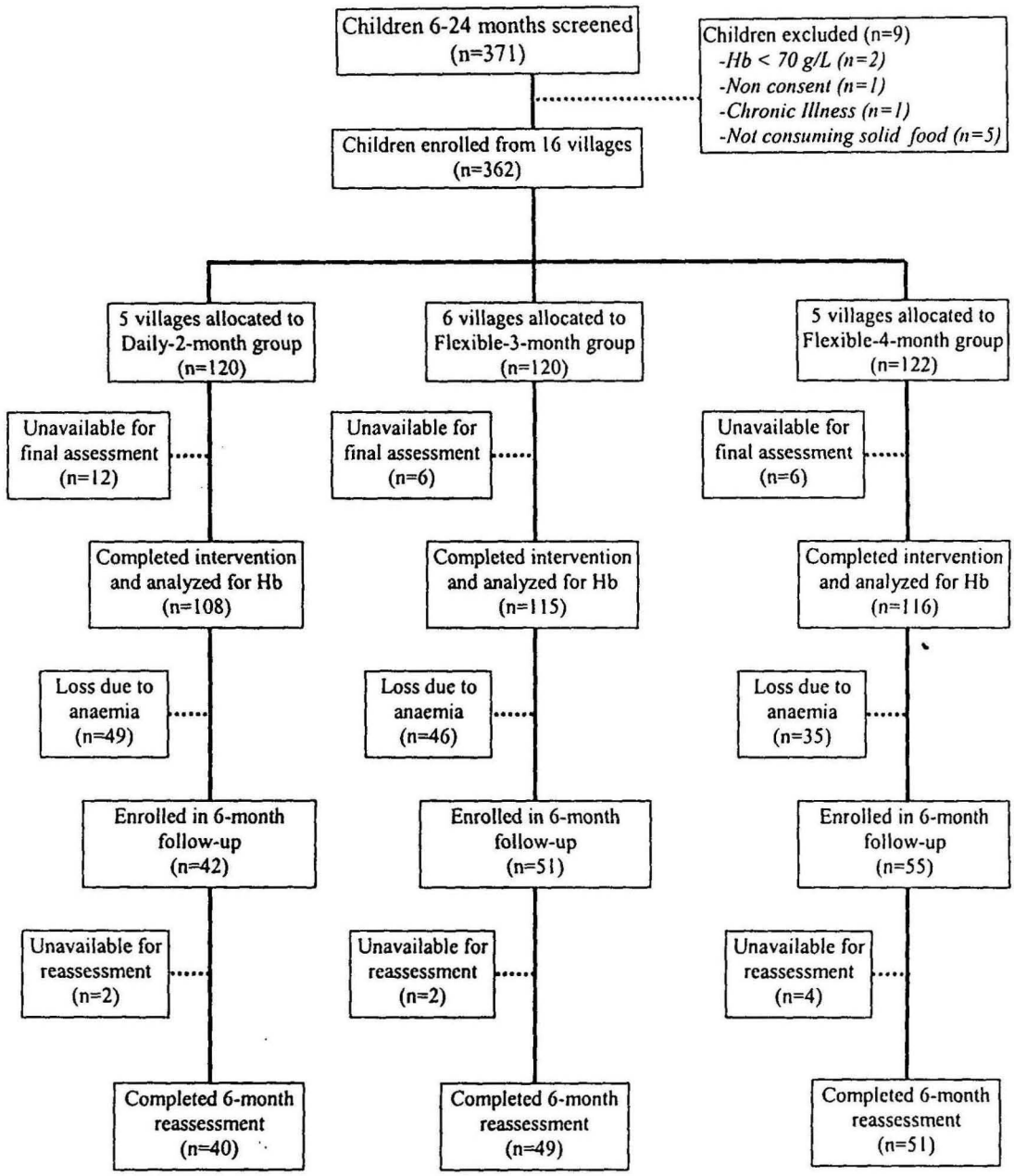


Table 1. General baseline characteristics of study children

Characteristic	Sprinkles administration group			
	Daily-2-month (n=120)	Flexible-3-month (n=120)	Flexible-4-month(n=122)	*P*-value[1]
Boys (%)	53.3	44.2	51.6	0.32
Age ± SD (months)[a]	15.4 ± 5.0	14.2 ± 4.3	16.3 ± 5.1	<0.01
Family size ± SD	5.6 ± 2.3	5.7 ± 2.4	6.1 ± 5.3	0.47
Mother's literacy (%)	60.8	60.8	56.5	0.67
Complementary food introduced >6 months (%)	19.1	14.2	22.1	0.29
Length ± SD (cm)[b]	74.7 ± 5.3	72.5 ± 4.9	74.8 ± 5.2	<0.01
Weight ± SD (kg)[b]	8.7 ± 1.4	8.1 ± 1.1	8.6 ± 1.2	<0.01
Wasting (%)[2]	14.2	11.7	15.6	0.67
Stunting (%)[2]	26.7	35.0	26.2	0.24
Underweight (%)[2]	40.8	40.8	43.4	0.89
Haemoglobin ± SD (g/L)	99.6 ± 15.0	97.6 ± 13.3	99.1 ± 15.0	0.53
Anaemia (%)	75.8	81.7	73.0	0.26

