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Introduction

Moving ahead with maternal, infant, and young child nutrition: Need to integrate actions

Sandra L. Huffman, Kathryn G. Dewey, and Dominic Schofield

This Supplement is the second in a series devoted to focusing attention on the need to improve maternal, infant, and young child nutrition (MIYCN) across the different stages of the key “window of opportunity” from preconception through pregnancy, the period of exclusive breastfeeding (0 to 6 months), and the target age for complementary feeding (6 to 24 months). It brings together a broad range of expertise from around the world. These papers are linked to an international dialogue to build support for MIYCN programs in a series of meetings, including those held at the Micronutrient Forum in Beijing in 2009 and the International Congress of Nutrition in Bangkok in 2009.

As with last year’s Supplement [1], this volume covers topics such as how to enhance women’s nutrition, improve breastfeeding practices, and optimize the composition of complementary foods. Additionally, this Supplement includes papers discussing evaluations of programmatic interventions and why integrating child nutrition with early child development interventions can have multiple benefits for child growth and development. The role of policy, such as changes in the international Codex Alimentarius guidelines, is also highlighted.

Although action is needed at each of the above stages of the life cycle, it is imperative that we find means to integrate actions to achieve greater impact and efficiency. For example, production of fortified foods that can be used for both pregnant women and young children, with minor changes in micronutrient content and serving sizes, will help address problems of anemia and other micronutrient deficiencies in both target groups, as well as low body mass index in women and stunting in children [2, 3]. Such efforts can also help to reduce costs of products and facilitate their manufacture and distribution through public–private partnerships.

Linking messages on the need for iron supplementation to reduce anemia before and during pregnancy with information on immediate and exclusive breastfeeding, delayed cord clamping, and how to improve maternal–child interaction can have long-lasting impacts on both maternal health and child development. Similarly, combining behavior change approaches for enhancing complementary feeding and encouraging simple play activities can help enhance child growth and development.

We hope that soon we will have illustrations of how such actions have been integrated at large scale.

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References

Maternal iron–folic acid supplementation programs: Evidence of impact and implementation

Tina G. Sanghvi, Philip W. J. Harvey, and Emily Wainwright

Abstract

Background. According to a World Health Organization (WHO) review of nationally representative surveys from 1993 to 2005, 42% of pregnant women have anemia worldwide. Almost 90% of anemic women reside in Africa or Asia. Most countries have policies and programs for prenatal iron–folic acid supplementation, but coverage remains low and little emphasis is placed on this intervention within efforts to strengthen antenatal care services. The evidence of the public health impact of iron–folic acid supplementation and documentation of the potential for scaling up have not been reviewed recently.

Objective. The purpose of this review is to examine the evidence regarding the impact on maternal mortality of iron–folic acid supplementation and the evidence for the effectiveness of this intervention in supplementation trials and large-scale programs.

Methods. The impact on mortality is reviewed from observational studies that were analyzed for the Global Burden of Disease Analysis in 2004. Reviews of iron–folic acid supplementation trials were analyzed by other researchers and are summarized. Data on anemia reduction from two large-scale national programs are presented, and factors responsible for high coverage with iron–folic acid supplementation are discussed.

Results. Iron-deficiency anemia underlies 115,000 maternal deaths per year. In Asia, anemia is the second highest cause of maternal mortality. Even mild and moderate anemia increase the risk of death in pregnant women. Iron–folic acid supplementation of pregnant women increases hemoglobin by 1.17 g/dL in developed countries and 1.13 g/dL in developing countries. The prevalence of maternal anemia can be reduced by one-third to one-half over a decade if action is taken to launch focused, large-scale programs that are based on lessons learned from countries with successful programs, such as Thailand and Nicaragua.

Conclusions. Iron–folic acid supplementation is an under-resourced, affordable intervention with substantial potential for contributing to Millennium Development Goal 5 (maternal mortality reduction) in countries where iron intakes among pregnant women are low and anemia prevalence is high. This can be achieved in the near term, as policies are already in place in most countries and iron–folic acid supplements are already in lists of essential drugs. What is needed is to systematically adopt lessons about how to strengthen demand and supply systems from successful programs.

Key words: Anemia, hemoglobin, iron deficiency, maternal health programs, maternal mortality, neonatal health programs, perinatal mortality, pregnancy
those of vitamins A and B₁₂, folate, riboflavin, and copper, and the presence of hemoglobinopathies may raise anemia levels within some populations. There is global agreement that iron deficiency accounts for by far the largest burden of all grades of anemia in pregnancy worldwide [1].

Current World Health Organization (WHO) guidelines for nutrition and antenatal care recommend universal iron and folic acid supplementation for pregnant women where anemia is widespread [3]. However, many countries are not giving priority to implementing this recommendation, and anemia remains the most common health condition of pregnancy. According to a WHO review of nationally representative surveys from 1993 to 2005, 42% of pregnant women worldwide have anemia [2].

National health authorities have paid insufficient attention to iron–folic acid supplementation, in part because of the lack of easily accessible information regarding the importance of anemia in pregnancy, evidence that intervention programs can be successful in addressing the problem, and how large-scale programs have achieved results. This review summarizes current studies on the risk of maternal and perinatal mortality associated with iron-deficiency anemia, evidence of the impact of iron and folic acid supplementation on anemia from supplementation trials, and key factors for success in well-documented national programs.

Methods

Evidence of anemia–mortality relationships

The analysis showing the association of maternal mortality with anemia is described by Stoltzfus et al in detail [4]. The authors reviewed prospective observational studies of pregnant women in which hemoglobin concentration was the risk factor for mortality. The relative risks for perinatal mortality (10 studies) and maternal mortality (6 studies) were estimated using random-effects models. Global anemia prevalence data were taken from the WHO database [5]. Anemia prevalence was converted to mean hemoglobin concentrations assuming normal distribution and observed standard deviations from a large number of studies. To estimate the effects of reduction of iron deficiency on hemoglobin levels, the authors assumed that the prevalence of anemia in women would be reduced by 51% based on evidence from supplementation trials. The authors explored the possibility of an impact on maternal mortality at hemoglobin levels between 5 and 12 g/dL, the range that includes the vast majority of pregnant women. Six studies provided information on the relationship between the risk of death and maternal anemia in this range. These studies were selected from the systematic review by Brabin et al. [6]. All six studies were observational. There were no intervention trials with maternal mortality as outcome. Odds ratios were calculated for maternal mortality associated with a 1 g/dL increase in hemoglobin during pregnancy for high malaria-prone areas and nonmalaria areas. Ezzati et al. [7] then converted lives saved due to direct and indirect effects on mortality to disability-adjusted life years (DALYs) using standard procedures for risk factors that were applied for all interventions in the Global Burden of Disease project.

Evidence of impact from iron supplementation trials on anemia outcomes

Kulier et al. [8] provided a synthesis of systematic reviews and individual randomized, controlled trials of nutritional interventions during pregnancy. In all, 25 randomized or quasirandomized trials were included. The authors systematically extracted data on pretrial hemoglobin levels, the trial settings, the number of trials, and participants’ characteristics. The same paper examined other nutrient interventions and selected maternal outcomes.

The analysis of Stoltzfus et al. (2004) [4] also reviewed meta-analyses of iron supplementation studies, including one by Sloan et al. [9]. Data from randomized, controlled trials published between 1966 and 1998 were pooled in the Sloan paper. Meta-analyses of the relative change in maternal hemoglobin that was associated with iron supplementation were stratified by initial hemoglobin levels, duration of supplementation, daily gestational supplement dose, and supplementation with other nutrients.

Evidence on the impact of scaled-up iron supplementation programs on anemia

Two national programs that are well documented include the Integrated Anemia Control Strategy (IACS) in Nicaragua and Thailand’s National Anemia Reduction Program [10]. In order to establish whether the observed trends in anemia rates in these countries may plausibly be attributed to iron–folic acid supplementation, the available data on program performance indicators (provision, utilization, coverage) were examined vis-à-vis the observed effects on the prevalence of anemia. Other possible contributing factors and potential confounding variables were taken into account.

Results

Evidence of anemia–mortality relationships

The study for the Global Burden of Disease (GBD II) project in 2004 showed the well-known relationship between hemoglobin levels and maternal deaths [4].
As hemoglobin increased, maternal deaths declined. The first set of analyses indicated a threshold effect at about 5 g/dL below which maternal mortality increased rapidly. The authors went a step further to look more closely at possible impacts of mild, moderate, and severe ranges of anemia from 5 to 12 g/dL. This analysis showed an increased risk of death from even mild and moderate forms of anemia. The results showed that the risk relationship was continuous. When the risks of all forms of anemia were summed up, this represented a large number of attributable maternal deaths. Similar analyses of perinatal mortality by the same authors also showed even greater reductions in risk of death. The relationship held in areas with high malaria prevalence and in other settings.

This Stoltzfus analysis [4] concluded that the relative risks associated with a 1 g/dL increase in population mean hemoglobin were 0.75 (95% CI, 0.62 to 0.89) for maternal mortality and 0.72 (95% CI, 0.65 to 0.81) for perinatal mortality. Subgroup analyses suggested that the relative risk for perinatal mortality in malaria-endemic regions (0.65; 95% CI, 0.56 to 0.75), was lower than in regions without endemic Plasmodium falciparum malaria (0.80; 95% CI, 0.73 to 0.87).

The authors then applied the relative risks to current prevalence levels of anemia in pregnancy and estimated the potential impact of reduction in iron deficiency. Based on these estimates of iron-deficiency anemia as a risk factor for mortality, iron deficiency was found to result in 591,000 perinatal deaths and 115,000 maternal deaths globally [11]. The associated loss of healthy life-years amounts to more than 19 million DALYs from perinatal causes and more than 3 million DALYs from maternal causes.

A recent WHO survey of the causes of maternal mortality found that in Asia, anemia is the second highest cause of maternal deaths [12]. Anemia, independently of deaths from postpartum hemorrhage, accounted for 12.8% of all maternal deaths. This is also the region with the largest numbers of anemic pregnant women.

**Evidence of the impact of iron supplementation on anemia outcomes**

The review of iron supplementation trials by Kulier et al [8] showed consistent positive effects of iron–folic acid supplementation across different settings, although the impact was not large. Routine iron supplementation resulted in a substantial reduction in women with hemoglobin levels below 10 g/dL in late pregnancy. One trial compared selective supplementation based on the presence of anemia with routine or universal supplementation and found a reduction in need for blood transfusion in the routine-supplementation group as compared with the group that was supplemented only after screening for the presence of anemia [13]. The Kulier review concluded that increasing iron and folic acid intake through supplements will reduce the number of women with low predelivery hemoglobin. Researchers in Asia have provided further evidence that weekly supplementation of adolescent girls and women of reproductive age also improves iron status and reduces anemia [14].

Sloan et al. [9] conducted a meta-analysis of hemoglobin response to iron supplementation in pregnant women in randomized, controlled trials. Of 70 trials in the literature, 23 met their inclusion criteria, and 15 of those were from developing countries. The response to iron supplementation was strongly related to iron dose, and the hemoglobin response was smaller in study samples with higher initial hemoglobin.

The GBD analysis concluded that 1.17 g/dL is the best estimate of the size of the predicted effect of iron supplementation on hemoglobin, as this was the average effect seen in women from developed countries and was very similar to that seen in women from developing countries with initially low hemoglobin (1.10 to 1.13 g/dL).

**Evidence on the impact of scaled-up iron supplementation on anemia prevalence**

Several countries, including Indonesia, Nepal, Thailand, Nicaragua, Honduras, Uganda, and India, attempted to strengthen their anemia control programs through prenatal iron–folic acid supplementation [15]. However, only two national programs for prenatal anemia reduction have been well documented, those in Nicaragua and Thailand.

**Nicaragua**

Nicaragua had experienced high levels of anemia in the 1990s, with a prevalence of 28.5% among children 1 to 4 years of age and 33.6% among nonpregnant women 15 to 45 years of age.* The Ministry of Health subsequently developed and implemented an Integrated Anemia Control Strategy (IACS). Anemia levels in women declined to 23.7% in 2000. Under the IACS, Nicaragua developed and distributed anemia control policies and updated technical guidelines that, among other principles, listed iron and iron–folic acid supplements as essential medicines. They established efficient supply systems to procure and manage iron supplement stocks and processes to monitor adherence to protocols. Operational research was conducted to address implementation constraints. Community health volunteers (brigadistas) were expected to deliver supplements and provide clients with follow-up counseling. Eventually the program reached high coverage with iron and iron–folic acid supplements for pregnant women and iron

fortification of wheat flour. These activities are likely to have combined to result in a reduction of anemia in the population.

The causal link between iron supplementation and anemia reduction is strengthened by data showing that 87% of women recalled taking iron–folic acid supplements during the last pregnancy, and of these, 53% took the supplements for more than 6 months. The supplements were distributed and promoted for daily intake. Weekly supplementation was introduced as a policy in 1997, but it was not widely adopted, as by then government health services were decentralized, leaving decisions regarding these alternatives up to district health managers.

Behavior change communication activities in Nicaragua were monitored in 2001 after 1 year of implementation. Women knew about the importance, causes, and consequences of anemia and the need for taking iron supplements with enhancers of iron absorption and avoiding inhibitors. Women recognized adverse effects but also significant beneficial effects, and they did not perceive difficulties in accessing iron supplements either at health posts or at local pharmacies. About 77% reported having been taught by healthcare personnel about the importance of iron during pregnancy and childhood; 96% got clear instructions on how to take iron–folic acid tablets; 52% were advised to take the tablets with orange juice or lemonade, and 27% were advised not to take them with coffee; and 96% reported no significant side effects for themselves or their children. The behavior change communication strategy also aimed at increasing iron intake from natural sources and fortified foods by promoting changes in feeding practices resulting in dietary diversification.

There is good agreement about what key elements explain Nicaragua’s success:

- The supplements were distributed universally (no screening) and routinely through several channels, such as antenatal care clinics and community-based workers;
- Community-based workers provided follow-up and counseling;
- The supply was acceptable, although improvements were still needed;
- There was a good behavior change program, and extensive training was undertaken;
- Side effects were not reported as a major issue, possibly due to good community-based follow-up and counseling.

In considering alternative explanations for Nicaragua’s drop in anemia, improvement in socioeconomic conditions has been noted. But only moderate changes in poverty levels took place during this period. Improvement in health status due to greater access to safe water, declining fertility rates, and better availability of education has also been identified. Although expenditure on health increased from 11% to 13% and expenditure on education increased from 9% to 15% of the national budget, it is unlikely that the impact on anemia would have occurred at the observed rate and on this scale without direct interventions.

**Thailand**

Thailand successfully reduced the prevalence of anemia among pregnant women over a 10-year period from more than 25% in 1988 to below 15% in 1997, according to data from the national anemia surveillance system, by integrating iron supplementation, deworming, community-based follow-up, and other related programs into primary health care and community development programs [10].

Since the mid-1970s, Thailand has addressed nutrition in national development policy, including efforts to reduce iron-deficiency anemia. Nutritional improvement has been implemented as an integral part of primary health care and community development extending beyond government services to include community participation. Village health volunteers have been a crucial feature of the program.

Thai policy recommended giving iron supplements to all pregnant women during antenatal care visits. Village health volunteers oversaw compliance and encouraged pregnant women to complete the antenatal care schedule. Health service providers shifted their focus to preventing anemia rather than treating anemia in pregnant women (i.e., screening before supplementing). The Thai government also supported other anemia prevention strategies, such as food fortification, promoting improved diets, and complementary public health measures to reduce infections.

Survey and surveillance data indicate that anemia rates declined among pregnant women and preschool children, although there has been no formal evaluation of the program effect. Universal iron supplementation has been the major strategy for pregnant women, using village health volunteers to encourage continuation of the antenatal care schedule and encouraging a preventive approach by health service providers. Program obstacles have included a lack of access to iron tablets by some populations and lack of understanding of the importance of anemia. Women’s compliance was a constraint due to the fear of having a large fetus, forgetting to take pills daily, and some side effects.

Other strategies that contributed to reducing iron deficiency included food fortification, dietary improvement, and complementary public health measures. The results are not definitive, as program monitoring and evaluation required strengthening to attribute the results to intervention strategies. The possibility that the decline in anemia was partly due to socioeconomic conditions is strengthened by reports that in the midst of steadily declining trends, a small increase was observed in anemia prevalence among pregnant women.
women around 1998, which coincided with Thailand's economic crisis.

**Discussion**

Nutrient requirements increase during pregnancy to support fetal growth and maternal health. The iron requirements of pregnant women are approximately 50% of those of nonpregnant women because of increased blood volume during pregnancy, increased needs of the fetus, and blood losses that occur during delivery [16]. If iron intake does not meet increased requirements, iron-deficiency anemia is likely, particularly when iron status before pregnancy is poor [17]. Iron-deficiency anemia of pregnancy is responsible for significant morbidity, such as premature delivery and low birthweight [18–23]. Now the evidence for the impact of any level of anemia on maternal mortality has also been identified.

