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Research Article

Evaluating Acceptability of Fortification Approach for Delivery of Zinc and Iron in Children Aged 6-24 Months

Pratibha Dhingra[1,2], Sunil Sazawal[1,2,3]*, Usha Dhingra[1,2], Venkatesh Iyengar[4], Venugopal P. Menon[2], and Robert E. Black[3]

[1]Center for Public Health Kinetics, New Delhi, India

[2]Center for Micronutrient Research, Department of Biochemistry, Annamalai University, Chidambaram, India

[3]Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD, USA

[4]Biomineral Sciences International, Inc. Washington DC, USA

*Corresponding author

Sunil Sazawal, Center for Public Health Kinetics, Executive Director, 214A, LGF, Vinoba Puri, Lajpat Nagar-II, New Delhi -110024, India, Tel: 91-11-41724901; Fax: 91-11-41724904; Email: ssazawal@jhu.edu

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Keywords

- Zinc; Iron; Micronutrient powder; Pre-fortified weaning food; Acceptability; Young children

Abstract

Background: Micronutrient deficiencies predispose the infants and children to infections, anemia, impaired growth and development, thus, cost effective strategies are urgently required to combat these deficiencies. Fortification of iron/zinc appears to be an effective alternative strategy for delivery of these micronutrients, in comparison to short term supplementary programmes. Acceptability of this concept by mothers is a key determinant for successful implementation of such a fortification program.

Objective: We evaluated the acceptability of two innovative food fortification approaches, by mothers and children.

Methods: In peri-urban settlement of New Delhi, 796 children aged 6-24 months were randomly allocated to receive either micronutrient powder added to regular food (MNP = 265) or one of three products of pre-fortified weaning food (reconstituted with water) [Ragi (RG) =265; Extruded Rice (EX) =134; Roasted Rice (RR) = 132] once daily for 15 days. Home visits were undertaken twice a week and at the exit interview, information on overall acceptance of these approaches was explored.

Results: The percentage of children who consumed more than 50% of fortified food given in each offering was MNP 62.0%, RG 72.7%, EX 72.6%, RR 67.2%. Evaluation of overall acceptance from mother's perspective indicated that they accepted and liked the concept of fortification MNP 97.8%, RG 93.7%, EX 100%, RR 95.3%.

Conclusion: Fortification using both tested approaches is highly acceptable and feasible strategy for delivery of zinc and iron among children. Our findings suggest that evaluation of the impact of these approaches will not be impeded by poor acceptance of these products.

ABBREVIATIONS

CFTRI: Central Food Technological Research Institute; MNP: Micronutrient powder; RG: Ragi; Ex: Extruded Rice; RR: Roasted Rice; WHO: World Health Organization

INTRODUCTION

Infants and children are the most vulnerable groups with regard to micronutrient malnutrition (especially of zinc and iron), given the high vitamin and mineral intake they need to support their rapid growth and adequate development. These deficiencies predispose them to infectious diseases, anemia, impaired growth and development [1-8]. Sustainable strategies to combat these deficiencies are thus a public health priority. The WHO recommends the use of nutritional supplements or fortified products in prevention of these deficiencies [9]. Supplementation trials of zinc or iron have shown beneficial effects in reducing morbidity, anemia and mortality [1,3,10,11]. However, combined supplementation of zinc and iron resulted in antagonistic interactions between these two minerals and iron alone has been shown to have adverse effects in regard to infectious diseases, especially in iron replete children [12-14]. Fortification of commonly consumed food has been suggested as an attractive alternative as this may reduce zinc-iron interactions and also iron toxicity [15-17].