[a] Statistically significant between flexible-3 month and flexible-4- month group

[b] Statistically significant between daily daily-2-month and flexible-3-month group, and between flexible-3-month and flexible-4-month group

[1] P-values < 0.01 are for groups with different superscripts, derived from using one-way ANOVA analysis with Bonferroni multiple comparisons test.

[2] Proportion of children with *Z* scores < -2.0.

HAEMATOLOGICAL RESPONSE

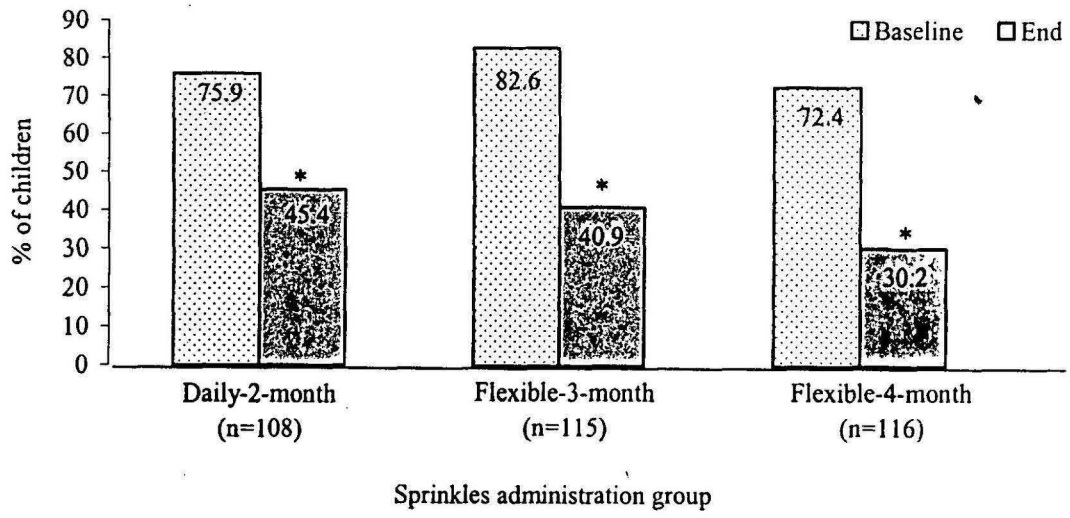
Mean Hb significantly increased from baseline to end of intervention for all groups (*P*<0.01) (Table 2). The flexible-4-month group showed a significantly greater increase in mean Hb from baseline to end (increment of 17g/L) compared to the daily-2-month (13g/L) group (*P*<0.01). However, there was no significant difference in Hb increase between the flexible-3-month group and the other two groups. The prevalence of anaemia among children at baseline and end of intervention was similar among groups (baseline *P* =0.41, end *P*=0.06) (Figure 2). A significant reduction in anaemia prevalence was observed among study children from thebeginning to end of intervention in all groups (*P*<0.01). Overall, 199/339 (58.7%) children responded positively to Sprinkles (Hb increase of ≥ 10g/L during intervention), which was comparable among groups (data not shown). There was no difference in socioeconomic status between children who became non-anaemic at the end of intervention and those that did not. Overall, anaemia resolved in 42/81 (51.5%), 51/95 (53.7%), 55/84 (65.5%) of children in the daily-2-month, flexible-3-month and flexible-4-month groups, respectively. The cure rate of anaemia was significantly higher in the flexible-4-month group compared to the daily-2-month group (*P*=0.05), although cure rate in the flexible 3-month group did not significantly differ from the flexible-4-month or daily-2-month groups (Table 2).

Table 2. Mean haemoglobin at baseline and end of intervention and percentage of children successfully treated for anaemia by administration group

Characteristic	Sprinkles administration group			
	Daily-2-month (n=108)	Flexible-3-month (n=115)	Flexible-4-month(n=116)	*P*-value
Haemoglobin ± SD[1] (g/L)				
Baseline	99.3 ± 15.2	97.5 ± 13.3	99.4 ± 14.7	0.52
End of intervention[a]	109.8 ± 15.1	110.9 ± 11.8	116.0 ± 12.2	<0.01[2]
Difference[b]	10.6 ± 18.0	13.4 ± 15.1	16.6 ± 16.2	0.03[2]
P-value for difference	<0.01	<0.01	<0.01	
Cure rate of anaemia[3,b] (%)	51.5	53.7	65.5	<0.01[4]

[a] Statistically significant between daily daily-2-month and flexible-4-month group, and between flexible-3-month and flexible-4-month group
[b] Statistically significant between flexible-2 month and flexible-4- month group
[1] SD = Standard deviation.
[2] P-value for groups derived from using ANCOVA analysis with Bonferroni multiple comparisons test.
[3] Proportion of anaemic children at baseline who became non-anaemic (Hb > 110g/L) at the end of intervention.
[4] P-value for groups derived from using Chi-square test.