Iron deficiency is by far the primary cause of anemia of any severity. In some areas, malaria, worm infections, other micronutrient deficiencies, and genetic disorders can play a part. The extent to which iron deficiency is the main factor can be determined through dietary surveys or hematologic studies. The Maternal Survival Lancet series recently summarized global evidence on maternal survival interventions and placed universal iron–folic acid supplementation for anemia prevention at the top of the list for all pregnant women [19].

Several major health organizations recommend universal prenatal iron supplementation to help women meet their heightened iron needs in pregnancy. According to WHO, each pregnant woman should follow a 6-month regimen of a daily supplement (for a total of 180 supplements) containing 60 mg of elemental iron along with 400 µg of folic acid [3]. In settings where anemia prevalence is high (> 40%), WHO recommends postpartum doses for 3 additional months. The US Centers for Disease Control and Prevention and the Institute of Medicine of the National Academy of Sciences also support iron supplementation during pregnancy [19, 20].

**Iron–folic acid supplementation and maternal mortality**

The current evidence suggests that severe anemia directly causes maternal death from heart failure and that moderate anemia causes maternal death from other causes, such as hemorrhage, infection, obstructed labor, and others due to poor ability to withstand the adverse effects of excessive blood loss, an increased risk of infection, or maternal fatigue. These potential contributions of low hemoglobin to various causes of maternal mortality have not been quantified systematically. Some argue that women with a massive postpartum hemorrhage would die without treatment, irrespective of their hemoglobin levels. Some argue that anemia may be over-reported as a cause of death, as it provides an alternative explanation to poor quality of obstetric care. Another issue is that the low hemoglobin seen in women who went on to die shortly afterwards may be a marker for another event precipitating admission. Some studies may not have fully adjusted for other confounders. It is possible that severe anemia is caused primarily by malaria, hemoglobinopathies, and hookworm, and not dietary iron deficiency. However, recent evidence points to all grades of anemia increasing the risk of death.

Arguments that stepped action is needed to reduce anemia in pregnancy are based on proven high levels of anemia, affecting 42% of the world's pregnant women [2] Mortality assessments have shown that anemia is a nontrivial cause of maternal death [13]. It is a significant risk factor that increases pregnant women's chances of dying from other causes and often goes unreported. Clinicians often fail to record the contribution of anemia as an underlying cause of death, and WHO only recently moved ahead with a revised classification scheme to record underlying risk factors.

About half of anemia cases (51%) are iron-deficiency anemia resulting from low intakes of absorbable iron, as found in dietary surveys in Asia and Africa in particular. Supplementation of pregnant women increases hemoglobin levels by 1.17 g/dL in developed countries and 1.13 g/dL in developing countries. According to the Global Burden of Disease analysis [20] iron-deficiency anemia is the ninth most important factor contributing to the global burden of disease. Iron supplementation should have a considerable impact on maternal mortality.

Iron deficiency anemia can be considered a risk factor for maternal mortality due to its direct and indirect effects. It is recognized that the sum of the mortality attributable to a single risk factor separately is often more than the combined mortality attributable to a groups of risk factors [21]. Only 46% of child mortality can be attributed to the joint effects of three leading risk factors of child underweight; unsafe water, sanitation and hygiene, and indoor smoke. But individually they add up to 75%. Similarly when joint effects are taken into account the additional contribution of iron deficiency alone may not be as high as we have reported in this paper.

**Evidence of program effectiveness**

The national programs of Thailand and Nicaragua were implemented effectively, and anemia prevalence decreased in pregnant women and women of reproductive age. The Innocenti review [11] concluded that the iron supplementation program components probably contributed to the decrease in anemia prevalence, but
the evidence available was not sufficient to quantify those contributions. Applying a rigorous evaluation framework to program implementation is challenging, given the multiple etiologies of anemia and ethical considerations that rule out randomization with and without supplementation. It is questionable whether the evidence for program effectiveness is likely to improve significantly in the near future.

The plausibility that the observed changes in anemia are most likely related to the national programs in Thailand and Nicaragua derives from the temporal relationship between program implementation and and the rapid declines in anemia prevalence when coverage of iron–folic acid supplementation increased and the absence of documented changes in other known determinants of anemia. This relationship would have been even stronger if data on iron status indicators were also available. In Nicaragua, as the breadth and intensity of the iron interventions increased at two distinct stages, anemia levels were found to decline in parallel. Other public health programs that may have contributed to anemia reduction were also reviewed, but coverage of these programs, e.g., improving women’s reproductive health and survival during pregnancy, was not found to improve in the same time frame as the reduction in anemia.

Monitoring and evaluation of the supplementation programs has proved to be challenging, even in the well-documented programs. Several programs have had to rely on maternal recall of the last pregnancy (e.g., Demographic and Health Survey questions). Routine health information systems rarely include data from the distribution points of supplements. Coverage rates at the national, district, and even local level are rarely available, unlike the case for vitamin A supplementation. Establishing an effective monitoring system for supplies, distribution, and inventories of supplements at key administrative levels has been a difficult task, but when addressed systematically it has proved feasible.

Lessons learned

It was documented some time ago that assured supplies at distribution points were the main challenge in achieving success in programs. Supply systems for iron–folic acid supplements (and for malaria and deworming drugs) have been given more attention recently. This resulted from assessments by the US Agency for International Development A2Z Project and the Micronutrient Initiative, which found supply systems underlying poor results in several programs.

Behavior change communication has been an important component of effective programs when it is designed to create awareness, provide relevant information (e.g., preventing side effects), and motivate changes in behavior (e.g., importance for fetal brain development, maternal mortality risks). Systematic use of procedures to assure quality and impact is key and is often missed in behavior change communication programs with poor results.

Wasantwisut and Winichagoon* recently summarized the lessons learned from Indonesia as well. They found that commitment from the government was a major factor, in addition to raising awareness and program promotion through community and religious leaders. Operational elements of the program that led to successful scaling up included availability of clear program guidelines and protocols, increased availability of supplements, use of health facilities and community health workers to distribute the supplements, and also private sales. On the demand factors, clear messages were provided to mitigate side effects, and efforts were made to improve the packaging and taste of the commodities. In India, USAID supported the states of Jharkhand and Uttar Pradesh (UP) to successfully strengthen supplies and expanded the direct promotion of iron–folic acid supplements through auxiliary nurse midwives (ANMs) and community-based Integrated Child Development Services (ICDS) workers with an emphasis on interpersonal communication.

In summary, the main lessons are the following:

- Effective country programs used multiple-intervention, comprehensive approaches for addressing major preventable causes of anemia. The key program interventions included iron and iron–folic acid supplementation for pregnant women, mandatory universal fortification, behavior change communication, intensive training of health services delivery staff, and person-to-person education and counseling targeted to mothers through local health services and community-based volunteers.
- Increasing the scale of the program was a goal of effective programs from the start, and the program expanded coverage and quality of iron supplementation through antenatal services with the active participation of community health workers. Strengthening of health systems was accompanied by community-based promotion and support. In both Thailand and Nicaragua, program interventions have been implemented countrywide with increasing coverage and quality over at least a decade.
- Successful programs systematically identified barriers and addressed them in a focused way. A key component has been comprehensive training of both health service personnel and community health workers, and use of multiple communications and supplement distribution channels focused on reaching the target groups.
- Special attention to removing supply constraints

included effective logistics management systems to secure a continuous supply of supplements and establishing effective delivery systems to local levels and frontline providers, eventually utilizing nonconventional distribution networks (e.g., nongovernmental organizations, community health workers). A prerequisite for effective and sustained program performance is a functional health system that facilitates reaching and maintaining high enough coverage and quality of health care, particularly of antenatal services. Important program features are proper selection of target groups and interventions, updated protocols and guidelines for program implementation, intensive and motivating training of health-care personnel, a properly designed behavior change strategy, provisions to address supply, and a functional program monitoring and evaluation system. In some countries, pharmaceutical companies have successfully marketed a range of products for pregnant women that contain various levels of iron combined with one or more other nutrients. The public health impact of these activities has not been documented, but they provide an important adjunct strategy to support large-scale adoption of routine prenatal supplementation.

Conclusions

The available evidence suggests that iron-deficiency anemia contributes substantially to death and disability in women, in addition to impacts on neonatal mortality and morbidity. The great majority of this disease burden derives from anemia in pregnancy and is highest in Asia and Africa, where almost 90% of anemic women reside. The prevalence of maternal anemia can be reduced by one-third to one-half within a decade.

In areas where nutritional anemia is highly prevalent, as seen in dietary surveys showing low absorbable iron intakes and/or where hematologic anemia studies so indicate, routine iron and folic acid supplementation will reduce anemia and contribute to Millennium Development Goal 5 (lowering maternal mortality).

As summarized in this paper, program processes have been documented to improve supply systems and to improve adherence to protocols through behavior change strategies. Two countries where documentation resources were available have shown how large-scale national programs can achieve success.

A combination of adequacy and plausibility assessments supports the contention that the remarkable declines in anemia rates in Thai and Nicaraguan women are plausibly the results of the implementation of focused nationwide programs.

Meanwhile, the evidence base for improving the effectiveness of iron–folic acid supplementation programs can be further strengthened with additional country experiences and evidence of anemia reduction with improvement in iron status. Because the estimates in this paper are uncertain in some respects, countries should motivate their public health scientists to provide more definitive evidence through improved monitoring and evaluation of such programs.

References


Effects of docosahexaenoic acid supplementation during pregnancy on gestational age and size at birth: Randomized, double-blind, placebo-controlled trial in Mexico

Usha Ramakrishnan, Aryeh D. Stein, Socorro Parra-Cabrera, Meng Wang, Beth Imhoff-Kunsch, Sergio Juárez-Márquez, Juan Rivera, and Reynaldo Martorell

Abstract

**Background.** The need for omega-3 fatty acids, especially docosahexaenoic acid (DHA), during pregnancy has received much attention, but evidence of effects on birth outcomes is limited.

**Objective.** To evaluate whether prenatal DHA supplementation increases gestational age and birth size.

**Methods.** We conducted a double-blind, randomized, placebo-controlled trial in Cuernavaca, Mexico. We randomly assigned 1,094 pregnant women (18 to 35 years of age; median DHA dietary intake, 55 mg/day) to 400 mg/day of algal DHA or placebo from 18 to 22 weeks of gestation through delivery. Birth outcomes (968 live births and 5 stillbirths) were ascertained from hospital records within 24 hours of delivery.

**Results.** Intention-to-treat analysis showed no differences between the control and DHA group (all p > .05) in mean gestational age (39.1 ± 1.7 and 39.0 ± 1.9 weeks, respectively), weight (3.20 ± 0.47 and 3.21 ± 0.45 kg, respectively), length (50.3 ± 2.7 and 50.3 ± 2.3 cm, respectively) and head circumference (34.3 ± 1.8 and 34.3 ± 1.5 cm, respectively) at birth. Offspring of supplemented primigravidae (n = 370) were heavier (difference, 99.4 g; 95% CI, 5.5 to 193.4) and had larger head circumferences (difference, 0.5 cm; 95% CI, 0.1 to 0.9) than controls; the differences in multigravidae (n = 603) were −53.3 g (95% CI, −126.8 to 20.2) and −0.2 cm (95% CI, −0.4 to 0.1), respectively (p < .05 for heterogeneity).

**Conclusions.** Prenatal DHA supplementation of primigravid women may result in increased birth size in a population where dietary DHA intakes are very low. Benefits of the intervention on infant health and neurodevelopment are under study.

**Key words:** Birth size, DHA, gestational age, Mexico, omega-3 fatty acids, pregnancy, randomized controlled trial

Introduction

Poor growth and development during the prenatal period and early childhood continue to be significant global public health problems. One of five children in developing countries is born with low birthweight, placing them at increased risk for death, morbidity, and poor development [1, 2].

Maternal nutritional status, both prior to and during pregnancy, is an important determinant of birth size and perinatal mortality [3]. Historically, recommendations for maternal nutrition have emphasized protein, energy, vitamin, and mineral requirements, but dietary lipids, especially essential fatty acids (EFAs), have received attention recently [4]. In particular, the n-3 fatty acid, docosahexaenoic acid (DHA), synthesized from α-linolenic acid (ALA) and found preformed in oil-rich fish, breastmilk, and algae, is essential for membrane function and plays a key role in the development of the fetal brain and retina. Long-chain polyunsaturated fatty acids (LCPUFAs) are transported across the placenta to the fetus; fetal accretion is especially high (50 to 60 mg/day) during the last trimester [5, 6]. It remains unclear, however, whether maternal needs for n-3 LCPUFAs during pregnancy, especially DHA,
can be met in most women by synthesis from precursor EFAs and stores, since the efficiency of conversion of DHA from the parent n-3 fatty acid ALA may be low [7, 8].

LCPUFA intake during pregnancy influences both maternal and infant fatty acid status at birth [9–11], which in turn is associated with birthweight and gestational age at birth [12, 13]. In observational studies, maternal dietary DHA intakes are positively associated with gestational age at birth and birth size [14–16], but the evidence from randomized, controlled trials is limited and weak [17–19]. Most of the intervention trials have included few participants and provided fish-oil supplements that contain large and varying doses of both DHA and eicosapentaenoic acid (EPA). Only one study conducted in the United States has evaluated the role of just DHA. Smuts et al. [20] randomized 300 women, recruited between 24 and 28 weeks of gestation, to receive either DHA-enriched eggs (mean DHA content, 133 mg per egg) or ordinary eggs (mean DHA content, 33 mg per egg) and found that a mean daily intake of one DHA-enriched egg increased the duration of gestation by 6 ± 2.3 days (p = .009). Mean birthweight was also greater in the intervention group (103 ± 64 g, p = .1).

We therefore conducted a large, placebo-controlled trial (POSGRAD) in Cuernavaca, Mexico to evaluate the benefits of Prenatal DHA (Omega-3 fatty acid) Supplements on infant Growth And Development. The primary outcomes were gestational age and size at birth and offspring size and development at 18 months of age. The objective of this study was to examine the effects of prenatal DHA supplementation on birth outcomes.

Methods

Experimental design

We conducted a double-blind, randomized, placebo-controlled trial. Pregnant women were randomly assigned to receive 400 mg of DHA or a placebo daily from mid-pregnancy (18 to 22 weeks to gestation) to delivery. This study was a collaborative effort among the Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta Georgia, USA; and the Instituto Nacional de Salud Pública (INSP) and the Instituto Mexicano del Seguro Social (IMSS) General Hospital I in Cuernavaca, Mexico. The study is a registered clinical trial (registered at INSP in Mexico: #CI-011, and at clinicaltrials.gov: NCT00646360). The study protocol was approved by the Emory University Institutional Review Board and by the INSP Biosafety and Ethics Committees. Written informed consent was obtained from each participant after a thorough explanation of the study details. An external Data and Safety Monitoring Committee (DSMC) reviewed the study data periodically.

Study setting

Study participants were recruited at the Mexican Institute of Social Security (IMSS) General Hospital I, a large hospital located in Cuernavaca, Mexico, and three small health clinics within the IMSS system in Cuernavaca during routine prenatal care visits between February 2005 and February 2007. The IMSS healthcare system provides employed persons access to medical care. Generally, the women who use the hospital are of medium-to-low socioeconomic status and either they or their husbands, or both, are employed. In most cases, the IMSS hospital patient pays one-third of the healthcare costs and the employer and the federal government pay the remaining two-thirds of the costs.

Sample size

Using data from the literature and our previous work in Mexico [21, 22], we estimated that a final sample of 338 infants per group would have at least 90% power to detect an effect size of 0.25 SD or greater for the major outcomes at the end of the study, assuming a significance level of α = .05 for a two-tailed test. We therefore planned to recruit at least 994 pregnancies, assuming a 15% loss to follow-up during pregnancy and a further 20% loss in infancy, to have 393 births and 338 mother–child pairs per group complete the study at 18 months of age. This sample size would allow us to detect differences in birthweight of 100 g (0.2 SD) with at least 80% power.

Eligibility criteria

Eligible women were 18 to 35 years old, were in gestation weeks 18 to 22, and planned to deliver at the IMSS General Hospital in Cuernavaca, exclusively or predominantly breastfeed for at least 3 months, and live in the area for at least 2 years after delivery. Women were excluded if any of the following criteria were present: high-risk pregnancy (history and prevalence of pregnancy complications, including abruptio placenta, preeclampsia, pregnancy-induced hypertension, any serious bleeding episode in the current pregnancy, and/ or physician referral); lipid metabolism or absorption disorders; regular intake of fish oil or DHA supplements; or chronic use of certain medications (e.g., medications for epilepsy).