Research has shown that micronutrient powder added to weaning foods or pre-fortified weaning foods or lipid-based nutrient supplements added to complementary food seem to be feasible options for delivery of micronutrients [18-23]. To date, the strongest evidence in favor of this approach comes from studies using multi-nutrient Sprinkles® or crushable tablets or products that include both micronutrients and a small amount of energy (including fat and protein), some of which have documented favorable effects both on linear growth and anemia alleviation [20,22,24-27]. Although, micronutrient powder have no taste

or color, which results in the ability to feed children the product without their knowledge and can deliver several micronutrients at the same time, there is a limit to the number and amounts of nutrients that can be incorporated in its formulation, compared with cereal/rice-based pre-fortified weaning food, which has a sweet taste and can provide energy, protein and essential fatty acids along with several essential nutrients. The investigational pre-fortified weaning products are traditionally consumed and popular local foods in India. Until now, however, information on their use among young children is scarce, even though risk of malnutrition is highest in this age group in low-income countries.

We evaluated the acceptability of two food fortification approaches; micronutrient powder as a sprinkle on home cooked food/beverage and pre-fortified weaning foods (three products), namely, Ragi, Roasted rice and Extruded rice, among zinc and iron deficient children of poor socio-economic stratum. The outcome of this study would provide data that would facilitate the design of more focused interventions in similar target groups to address the problem of micronutrient deficiencies.

METHODS

Study area, subjects and recruitment

The study was undertaken in Sangam Vihar, a peri-urban settlement in Delhi, India between May and November 2000. A survey was conducted to identify children in the age group of 6-24 months among the poor socio-economic status. The study included only children with no major illnesses and those consuming complementary foods in addition to breast milk; mothers willing to feed the infant with the assigned preparation over a 15 days period, to report his/her consumption and reactions and practices for daily use; and planned to remain in the study area for at least the following 15 days.

Study design

Two stage randomization was done, in stage 1, children were randomly allocated to receive either micronutrient powder (MNP, n= 265), or one of the varieties of pre-fortified weaning foods namely Ragi (RG, n = 265), or Rice (n=266). In case of rice allocation, second stage randomization was done to randomly allocate the child to either receive Extruded Rice (EX, n = 134), or Roasted Rice (RR, n = 132), to evaluate the effect of processing on acceptability. Randomization was undertaken using permuted block randomization method (Block length of 16), which generated a list of randomly allocated group codes against a serial number. Envelopes were prepared with serial number written on it and the assigned group code sealed inside the envelope. On enrollment each child was assigned the next available envelope and allocated to the group printed inside it.

In the trial, each child was given 15 sachets of the micronutrient powder/pre-fortified weaning food at the beginning of the study to be consumed daily for 15 days. During the initial interview of the mothers, information pertaining to health status of the child was ascertained and demonstration was given on the preparation of micronutrient powder/pre-fortified weaning food by the nutritionist. Home visitation was done twice a week by the health worker during the trial period. At each visit, structured interviews were conducted to obtain information regarding the fortified product consumed during the previous day, as well as in the prior 48 hours. At the completion of the study, exit interviews were conducted with the mother to ascertain her views on the acceptability of fortifying the child's food, the child's acceptance of the fortified food and the feeding behavior of the child were obtained. To evaluate adherence, the number of used and remaining unused sachets were also counted.

Ethical approval and consent

The study was reviewed and approved by the human research review committees at the Center for Micronutrient Research, Annamalai University, the Johns Hopkins Bloomberg School of Public Health, and World Health Organization. Informed signed consent was obtained from the parents or guardians of children.

Table 1: Nutrient composition of the fortified powder and pre-fortified weaning food used in this study.

	Micronutrient powder	Pre-fortified weaning food	
Nutrients	**1.5 g/Sachet**	**In 20 g-100ml**	**In 40 g - 200ml**
Protein, g	-	3	6
Fat, g	-	1.5	3
Linoleate, g	-	0.18	0.36
Carbohydrates	-	13.9	27.8
Calories, Kcal	-	80.4	160.8
Vitamin A, IU	3260.87	1800	3600
Thiamine, mg	0.98	0.51	1.03
Riboflavin, mg	1.11	0.58	1.17
Niacin, mg	13.04	6.6	13.2
Pyridoxine, mg	1.3	0.83	1.67
Cynocobalamine, mg	0.0039	0.21	0.42
Biotin, mg	0.019	0.11	0.22
Pantothenic acid, mg	6.52	-	-
Folic acid, mg	0.261	0.144	0.288
Vitamin C, mg	39.13	23.4	46.8
Vitamin D, IU	260.8	145	290
Vitamin E, IU	0.015	10.5	21
Vitamin K, µg	16.3	-	-
Calcium, mg	494.02	138.7	277.5
Magnesium, mg	69.13	20	40
Phosphorus, mg	81.52	64	128
Potassium, mg	-	100	200
Sodium, mg	-	6	12
Chromium, µg	-	11	22
Copper, mg	1.3	1	2
Iodine, mg	-	0.07	0.15
Iron, mg	12.5	7.9	15.9
Manganese, mg	2.58	0.16	0.32
Molybdenum, µg	-	16	32
Selenium, µg	-	3	6
Zinc, mg	10	6.5	13
Lithium	in traces	-	-