Figure 2. Prevalence of anaemia (Hb < 110g/L) in children at baseline and end of intervention by administration group



* Statistically different from baseline, McNemar's test, $P<0.01$.

At the six-month follow-up, 148/260 (56%) children were eligible for reassessment because their anaemia resolved by the end of intervention. Finally 40/42, 49/51 and 51/55 children had their Hb measured in the daily-2-month, flexible-3-month and flexible-4-month groups, respectively. Table 3 shows that mean Hb at six-month follow-up significantly decreased from the end of intervention for the daily-2-month group only ($P<0.01$). However, mean Hb at follow-up and the end of intervention did not significantly differ in the flexible-3-month and flexible-4-month groups ($P>0.05$). The percent of children who maintained their non-anaemic status at six-month post-intervention was significantly higher in the flexible-4-month (82%) and flexible-3-month (80%) groups than the daily-2-month group (53%) ($P<0.01$). No difference in baseline socioeconomic characteristics was observed between children who remained non-anaemic and those who did not. Six-month post-intervention, the flexible-3-month and flexible-4-month groups maintained mean Hb achieved at the end of intervention (Table 3).

Table 3. Mean haemoglobin for children who became non-anaemic at the end of intervention and percent remaining non-anaemic at 6-month post-intervention by administration group

Characteristic	Sprinkles administration group			
	Daily-2-month (n=40)	Flexible-3-month (n=49)	Flexible-4-month(n=51)	*P*-value
Haemoglobin ± SD (g/L)				
Baseline	96.4 ± 11.4	93.0 ± 9.8	93.8 ± 9.9	0.30
End of intervention	120.1 ± 7.3	118.5 ± 6.4	120.5 ± 7.9	0.35
6-months follow-up[a]	110.2 ± 16.1	118.6 ± 12.0	118.6 ± 8.8	<0.01[2]
P-value within group[3]	<0.01	0.97	0.11	
Non-anaemic six-month post-intervention (%)[a]	52.5	79.6	82.4	<0.01[4]

[a] Statistically significant between daily daily-2-month and flexible-3-month group, and between daily-3-month and flexible-4-month group

[1] Only children who were successfully treated for anaemia at the end of intervention were included.

[2] P-value for groups derived from using ANCOVA analysis with Bonferroni multiple comparisons test.

[3] P-values for within group differences between mean Hb at the end of intervention and 6-months follow-up.

[4] P-value for groups derived from using Chi-square analysis.

ADHERENCE TO INTERVENTION

Mean adherence among groups was expressed as the mean percent of sachets given by caregivers out of the total 60 sachets recommended in the study (Table 4). On average, children in the flexible-4-month group consumed 98.2±5.6% of the 60 sachets throughout their intervention period. This mean adherence was significantly higher than the flexible-3-month group (92.7±14.6%) and daily-2-month group (88.4±12.3%) (P<0.01). The flexible-4-month group had the greatest proportion of children receiving all 60 sachets compared to the flexible-3-month and daily-2-month groups (P<0.01). In monthly assessment surveys, no caregiver reported of giving more than one sachet of Sprinkles a day to their children. All caregivers reported of mixing the full content of each sachet into weaning food during meals and over 90% reported that their children ate the entire amount of Sprinkles-mixed food at every meal. Less than 1% of mothers reported sharing or giving Sprinkles to a non-study child. A positive dose response relationship was observed between final Hb and the number of sachets consumed. Monthly assessment of adherence also revealed that caregivers in the daily-2-month group on average gave 27 (45% of 60) sachets in the first month and 26 (43%) sachets in the second month (data not shown). For the flexible-3-month group, a mean of 22 (37%) sachets were given in the first month, 21 (35%) in the second month and 12 (20%) in the third month. Mean percent administration of sachets for the flexible-4-month group was 21 (35%), 20 (33%), 13 (22%) and 5 (8%) for months 1, 2, 3 and 4 of the intervention, respectively. No caregivers in the flexible-3-month or flexible-4-month group gave all the 60 sachets to their children within the first two months of intervention.

Table 4 Mean percent adherence and percent of recommended sachets consumed by administration group

Characteristic	Sprinkles administration group			
	Daily-2-month (n=111)	Flexible-3-month (n=113)	Flexible-4-month (n=110)	*P*-value
Mean adherence[1] ± SD[a]	88.4 ± 12.3	92.7 ± 14.6	98.2 ± 5.6	<0.01[2]
Consumed all 60 sachets (%)	13.5	58.4	86.4c	<0.01[3]

[a] Statistically significant differences among groups.