Randomization and blinding

We used block randomization to randomly create balanced replication of four treatments (two colors for DHA and two for control) using a block size of eight.
The list was generated for a sample size of 1,104. The assignment codes were placed in sealed envelopes at the beginning of the study, and these envelopes were held in a sealed location by a faculty member at Emory University who was not involved in the study. All study participants and members of the study team remained blinded to the treatment scheme throughout the intervention period of the study. Data were unblinded for the analytical study team after the last baby in the study was born and had reached 6 months of age, at which time the participants were no longer taking supplements. Since the study is ongoing for follow-up of child development, the participants and fieldworkers in Mexico remain blinded to the treatment allocation.

Enrollment

Pregnant women were approached by study personnel when they came to IMSS for their routine prenatal visit and were screened for eligibility if they were interested in participating in the study. Once eligibility was confirmed by the study physician, the participants were contacted at home, where details of the study protocol were explained to them, written informed consent was obtained, and dietary intakes and socioeconomic status were measured by trained fieldworkers using pretested questionnaires from previous studies [23]. Dietary intakes of fatty acids were evaluated with the use of a previously validated food-frequency questionnaire that was adapted for use in pregnant women who were asked to recall intakes of 110 food items in the past 3 months. Women who agreed to participate were then scheduled for a hospital visit and were randomly assigned to treatment or placebo. Baseline measurements of body size (weight, height, and skinfolds) and obstetric history were obtained by trained nurses at this scheduled visit, at which time the study participants also received the first week’s supply of supplements.

Interventions

The supplements (produced by Martek Biosciences and distributed by Mead Johnson) were provided in color-coded bottles (two colors per treatment arm) and were distributed by trained fieldworkers during weekly visits at the participant’s home or workplace. The DHA capsules contained 200 mg of DHA derived from an algal source. The placebo capsules contained olive oil and were similar in appearance and taste to the DHA capsules. The women were instructed to take two capsules daily, together, at the same time each day.

During each weekly home visit, the subjects received 14 capsules in a precoded container, and the capsules remaining from the prior visit were counted. Supplements were provided for more than 1 week in cases where the subject planned to travel. Compliance was calculated as the total number of capsules actually consumed, expressed as a percentage of the total number expected to be consumed. Details of any side effects and illness and capsule count were recorded by the fieldworkers during the weekly home visits using precoded questionnaires. Adverse events were reported either by the participant contacting the study staff or at the weekly visit. All adverse events were evaluated immediately by the study physician. The study principal investigator was notified of any severe adverse events within 24 hours, and this information was furnished to the institutional review board at Emory University and INSP and to the DSMC at routine intervals and upon request.

Measurement of outcomes

Data on birth outcomes were obtained from hospital records by study personnel within 24 hours after delivery. The data included whether the birth was a live birth, occurrence of multiple births, sex of baby, type of delivery, and anthropometric measurements obtained within 1 hour after birth. Birthweight was measured to the nearest 10 g by a pediatric scale. Low birthweight was defined as less than 2,500 g. Birth length and head circumference were measured by trained hospital staff to the nearest 1 mm using a portable anthropometer with a fixed headpiece and a flexible tape, respectively, according to standard procedures [24]. Gestational age at birth in days was determined based on the date of the last menstrual period reported at recruitment, unless the woman had delivered in the previous 6 months, in which case we used the dating ultrasound. Preterm delivery was defined as delivery before 37 weeks of gestation. Intrauterine growth retardation was defined as birthweight below the 10th percentile of the gestational age- and sex-specific reference [25].

Fetal losses during pregnancy were ascertained by study personnel during the home visits. Stillbirths were defined as fetuses delivered at 28 weeks or later with no signs of life and recorded as occurring before or during the onset of labor; neonatal deaths were defined as deaths among liveborn infants occurring within 28 days after delivery. These details were confirmed by study personnel who reviewed hospital records and interviewed the women during a home visit at 15 days postpartum and/or during the 1-month postpartum visit at the hospital.

Data analysis

We first compared control and intervention groups on several baseline maternal and household characteristics to evaluate the effectiveness of randomization. This was done for the total sample (i.e., everyone randomized) and for the final analytic sample with data on birth outcomes. We also compared the final analytic sample
with those lost to follow-up on several baseline characteristics and compliance. We used Student’s t-test for normally distributed continuous variables and chi-square tests for categorical variables.

All analyses were done following the intention-to-treat design. For normally distributed continuous outcomes (birthweight, length, head circumference, and gestational age), we estimated unadjusted group differences (DHA vs. control) and their 95% confidence intervals using general linear models. For dichotomous outcomes (presence or absence of low birthweight, intrauterine growth retardation, and preterm birth), we calculated odds ratios and 95% confidence intervals using logistic regression. We also conducted analyses after restricting the sample to singleton births. We also tested for effect modification by maternal gravidity, body mass index at baseline, and socioeconomic status and the infant’s sex. A p value less than .05 was considered to indicate statistical significance.

Results

Enrollment began in February 2005 and ended in March 2007. The last child was born in July 2007. Of 1,762 eligible women, 1,094 were randomized and 1,040 began treatment; 54 women who had originally agreed to participate and were randomized declined to begin treatment (fig. 1). An additional 67 women dropped out after they began the intervention; the reasons were lack of family support, moving away from the area, and side effects of the supplement (disliked flavor, heartburn, nausea). The majority (85.5%) of women delivered at IMSS General Hospital I; data on birth outcomes were available for 973 pregnancies. The rate of loss to follow-up after treatment began was 6.4% and did not differ by treatment group. The women in the final sample with birth outcomes (n = 973), however, were of higher socioeconomic status (p = .03) than randomized women for whom childbirth outcomes were not available (n = 121).

Mean age and body mass index at entry were 26.2 ± 4.7 years and 26.0 ± 4.2 kg/m², respectively; 38% were primigravidae and 57% had completed high school. Intakes of preformed DHA were very low (median intake, 55 mg/day; interquartile range, 37 to 99 mg/day) combined with a high ratio of n-6 to n-3 fatty acids [12:1]. The median intake of ALA was 1,480 mg, compared with the recommended Adequate Intake (AI) in pregnancy of 1,400 mg; the median intake of linoleic acid (LA) was 17.7 g, compared with the AI of 13 g [26]. Maternal characteristics at recruitment were similar between the two treatment arms (table 1); compliance was high and did not differ by treatment group (table 2). Nearly 87% of women with birth outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n = 547)</th>
<th>DHA (n = 547)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age (yr)</td>
<td>26.2 ± 4.6</td>
<td>26.3 ± 4.8</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>20.5 ± 2.1</td>
<td>20.6 ± 2.1</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td>0.0 ± 1.0</td>
<td>0.0 ± 1.0</td>
</tr>
<tr>
<td>High school education or above</td>
<td>59.5</td>
<td>56.6</td>
</tr>
<tr>
<td>Primigravidae (%)</td>
<td>39</td>
<td>36.9</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>63.3 ± 11.1</td>
<td>62.1 ± 11.3</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>155.4 ± 5.7</td>
<td>154.9 ± 5.8</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.2 ± 4.2</td>
<td>25.9 ± 4.2</td>
</tr>
<tr>
<td>Dietary intake—median (25th,75th %ile)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LA (mg/day)</td>
<td>17,846 (13,708, 21,982)</td>
<td>17,645 (13,738, 23,024)</td>
</tr>
<tr>
<td>AA (mg/day)</td>
<td>137 (102, 172)</td>
<td>140 (103, 182)</td>
</tr>
<tr>
<td>ALA (mg/day)</td>
<td>1,488 (1,033, 2,056)</td>
<td>1,477 (1,051, 2,068)</td>
</tr>
<tr>
<td>EPA (mg/day)</td>
<td>18 (10, 37)</td>
<td>18 (11, 39)</td>
</tr>
<tr>
<td>DHA (mg/day)</td>
<td>54 (38, 93)</td>
<td>56 (38, 101)</td>
</tr>
<tr>
<td>Ratio of n-6 to n-3 fatty acids</td>
<td>11.4 (8.5, 14.7)</td>
<td>11.8 (8.3, 15.4)</td>
</tr>
</tbody>
</table>

AA, arachidonic acid; ALA, α-linolenic acid; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; LA, linoleic acid

a. Mean ± SD unless otherwise indicated. No significant differences by group (p > .05) according to t-test for comparison of means and chi-square test for comparison of proportions.
b. Based on principal components analysis.
c. (LA + AA)/(ALA + EPA + DHA)
consumed at least 180 capsules, representing 90 days of intervention.

**Safety and side effects of intervention**

Of a total of 98 adverse events, there were 21 and 25 serious adverse events in the control and DHA groups, respectively; these included 5 stillbirths (3 control, 2 DHA) and 12 infant deaths (8 control, 4 DHA). There were no significant differences in the total number of adverse events or serious adverse events by treatment group in mothers or their offspring. Thirty-one infants (15 control, 16 DHA) were born with congenital anomalies such as spina bifida and heart malformations; these were considered unrelated to the study intervention, as they represent early-gestation disorders. Side effects such as nausea, headache, swelling, and vaginal fluid were common. Specifically, the proportions of women who reported ever vomiting were 23.8% and 26.9% in the control and DHA groups, respectively; the proportions reporting ever having nausea were 30.3% and 33.7%, respectively. Vaginal bleeding or fainting was reported by fewer than 10% of women; this proportion did not differ by treatment group (data not shown).

DHA concentrations in maternal plasma at delivery and cord blood were significantly higher \( (p < .05) \) in the intervention group than in the control group in a random subsample of study subjects. The mean ± SD DHA levels in maternal plasma at delivery were 1.36 ± 0.38 \((n = 109)\) and 1.71 ± 0.46 \((n = 110)\) in the control and DHA groups, respectively; the cord blood DHA levels were 2.04 ± 0.54 \((n = 96)\) and 2.43 ± 0.61 \((n = 93)\), respectively. There were no significant differences in the concentrations of the other \( n-3 \) (EPA) and \( n-6 \) (arachidonic acid [AA] and LA) fatty acids measured, although the ratio of \( n-6 \) to \( n-3 \) fatty acids in maternal blood at delivery was significantly lower \( (p < .05) \) in the DHA group \( (8.71 ± 2.46, n = 110) \) than in the control group \( (9.85 ± 2.49, n = 109) \).

The results of the intention-to-treat analysis are presented in table 3. The proportion of live births was similar in both groups. There were four sets of twins in the DHA group as compared with one set in the control group. There were no differences between groups in the sex ratio, the prevalence of preterm births (gestational age at delivery < 37 weeks) and the incidence of congenital anomalies.
a larger head circumference (difference, 0.5 cm; 95% CI, 0.1 to 0.9) (table 4); among multigravid women, there were no differences according to treatment group. Similar findings were observed for the prevalence rates of low birthweight and intrauterine growth retardation; the relative risks were 0.3 (95% CI, 0.1 to 0.8) and 0.5 (95% CI, 0.3 to 1.0), respectively, in primigravid women, whereas among multigravid women the prevalence of intrauterine growth retardation was higher for those who received DHA than for those who received placebo (adjusted RR, 1.5; 95% CI, 1.0 to 2.4). Although primigravid women were younger, taller, and more educated than multigravid women (with no difference in these characteristics between treatment groups), adjusting for these baseline characteristics and infant sex did not change our findings. Dietary intakes of n-3 (ALA, EPA, and DHA) and n-6 (LA, AA) fatty acids and DHA status at entry and delivery also did not differ by gravidity. Within strata of gravidity, the DHA and control groups were also similar in gestational age at entry; supplement consumption did not differ by gravidity or treatment group. There was no evidence of heterogeneity by maternal characteristics or offspring sex for birth length or gestational age.

### Discussion

In a large, randomized, controlled trial, supplementation from mid-pregnancy to delivery with 400 mg/day of DHA did not affect gestational age at birth or birth size. The two groups were well matched at baseline, compliance was high, and loss to follow-up was minimal. However, we observed heterogeneity, in that the offspring of primigravid women who received DHA were heavier at birth than the offspring of primigravid women who received placebo (difference, 9.4 g; 95% CI, 5.5 to 19.3) and had larger head circumferences (difference, 0.5 cm; 95% CI, 0.1 to 0.9 cm). The reason for this selective effect, however, remains unclear.

### TABLE 2. Compliance and number of capsules consumed according to treatment group

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Control</th>
<th>DHA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 547)</td>
<td>(n = 547)</td>
</tr>
<tr>
<td>0–25</td>
<td>1 (0.2)</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>26–50</td>
<td>5 (1.0)</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>51–75</td>
<td>34 (7.0)</td>
<td>42 (8.7)</td>
</tr>
<tr>
<td>76–100</td>
<td>444 (91.7)</td>
<td>437 (90.1)</td>
</tr>
<tr>
<td></td>
<td>88.6 ± 10.0c</td>
<td>88.0 ± 11.4c</td>
</tr>
</tbody>
</table>

Intrauterine growth retardation is defined as less than the 10th percentile of birthweight for gestational age [25].

### TABLE 3. Birth outcomes for all live births according to treatment group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>DHA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 486)</td>
<td>(n = 487)</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>52.3</td>
<td>53.4</td>
</tr>
<tr>
<td>Gestational age (wk)b</td>
<td>39.1 ± 1.7</td>
<td>39.0 ± 1.9</td>
</tr>
<tr>
<td>Preterm (% &lt; 37 wk)b</td>
<td>8.3</td>
<td>10.1</td>
</tr>
<tr>
<td>Birthweight (g)</td>
<td>3,202.0 ± 472.0</td>
<td>3,207.2 ± 449.4</td>
</tr>
<tr>
<td>Birth length (cm)</td>
<td>50.3 ± 2.7</td>
<td>50.3 ± 2.3</td>
</tr>
<tr>
<td>Head circumference (cm)</td>
<td>34.3 ± 1.8</td>
<td>34.3 ± 1.5</td>
</tr>
<tr>
<td>Low birthweight (% &lt; 2,500 g)</td>
<td>5.6</td>
<td>5.5</td>
</tr>
<tr>
<td>Intrauterine growth retardation (%)c</td>
<td>11</td>
<td>11.3</td>
</tr>
</tbody>
</table>

a. All values for the DHA and control groups are expressed as mean ± SD unless otherwise indicated. For categorical variables, the p values are calculated by the chi-square test for equality of proportions (Fisher’s exact test); for continuous variables, the p values are calculated by the t-test for equality of means.
b. The sample sizes are 484 and 486 for the DHA and control groups, respectively.
c. Intrauterine growth retardation is defined as less than the 10th percentile of birthweight for gestational age [25].
The DHA and control groups were similar on a range of baseline characteristics in these subgroups, and the infant sex ratio, gestational age at entry, and supplement consumption did not differ by gravidity or treatment group. Primigravidae, however, were younger, taller, and had more years of schooling than multigravidae. An inverse relationship between plasma DHA levels and number of previous pregnancies has been reported [27], but this was not the case in our population; DHA status did not differ by gravidity. Primigravid women, however, typically had smaller infants than did multigravidae [28, 29], and DHA supplementation may have removed one aspect of this constraint.

In a recent meta-analysis, Szajewska et al. [17] found that supplementation with n-3 LCPUFAs during pregnancy increased the duration of pregnancy (weighted mean difference, 1.57 days; 95% CI, 0.35 to 2.78) and head circumference at birth (weighted mean difference, 0.26 cm; 95% CI, 0.02 to 0.49 cm) in low-risk pregnancies, but the mean effect size was small and disappeared for the low-risk pregnancies in sensitivity analysis. Infants of mothers supplemented with n-3 LCPUFAs were heavier (weighted mean difference, 0.54 g; 95% CI, −3.1 to 111) and longer (0.23 cm; 95% CI, −0.04 to 0.5) at birth. Supplementation with n-3 LCPUFAs had no significant effect on the percentage of preterm deliveries or low-birthweight infants or the rate of preeclampsia or eclampsia. Most of the studies in the meta-analysis tested fish oils that provide both EPA and DHA; only one study that provided DHA alone was included in the analysis [20]. Our study more than doubles the number of women who have participated in these trials. We tested a dosage of 400 mg/day, which is closer to the current recommendations [26, 30] and feasible for dietary interventions; approximately two fish meals per week would provide similar amounts of DHA.

In conclusion, supplementation with DHA during the second half of pregnancy did not show large benefits with respect to gestational age or size at birth. The heterogeneity by gravidity needs to be replicated in other ongoing studies. To our knowledge, this is the first large study that has examined the benefits of providing DHA supplements in a developing-country setting such as Mexico, which is experiencing the nutrition transition that is characterized by the coexistence of problems of undernutrition and obesity [31]. The median dietary intake of DHA at recruitment was only 55 g/day, as compared with the current recommendation of 200 mg/day in pregnancy [4], and less than 20% of the women consumed fish, a major source of n-3 fatty acids, at least weekly [32]. More importantly, the ratio of n-6 to n-3 PUFAs was high (~12:1), which could have adverse effects on lipid metabolism, as these PUFAs classes compete for the same enzyme system [7].