Study groups

The nutrient composition of the micronutrient powder and pre-fortified weaning food is given in Table **1**.

Group I: Micronutrient powder: Powder in the form of micronutrient premix was prepared by NUTRISET, Malaunay France, and was procured by the WHO for this study. Each sachet of powder weighed 1.5 g. The composition was similar to WHO supplement for persistent diarrhea with additional 12.5 mg of iron (ferrous fumerate) and 10 mg of zinc (zinc gluconate), along with other vitamins and minerals (http://www.childhealthresearch.org/doc/spec1.pdf). A sachet of powder was recommended to be added to any semi-solid/liquid food served to children once daily.

Group II: Micronutrient pre-fortified weaning foods: Three cereal/rice-based pre-fortified weaning foods; Ragi (birdsfoot millet/finger millet) (RG); Extruded rice (EX); Roasted rice (RR)] was developed by Jee Vee Foods Pvt Ltd, India, using expertise of Central Food Technological Research Institute (CFTRI), Mysore, India. Sachets weighing 20 g or 40 g of pre-fortified weaning food were designed for children ≤12 months and 13-24 months, respectively. 20 g sachets contained 6.5 mg elemental zinc, 7.9 mg elemental iron and other micronutrients; whereas 40 g sachets contained 13 mg of zinc, 15.9 mg iron with other micronutrients and was to be reconstituted with water to make 100 ml or 200 ml food, respectively, and to be consumed once daily.

Statistical Analysis

Data were analyzed with SPSS/PC Statistical Program Version 18.0 (SPSS, Chicago, IL) and included descriptive statistics such as mean, standard deviation, frequency, proportions and percentages. As there was no difference in the information collected for two days (previous day and the prior 48 hours of each biweekly visitation) on the consumption patterns of the products, the data were pooled.

RESULTS

Of the total of 850 children identified initially, 54 declined participation, leaving 796 children who were randomized into four fortification groups. Of 796 children, 117 children opted out (or withdrew), before completing the 15 day study period. These included 31 children (11.7%), of the MNP group reported having problems with the taste; 18 (6.7%), children of the RG group; 19 (14.4%), children of EX group and 17 (12.7%), children of the RR group due to unacceptability of the pre-fortified weaning foods. A