[1] Mean percentage of sachets consumed out of the 60 sachets recommended.

[2] P-value for groups derived from using ANCOVA analysis with Bonferroni multiple comparisons test.

[3] P-value for groups derived from using Chi-square analysis.

CAREGIVER ACCEPTABILITY

During in-depth interviews on acceptability, caregivers were asked to rank the necessity of Sprinkles for their children's health based on a five point scale where 1 meant 'extremely needed', 2 'somewhat needed', 3 'not sure', 4 'somewhat not needed' and 5 'extremely not needed'. Over 94% of mothers felt the Sprinkles intervention was 'extremely useful'. More than 95% of mothers reported noticeable changes in their children after using Sprinkles. The most commonly observed changes were an increase in appetite, increase in activity and playfulness, more strength and 'chubbiness'. Sprinkles were also found to mix well with food by most mothers (>98%) and to have 'no' or 'mild' effect on the colour, taste or smell of food. When asked whether caregivers would buy Sprinkles for their children if available in the market, the majority of those mothers said they would 'definitely' (82%) or 'most likely' (16%) purchase Sprinkles. No mothers reported experiencing a problem using Sprinkles and caregivers from both the flexible-3-month and flexible-4-month groups found instructions for flexible administration clear and easy to follow. Table 5 summarizes caregivers' main perceptions of the strengths and weaknesses of daily and flexible administration (over three and four months), as revealed in FGDs. These points reflect the majority of mothers' opinions and were the most commonly discussed issues during FGDs. The mothers were asked to decide as a group which administration models (daily vs. flexible) would be most preferred if Sprinkles were available in their village. Main themes in Table 5 guided the debate and decision of mothers. Almost all mothers preferred flexible administration because of benefits such as more time, autonomy and lass anxiety associated with giving sachets. Many mothers revealed in FGDs that since using Sprinkles, they have spent more time and efforts to prepare complementary meals for their child.

Table 5. Caregivers' perceptions on the strengths and weaknesses of Sprinkles administration models from focus group discussions

Model	Daily Administration (over 2 months)	Flexible Administration (over 3 or 4 months)
Strengths	• May be easier to remember since daily use can turn into a daily habit • "Sprinkles will work faster on child if given daily" • Short intervention period	• More time to finish using all sachets, therefore less pressure and anxiety associated with giving sachets • More efficient use of Sprinkles, as sachets can be saved for a more appropriate time (eg. a day when child has good appetite or is not ill) • "More freedom to feed Sprinkles at my own wish"
Weaknesses	Too rigid and causes caregivers to worry about forgetting to give sachets and missing a dose Need to forcefully feed child if he/she has low appetite on a particular day, in order to comply with daily use	"Takes more time for Sprinkles to work on child" Longer intervention period 'Occasional' feeding of Sprinkles may make the giving of sachets seem less important

SIDE EFFECTS

During monthly visits by fieldworkers to assess adherence, caregivers were asked about any side effects. After the first month of intervention, change in the colour of stool was reported by 291/334 (87%) caregivers and diarrhoea was observed in 136/334 (41%) children. Constipation and vomiting were reported by 254/334 (76%) and 110/334 (33%) caregivers after the first

month, respectively. The occurrence of dark stool, vomiting and constipation were similar among groups. Diarrhoea was significantly higher in the flexible-4-month group compared to the other two groups ($P<0.01$). Few caregivers reported stomach upset as a side effect. It is likely that many side effects reported were a result of other factors than Sprinkles such as acute illness and disease. Since a placebo group was not included in this study, it was not possible to determine whether reported side effects were due to Sprinkles or other causes.

DISCUSSION

The current study was designed to test the practicality of a more flexible approach to Sprinkles administration in terms of haematological status, adherence and acceptability. Findings support our hypothesis that flexible administration is more effective than daily Sprinkles use in a rural community setting. In terms of haematological impact, we found both short and long-term benefits of a 3-month and 4-month flexible regimen of Sprinkles use. In the short-term, flexible administration achieved better outcomes on improvement of Hb and anaemia cure rate compared to a daily regimen. In the long-term, a flexible regimen over three and four months prevented the reoccurrence of anaemia in the majority of study children even six-months after receiving Sprinkles.