The high intakes of ALA, however, may account for the lack of an overall effect if the efficiency of conversion to DHA is high. It is plausible that the benefits may be

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>DHA</th>
<th>Difference or relative risk (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primigravidae</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birthweight (g)</td>
<td>3,134.0 ± 503.1</td>
<td>3,233.4 ± 409.5</td>
<td>99.4 (5.5 to 193.4)</td>
<td>.04</td>
</tr>
<tr>
<td>Birth length (cm)</td>
<td>50.2 ± 3.0</td>
<td>50.3 ± 2.3</td>
<td>0.1 (−0.4 to 0.7)</td>
<td>.69</td>
</tr>
<tr>
<td>Head circumference (cm)</td>
<td>33.9 ± 2.1</td>
<td>34.4 ± 1.6</td>
<td>0.5 (0.1 to 0.9)</td>
<td>.02</td>
</tr>
<tr>
<td>Low birthweight (% &lt; 2,500g)</td>
<td>7.4</td>
<td>3.3</td>
<td>0.4 (0.2 to 1.1)</td>
<td>.08</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>39.2 ± 1.8</td>
<td>39.2 ± 1.9</td>
<td>0.0 (−0.4 to 0.4)</td>
<td>1.00</td>
</tr>
<tr>
<td>Preterm (% &lt; 37 wk)</td>
<td>9.1</td>
<td>9.3</td>
<td>1.0 (0.5 to 1.9)</td>
<td>.95</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>55.3</td>
<td>52.7</td>
<td>1.1 (0.8 to 1.3)</td>
<td>.62</td>
</tr>
<tr>
<td>Intrauterine growth retardation (%)</td>
<td>14</td>
<td>7.1</td>
<td>0.5 (0.3 to 1.0)</td>
<td>.03</td>
</tr>
<tr>
<td><strong>Multigravidae</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birthweight (g)</td>
<td>3,244.8 ± 446.8</td>
<td>3,191.6 ± 471.5</td>
<td>−53.3 (−126.8 to 20.2)</td>
<td>.16</td>
</tr>
<tr>
<td>Birth length (cm)</td>
<td>50.3 ± 2.6</td>
<td>50.3 ± 2.3</td>
<td>−0.0 (−0.4 to 0.4)</td>
<td>.95</td>
</tr>
<tr>
<td>Head circumference (cm)</td>
<td>34.5 ± 1.5</td>
<td>34.3 ± 1.5</td>
<td>−0.2 (−0.4 to 0.1)</td>
<td>.20</td>
</tr>
<tr>
<td>Low birthweight (% &lt; 2,500 g)</td>
<td>4.4</td>
<td>6.9</td>
<td>1.6 (0.8 to 3.1)</td>
<td>.18</td>
</tr>
<tr>
<td>Gestational age (wk)</td>
<td>39.1 ± 1.6</td>
<td>39.0 ± 1.8</td>
<td>−0.1 (−0.4 to 0.1)</td>
<td>.36</td>
</tr>
<tr>
<td>Preterm (% &lt; 37 wk)</td>
<td>7.7</td>
<td>10.5</td>
<td>1.4 (0.8 to 2.3)</td>
<td>.23</td>
</tr>
<tr>
<td>Sex (% male)</td>
<td>50.3</td>
<td>53.8</td>
<td>0.9 (0.8 to 1.1)</td>
<td>.40</td>
</tr>
<tr>
<td>Intrauterine growth retardation (%)</td>
<td>9.1</td>
<td>13.8</td>
<td>1.5 (1.0 to 2.4)</td>
<td>.07</td>
</tr>
</tbody>
</table>

a. All values for the DHA and control groups are expressed as mean ± SD unless otherwise indicated. For categorical variables, the p values are calculated by the chi-square test for equality of proportions; for continuous variables, the p values are calculated by the t-test for equality of means.

b. Intrauterine growth retardation is defined as less than the 10th percentile of birthweight for gestational age [25].
larger in populations with similar intakes but higher prevalence rates of intrauterine growth retardation, since the rate of low birthweight was quite low (5% to 6%). Our study population was predominantly a middle-class urban population with access to healthcare; the infant mortality rates were lower than the Mexican national average of 29/1,000 [33]. Genetic differences in the activity of the key enzyme δ-6-saturase [34], which is involved in the conversion of the n-3 and n-6 precursors to DHA and AA, respectively, may also predict differential response to this intervention [4, 5]. Follow-up of the growth and development of the offspring is ongoing.

Acknowledgments

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References


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Increases in breastfeeding duration observed in Latin America and the Caribbean and the role of maternal demographic and healthcare characteristics

Camila M. Chaparro and Chessa K. Lutter

Abstract

To understand the factors contributing to changes in breastfeeding duration, we analyzed data from seven countries in Latin America and from Haiti to document changes in breastfeeding duration between 1986 and 2005. We used a novel method that permits the overall change to be separated into the portion attributable to changing population characteristics (e.g., greater urban population or increased maternal employment) and the portion resulting from changing breastfeeding behaviors within population subgroups (e.g., more breastfeeding among urban women). Our results indicate that in the low-to-middle-income countries studied, which are experiencing socioeconomic and demographic changes, improvements in breastfeeding duration occurred. These improvements are explained almost entirely by changing breastfeeding behaviors, which were particularly evident in certain subgroups of women, such as those with higher levels of education, and very little by changing population characteristics. The socioeconomic and demographic changes we studied that were previously associated with less breastfeeding no longer appear to have a large negative effect. Our findings show that individual behaviors are amenable to change and that changes in individual behaviors collectively contribute to positive national trends in breastfeeding.

Key words: Breastfeeding, child health, Latin America

Introduction

Few would disagree with the statement that breastfeeding promotion is a public health “best buy”; the behavior has a large biologic impact and is also amenable to change. Promoting breastfeeding is the single most effective intervention to prevent child mortality, and it reduces child morbidity and improves health and cognitive development in ways that have been amply documented [1–8]. Breastfeeding also positively influences maternal health [9, 10–13]. In each of the four recent Lancet series on “Child Survival,” “Early Childhood Development in Developing Countries,” “Newborn Health and Maternal and Child Undernutrition,” breastfeeding was highlighted because of its important effect on reducing neonatal and infant mortality [1, 14, 15] and also because of its responsiveness to interventions for its promotion [16].

Historically, population characteristics associated with economic and social development, such as increased urbanization, female education, prenatal care and skilled attendance at birth, and use of modern contraceptives [17–19], have been shown to be negatively associated with breastfeeding duration. Thus, as populations develop over time and adopt more of these socioeconomic and demographic characteristics, the overall duration of breastfeeding may decrease if not counteracted by an equal or greater shift toward behaviors that maintain and increase breastfeeding, promoted and supported by public health interventions well documented to be highly effective [19–23] and cost effective [24]. Inasmuch as breastfeeding promotion is among the most effective and cost-effective interventions for preventing child mortality [24, 25] and also has many other short- and long-term benefits for maternal and child health [9, 26], understanding how the determinants of breastfeeding identified above change over time and affect breastfeeding duration is important for developing sound public health policy. To better understand the factors contributing to changes in breastfeeding duration, we analyzed...
Data and methods

We analyzed data from nationally representative Demographic and Health Surveys that took place between 1986 and 2005 in Bolivia, Brazil, Colombia, the Dominican Republic, Guatemala, Haiti, Nicaragua, and Peru. The sample sizes for each country analyzed ranged from roughly 2,600 to 11,000 mother–child pairs. Because the questionnaires used in Demographic and Health Surveys are highly standardized, they permit valid comparisons of population young-child feeding practices and demographic characteristics across countries and time. The surveys target women of reproductive age (15 to 49 years) and include detailed questions on young-child feeding among women with a child less than 3 or 5 years of age, depending on the country. The data are publicly available and were downloaded from the Demographic and Health Surveys Website (www.measuredhs.com).

The span between the oldest and the most recent surveys for the selected countries ranged from 3 to 19 years. Therefore, to make comparisons over roughly similar time intervals, we organized the surveys into three chronological groups: those that occurred between the late 1980s and the late 1990s, representing an approximately 10-year time span (group 1); those that occurred between the middle to late 1990s and the early 2000s, representing an approximately 3- to 5-year time span (group 2); and those that occurred between 2000 and 2005, representing an approximately 4- to 5-year time span (group 3). Thus, each chronological group is composed of “early” and “late” surveys. For group 1, the early surveys were conducted between 1986 and 1989 and the late surveys between 1995 and 1999; the group includes Bolivia, Brazil, the Dominican Republic, Guatemala, and Peru. For group 2, the early surveys were conducted between 1995 and 1999 and the late surveys between 2000 and 2003; the group includes Bolivia, Colombia, the Dominican Republic, Haiti, Nicaragua, and Peru. For group 3, the early surveys were conducted in 2000 and the late surveys between 2004 and 2005; the group includes Colombia, Haiti, and Peru. For each country and within each chronological group, we assessed the trend in the overall predicted mean duration of breastfeeding between survey time points.

The methods used for data analysis were based on the analysis of Grummer-Strawn [27], where the effects of various covariates on the probability of still breastfeeding for all postpartum women at the time of the survey (and thus, indirectly, the mean duration of breastfeeding) were estimated. Covariates included in that analysis, as well as the current analysis, were those that have been identified in the literature as associated with breastfeeding behavior, such as urban or rural residence, maternal age, maternal education, parity, modern contraceptive use, number of antenatal visits, assistance at delivery, and maternal employment (table 1) [17, 28, 29]. As seen in the table, many of the covariates—which are generally associated with increasing development, including urbanization, increased maternal education, and decreased parity—are hypothesized to have a negative effect on breastfeeding duration.

Statistical methods

Because of the documented problems with using maternal recall data for the date of breastfeeding cessation or the duration of breastfeeding [30], current breastfeeding status was analyzed for all living children under 5 years of age in the respondent’s household at the time of each survey. Briefly, logistic regression (SAS for Windows, version 9.1) was used to model the log-odds of currently breastfeeding in each month, with age modeled with a natural cubic spline as described by Grummer-Strawn [31]. For each survey for each country, all covariates (table 1) were entered into the model simultaneously to determine the effect of each variable on the probability of breastfeeding at any given age while controlling for the other covariates. The parameter estimates used for the subsequent calculations are thus from the logistic regression model that simultaneously controlled for all covariates.

In order to assess the overall trend in breastfeeding duration within each country from the first survey to
TABLE 1. Description of variables used in analysis of breastfeeding determinants, with hypothesized effects on the duration of breastfeeding

<table>
<thead>
<tr>
<th>Variable</th>
<th>Categories and definition</th>
<th>Effect&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Socioeconomic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residence</td>
<td>Rural</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Urban</td>
<td></td>
</tr>
<tr>
<td>Mother’s education (yr)</td>
<td>None</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1–6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7–11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 12</td>
<td></td>
</tr>
<tr>
<td>Partner’s education (yr)</td>
<td>None</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>1–6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7–11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 12</td>
<td></td>
</tr>
<tr>
<td>Partner’s occupation</td>
<td>Agriculture or not employed</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Manual (skilled or unskilled)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Service or domestic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Professional, managerial, or technical</td>
<td></td>
</tr>
<tr>
<td>Mother currently employed</td>
<td>No</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Prenatal care</td>
<td>No prenatal care</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Received any prenatal care</td>
<td></td>
</tr>
<tr>
<td>Assistance at delivery</td>
<td>Received assistance at delivery by a non-health professional (traditional birth attendant, relative, other) or did not receive delivery assistance</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Received assistance at delivery by a skilled health professional (doctor, nurse, or midwife)</td>
<td></td>
</tr>
<tr>
<td><strong>Demographic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother’s age at time of birth of index child (yr)</td>
<td>&lt; 24</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>25–29</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30–34</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 35</td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td>1</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>2–3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4–6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>≥ 7</td>
<td></td>
</tr>
<tr>
<td>Contraceptive use (current method)</td>
<td>None, traditional, or folkloric&lt;sup&gt;b&lt;/sup&gt;</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>“Modern” method other than oral contraceptives&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral contraceptives</td>
<td></td>
</tr>
<tr>
<td>Sex of child</td>
<td>Female</td>
<td>+/–</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Children &lt; 5 yr in household (other than index child)</td>
<td>None</td>
<td>+/–</td>
</tr>
<tr>
<td></td>
<td>≥ 1</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Hypothesized effect is relative to the last category listed for each variable (e.g., for residence, the hypothesized negative effect is relative to urban residency).

<sup>b</sup> Traditional or folkloric methods of birth control are defined by Demographic and Health Surveys to include periodic abstinence (rhythm), withdrawal, abstinence, or methods under "other."

<sup>c</sup> "Modern" methods of birth control are defined by Demographic and Health Surveys to include IUD, injections, diaphragm, condom, female sterilization, male sterilization, implants, female condom, foam or jelly, and lactational amenorrhea.
the final survey, an overall predicted mean duration of breastfeeding was calculated for each survey, using the logistic regression parameter estimates and the distribution of the covariates of interest in each population. For each population subgroup (e.g., urban versus rural, each category of maternal age) within each survey, we used the parameter estimates from the logistic regression models to estimate the probability of being breastfed at each age (0 to 59 months). To calculate the predicted mean duration of breastfeeding for each subgroup, we calculated the area under the curve of the predicted probabilities of being breastfed at each age. Using this calculated predicted mean duration of breastfeeding for each subgroup and the proportion of children falling into each subgroup, we calculated a weighted average to provide an estimate of the overall predicted mean duration of breastfeeding for each survey.

Finally, to decompose the overall trend in breastfeeding duration from the first available survey to the most recent survey completed for each country, the following calculations were done, as described in Grummer-Strawn [27]. The portion of the overall trend attributable to behavioral changes alone (TrendΔB) (i.e., what the change in the mean duration of breastfeeding would have been if there were no changes in the population distribution of covariates) can be calculated as:

\[
\text{Trend}_B = \frac{(\mu_{12} - \mu_{11}) + (\mu_{22} - \mu_{21})}{2}
\]

where \(\mu_{12}\) is the predicted mean duration of breastfeeding using the early survey’s population distribution and the late survey’s regression coefficients; \(\mu_{11}\) is the predicted mean duration of breastfeeding using the early survey’s population distribution and regression coefficients; \(\mu_{22}\) is the predicted mean duration of breastfeeding using the late survey’s population distribution and regression coefficients; and \(\mu_{21}\) is the predicted mean duration of breastfeeding using the late survey’s population distribution and the early survey’s regression coefficients.

The trend attributable to population distribution changes (TrendΔP) (i.e., what the change in the mean duration of breastfeeding would have been if only the population distribution changed and behaviors did not change) can be calculated as:

\[
\text{Trend}_P = \frac{(\mu_{21} - \mu_{11}) + (\mu_{22} - \mu_{12})}{2}
\]

Thus, the overall trend in breastfeeding duration is:

\[
\text{Overall trend} = \mu_{21} - \mu_{11} = \text{Trend}_B + \text{Trend}_P
\]

Each country’s trend was analyzed separately for the purpose of describing the overall effects of population characteristics on the probability of breastfeeding and the distribution of population characteristics across the region.

**Results**

**Determinants of breastfeeding duration**

The odds ratios for the probability of being breastfed varied with maternal and family characteristics and over time (table 2). Overall, the most important and consistent predictor of whether a mother continued to breastfeed was her level of education. Higher maternal education was associated with a lower probability of breastfeeding at any given age of the child. As an example of the strength of this relationship, for group 1 surveys, the odds of breastfeeding for children of mothers with no education were 2.7 times higher than those for children born to mothers with 12 or more years of education. The negative relationship between greater maternal education and breastfeeding was seen across all countries and survey years, although the relationship was attenuated with the more recent surveys. The notable exception is the most recent survey in Brazil, completed in 1996, where higher maternal education was associated with a longer duration of breastfeeding (data not presented).

Maternal age was also an important predictor of breastfeeding across countries and survey years, although in the opposite direction of maternal education. The odds of a child born to a mother in the oldest age category (35 years or greater) being breastfed were 1.4 to 2.8 times higher than the odds of a child of a mother in the youngest age category (less than 25 years). Greater parity was positively associated with the probability of breastfeeding across the time periods, although the relationship was not always consistent. There tended to be a weak, but consistently negative, bias between male sex and the probability of being breastfed: on average, the odds of a female child being breastfed were slightly higher than the odds of a male child being breastfed. Living in an urban environment was consistently associated with a shorter duration of breastfeeding, and this negative relationship was strengthened in the later time periods.