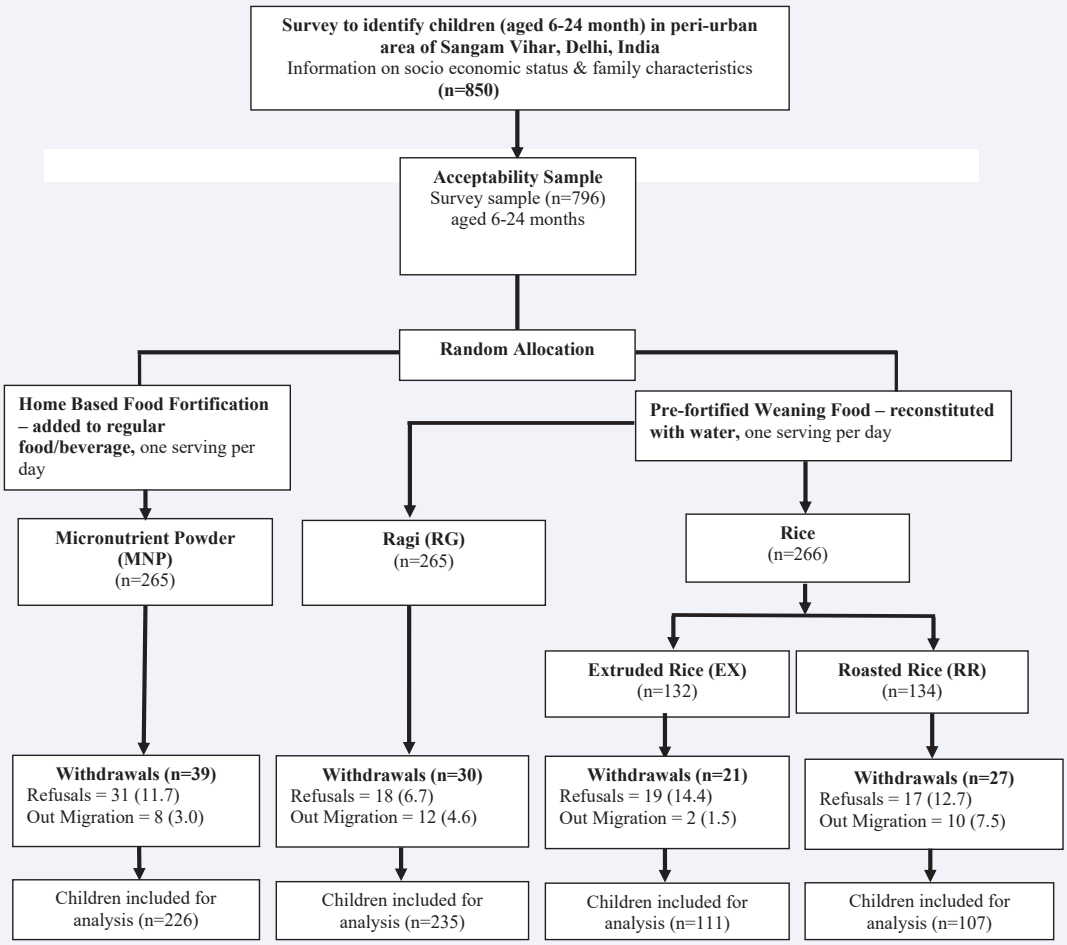

Figure 1 Trial profile.

total of 32 families moved away from the study area; MNP group (8, 3%), RG group (12, 4.6%) EX group (2, 1.5%) and RR group (10, 7.5%) (Figure **1**). At enrollment, the four groups were similar in terms of age, sex distribution, sickness status (one week prior to enrollment), types of foods given to children and family's socio-economic characteristics (Table **2**). These characteristics of those who dropped out did not differ from those who completed the study.

The percentage of children who consumed more than 50% of fortified food given in each offering was MNP 62.0%, RG 72.7%, EX 72.6%, RR 67.2% (Table 3). Mother's perspective on the concept of fortification and overall acceptance of fortified food was high (MNP 97.8%, RG 93.7%, EX 100.0%, RR 95.3%). Overall, more than 85% of the mothers indicated willingness to give the fortified products to the children in the future, although the preference was high for RR (93.5%). In all the four groups, mothers observed a change in child's eating habits in terms of increased frequency of meals (36-44% of children) and increased quantity of over all food consumption (>80% of children), while 17-27% of the mothers reported that an extra effort was required to feed the child (Table 4). Overall unacceptability (assessed from mother did not like fortified feed, neighbors/relatives prohibited to use the product, difficulty in mixing of the product and child did not like fortified food) was low (ranging from 1.4%-15%), being lowest reported for RR (1.4%), or RG group (1.9%). Taste was the major factor that influenced their decision. As compared to pre-fortified weaning food, the acceptability of the MNP group was poor (15%) mainly due to taste even though the quantity of food consumed by the child was not affected (Table 5). Addition of the micronutrient powder to milk was the most preferred method (>90%) to feed the child even though it could have been easily mixed with other commonly consumed foods by children such as tea, rice, khichri, dal, milk-rice and vegetable.