The 'mucosal block' theory suggests that less frequent or intermittent supplementation may yield better iron absorption and retention than daily by matching mucosal turnover (22). Based on this concept, an initial oral dose of iron would load the mucosa and impair the absorption of subsequent daily doses of iron. Thus, it has been suggested that a weekly or intermittent dose frequency may be more efficacious than daily regimens by overcoming the inhibition in absorption from iron given the previous day and because absorption decreases as haematological status improves (23,24). Although the mucosal block has mainly been observed in animal studies, it may help explain the better haematological outcomes observed with flexible administration since the average number of sachets used monthly was less in the two flexible groups than in the daily group. However, in this study we could not assess whether flexible administration would have followed an intermittent pattern since adherence was not supervised. Monthly calendars used in this study were subject to errors from reporting and memory aid were not a reliable source to observe the day-to-day consumption pattern of sachets in study groups. Therefore, a physiological benefit of flexible administration may be possible, but was not measured.

With regard to adherence and ease of use, we found that a flexible regimen was also preferable to daily Sprinkles use. Greater adherence was achieved with the flexible-4-month approach, possibly due to a longer duration of intervention, which allowed more sachets to be consumed. Indeed, adherence was observed to have a significant positive relation with the degree of Hb increase. The build-up of iron stores during the intervention may explain the long-term effect of flexible administration. As a result of greater or less frequent Sprinkles usage, children in the flexible groups were likely to build up more iron stores, which may explain the favourable sustained long-term effect on Hb observed. The measurement of iron stores through serum ferritin concentration would have been informative, however was not feasible in the current study due to discomfort associated with withdrawing a blood sample from young children.

As revealed in FGDs, most caregivers regarded Sprinkles as a food-based strategy rather than a medicine and thus found the flexible use of Sprinkles more attractive and easier to adapt to since it was not rigid like typical medicinal models. Caregivers' perceived benefits of flexible administration likely accounted for higher adherence observed in the two flexible groups, whereas side effects seemed to have no significant effect on adherence in this study.

The greater increase in Hb achieved in the two flexible groups can be explained by higher adherence based on the positive dose response observed.

Although safety was not measured in this study, the over use of Sprinkles sachets with daily or flexible administration in an unsupervised setting is unlikely. No incidences were found or reported where a child received more than one sachet a day. The iron dose in each sachet was also relatively low (12.5 mg) and the number of sachets supplied at a time was limited to 30.

STUDY LIMITATIONS

Although a control group was not included in the study due to ethical considerations, it is highly unlikely that improved Hb status seen in children would have occurred had no treatment been provided. Dietary iron intake is insufficient for young children in rural Bangladesh due to poor quality food and weaning practice (25). Other factors that could influence Hb, such as prevalence of disease and infection, access to healthcare facilities and food supply are also similar among villages in the study area and were unlikely to have changed during the study. Examination of the socioeconomic and demographic characteristics of study groups showed little or no difference, indicating that differences observed in study outcomes were most likely due to the three administration models.

From a programme evaluation standpoint, it was meaningful to compare the three administration models as whole strategies by measuring final Hb at the end of each intervention period. However, as final assessment of Hb was not measured at the same time for the three groups, it could be argued that this may bias Hb response. It is possible that the favourable Hb response observed in the flexible-4-month group may have been influenced by increased mean age. However, it is unlikely that Hb status in older children would have been significantly different than children younger by 2-3 months since foods consumed by older children in the villages are insufficient to meet iron needs. Furthermore, age was controlled in the analysis and no significant association was found between age and Hb status.

GENERALIZATION

The study villageswere homogeneous with other villages in the rural plains of Bangladesh with respect to socioeconomic and agro demographic characteristics. The sample of children aged 6-24 months showed an anaemia prevalence profile similar to figures obtained by a recent national anaemia survey and may be considered representative of the under-2 children in Bangladesh (2). We believe that the results from this study may be generalized to most rural communities in South Asia as the prevalence of anaemia is high, complementary foods are insufficient in dietary iron, late introduction of semi-solid foods, and prolonged exclusive breastfeeding is common in the region (17, 27). Anaemia is not always associated with iron deficiency. It is therefore likely that many children in rural Bangladesh suffer from anaemia due to other nutritional deficiencies, chronic bacterial, fungal and parasitic infections, which could account for part of the anaemia prevalence (26). This would explain why about half of the children were non-responders to the intervention in the current study.

IMPLICATION OF FINDINGS

The use of a flexible administration model is potentially important in large-scale public health programme for several reasons. A flexible approach is more convenient and thus more likely to be adhered to. The flexible administration of Sprinkles is also important for programme settings where the supervision of adherence is difficult. Since 1998, WHO has recommended long term iron supplementation to infants aged 6-24 months to control anaemia where the prevalence is 40% or higher (28). Currently, there are no successful public health interventions

to control childhood anaemia that are implemented on a large-scale. Based on our findings, the flexible administration of Sprinkles has the potential to fill the need for an effective programme to control childhood anaemia. Furthermore, Sprinkles can be integrated as a community-based approach into existing healthcare programmes for sustainability, as demonstrated by involving *Shashto Shebikas* in the distribution of sachets in our study. Moreover, Sprinkles may yield additional public health benefits by promoting the timely introduction of weaning food since semi-solid foods are required to be mixed with Sprinkles for use.