The association between breastfeeding and access to medical care during the pre- and perinatal periods was not consistent over time. Having a skilled attendant at delivery was negatively associated with breastfeeding in the earliest time period (1986–89) but weakly positively or neutrally associated with breastfeeding in the surveys conducted during the most recent time periods. The use of oral contraceptives was negatively associated with breastfeeding, which diminished over time so that there was no relationship in the last time period (2004–05). Other “modern” methods of birth control
TABLE 2. Median odds ratios (OR) for currently breastfeeding for each chronological group of surveys

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>Group 1 median OR</th>
<th>Group 2 median OR</th>
<th>Group 3 median OR</th>
</tr>
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<tbody>
<tr>
<td>Prenatal care</td>
<td>Received any prenatal care</td>
<td>0.95</td>
<td>0.98</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>No prenatal care (reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;Modern&quot; method other than oral contraceptives</td>
<td>0.82</td>
<td>0.96</td>
<td>1.07</td>
</tr>
<tr>
<td></td>
<td>Oral contraceptives</td>
<td>0.44</td>
<td>0.89</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>None, traditional, or folkloric (reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contraceptive use (current method)</td>
<td>Skilled or trained health professional (doctor, nurse, or midwife)</td>
<td>0.76</td>
<td>0.85</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>No assistance or assistance by a non-health professional (reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assistance at delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother's age at time of birth of index child (yr)</td>
<td>25–29</td>
<td>1.31</td>
<td>1.49</td>
<td>1.37</td>
</tr>
<tr>
<td></td>
<td>30–34</td>
<td>1.52</td>
<td>1.77</td>
<td>1.79</td>
</tr>
<tr>
<td></td>
<td>≥ 35</td>
<td>2.30</td>
<td>1.83</td>
<td>2.79</td>
</tr>
<tr>
<td></td>
<td>≤ 24 (reference)</td>
<td></td>
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<tr>
<td>Mother's education (yr)</td>
<td>1–6</td>
<td>0.82</td>
<td>0.69</td>
<td>0.80</td>
</tr>
<tr>
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<td>7–11</td>
<td>0.51</td>
<td>0.64</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>≥ 12</td>
<td>0.37</td>
<td>0.35</td>
<td>0.32</td>
</tr>
<tr>
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<td>None (reference)</td>
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</tr>
<tr>
<td>Mother currently employed</td>
<td>Yes</td>
<td>0.89</td>
<td>0.98</td>
<td>1.07</td>
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<tr>
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<td>No (reference)</td>
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<tr>
<td>Parity</td>
<td>2–3</td>
<td>1.19</td>
<td>1.03</td>
<td>1.01</td>
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<td>1.26</td>
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<td>≥ 7</td>
<td>0.98</td>
<td>1.21</td>
<td>0.81</td>
</tr>
<tr>
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<td>1 (reference)</td>
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<td></td>
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<tr>
<td>Partner's education (yr)</td>
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<td>0.81</td>
<td>0.84</td>
<td>1.00</td>
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<tr>
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<td>7–11</td>
<td>0.67</td>
<td>0.78</td>
<td>0.96</td>
</tr>
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<td></td>
<td>≥ 12</td>
<td>0.52</td>
<td>0.67</td>
<td>0.95</td>
</tr>
<tr>
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<td>None (reference)</td>
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</tr>
<tr>
<td>Partner's occupation</td>
<td>Manual (skilled or unskilled)</td>
<td>0.98</td>
<td>1.06</td>
<td>1.05</td>
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<tr>
<td></td>
<td>Service or domestic</td>
<td>1.03</td>
<td>1.09</td>
<td>1.09</td>
</tr>
<tr>
<td></td>
<td>Professional, managerial, or technical</td>
<td>0.86</td>
<td>1.25</td>
<td>0.86</td>
</tr>
<tr>
<td></td>
<td>Agriculture or not employed (reference)</td>
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<tr>
<td>Sex of child</td>
<td>Male</td>
<td>0.83</td>
<td>0.98</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>Female (reference)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Children &lt; 5 yr in household (other than index child)</td>
<td>≥ 1</td>
<td>0.86</td>
<td>0.77</td>
<td>0.96</td>
</tr>
<tr>
<td></td>
<td>None (reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residence</td>
<td>Urban</td>
<td>0.94</td>
<td>0.95</td>
<td>0.76</td>
</tr>
<tr>
<td></td>
<td>Rural (reference)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE 3. Median prevalence (%) of selected demographic and socioeconomic characteristics, by chronological groups of surveys$^a$

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal care</td>
<td>Received any prenatal care</td>
<td>63.3</td>
<td>83.5</td>
<td>78.0</td>
<td>85.7</td>
<td>86.1</td>
<td>92.1</td>
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<td>Contraceptive use (current method)</td>
<td>None, traditional, or folkloric</td>
<td>69.5</td>
<td>71.2</td>
<td>56.3</td>
<td>48.2</td>
<td>52.4</td>
<td>61.5</td>
</tr>
<tr>
<td></td>
<td>&quot;Modern&quot; method other than oral contraceptives</td>
<td>20.1</td>
<td>24.1</td>
<td>33.5</td>
<td>39.6</td>
<td>41.0</td>
<td>30.8</td>
</tr>
<tr>
<td></td>
<td>Oral contraceptives</td>
<td>8.4</td>
<td>4.9</td>
<td>10.3</td>
<td>10.1</td>
<td>6.6</td>
<td>7.7</td>
</tr>
<tr>
<td>Assistance at delivery</td>
<td>Skilled or trained health professional (doctor, nurse, or midwife)</td>
<td>51.5</td>
<td>50.1</td>
<td>58.2</td>
<td>75.9</td>
<td>42.2</td>
<td>68.7</td>
</tr>
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<td>Mother's age at time of birth of index child (yr)</td>
<td>≤ 24</td>
<td>40.1</td>
<td>44.1</td>
<td>40.7</td>
<td>41.6</td>
<td>38.1</td>
<td>37.5</td>
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<tr>
<td></td>
<td>25–29</td>
<td>31.2</td>
<td>29.9</td>
<td>29.9</td>
<td>28.2</td>
<td>28.5</td>
<td>27.8</td>
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<tr>
<td></td>
<td>30–34</td>
<td>17.1</td>
<td>16.1</td>
<td>16.0</td>
<td>16.3</td>
<td>18.2</td>
<td>18.8</td>
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<tr>
<td></td>
<td>≥ 35</td>
<td>11.3</td>
<td>14.1</td>
<td>12.9</td>
<td>12.8</td>
<td>15.3</td>
<td>15.4</td>
</tr>
<tr>
<td>Mother's education (yr)</td>
<td>None</td>
<td>15.3</td>
<td>12.8</td>
<td>12.8</td>
<td>9.1</td>
<td>9.3</td>
<td>6.6</td>
</tr>
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<td></td>
<td>1–6</td>
<td>52.0</td>
<td>48.5</td>
<td>47.5</td>
<td>45.1</td>
<td>44.5</td>
<td>40.0</td>
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<td>7–11</td>
<td>25.4</td>
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<td>≥ 12</td>
<td>4.8</td>
<td>4.6</td>
<td>6.9</td>
<td>7.5</td>
<td>7.1</td>
<td>9.9</td>
</tr>
<tr>
<td>Mother currently employed</td>
<td>Yes</td>
<td>18.5</td>
<td>40.4</td>
<td>42.7</td>
<td>45.6</td>
<td>51.5</td>
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<td>40.1</td>
<td>40.3</td>
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<td>28.9</td>
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<td>24.6</td>
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<td>≥ 7</td>
<td>16.8</td>
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<td>15.9</td>
<td>13.6</td>
<td>12.7</td>
<td>10.0</td>
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<tr>
<td>Partner's education (yr)</td>
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<td>11.9</td>
<td>18.3</td>
<td>7.5</td>
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<tr>
<td></td>
<td>1–6</td>
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<td>42.0</td>
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<td>31.2</td>
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<td>12.7</td>
<td>10.4</td>
<td>9.6</td>
<td>11.6</td>
</tr>
<tr>
<td>Partner's occupation</td>
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<td>43.9</td>
<td>43.9</td>
<td>42.4</td>
<td>49.1</td>
<td>47.2</td>
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<td></td>
<td>Manual (skilled or unskilled)</td>
<td>29.8</td>
<td>27.3</td>
<td>36.0</td>
<td>34.5</td>
<td>21.8</td>
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<td>Service or domestic</td>
<td>18.0</td>
<td>11.2</td>
<td>11.5</td>
<td>16.9</td>
<td>18.4</td>
<td>19.1</td>
</tr>
<tr>
<td></td>
<td>Professional, managerial, or technical</td>
<td>13.2</td>
<td>11.8</td>
<td>11.4</td>
<td>11.3</td>
<td>10.8</td>
<td>10.8</td>
</tr>
<tr>
<td>Sex of child</td>
<td>Male</td>
<td>50.8</td>
<td>50.5</td>
<td>50.5</td>
<td>50.8</td>
<td>50.7</td>
<td>50.3</td>
</tr>
<tr>
<td>Children &lt; 5 yr in household (other than index child)</td>
<td>≥ 1</td>
<td>68.0</td>
<td>63.9</td>
<td>63.9</td>
<td>59.4</td>
<td>52.7</td>
<td>48.4</td>
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<tr>
<td>Residence</td>
<td>Urban</td>
<td>53.9</td>
<td>69.7</td>
<td>51.8</td>
<td>57.6</td>
<td>63.9</td>
<td>63.9</td>
</tr>
</tbody>
</table>


$^b$ For bivariate variables, the prevalence is shown for the highest category only.
were generally positively associated with breastfeeding, except in the earliest time period (1986–89).

**Changes in population characteristics**

Changes in maternal and family characteristics consistent with increased development continued over the period of study (table 3). Several variables that were shown to be negatively associated with breastfeeding increased in prevalence over the time periods analyzed. For example, improvements in maternal education were dramatic: the proportion of women with no education was reduced by more than half on average from 15.3% in the earliest surveys to 6.6% in the latest surveys, and the proportion of women with some secondary or postsecondary education also increased. Similarly, urbanization continued, increasing 10 percentage points on average between the earliest and latest surveys. Although the association between maternal education and breastfeeding was not entirely consistent across survey years, the proportion of mothers working increased dramatically, from 18% in the earliest surveys (1986–89) to over 50% in the latest surveys (2004–05).

At the same time, variables that were shown to be positively associated with breastfeeding also showed increases. There was a general upward shift in maternal age, and access to prenatal or skilled care at delivery (which was positively related to breastfeeding, particularly in the more recent surveys, although negatively associated in the early surveys) increased. Approximately 92% of respondents, on average, received some prenatal care in the latest surveys. Likewise, the proportion of mothers having a skilled attendant at delivery increased from slightly over half in the earliest surveys to nearly 70% in the latest surveys. The use of modern contraceptive methods (except for oral contraceptives) also increased, although approximately half of all women interviewed in the latest surveys were still using either a traditional or a folkloric birth control method or no birth control.

**Trends in breastfeeding duration: Population and behavioral trends**

The predicted mean duration of breastfeeding increased in five of six countries with surveys from the mid to late 1980s to the mid to late 1990s, four of six countries with surveys from the mid to late 1990s to the early 2000s, and one of three countries with surveys from 2000 to 2004–05 (table 4 and fig. 1). The behavioral component of the overall trend explained most of the increase.

---

**TABLE 4. Predicted mean breastfeeding durations and trends, by country and survey year**

<table>
<thead>
<tr>
<th>Country</th>
<th>Survey year 1</th>
<th>Survey year 2</th>
<th>Mean predicted breastfeeding duration 1 (mo)</th>
<th>Mean predicted breastfeeding duration 2 (mo)</th>
<th>Overall change</th>
<th>Overall change attributable to changes in population characteristics</th>
<th>Overall change attributable to changes in behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bolivia</td>
<td>1989</td>
<td>1998</td>
<td>16.3</td>
<td>18.5</td>
<td>2.1</td>
<td>−0.2</td>
<td>2.3</td>
</tr>
<tr>
<td>Brazil</td>
<td>1986</td>
<td>1996</td>
<td>9.5</td>
<td>12.9</td>
<td>3.3</td>
<td>−0.1</td>
<td>3.4</td>
</tr>
<tr>
<td>Colombia</td>
<td>1986</td>
<td>1995</td>
<td>11.3</td>
<td>13.5</td>
<td>2.2</td>
<td>−0.1</td>
<td>2.3</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>1986</td>
<td>1999</td>
<td>9.6</td>
<td>11.0</td>
<td>1.4</td>
<td>−0.3</td>
<td>1.7</td>
</tr>
<tr>
<td>Guatemala</td>
<td>1987</td>
<td>1999</td>
<td>20.8</td>
<td>20.8</td>
<td>0</td>
<td>−0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Peru</td>
<td>1986</td>
<td>1996</td>
<td>17.0</td>
<td>20.2</td>
<td>3.2</td>
<td>−0.1</td>
<td>3.3</td>
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<tr>
<td><strong>Group 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Bolivia</td>
<td>1998</td>
<td>2003</td>
<td>18.5</td>
<td>21.0</td>
<td>2.6</td>
<td>−0.1</td>
<td>2.7</td>
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<tr>
<td>Colombia</td>
<td>1995</td>
<td>2000</td>
<td>13.5</td>
<td>15.4</td>
<td>1.9</td>
<td>0</td>
<td>1.9</td>
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<tr>
<td>Dominican Republic</td>
<td>1999</td>
<td>2002</td>
<td>11.0</td>
<td>10.9</td>
<td>−0.1</td>
<td>0</td>
<td>−0.1</td>
</tr>
<tr>
<td>Haiti</td>
<td>1995</td>
<td>2000</td>
<td>19.4</td>
<td>18.2</td>
<td>−1.2</td>
<td>−0.2</td>
<td>−1.0</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>1998</td>
<td>2001</td>
<td>16.8</td>
<td>19.3</td>
<td>2.5</td>
<td>−0.1</td>
<td>2.6</td>
</tr>
<tr>
<td>Peru</td>
<td>1996</td>
<td>2000</td>
<td>20.2</td>
<td>22.8</td>
<td>2.5</td>
<td>−0.1</td>
<td>2.6</td>
</tr>
<tr>
<td><strong>Group 3</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colombia</td>
<td>2000</td>
<td>2005</td>
<td>15.4</td>
<td>17.5</td>
<td>2.1</td>
<td>0</td>
<td>2.1</td>
</tr>
<tr>
<td>Haiti</td>
<td>2000</td>
<td>2005</td>
<td>18.2</td>
<td>18.2</td>
<td>0.0</td>
<td>−0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Peru</td>
<td>2000</td>
<td>2004</td>
<td>22.8</td>
<td>21.7</td>
<td>−1.0</td>
<td>−0.1</td>
<td>−0.9</td>
</tr>
</tbody>
</table>

a. The predicted mean breastfeeding durations were calculated as the area under the curve of the predicted probabilities of being breastfed at each age, and then calculating a weighted average, based on the population distribution of different population characteristics, to provide an estimate of the overall predicted mean duration of breastfeeding for each survey.
or decrease in breastfeeding duration observed, only being counteracted by a small and negative effect of changing population profiles (e.g., more women living in urban areas, higher levels of female education, etc.). For the first 10-year time period, the observed increase in breastfeeding duration was greater than 1.4 months in five countries. The only other country in this group, Guatemala, experienced no change; however, it already had the longest breastfeeding duration. For the second 3- to 5-year period, the increase in breastfeeding duration was 1.9 months or more in the four countries with positive change. There was virtually no change in the Dominican Republic, and only Haiti experienced a decline, which amounted to 1.2 months. For the 4- to 5-year time period ending in 2004–05, the only increase in breastfeeding duration observed was in Colombia, where an increase of 2.1 months was observed. Breastfeeding duration remained virtually unchanged in Haiti and decreased by 1.0 month in Peru.

Only two countries, Colombia and Peru, are represented in all three time periods. In Colombia, breastfeeding duration increased consistently by approximately 2 months per time period, so that the predicted mean duration rose from 11.3 months in 1986 to 17.5 months in 2005. In Peru, the overall predicted mean duration increased by 3.2 months and 2.5 months for the first and second time periods, respectively. However, this positive trend did not continue into the third time period, where a decrease of 1 month was observed.