DISCUSSION

In the present study, the acceptability of both fortification

Table 2: Baseline child and socio-economic characteristics.

Variables	MNP n =265	RG n =265	EX n =134	RR n =132
Age, mo, mean ± SD	15. 87±5.10	15.56 ± 5.02	15.2 ± 5.39	15.81± 4.62
Gender, male, n (%)	143 (54.0)	158(59.6)	76(56.7)	72(54.5)
Illiterate father, n (%)	40 (15.1)	41(15.5)	14(10.4)	18(13.6)
Illiterate mother, n (%)	131 (49.4)	146(55.1)	80(59.7)	72(54.5)
Father occupation				
Business, n (%)	65 (24.5)	61(23.0)	36(26.9)	38(28.8)
Daily wage labor, n (%)	45 (17.0)	56(21.1)	29(21.6)	30(22.7)
Service, n (%)	149 (56.2)	145 (54.7)	67 (50.0)	63 (47.7)
Mother occupation				
Housewives, n (%)	244 (92.1)	245(92.5)	122(91.0)	120(90.9)
Article score sum[1], mean±SD	713(2.69±2.08)	613 (2.31±1.99)	327 (2.44±1.98)	331 (2.51±1.87)
SES score sum[2], mean±SD	1979 (7.5±2.5)	1857 (7.0±2.7)	969 (7.23±2.52)	975 (7.39 ±2.45)
Household type				
Nuclear, n (%)	180 (67.9)	176 (67.2)	93 (69.9)	92 (69.7)
Sickness profile				
Sickness one week prior to enrollment				
Days of follow –up	1855	1855	938	924
Prevalence of diarrhea[3]	0.13	0.17	0.07	0.085
Prevalence of ALRI[4]	0.014	0.017	0.005	0.021
Prevalence of other illnesses[5]	0.45	0.23	0.27	0.19
Foods given at baseline				
Milk with no solids, n (%)	6 (2.3)	4 (1.5)	4 (3.0)	0 (0.0)
Milk with solids, n (%)	214 (80.8)	208 (78.5)	103 (76.9)	107(81.1)
Solids, n (%)	45 (17.0)	53 (20.0)	27 (20.1)	25 (18.9)

MNP=Micronutrient powder, RG=Ragi, EX=Extruded rice, RR=Roasted rice

[1]Article score is based on family ownership of the household assets i.e. for ownership of expensive assets a score of 3 was assigned; for less expensive a score of 2 and for least expensive assets a score of 1 was given

[2]SES score is based on ownership/possession of house, household assets and type of house; maximum=26; higher scores=higher status

[3]proportion of days the child had diarrhea

[4]proportion of days the child had ALRI

[5]proportion of days the child had other illnesses

Table 3: Acceptability of fortified foods by children (aged 6-24 months) during the follow up visits.

Variables	MNP n =265	RG n =265	EX n =134	RR n =132
No. of days fortified food offered, n	1608	1653	829	819
No. of times fortified food offered[1], n	1616	1960	996	930
Quantity of fortified food offered (daily)[1]				
All	402 (25.0)	579 (35.0)	303 (36.6)	107 (13.1)
≥Half	978 (60.8)	999 (60.4)	486 (58.6)	619 (75.6)
< Half	228 (14.2)	75 (4.5)	40(4.8)	93 (11.4)
Amount of fortified food eaten in each offering[2]				
All	204 (12.7)	402 (24.3)	224 (27.0)	77 (9.4)
≥ Half	792 (49.3)	800 (48.4)	378 (45.6)	473 (57.8)
< Half	510 (31.7)	387 (23.4)	195 (23.5)	237 (28.9)
None	102 (6.3)	64 (3.9)	32 (3.9)	32 (3.9)

Values are n (%).
[1]In some cases, children were not able to consume the entire content in a single serving therefore mothers were asked to split the sachet i.e. to give half in the morning and half in the afternoon or evening.
[2]For calculation purposes, the number of days the fortified food offered was used as denominator

Table 4: Mother's experience in acceptability of fortified food of children who completed the study.