One major development priority for 2010 is to reduce the worldwide prevalence of anaemia in children by one-third of 2003 levels (9). In this study, both daily and flexible administration of 60 Sprinkles sachets was able to decrease overall anaemia prevalence by 51% –exceeding the one-third target. These results suggest an important role of Sprinkles towards achieving this global development goal.

CONCLUSION

1. Sprinkles with iron and other essential micronutrients such as zinc and vitamin A could play a significant role in reducing anaemia in under-2 children.
2. Flexible administration of Sprinkles over three and four months was more acceptable, more effective in treating anaemia and better able to prevent the reoccurrence of anaemia within six months after intervention, compared to daily administration.
3. There are both short- and long-term benefits of flexible administration over three and four months on haematological status.
4. Flexible administration of Sprinkles over four months yielded better outcomes on haemoglobin increase, anaemia cure rate and adherence than flexible administration over three months.
5. The flexible administration of 60 Sprinkles sachets over a 4-month period may be more effective to control anaemia in young children at the population level.
6. Once the iron status of the children is restored, iron stores are likely to remain adequate for a long period of time.
7. The Sprinkles intervention in general was well accepted by the mothers and caregivers as well as by the community at large.
8. The Sprinkles intervention may promote healthier weaning practice through its instructions of use and education component.

FUTURE DIRECTIONS

On the basis of the results from this study the following recommendations are made for further research:

1. A study should be carried out to see why a proportion of young children did not respond to treatment and recover from anaemia.
2. A longer-term evaluation study should be conducted to assess the impact of flexible administration over four months in preventing the reoccurrence of anaemia up to one year after receiving Sprinkles.
3. Important next steps in the scaling-up of Sprinkles distribution will be to evaluate the true effectiveness of flexible administration to control childhood anaemia through large pilot projects.
4. A cost-benefit analysis should be conducted to estimate the cost-effectiveness of the flexible administration of Sprinkles over four months as a public health programme for young children.
5. The trial effectiveness of flexible administration of Sprinkles should be studied as a potential strategy to control anaemia in other vulnerable populations such as pregnant women and adolescent girls.
6. Sprinkles studies have mainly been conducted in rural settings. Recognizing that iron deficiency anaemia is a major problem in diverse populations and communities within developing countries, Sprinkles effectiveness studies should extend to include other settings such as urban slum areas.
7. Studies on the flexible administration of Sprinkles should be carried out in other developing countries to assess its effectiveness under different sociocultural settings.
8. In this study, village community health workers were used in the local distribution of Sprinkles. Other methods of distribution should be explored and examined such as the private sector.
9. Appropriate measure should be taken to scale-up the Sprinkles intervention in Bangladesh to reduce iron deficiency anaemia among infants and young children.
10. While Sprinkles should be available to the general population, efforts need to be made to cover the poorest through BRAC's TUP (Target Ultra Poor) Programme.

REFERENCES

1. ACC/SCN. Nutrition for improved development outcomes. 5th Report on the world nutrition situation. Geneva: Administrative Committee on Coordination: Subcommittee on Nutrition (ACC/SCN), 2004.
2. BBS/UNICEF. Anaemia prevalence survey of urban Bangladesh and rural Chittagong hill tracts 2003. Dhaka: Bangladesh Bureau of statistics and UNICEF, 2004.
3. Walter T, et al. Cognitive effect at 5 years of age in infant who were anemic at 12 months: a longitudinal study [Abstract]. Padiatr Res. 1990; 28:295.
4. Lozoff B, et al. Poorer behavioural and developmental outcome more than 10 years after treatment for iron deficiency in infancy. Padiatrics 2000;105(4):E51.
5. Ross J and Horton S. Economic consequences of iron deficiency. Ottawa: Micronutrient Initiative.
6. Gibson RS, Ferguson EL, Lehrfeld J. Complementary foods for infant feeding in developing countries: their nutrient adequacy and improvement. *Eur J Clin Nutr* 1998;52(10):764-70.
7. WHO. Malnutrition. The global picture. Geneva: World Health Organization, 2000.
8. Nestel P and Alnwick D. Iron/multi-micronutrient supplements for young children. Summary and conclusions of consultation held at UNICEF. 1997. Copenhagen: August 19-20, 1996: Washington DC, ILSI.
9. UNICEF, Delivering essential micronutrients: Iron. http://www.unicef.org/nutrition/index_iron.html. 2003.
10. Schauer C and Zlotkin S, Home-fortification with micronutrient sprinkles-a new approach for the prevention and treatment of nutritional anemias. *Paediatric Child Health* 2003;8(2):87-90.
11. Zlotkin S, et al. Treatment of anaemia with microencapsulated ferrous fumarate plus ascorbic acid supplied as sprinkles to complementary (weaning) foods. *Am J Clin Nutr* 2001;74(6):791-5.
12. Tondeur MC, et al. Determination of iron absorption from intrinsically labeled microencapsulated ferrous fumarate (sprinkles) in infants with different iron and hematologic status by using a dual-stable-isotope method. *Am J Clin Nutr* 2004;80(5):1436-44.
13. Chan M, et al. The role of microencapsulated ferrous fumarate sprinkles in improving iron status and cognitive ability in preschool children in Northern China [Abstract]. *In:* International Anemia Consultative Group. INACG Symposium: 42. Washington DC:ILSI, 2003.
14. Zlotkin SH, et al. Home fortification using sprinkles containing 12.5 mg of iron successfully treats anemia in Ghanian infants and young children [Abstract]. *FASEB J* 2004:18.
15. Hyder SMZ, et al. Efficacy of daily vs. weekly home fortification of weaning foods with Sprinkles among infants and young children in Bangladesh. *In:* Workshop proceedings of the national workshop on home fortification of weaning food with sprinkles: a new strategy to control iron deficiency anemia among infants and young children. Dhaka:BRAC, 2004:1-24.
16. Zlotkin S, et al. Use of microencapsulated iron(II) fumarate sprinkles to prevent recurrence of anemia in infants and young children at high risk. Bull World Health Organ, 2003. 81(2):108-15.
17. HKI/IPHN. High anemia prevalence among Bangladeshi children in urban slums: an ethical and economic rationale for multi-micronutrient supplementation? *In:* Nutritional surveillance project urban anemia prevalence bulletin. Dhaka: Helen Keller International/Institute of Public Health, 2000.
18. UNICEF. The state of the world's children 2005: Focus on nutrition. 2005: Oxford: Oxford University Press, 2005.
19. WHO. Measuring changes in nutritional status. Geneva: World Health Organization, 1993.