Discussion

Our results show that the positive changes in breastfeeding duration observed throughout the period of analysis are almost entirely explained by improved breastfeeding behaviors, as the effect of overall population characteristic changes, though small, was consistently negative across time periods analyzed. These results confirm and extend analyses previously published by Pérez-Escamilla with respect to the effect of maternal education and urban versus rural residence on breastfeeding duration [32]; however, they add to these earlier findings by also examining the effect of 10 additional maternal and paternal characteristics, such as prenatal care, assistance at delivery, maternal age, maternal employment, parity, paternal education, and paternal occupation. These positive behavioral changes were observed despite increases over time in particular population characteristics (e.g., maternal education) that have been negatively associated with breastfeeding. Greater maternal education has traditionally been associated with shorter breastfeeding durations, and with increased levels of maternal education, one might expect breastfeeding duration to decrease. However, some of the largest gains in breastfeeding duration in the countries analyzed occurred among better-educated women (data not shown). In developed countries such as the United States, greater maternal education is associated with improved breastfeeding duration. This may be because educated women have more knowledge about the benefits of breastfeeding and more control over their lives to act on this knowledge. Previous work has also shown that breastfeeding interventions have larger positive impacts in more educated women [33–35]. During the time period studied in our analyses, levels of maternal education generally increased, yet the negative effect of maternal education on breastfeeding duration decreased, indicating that breastfeeding behaviors among this group changed. Thus, with a sustained emphasis on education for women, future
public health interventions may have an even greater impact on breastfeeding behaviors among an increasingly better-educated, and perhaps more receptive, population. This population may also serve as models to aspire to, in that breastfeeding would be associated with development and economic achievement. As such, it may be useful to integrate information about the benefits of breastfeeding to maternal and child health in primary and secondary education to ensure that improved female education goes hand in hand with breastfeeding knowledge.

Similarly, increased access to and utilization of medical care—including both prenatal and delivery care and the use of modern forms of contraception—was, in the earlier surveys, negatively associated with breastfeeding duration. With the more recent surveys, the negative relationship between variables reflecting increased access to and use of medical care and breastfeeding duration had diminished and become more positive, and the percentage of women reporting such care had increased. The more positive relationship between these variables and breastfeeding duration, as well as the generally larger breastfeeding gains among this subgroup (data not shown), suggests that breastfeeding behaviors among women receiving medical care have changed, possibly because of changes in the quality of care provided prenatally or at delivery favoring practices that support and promote breastfeeding. Ensuring that the opportunity for counseling regarding breastfeeding practices during prenatal care is not missed and that delivery care services create an environment that is supportive and protective of breastfeeding will add to the obvious health benefits to mother and infant already provided by these medical services.

Overall, our findings show that breastfeeding duration increased consistently from the mid 1980s into the late 1990s. In at least one country (Peru), however, the most recent surveys between 2000 and 2004 show a decline in the predicted mean duration of breastfeeding, as a result of a negative behavioral trend. It is not known whether the downward movements in breastfeeding duration observed in Peru may be occurring in other Latin American and Caribbean countries; as more surveys become available, additional analyses will be needed. The results emphasize the importance of continued monitoring of breastfeeding trends (and their components) for the development and/or reorientation of policies and programs to promote breastfeeding.

There are several limitations to our analysis. We were not able to look at changes in the predicted mean duration of exclusive breastfeeding, which would have been very useful, given the importance of exclusive breastfeeding for infant survival. The low numbers of infants currently being exclusively breastfed at each age prevented a similar analysis for this behavior; however, other authors have shown increases in exclusive breastfeeding trends using different modeling techniques [36]. We also were not able to test for statistical significance of the trend in breastfeeding duration, as the modeling procedure did not permit this test to be performed.

In conclusion, our results indicate that in low-to-middle-income countries in Latin America and the Caribbean that are experiencing socioeconomic and demographic changes, improvements in breastfeeding occurred over the time period studied. They demonstrate that most of this increase is explained by changes in individual behaviors and that the socioeconomic and demographic changes we studied that were previously associated with less breastfeeding no longer have this negative association. Most importantly, our findings show that individual behaviors are amenable to change and that changes in individual behaviors collectively contributed to positive national trends in breastfeeding.

These results are a reminder that there are effective [37, 38] and cost-effective [24] methods that can increase breastfeeding initiation and duration. These include health sector initiatives such as the Baby Friendly Hospital Initiative [38], prenatal health education, peer-support and peer-counseling programs, media campaigns, and multifaceted interventions including several of these components, as has been shown in Brazil [39]. Understanding which methods are most effective within different countries, and within different demographic groups of women, should be a subject of further research. This is particularly important in light of recent data from one country we analyzed, Peru, indicating that improvements in breastfeeding may not be continuing into the present decade. It will be important to continue monitoring changes in trends and determinants of breastfeeding to understand why a decrease in breastfeeding behaviors may be occurring. Public health interventions can then be implemented to promote optimal breastfeeding behaviors, so that the resulting benefits for maternal and child health are realized.

References

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The role of the Codex Alimentarius process in support of new products to enhance the nutritional health of infants and young children

Stanley Zlotkin, Jonathan Siekmann, Anna Lartey, and Zhenyu Yang

Abstract

The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety. Among other functions, it is responsible for setting international standards for safety and hygiene. Codex food standards and guidelines directed at foods produced primarily for young infants and children have important implications for maintaining nutritional status and health, especially given the positioning of these products as components of established World Health Organization (WHO)/UNICEF-recommended feeding strategies. Recently, new products targeted at this age group (e.g., lipid-based nutrient supplements and micronutrient powders) have been produced and used, but these are not totally covered under existing Codex guidelines or standards. The objective of this paper is to review the role of the Codex process and specifically to suggest revisions to existing Codex guidelines on formulated complementary foods (Guidelines for Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL 08-1991) to encompass this new category of fortified complementary foods and home fortificants. In reviewing the existing guidelines, potential areas for revision included the sections on the recommended nutrients in these foods and their intended use. Updating the Codex guidelines provides the opportunity to encourage production and use of new products for children and help ensure that such foods, when used as directed, do not interfere with breastfeeding. The revised guidelines would help governments develop national regulations covering all forms of formulated complementary foods. They would also lessen impediments to international trade by providing clear guidance for foods used in feeding programs and for young children, particularly in developing countries.

Key words: Codex Alimentarius, complementary food supplements, food, fortified complementary foods, home fortification, infants and young children, micronutrient powders (MNPs), nutrition

Background

Nutrition has been recognized as the foundation for survival, growth, and development of children. The recent Lancet series released in January 2008 concluded that more than a third of child deaths and 10% of the global disease burden are associated with child and maternal malnutrition [1]. The highest proportion of these deaths is in children under 2 years of age. It is somewhat ironic that this age period is both the period of greatest vulnerability and also the largest window of opportunity for influencing the child’s potential for optimizing growth and development. Most (around 80%) of the malnourished children of the world live in just 20 countries across four regions—Africa, Asia, Western Pacific, and the Middle East [2]. Intensified nutrition action in these countries can lead to achievement of the first Millennium Development Goal to reduce poverty and hunger and greatly increase the chances of achieving goals for reducing child mortality and improving maternal health (Millennium Development Goals 4 and 5). Despite isolated successes in many countries for interventions such as iodized salt and vitamin A supplementation, most countries with high rates of undernutrition are failing to reach malnourished children with effective interventions supported by appropriate policies to improve child growth. It is estimated that exclusive breastfeeding and the appropriate use of complementary foods have the potential to...
reduce mortality among children under 2 years of age by as much as 13% and 6%, respectively [3]. Standards for fortified complementary foods and complementary food supplements have important implications for the nutrition and health of malnourished infants and young children, particularly those living in developing countries.

Children with severe acute malnutrition have the highest risk of morbidity and death as individuals, but the greatest population-level burden is from the more prevalent moderate malnutrition [4]. Adequate nutrition during infancy and early childhood is fundamental to the development of each child’s full human potential. Whereas exclusive breastfeeding provides optimal nutrition in the first 6 months of life, and continued breastfeeding to 2 years and beyond provides a source of high-quality protein, fat, and other nutrients, at 6 months of age infants need additional high-quality foods to complement breastmilk in order to grow optimally. The majority of infants in developing countries currently rely on various combinations of local cereals, legumes, pulses, and oilseeds that are typically used for preparing complementary foods. Even where feeding practices are optimal, these foods are not normally fortified with minerals and vitamins, but even if they are fortified, the levels are often too low, the amounts of energy, high-quality protein, macrominerals (calcium, magnesium, potassium, and phosphorus), and essential fatty acids are often insufficient, and the levels of antinutrients, including phytates and tannins, are often too high [5]. Most processed, cereal-based complementary foods currently available at low cost do not provide optimal nutrition because they are not fortified or are fortified at low levels, and/or may contain forms of certain nutrients that have poor bioavailability. As with local foods, most also often do not contain enough high-quality protein, micronutrients, macrominerals, and essential fatty acids needed for optimal growth and development.

In addition to production of complementary foods with improved macro- and micronutrient content, a strategy to improve the nutritional quality of home-prepared foods is home fortification of complementary foods with either fortified complementary food supplements or micronutrient powders (powdered mineral and vitamin supplements). Complementary food supplements that contain an energy-dense source (fat), protein, and other nutrients are eaten in addition to breastmilk and home-prepared complementary foods. The function of this type of product is to improve the energy and nutrient density and quality of traditionally home-prepared complementary foods. The ultimate goal associated with their use is to prevent energy and nutrient deficiencies and reverse or prevent growth faltering and malnutrition.

For circumstances where the macronutrient and energy density of food provided to children is adequate, but the foods are lacking in micronutrients, a second type of home-fortification product, known as micronutrient powders, is now available. The micronutrients (with or without small amounts of other food-based nutrients) are packaged in a single-serving sachet and sprinkled on the food after the food has been cooked or reheated.

This new class of home-fortification products has been incorporated as a component of established World Health Organization (WHO)/UNICEF-recommended feeding strategies (http://www.who.int/nutrition/publications/infantfeeding/9789241597494/en/index.html). As these new products are introduced through governments, development organizations, or market-driven initiatives, it has been recognized that there is a need to ensure both the safety and the efficacy of the products, as well as to provide a clear and unambiguous description of serving sizes, nutrient levels, and forms. The only global organization that has the authority and reach to take on this role is the Codex Alimentarius Commission. The objective of this article is to report on the outcome of a comprehensive review of the currently available Codex standards and guidelines to determine if they meet the needs for the new categories of foods known as fortified complementary foods and complementary food supplements and to highlight possible revisions in Codex standards and guidelines where the current documents may not meet newer nutrient-specific international guidelines.

Having Codex texts related to these new categories of foods that are up to date and reflect current recommendations and scientific evidence will ensure that guidance is available for the formulation and use of these important products for infant and young child feeding.

An ad hoc technical review team (consisting of physicians, nutrition experts, breastfeeding experts, and a food scientist and chaired by a pediatrician/nutrition expert) met in Geneva in October 2008 to review relevant Codex documents. The team included representatives from China, India, Malawi, South Africa, Uganda, Canada, and the United States. Several members of the team had attended the WHO meeting on Dietary Management of Moderate Malnutrition held the previous week [6]. The background documents from the WHO meeting were used in the review of the Codex standards and guidelines related to complementary foods and supplements.

**What is the Codex Alimentarius and why is it important?**

The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety. The Codex Alimentarius Commission was created in 1963 by the Food
and Agriculture Organization (FAO) and WHO to develop food standards, guidelines, and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. Among other functions, it is responsible for setting international standards for safety and hygiene. Its main functions are “to protect health of the consumers and ensuring fair trade practices in the food trade and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations” [7]. The Codex Alimentarius is recognized by the World Trade Organization as an international reference point for the resolution of disputes concerning food safety and consumer protection. Codex texts are especially important for countries where national policies, laws, or guidelines are weak or do not exist. Such countries can refer to the relevant Codex texts to inform and guide decision-making or can even adopt Codex standards as national law.

Embedded within the Codex process is the important concept of “standards” versus “guidelines.” A Codex standard contains provisions relating to product characteristics and essential composition (including, as appropriate, ingredients and/or nutritional components), as well as provisions for food additives, contaminants, labeling, packaging, and hygiene. A Codex standard provides a template for translation into domestic food law, and the resultant domestic standard can then be enforced with authority. Standards deal with ingredients and/or nutritional composition of the finished product, although they can also address quality factors related to raw ingredients or processing. Standards describe, for example, nutrient composition, but they do not have practical information on how to produce the finished product. Guidelines, on the other hand, focus on how to comply with a standard and sometimes provide practical information on how to produce finished products. A Codex guideline is advisory in nature and does not have to be complied with. It has no force of law and cannot be legally enforced. It need not cover the same material as a standard and so can leave certain matters out or include other matters not usually included in a standard. However, depending on the level of voluntary compliance expected by local authorities, the guideline might have the same moral authority or some other incentive as the force of law. Guidelines and standards are complementary to each other; the standard is designed for the final product, whereas guidelines are used more to explain how a specification in the standard could be achieved in practice.

The review panel identified three Codex guidelines and two standards that were relevant to these new categories of foods for older infants and young children:

» Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) [8];

» Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005);


» Codex Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex Stan 074-1981, Rev 1-2006).

In the current article, we will focus only on our evaluation of “Guidelines for Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991),” which has the most relevance to the new classes of infant foods. The purpose of this guideline is to “provide guidance on nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children, including:

1. Formulation of such foods based on the nutritional requirements of older infants and young children;
2. Processing techniques;
3. Hygienic requirements;
4. Provisions for packaging;
5. Provisions for labelling and instructions for use.”

The guidelines state: “Formulated supplementary foods means foods suitable for use during the infant’s weaning period and for feeding young children as a supplement to breastmilk or breastmilk substitutes or other food available in a country where the product is sold. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the basic staple foods.”

The foods referred to in the guidelines are for use during the period when the infant transitions from exclusive breastfeeding to eating the normal family diet (previously referred to as the “weaning period,” a term no longer used because of its possible misinterpretation, since weaning can also mean stopping breastfeeding). The term “supplementary” was used at the time the guidelines were developed, but currently, the term “complementary” is used rather than supplementary to refer to foods used in addition to breastmilk because they complement what breastmilk provides for infants over 6 months of age.

Since the time these guidelines were written, there have been extensive research and program evaluations showing that many of the characteristics of foods covered are not adequate to support optimal child growth. For example, in the current guidelines, five oilseed flours and protein products were listed: soya beans: flour (full fat and defatted) concentrate and isolate; groundnuts: defatted flour, isolate; sesame seed: whole ground and defatted flour; cottonseed: defatted flour; and sunflower seed: defatted flour.

Dehulled soya beans should preferentially be recommended to reduce the phytate and fiber content. Full-fat soya beans, adequately processed to isolate
desired properties from undesirable ones, provide a
good essential fatty acid composition, but defatted
forms have few essential fatty acids. Full-fat groundnuts
would provide higher energy. The currently recom-
mended oilseeds (sesame, cottonseed, and sunflower)
could be expanded to include, for example, canola/rapeseed,
which is a good source of total, n-3, and
n-6 fatty acids, whereas coconut and palm oil in small
amounts may be acceptable because of their low cost.

There are now comprehensive data demonstrating
the negative health effects of partially hydrogenated
(trans) fatty acids. Yet, there is no mention of partially
hydrogenated (trans) fatty acids, as there are in other
standards (e.g., 074-1981, Rev 1-2006). Revision of
Section 4.1.5 is needed to exclude partially hydrogcnated
(trans) fatty acids from complementary food and
complementary food supplements for infants and young
children.

Nutritional aspects: General

Section 6.1.2 of the guideline suggests a daily dose of
100 g/day, whereas Section 6.2.3 suggests that 100 g
of the product should provide at least 400 kcal. Thus,
a child receiving the recommended quantity of the
product (100 g) would receive a supplement of 400 kcal
in addition to the energy contributed by the rest of the
child’s diet, including breastmilk.

Since the Codex guidelines were written (1991) [8],
new evidence suggests that breastfed children do not
need such large amounts of energy and that consump-
tion of a large amount of energy will probably interfere
with breastmilk intake [9]. One hundred grams of food
(400 kcal) would exceed the requirements for breastfed
infants 6 to 11 months of age. This amount of food
could displace breastmilk intake and allow little room
for additional foods for breastfed infants.

Table 1 gives best estimates of recommended feeding
frequencies of complementary foods and the energy
needed from complementary foods in breastfed infants
of various ages [8, 10, 11]. It is recommended that the
guidelines be revised to bring them in line with new
evidence pertaining to the energy needs of breastfed
infants.

<table>
<thead>
<tr>
<th>Age (mo)</th>
<th>Recommended feeding frequency of complementary foods (no. of meals and snacks/day)</th>
<th>Energy needs from complementary foods (kcal/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Breastfed</td>
<td>Not breastfed</td>
</tr>
<tr>
<td>6–8</td>
<td>2–3</td>
<td>4–5</td>
</tr>
<tr>
<td>9–11</td>
<td>3–4</td>
<td>4–5</td>
</tr>
<tr>
<td>12–23</td>
<td>3–4</td>
<td>4–5</td>
</tr>
</tbody>
</table>


Protein

Section 6.3.5 states that the protein content of the
product should be on the order of 15 g per 100 g of
the food on a dry matter basis, and Section 6.1.2 rec-
mends the ingestion of 100 g of product per day.
During the first year of life, protein recommendations
range between 9 and 14 g/day. Between the ages of 1
and 8 years, they range from 13 to 19 g/day. Thus, 100 g
of a supplement providing 15 g of protein is too much,
since infants will also receive protein from breastmilk
and other complementary foods [12]. Revision of this
section is suggested to change the recommended serving size.