Variables	MNP n=226	RG n=235	EX n=111	RR n=107
Mother's perception of concept of fortification				
Highly acceptable	50 (22.1)	4 (1.7)	29 (26.1)	3 (2.8)
Acceptable	171 (75.7)	216 (92.0)	82 (73.9)	99 (92.5)
Non-acceptable	5 (2.2)	15 (6.4)	-	5 (6.4)
Mother's experience of ease of offering				
Easy	140 (61.9)	130 (55.3)	60 (54.1)	72 (67.3)
Average	83 (36.7)	100 (42.6)	51 (45.9)	33 (30.8)
Difficult	3 (1.3)	5 (2.1)	-	2 (1.9)
Mother had to make extra efforts to feed the child	61 (27.0)	64(27.2)	22(19.8)	18(16.8)
Mother observed change in child's eating habits				
Change in eating habits	43 (19.0)	46 (19.6)	25 (23.4)	25 (22.5)
Increased frequency of meals[1]	17 (39.5)	19 (41.3)	11 (44.0)	9 (36.0)
Increased quantity of consumption[1]	35 (81.4)	40 (87.0)	22 (88.0)	22 (88.0)
Time taken to feed the child not affected[1]	41 (95.4)	41 (89.1)	24 (96.0)	23 (92.0)
Willing to give fortified food to the child in future	193 (85.4)	204 (86.8)	97 (87.4)	100 (93.5)

Values are n (%)
[1]For calculation purposes, change in eating habits was used as denominator

Table 5: Summary of mother/child's experience of non-acceptance of fortification concept and food.

Variables	MNP n=31	RG n-=18	EX n=19	RR n=17
Mother's experience				
Mother did not like fortified feed/ neighbors/ relatives prohibited/ difficulty in mixing	17 (6.4)[1]	4 (1.5)	5 (3.8)	0 (0.0)
Child did not like fortified food	23 (8.6)	1 (0.38)	3 (2.2)	2 (1.4)
Child fell sick	5 (1.9)	14 (5.2)	13 (9.8)	10 (7.4)
Mother's perception of child acceptance				
Reasons for child not liking the fortified food				
Consume less food	24 (9.06)	15 (5.7)	15 (11.4)	13 (9.7)

Extra effort required to feed	19 (7.1)	12 (4.5)	12 (9.1)	8 (6.0)
Child took more time to eat	4 (1.5)	5 (1.8)	4 (3.0)	4 (3.0)
Smell	2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Color	3 (1.1)	1 (0.38)	0 (0.0)	0 (0.0)
Taste	24 (9.0)	15 (5.7)	13 (9.8)	15 (11.2)
[1]% is calculated from total number of children and responses can be multiple for a child				

approaches; using micronutrient powder and three products of pre-fortified weaning foods for delivery of micronutrients especially zinc and iron were found to be high among children and their mothers. There was no reported evidence of any adverse effects or allergic reactions of these two approaches. The willingness and enthusiasm of the mothers to provide fortified food to their children was good. They found both the powder and the pre-fortified weaning food convenient to feed. The pre-fortified weaning food was a cereal/rice based product and appeared similar to the common weaning foods offered to the children of this age group. Ragi based food had higher acceptance among the pre-fortified weaning foods inspite of its slightly dark color. The acceptability of two rice-based products i.e. extruded and roasted variety of rice was similar indicating there was no processing effect of rice. A slight change in taste was reported in foods mixed with micronutrient powder. However, these changes did not prevent the child from eating the food to which powder had been added. Both approaches were easy to prepare and did not require measuring equipment. As compared to other foods, >90% of the time mothers reported that the milk was a suitable vehicle for mixing the powder indicating a higher acceptance with milk. This delivery method seems to be effective in terms of 'mixability' and providing an adequate dose of micronutrients to the children. Introduction of fortified foods had no negative effect on total daily food intake of the children as informed by the mothers, on the contrary, some mothers had observed positive changes in child's eating behavior in terms of increased frequency of meals and increased quantity of food consumption. Majority of the mothers considered these products/preparations to be beneficial for their children, and were willing to continue feeding it if asked to do so.