20. Cohen AR and Seidl-Friedman J, HemoCue system for hemoglobin measurement: evaluation in anemic and nonanemic children. *Am J Clin Pathol* 1988;90(3):302-5.

21. IDRC. Designing and conducting health systems research projects: Volume 1. Module 10C: Focus Group Discussion. Canada: International Development Research Centre, 2004. http://www.idrc.ca/fr/ev-56615-201-DO_TOPIC.html. Accessed in December 2004.

22. Viteri FE, et al. True absorption and retention of supplemental iron is more efficient when iron is administered every three days rather than daily to iron-normal and iron-deficient rats. *J Nutr* 1995;125(1):82-91.

23. Cook JD and Reddy M. Efficacy of weekly compared with daily iron supplementation. *Am J Clin Nutr* 1995;62:117-20.

24. Ekstrom EC, et al. Efficacy and trial effectiveness of weekly and daily iron supplementation among pregnant women in rural Bangladesh: disentangling the issues. *Am J Clin Nutr* 2002;76(6):1392-400.

25. Lutter CK and Rivera J. Nutritional status of infants and young children and characteristics of their diets. *J Nutr* 2003; 133:2941-9S.

26. Weiss G and Goodnough LT, Anemia of Chronic Disease. *N Engl J Med* 2005;352:1011-23.

27. Khan ME. Breast-feeding and weaning practices in India. *Asia Pacific Popul J* 1990;5(1):71-88.

28. INACG/WHO/UNICEF, Guidelines fot the use of iron supplements to prevent and treat iron deficiency anemia. Washington DC:International Life Science Institute, 1998.

APPENDIX B

SAMPLE OF FOCUS GROUP DISCUSSION CODED NOTE SHEET

Daily vs. Flexible Administration Sprinkles Study
Research and Evaluation Division, BRAC