Fat

Section 6.4.1 describes a level of 20% to 40% of energy
declared from fat as being desirable. This range is prob-
ably too low for most children (especially those who are
maldnourished or at risk for malnutrition) and does not
reflect the high fat content of new fortified food prod-
ucts (e.g., lipid-based nutrient supplements) designed
to be energy dense since they are intended to be used in
relatively small quantities. Some of these new products
contain up to 77% of energy as fat, and this high level
of fat is necessary to ensure a high energy intake in a
small volume of food. Because diets of malnourished
children are generally too low in fat and low in essential
fatty acids, a higher fat content will be beneficial and
is not likely to increase the long-term risks of obesity,
atherosclerosis, or other chronic diseases in children
consuming the product.

The level of linoleic acid in the guidelines
(> 300 mg/100 kcal) is appropriate for the new class of
foods; however, the guidelines do not provide a recom-
mendation for the inclusion of α-linolenic acid or the
ratio of linoleic to α-linolenic acid. The new products
are designed to also include α-linolenic acid in a ratio
(eniolaic:α-linolenic) of approximately 5:1 to 15:1, the
ratio proposed in the 2007 revision of infant formula
is recommended as an optimal ratio for foods described
in the revised guidelines.

Vitamins and minerals

It was noted that the reference daily requirements for
vitamins (table in Annex of CAC/GL 08-1991) are
derived from the FAO/WHO Handbook on Human

Nutritional Requirements, 1974. This reference is now outdated. Similarly, the requirements for vitamin A, iron, folate, and vitamin B₁₂ are derived from a Joint FAO/WHO Consultation from 1988. This reference is also outdated. Newer references published by FAO and WHO are available [13].

A table in the Annex to the guidelines (page 10) indicates that the total amount of the added vitamins or minerals contained in 100 g of the food on a dry matter basis should be at least two-thirds of the reference daily requirements. Because a revision of the size of the food portion to less than 100 g/day is recommended, the wording of the table would also need to be changed to reflect the position that the total recommended daily intake should supply at least two-thirds of the reference daily requirements. The Codex should also consider whether two-thirds of the reference daily requirements is sufficient. Finally, it is also suggested that additional nutrients be listed in this table, since currently the table is incomplete with regard to micronutrients and macrominerals (such as magnesium, phosphorus, and potassium, all of which are needed for growth).

Antinutritive factors

There are no standards for maximum levels of antinutritive factors such as phytate, tannins, and certain phenolic materials. There is a standard for fiber (Section 6.5.2), defined as a level not exceeding 5 g/100 g of food [14], and a new Codex recommendation of how fiber should be defined and measured [15, 16]. Antinutritive factors can interfere with the absorption and metabolism of nutrients and should be minimized or excluded from foods whenever possible. There is a need to develop standards for maximum levels of antinutritive factors and to reevaluate the standards for fiber based on updated research findings, particularly the effect of fiber on appetite [17].

Conclusions

Several revisions are needed in the Codex guidelines and standards in order to address the new array of nutrition products targeted to children, particularly children with malnutrition or at risk for malnutrition. Guidance needs to be updated based on recent evidence on the nutritional requirements of infants and young children and characteristics of diets and foods pertaining to this age group in developing countries. These new/revised standards/guidelines would help governments develop national regulations pertaining to foods targeted to these children and encourage the manufacturing sector to develop new products for this target population. To this end, in 2008 the government of Ghana representatives to the Codex Committee on Nutrition for Special Dietary Uses (CCNFSDU) put forward a proposal to the Codex Commission to revise the Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991) [8] (as described above). An electronic working group of the CCNFSDU will revise the guidelines to be in line with current evidence. The suggested revisions proposed by the electronic working group will again be discussed at the 2010 CCNFSDU. As articulated by the Ghanaian delegation to the Codex Commission, the revision would assist governments in improving the quality of the foods sold for use by infants and young children in developing countries and help ensure that such foods, when used as directed, do not interfere with breastfeeding. It would lessen impediments to international trade by providing clear guidance for foods used in feeding programs and for young children, particularly in developing countries.

References


A review of phytate, iron, zinc, and calcium concentrations in plant-based complementary foods used in low-income countries and implications for bioavailability

Rosalind S. Gibson, Karl B. Bailey, Michelle Gibbs, Elaine L. Ferguson

Abstract

Plant-based complementary foods often contain high levels of phytate, a potent inhibitor of iron, zinc, and calcium absorption. This review summarizes the concentrations of phytate (as hexa- and penta-inositol phosphate), iron, zinc, and calcium and the corresponding phytate:mineral molar ratios in 26 indigenous and 27 commercially processed plant-based complementary foods sold in low-income countries. Phytate concentrations were highest in complementary foods based on unrefined cereals and legumes (~600 mg/100 g dry weight), followed by refined cereals (~100 mg/100 g dry weight) and then starchy roots and tubers (< 20 mg/100 g dry weight); mineral concentrations followed the same trend. Sixty-two percent (16/26) of the indigenous and 37% (10/27) of the processed complementary foods had at least two phytate:mineral molar ratios (used to estimate relative mineral bioavailability) that exceeded suggested desirable levels for mineral absorption (i.e., phytate:iron < 1, phytate:zinc < 18, phytate:calcium < 0.17). Desirable molar ratios for phytate:iron, phytate:zinc, and phytate:calcium were achieved for 25%, 70%, and 57%, respectively, of the complementary foods presented, often through enrichment with animal-source foods and/or fortification with minerals. Dephytinization, either in the household or commercially, can potentially enhance mineral absorption in high-phytate complementary foods, although probably not enough to overcome the shortfalls in iron, zinc, and calcium content of plant-based complementary foods used in low-income countries. Instead, to ensure the World Health Organization estimated needs for these minerals from plant-based complementary foods for breastfed infants are met, dephytinization must be combined with enrichment with animal-source foods and/or fortification with appropriate levels and forms of mineral fortificants.

Key words: Bioavailability, calcium, children, complementary foods, infants, iron, low-income countries, phytate, zinc

Introduction

Complementary foods based almost exclusively on plants are often the major source of energy and nutrients from nonmilk foods for many infants and young children living in resource-poor households in low-income countries; consumption of animal-source foods is often low due to economic or religious concerns. Such plant-based complementary diets are frequently associated with micronutrient deficits, notably of iron, zinc, and calcium [1, 2], exacerbated in part by poor bioavailability, especially when the complementary foods are based on unrefined cereals and legumes. Unrefined cereals and legumes have a high content of phytate, a potent inhibitor of mineral absorption [3]. Moreover, if these high-phytate complementary foods are consumed with breastmilk, they may actually compromise the bioavailability of certain minerals in the breastmilk [4]. Such deficits in iron, zinc, and calcium can have far-reaching adverse consequences on growth, health, and cognitive development during childhood.

Several strategies, including the addition of organic acids (especially ascorbic acid), ethylenediamine tetraacetic acid (EDTA) complexes, and dephytinization, have the potential to reduce the negative effect of phytate on mineral absorption in cereal- and/or legume-based complementary foods. Only the impact of dephytinization on absorption of both intrinsic and mineral fortificants will be discussed in this review; details of the other approaches are available elsewhere [5, 6]. It is recognized, however, that the impact of
Phytate, iron, zinc, and calcium concentrations in plant-based complementary foods

located in the germ [11]. In whole legumes, the phytate in most cereals, phytate is concentrated in the bran with polished rice containing the lowest amount [10]. The content of phytate in cereals varies from 0.06% to 2.22%, in cereals, legumes, and oleaginous seeds. The content ranges from 0.17% to 9.15% and is uniformly distributed throughout the cotyledons, where it is associated with protein. Hence, when the hull or seed coat of legumes is removed, their phytate concentration increases. Environmental conditions (climate, soil, and irrigation), fertilizer applications, and stage of maturation influence the phytate content of cereals, legumes, and oleaginous seeds: the highest levels are reached at seed maturity [10]. Roots and tubers and most leafy vegetables and fruits contain very low amounts of phytate, and animal foods contain none.

Phytic acid chelates metal ions, especially zinc, iron, and calcium, but not copper [12], forming insoluble complexes in the gastrointestinal tract that cannot be digested or absorbed in humans because of the absence of intestinal phytase enzymes [13]. Phytic acid also complexes endogenously secreted minerals such as zinc [14] and calcium [15], making them unavailable for reabsorption into the body. The inhibitory effect of phytate on mineral absorption has been confirmed by in vivo radioactive and stable isotope studies, in which fractional absorption of iron, zinc, and calcium has been reported to be significantly lower from diets with a high content of phytate than from diets with a lower phytate content [12, 16–19]. This inhibitory effect is now recognized to be exaggerated, at least for iron [20] and zinc [21], in single test meal studies compared with that obtained on total diets.

At present, studies on the influence of phytate on the bioavailability of iron, zinc, and calcium in infants and young children are limited. Hence, whether the phytate-to-mineral molar ratios said to be desirable for adult diets are also appropriate for complementary diets of infants and young children is unclear [22]. Likewise, whether children have the ability to adapt to the inhibitory effect of a high-phytate complementary diet on absorption of these minerals is uncertain. There is some evidence that adults can adapt to diets with a low content of zinc and phytate by increasing intestinal zinc absorption. However, no comparable adaptation appears to occur with high-phytate diets [23], although there may be some decrease in endogenous excretion of fecal zinc [24]. Similarly, iron absorption is not increased in adults consuming high-phytate diets [25], a trend that is probably also apparent in children, given that the effects of enhancers and inhibitors on iron absorption are comparable in adults and infants [26]. Unlike zinc and iron, the high phytate content of cereal-based complementary foods does not have a major impact on calcium status during infancy and early childhood: apparent absorption of calcium was reported to be high (60%) in infants receiving a high-phytate complementary food [27]. Instead, calcium deficiency among young children is more likely to be due to a low intake rather than poor absorption [28].

The adverse effect of phytate on zinc absorption follows a dose-dependent response [29], and there is no
threshold for the inhibitory effects of dietary phytate on zinc bioavailability [30]. Indeed, Hambidge and coworkers [18] have demonstrated a negative relationship between fractional zinc absorption and dietary phytate over a range of dietary phytate:zinc molar ratios from 7:1 to 37:1.

There is some evidence that high dietary calcium impairs zinc absorption, but probably only in the presence of high intakes of phytate. Certainly, fractional zinc absorption from corn bread was reported to be significantly higher than that from calcium-rich tortillas prepared by nixtamalization of the same maize [31]. Nevertheless, the International Zinc Nutrition Consultative Group (IZiNCG) recommends that the phytate:zinc molar ratio of the diet alone can be used to estimate the negative effect of phytate on zinc bioavailability. They concluded that in most diets, neither calcium (nor protein) adds significant predictive power to the algorithm used to predict the percentage of zinc absorbed. As a result, Hotz and Brown [32] divided diets into two categories based on their range of phytate:zinc molar ratios. For diets with phytate:zinc molar ratios > 18 (i.e., unrefined cereal-based diets), IZiNCG estimates zinc absorption to be 18% and 25% for adult males and females, respectively, whereas for diets with phytate:zinc molar ratios between 4 and 18 (classified as mixed or refined vegetarian diets), the corresponding estimates for adults are 26% and 34%, respectively [32]. Hurrell [33] has estimated, based on data from isotope studies in adults, that in non-zinc-fortified foods, phytate:zinc molar ratios between 4 and 8 should result in a zinc absorption of ~20% in adults. Whether these absorption estimates are applicable to the complementary diets of infants and young children is less certain.

The inhibitory effect of phytic acid on iron absorption is also dose-dependent [34], and occurs even at very low phytate concentrations. For example, even when ratios are as low as 0.2:1.0, phytate still exhibits a strong inhibitory effect [34, 35]. Consequently, where possible, all of the phytate should be degraded from cereal- and legume-based complementary foods to achieve the maximum benefit of a four- to fivefold increase in nonheme iron absorption. If this is not feasible, then the phytate:iron molar ratio is less than 1.0:1.0. At this level, iron absorption would be expected to increase twofold, as would zinc absorption in adults [33].

The critical molar ratio above which calcium absorption is compromised by phytate is uncertain, although some investigators suggest that phytate:calcium molar ratios less than 0.17 are desirable [36]. Whether the adverse effect of inositol phosphates on calcium absorption is restricted to the higher inositol phosphates, such as IP5 and IP6, is currently unknown.

Analysis of phytate and mineral concentrations in complementary foods

Selection of the most appropriate method for the analysis of phytic acid is critical. In the past, the method most frequently used was an anion-exchange column separation of phytate, followed by acid hydrolysis and spectrophotometric determination of liberated inorganic phosphorus [37]. However, this method is not specific to inositol hexaphosphate, as it also measures lower inositol phosphates, some of which do not compromise mineral absorption, as noted earlier. Hence, if complementary foods also contain some lower inositol phosphates through phytase-induced hydrolysis, this anion-exchange method should not be used.

The preferred method for the analysis of phytate is the use of high-performance liquid chromatography (HPLC), which can separate and quantify the individual inositol phosphates. Several HPLC methods have been developed for the analysis of inositol phosphates. The most recent method developed by Oberleas and Harland [38] uses a spectrophotometric detector. A standard wheat bran sample is available from the American Association of Cereal Chemists, which can be used to determine the accuracy of the HPLC analytical method for phytate. If this is not available, then an interlaboratory comparison of replicates of a series of internal laboratory controls analyzed by the same HPLC method should be performed. To assess precision, replicates of a pooled sample, such as 95% extraction maize flour, can be analyzed and the inter-run coefficient of variation calculated.

Special precautions must be taken to avoid adventitious contamination during the collection, preparation, and analysis of complementary food samples for trace elements, including iron and zinc; details are given in Gibson and Ferguson [39]. Flame atomic absorption spectrophotometry (AAS) is the most widely used method for mineral analysis, although increasingly, multielement methods, including x-ray fluorescence [40], instrumental neutron activation analysis (INAA), inductively coupled plasma (ICP) spectroscopy, and ICP mass spectrometry, are employed. Some methods (e.g., AAS and ICP) are susceptible to interference from the sample matrix, so the organic material in the samples must first be removed by acid digestion or dry ashing using either a muffle furnace or a microwave digest method. Ashed samples are then dissolved in hyperpure hydrochloric acid prior to analysis. Standard reference materials must be included with each batch of analysis as a check on the accuracy and precision of the analytical procedures. These can be purchased from the National Institute of Standards and Technology (NIST) (Gaithersburg, MD, USA); examples include rice flour (SRM-1568a) and citrus leaves (SRM-1572).
Iron, zinc, calcium, and phytate concentrations of indigenous complementary foods based on recipes from low-income countries

Table 1 summarizes data on the iron, zinc, calcium, and IP5 + IP6 concentrations of complementary foods compiled from indigenous recipes and based on maize, wheat, rice, and starchy roots and tubers. Corresponding phytate:mineral molar ratios are also given. Details of the recipes have been published earlier [1, 41]. The ingredients of each recipe are listed, together with the concentrations of iron, zinc, calcium, and phytate (expressed as milligrams per 100 g dry weight) and the molar ratios of phytate:zinc, phytate:iron, and phytate:calcium for each complementary food. The mineral and phytate concentrations of most of these complementary foods were calculated from food composition values derived from the analysis of