The study had some limitations. One of them was the inability to record total daily food intake of the children. Further, as we did not conduct the direct observation of the feeding episode, we are not sure of the actual consumption of the fortified food by the child and rely on the information provided by the mother. Also, we were not able to gauge on the risk of replacement of other foods in infants' diets, and leakage/sharing of the fortified food to other family members. Although prior work conducted by other researchers in Malawi showed that food usage information collected by self-reported questionnaires is indeed similar to that observed by neutral observers [28,29]. Another limitation, the design of the study was not a cross-over design, each mother had experience with only one of the four products; therefore, it is not predictable what their responses would have been if they had the option to decide which of the four they preferred most. Mothers' views on the overall concept and acceptability of using fortified foods was evaluated using structured interviews at the completion of the study by independent nutritionists to avoid biased responses. As all the mothers were asked the same set of standardized questions in an interview so the responses obtained were easily quantifiable and analyzable; this helped in comparing the results across the delivery approaches. On one hand, this technique has provided insight into declarative knowledge used, maintained a focus on a given issue and provided detailed information on the issue but on the other hand, lack of open-ended or follow up questions regarding mother and child experiences with the fortified products, feeding practices, and overall acceptability could inevitably limit responses due to indicated decided preferences/restricted answers obtained and the data obtained may not be reliable if there are faults in the way questions are asked or understood by the respondent. Otherwise, this would have elicited more varied responses in acceptability preferences [30] and more information about the reasons behind some of the maternal feeding behaviors and child acceptance of the foods.

Fortified products that have been used for improving zinc/iron status in target groups/ high risk population include infant formula, infant cereal, sugar, fish sauce, curry powder, cookies, common salt, wheat flour, rice flour, sweets/candies, milk and soy based spreads or lipid-based nutrient supplements [12, 23,31-34]. This presents a challenge in the local setting as there are no centrally processed foods that are consumed by children. In addition, there is a need to establish the food processing facilities where the fortification can be done but the cost involved may be high. Traditional fortification approaches such as adding small i.e. partial recommended nutrient intakes of micronutrients to foods may not deliver adequate quantities of vitamins and minerals, to high risk populations. One alternative seems to be the home-based approach. In this study, we have tested a micronutrient powder that may be added to a single spoonful of food for the child to receive a full dose of minerals or vitamins; this is cheap, easy to deliver and is a little additional burden for the mother. Other alternatives of pre-fortified weaning foods, though slightly higher in cost, are also feasible for delivery of micronutrients. These are easy to prepare, not limited by the quantity of food the child consumes because they contain the total daily needs in one serving and provide additional food for the child. Although, it is essential that the child should ingest the entire serving to ensure that the full dose is provided.

Studies have documented that powder of microencapsulated iron can be mixed with weaning foods in the home and is acceptable and efficacious in several populations to treat iron deficiency anemia and is well tolerated by children. A number of community-based trials have been conducted in Asia (China, Indonesia, Bangladesh, Pakistan and India), Africa (Ghana) and Latin America (Bolivia and Haiti) to assess the efficacy, safety, bioavailability and acceptability of micronutrient powder to improve hemoglobin concentrations and iron status in young

children [16,20-22,27,35-37]. These studies also showed high parent/child acceptability rate that ranged between 56% and 92%. Our results also support these observations. Similar findings in acceptability were also observed in fortification studies using rice and wheat as vehicles for effective delivery of one or more micronutrients [38-40]. As three varieties of pre-fortified weaning food were new products, no data is available on their acceptability. Most significant advantage in this study is that it evaluated traditionally consumed and popular ragi/rice based weaning food, after fortification thus it offers an innovative approach of food fortification for delivery to address the problem of micronutrient deficiencies, especially of zinc and iron.

CONCLUSION

In conclusion, both the approaches of food fortification using micronutrient powder and pre-fortified weaning food were found to be acceptable among the mothers and their children (ages 6-24 months). Thus, both home-based food fortification approaches hold a potential for delivery of zinc and iron and need to be evaluated for long term adherence and impact on morbidity in adequate-size controlled clinical trials.

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