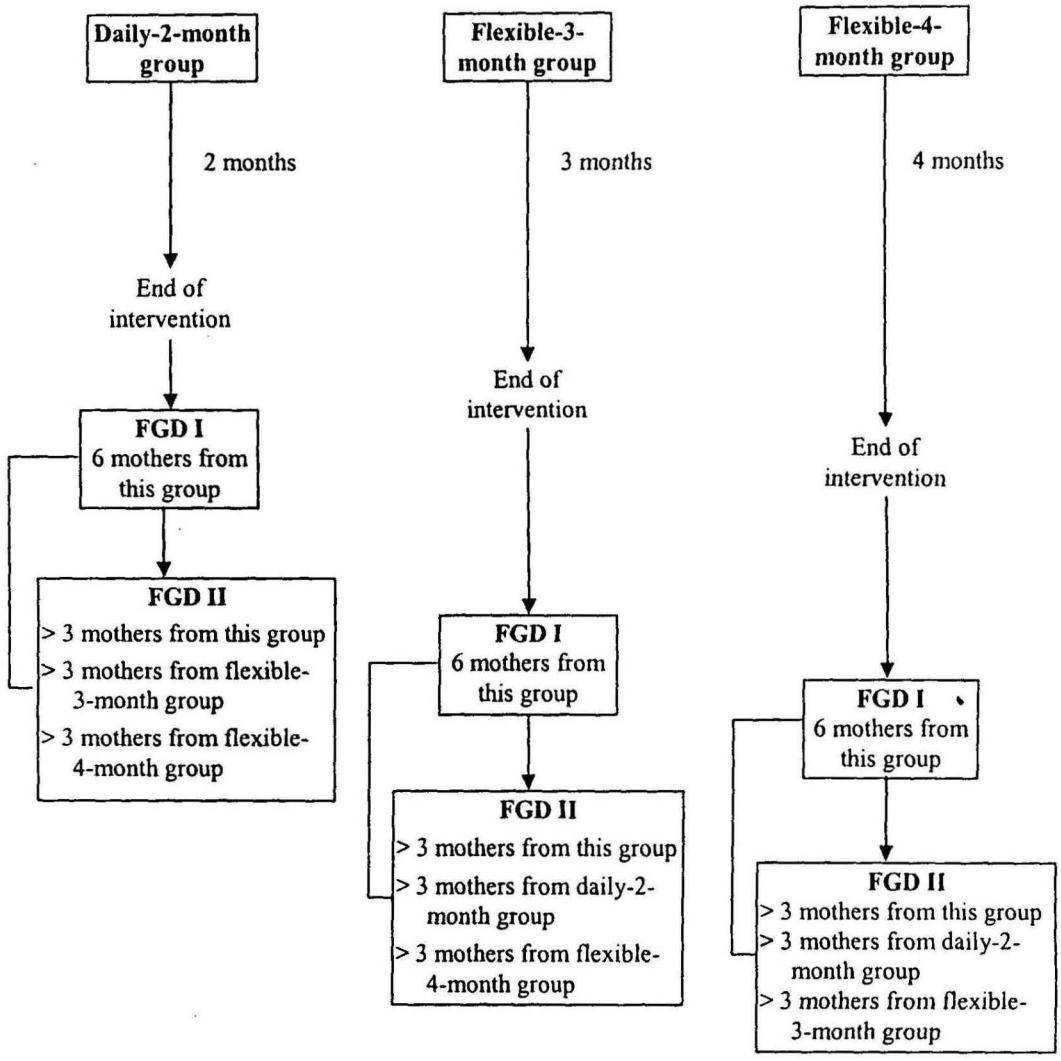
FGD Identification Code: F42	Date: September 19, 2004
Topic: Preference towards daily or flexible sprinkles administration	Page: 4
Location: Kaliganj BRAC research office	
Participant number: 9 mothers	
Moderator: Nuzhat Chowdhury	Note taker: Mizan Rahman

Codes	Notes	Observations
	M: What were some reasons why you did/could not give Sprinkles daily, even when given instructions for daily use?	
DFORGET	P1: Sometimes I am busy and have to go outside the home for chores. It is difficult to remember to give Sprinkles when I come back.	
DSICK	P4: Because of sickness, my baby does not want to eat any food. It is difficult to feed Sprinkles when this happens.	
DFORGET	P7: When I visited my friends in another village, I did not take any Sprinkles packets with me that day, so I couldn't give them to my baby	
	M: What did you like about flexible instructions for using Sprinkles?	
FTIME	P3: I think the process of 3 months is good. If I forget I can feed the next time when I remember.	
	P2: Since I had 4 months to use the packets I felt more relaxed because I could take my time to use to them.	Others nodded heads in agreement
FFREE	P5: I could feed my child according to my wish and my convenience	

M- Moderator; P-Participant

APPENDIX A

FOCUS GROUP DISCUSSION LAYOUT



APPENDIX C

LIST OF STUDY VILLAGES AND CHILD RECRUITMENT

	Village name (Total of 16)	Village community health worker	No. of listed children (6-24 months)	No. of recruited children
Daily-2-month group				
1	S. Shome	Halima	60	35
2	N. Bhadarti	Mukul Koria	26	19
3	Durbati	Anawara	42	26
4	Nalsata	Malina	22	20
5	N. Chara Khola	Jhunu Rozario	18	20
Flexible-3-month group				
1	S. Bhadarti	Minara	17	17
2	S. Chuaria Khola	Manju Rakkhit	33	26
3	S. Chara Khola	Bondona Rozario	28	15
4	Tumulia	Mozera	36	26
5	Rangamati (2)	Agnesh	24	18
6	Bhaiasuti	Marium	24	18
Flexible-4-month group				
1	N. Shome	Anita	32	24
2	Kaligonj	Joynab	34	25
3	Rangamati (1)	Birunika	38	25
4	Rangamati (3)	Rekha	27	21
5	Ghona Para	Parul	43	27
	Total:		**504**	**362**