<table>
<thead>
<tr>
<th>Recipe no.</th>
<th>Ingredients</th>
<th>Iron</th>
<th>Zinc</th>
<th>Calcium</th>
<th>IP5 + IP6</th>
<th>Phytate: iron</th>
<th>Phytate: zinc</th>
<th>Phytate: calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on maize flour or grits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>17:10:5:68 unrefined maize flour, cowpeas, groundnuts, water</td>
<td>3.4</td>
<td>2.2</td>
<td>19</td>
<td>634</td>
<td>15.8</td>
<td>29</td>
<td>2.03</td>
</tr>
<tr>
<td>2</td>
<td>8:2:90 unrefined maize flour, soy flour, water</td>
<td>3.0</td>
<td>3.0</td>
<td>50</td>
<td>770</td>
<td>21.7</td>
<td>25</td>
<td>0.94</td>
</tr>
<tr>
<td>3</td>
<td>20:3:4:1:72 unrefined maize flour, soy flour, groundnuts, sorghum, water</td>
<td>2.9</td>
<td>2.5</td>
<td>39</td>
<td>643</td>
<td>18.7</td>
<td>25</td>
<td>1.00</td>
</tr>
<tr>
<td>4</td>
<td>20:80 Refined maize grits (sieved), water</td>
<td>0.6</td>
<td>0.5</td>
<td>4</td>
<td>62</td>
<td>8.7</td>
<td>12</td>
<td>0.94</td>
</tr>
<tr>
<td>5</td>
<td>22:6:72 refined maize flour, soy flour, water</td>
<td>3.2</td>
<td>1.4</td>
<td>46</td>
<td>421</td>
<td>11.1</td>
<td>30</td>
<td>0.56</td>
</tr>
<tr>
<td>6</td>
<td>20:10:70 refined maize grits, mungbean grits, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.2</td>
<td>1.0</td>
<td>35</td>
<td>368</td>
<td>14.0</td>
<td>36</td>
<td>0.64</td>
</tr>
<tr>
<td>7</td>
<td>20:15:65 refined maize grits, chicken liver, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>10.4</td>
<td>3.5</td>
<td>12</td>
<td>26</td>
<td>0.2</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>8</td>
<td>23:7:70 refined maize grits, egg yolk, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>5.6</td>
<td>3.2</td>
<td>124</td>
<td>29</td>
<td>0.4</td>
<td>1</td>
<td>0.01</td>
</tr>
<tr>
<td>9</td>
<td>25:5:70 refined maize grits, dried anchovy powder, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.5</td>
<td>2.7</td>
<td>784</td>
<td>41</td>
<td>1.4</td>
<td>2</td>
<td>0.00</td>
</tr>
<tr>
<td>Based on refined wheat flour</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>15:12:3:2:68 wheat flour, brown sugar, oil, sorghum, water</td>
<td>2.5</td>
<td>0.9</td>
<td>94</td>
<td>256</td>
<td>8.7</td>
<td>28</td>
<td>0.17</td>
</tr>
<tr>
<td>11</td>
<td>5:9:5:1:103 wheat flour, water</td>
<td>2.1</td>
<td>0.4</td>
<td>10</td>
<td>130</td>
<td>5.2</td>
<td>32</td>
<td>0.79</td>
</tr>
<tr>
<td>Based on white rice flour or rice grains</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>12:88 rice flour, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.7</td>
<td>1.5</td>
<td>31</td>
<td>82</td>
<td>4.1</td>
<td>5</td>
<td>0.16</td>
</tr>
<tr>
<td>13</td>
<td>4:5:1:90 rice flour, mungbeans, sugar, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3.9</td>
<td>2.2</td>
<td>79</td>
<td>440</td>
<td>9.5</td>
<td>20</td>
<td>0.34</td>
</tr>
<tr>
<td>14</td>
<td>4:7:53 rice, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.5</td>
<td>1.5</td>
<td>5</td>
<td>19</td>
<td>3.2</td>
<td>1</td>
<td>0.23</td>
</tr>
<tr>
<td>15</td>
<td>20:10:70 rice, mungbean grits, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.4</td>
<td>2.0</td>
<td>19</td>
<td>275</td>
<td>16.6</td>
<td>14</td>
<td>0.88</td>
</tr>
<tr>
<td>16</td>
<td>20:15:65 rice, chicken liver, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>10.4</td>
<td>3.5</td>
<td>12</td>
<td>3</td>
<td>0.0</td>
<td>&lt; 1</td>
<td>0.02</td>
</tr>
<tr>
<td>17</td>
<td>23:7:70 rice, egg yolk, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4.9</td>
<td>4.5</td>
<td>138</td>
<td>7</td>
<td>0.1</td>
<td>&lt; 1</td>
<td>0.00</td>
</tr>
<tr>
<td>18</td>
<td>25:5:70 rice, dried anchovy, water&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.2</td>
<td>3.5</td>
<td>663</td>
<td>5</td>
<td>0.2</td>
<td>&lt; 1</td>
<td>0.00</td>
</tr>
<tr>
<td>19</td>
<td>20:4:4:72 rice, soy flour, sesame, water</td>
<td>3.9</td>
<td>2.5</td>
<td>125</td>
<td>504</td>
<td>10.9</td>
<td>20</td>
<td>0.24</td>
</tr>
<tr>
<td>20</td>
<td>7:4:1:7:1:87 rice, kidney beans, roasted sesame, sugar, water</td>
<td>6.9</td>
<td>3.8</td>
<td>377</td>
<td>792</td>
<td>9.7</td>
<td>21</td>
<td>0.13</td>
</tr>
</tbody>
</table>

continued
representative samples of staple foods collected from the country in which the recipe originated [40, 42-45]. Data for the few exceptions (identified by a superscript letter a) were based on direct chemical analysis of the complementary foods prepared from the recipes in our laboratory [41, 44].

Not surprisingly, the complementary food recipes based on starchy roots and tubers (recipes 24, 25, and 26), or prepared from white rice (recipe 14, 16, 17, and 18) and no added legumes, had the lowest concentrations of IP5 + IP6. In most cases, these same complementary foods also had very low concentrations of iron and zinc unless they were enriched with animal-source foods (recipes 16, 17, 18, 24, and 25). Molar ratios of phytate:zinc were also very low, indicating that zinc absorption was unlikely to be markedly compromised by phytate. In contrast, not all the complementary foods had phytate:iron molar ratios less than 1, the level considered desirable for iron bioavailability [33]. Indeed, only those complementary foods enriched with animal-source foods in Table 1 had molar ratios of phytate:iron less than 1.

The three complementary food recipes based mainly on unrefined maize with added legumes had some of the highest IP5 + IP6 concentrations, closely followed by those based on a mixture of cereals and legumes, notably soybean flour (recipe 5), mungbeans (recipes 6, 13, and 15), or sesame (recipes 19 and 20). Molar ratios of phytate:zinc, phytate:iron, and phytate:calcium for these complementary foods followed a similar trend, suggesting that, despite their higher iron and zinc concentrations compared with the complementary foods based on starchy roots and tubers, mineral bioavailability is likely to be low.

As expected, complementary foods prepared from recipes containing refined cereals such as degemerded maize grits (recipes 7, 8, and 9) or refined wheat flour (recipe 11) (unless another cereal or legume is also included) have lower phytate concentrations than their counterparts prepared from unrefined ingredients, because during processing most of the phytic acid is removed, as noted earlier. However, processing also removes some of the minerals, so that the phytate:mineral molar ratios for complementary foods prepared from refined versus unrefined cereals are not dramatically changed unless they are enriched with animal-source foods such as chicken liver (recipes 7 and 16), whole powdered anchovy with bones (recipes 9 and 18), egg yolk (recipes 8 and 17), or dried skim milk powder (recipe 24). Note that of the enrichment strategies, the complementary foods containing chicken liver (recipes 7 and 16), egg yolk (recipes 8 and 17), or dried anchovy powder (recipes 9 and 18) had zinc concentrations greater than 3.0 mg/100 g dry weight, and those containing dried anchovy powder, egg yolk, or dried skim milk powder had calcium concentrations greater than 100 mg/100 g dry weight. As a consequence, their corresponding molar ratios of phytate:zinc and phytate:calcium were lower than those of recipes without these animal-source foods.

Iron, zinc, calcium, and phytate concentrations of selected processed complementary foods

Table 2 lists the ingredients, including details of the fortificants when available, of selected manufactured processed complementary foods purchased from countries in Africa and Asia and analyzed in our laboratory. Concentrations of iron, zinc, calcium, and IP5 + IP6, expressed as milligrams per 100 g dry weight, together

---

**Table 1.** Iron, zinc, calcium, and hexa- (IP6)- and penta- (IP5)-inositol phosphate concentrations (mg/100 g dry weight) and phytate:mineral molar ratios of complementary foods based on indigenous recipes from low-income countries (continued)

<table>
<thead>
<tr>
<th>Recipe no.</th>
<th>Ingredients</th>
<th>Iron</th>
<th>Zinc</th>
<th>Calcium</th>
<th>IP5 + IP6</th>
<th>Phytate: iron</th>
<th>Phytate: zinc</th>
<th>Phytate: calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>13:18:24:45 banana flour, peanuts, sugar, water</td>
<td>2.0</td>
<td>1.1</td>
<td>71</td>
<td>113</td>
<td>4.8</td>
<td>10</td>
<td>0.10</td>
</tr>
<tr>
<td>22</td>
<td>72:12:4:8:4 coco yam, avocado, soybeans, coconut milk, pumpkin leaf</td>
<td>1.1</td>
<td>0.6</td>
<td>28</td>
<td>88</td>
<td>6.8</td>
<td>15</td>
<td>0.19</td>
</tr>
<tr>
<td>23</td>
<td>63:17:8:2:10 potato, kale, chickpea flour, oil, water</td>
<td>1.4</td>
<td>0.4</td>
<td>44</td>
<td>79</td>
<td>4.8</td>
<td>20</td>
<td>0.11</td>
</tr>
<tr>
<td>24</td>
<td>47:28:6:3:3:13 sweet potato, egg, dried skim milk, oil, brown sugar, water</td>
<td>1.8</td>
<td>0.9</td>
<td>122</td>
<td>7</td>
<td>0.3</td>
<td>1</td>
<td>0.00</td>
</tr>
<tr>
<td>25</td>
<td>35:12:41:12 sweet potato, pumpkin leaves, mackerel, water</td>
<td>2.0</td>
<td>0.5</td>
<td>53</td>
<td>14</td>
<td>0.6</td>
<td>3</td>
<td>0.02</td>
</tr>
<tr>
<td>26</td>
<td>16:1:10:4:69 sago flour, refined wheat, brown sugar, oil, water</td>
<td>1.3</td>
<td>0.3</td>
<td>35</td>
<td>16</td>
<td>1.1</td>
<td>5</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*a. Based on chemical analysis from recipes prepared in our laboratory*
TABLE 2. Iron, zinc, calcium, and hexa- (IP6)- and penta- (IP5)-inositol phosphate concentrations (mg/100 g dry weight) and phytate:mineral molar ratios of manufactured processed complementary foods from low-income countries

<table>
<thead>
<tr>
<th>Recipe no.</th>
<th>Ingredients</th>
<th>Iron (mg)</th>
<th>Zinc (mg)</th>
<th>Calcium (mg)</th>
<th>IP5 + IP6 (mg)</th>
<th>Phytate: iron</th>
<th>Phytate: zinc</th>
<th>Phytate: calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Based on maize flour</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Maize flour, semi-DSM, sugar, oil, vanilla. Fortificants: calcium, iron, vitamins</td>
<td>1.6</td>
<td>1.4</td>
<td>363</td>
<td>116</td>
<td>6.1</td>
<td>8</td>
<td>0.02</td>
</tr>
<tr>
<td>2</td>
<td>Maize flour, DSM. Fortificants: unspecified</td>
<td>3.8</td>
<td>6.1</td>
<td>205</td>
<td>152</td>
<td>3.4</td>
<td>2</td>
<td>0.05</td>
</tr>
<tr>
<td>3</td>
<td>Maize flour, soy flour, carrots, fish. Fortificants: iron, calcium, iodine</td>
<td>10.2</td>
<td>2.0</td>
<td>53</td>
<td>452</td>
<td>3.7</td>
<td>22</td>
<td>0.52</td>
</tr>
<tr>
<td>4</td>
<td>Unrefined maize flour, soy flour, DSM. Extrusion cooked. Fortificants: iron, zinc, calcium, vitamins A, C, B</td>
<td>43</td>
<td>7.8</td>
<td>126</td>
<td>593</td>
<td>1.2</td>
<td>8</td>
<td>0.29</td>
</tr>
<tr>
<td>5</td>
<td>Unrefined maize flour, soy flour. Fortificants: iron, zinc, calcium, vitamin C, other vitamins</td>
<td>21.9</td>
<td>8.1</td>
<td>135</td>
<td>586</td>
<td>2.3</td>
<td>7</td>
<td>0.26</td>
</tr>
<tr>
<td><strong>Based on wheat flour</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Wheat flour, sugar, honey, maltodextrin, salt. Fortificants: iron, calcium, vitamin C, other vitamins</td>
<td>7.8</td>
<td>1.7</td>
<td>318</td>
<td>326</td>
<td>3.5</td>
<td>19</td>
<td>0.06</td>
</tr>
<tr>
<td>7</td>
<td>Roasted unrefined wheat flour, salt. Fortificants: vitamins and minerals</td>
<td>4.1</td>
<td>2.3</td>
<td>25</td>
<td>468</td>
<td>9.7</td>
<td>20</td>
<td>1.14</td>
</tr>
<tr>
<td>8</td>
<td>Wheat flour, DWM, salt, flavors. Fortificants: vitamins and minerals</td>
<td>7.1</td>
<td>1.6</td>
<td>129</td>
<td>146</td>
<td>1.7</td>
<td>9</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>Based on refined wheat flour</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Refined wheat flour, DWM, sugar, pumpkin, salt. Fortificants: iron, calcium, vitamins A, C, folic acid, B vitamins</td>
<td>9.4</td>
<td>1.9</td>
<td>511</td>
<td>19</td>
<td>0.2</td>
<td>1</td>
<td>0.00</td>
</tr>
<tr>
<td>10</td>
<td>Refined wheat flour, milk solids, sugar, oil, salt, FOS, inulin, taurine, vanilla. Fortificants: iron, zinc, iodine, folic acid, biotin, vitamins</td>
<td>11.2</td>
<td>1.4</td>
<td>389</td>
<td>24</td>
<td>0.2</td>
<td>2</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Based on white rice flour</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Rice flour, corn starch, sugar, dried fruits, oil, soy lecithin, beetroot juice. Fortificants: iron, vitamins</td>
<td>8.3</td>
<td>0.3</td>
<td>18</td>
<td>7</td>
<td>0.1</td>
<td>2</td>
<td>0.02</td>
</tr>
<tr>
<td>12</td>
<td>Rice flour, soybean flour, sugar. Fortificants: vitamins and minerals</td>
<td>1.9</td>
<td>1.7</td>
<td>210</td>
<td>136</td>
<td>6.2</td>
<td>8</td>
<td>0.04</td>
</tr>
<tr>
<td>13</td>
<td>Rice flour, soy flour, sugar, DSM, oil, salt, taurine, vanilla. Fortificants: iron, calcium, biotin, vitamins</td>
<td>9.5</td>
<td>3.8</td>
<td>495</td>
<td>261</td>
<td>2.3</td>
<td>7</td>
<td>0.03</td>
</tr>
<tr>
<td>14</td>
<td>Rice flour. Fortificants: vitamins and minerals</td>
<td>4.6</td>
<td>4.3</td>
<td>9</td>
<td>12</td>
<td>0.2</td>
<td>&lt; 1</td>
<td>0.08</td>
</tr>
</tbody>
</table>

*continued*
TABLE 2. Iron, zinc, calcium, and hexa- (IP6)- and penta- (IP5)-inositol phosphate concentrations (mg/100 g dry weight) and phytate:mineral molar ratios of manufactured processed complementary foods from low-income countries (continued)

<table>
<thead>
<tr>
<th>Recipe no.</th>
<th>Ingredients</th>
<th>Iron</th>
<th>Zinc</th>
<th>Calcium</th>
<th>IP5 + IP6</th>
<th>Phytate: iron</th>
<th>Phytate: zinc</th>
<th>Phytate: calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on white rice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Rice, soy protein, DWM, maltodextrin, whey, FOS, inulin, DHA, taurine. Fortificants: iron, zinc, calcium, vitamins A, D, E, C, K, folic acid, B vitamins</td>
<td>8.1</td>
<td>5.0</td>
<td>294</td>
<td>743</td>
<td>7.8</td>
<td>15</td>
<td>0.15</td>
</tr>
<tr>
<td>16</td>
<td>Rice, beef, broccoli, lecithin, FOS. Fortificants: vitamins and minerals; omega-3 and -6 fatty acids</td>
<td>2.9</td>
<td>2.1</td>
<td>277</td>
<td>75</td>
<td>2.2</td>
<td>4</td>
<td>0.02</td>
</tr>
<tr>
<td>17</td>
<td>Jasmine rice, soybean flour, pumpkin. Fortificants: iodized salt</td>
<td>0.5</td>
<td>1.7</td>
<td>10</td>
<td>47</td>
<td>8.0</td>
<td>3</td>
<td>0.29</td>
</tr>
<tr>
<td>18</td>
<td>Rice flakes, DWM, oil, soy protein, inulin, fish powder, carrot, spinach, flavorings. Fortificants: vitamins and minerals</td>
<td>13.5</td>
<td>1.9</td>
<td>590</td>
<td>35</td>
<td>0.2</td>
<td>2</td>
<td>0.00</td>
</tr>
<tr>
<td>Based on brown rice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Brown rice, rice, lysine, FOS. Fortificants: vitamins and minerals</td>
<td>10.4</td>
<td>4.5</td>
<td>399</td>
<td>285</td>
<td>2.3</td>
<td>6</td>
<td>0.04</td>
</tr>
<tr>
<td>20</td>
<td>Brown rice, rice, chicken, vegetables. Fortificants: vitamins and minerals</td>
<td>8.2</td>
<td>2.6</td>
<td>508</td>
<td>256</td>
<td>2.6</td>
<td>10</td>
<td>0.03</td>
</tr>
<tr>
<td>Based on mungbeans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Mungbeans, rice, soy, corn, lecithin, FOS. Fortificants: vitamins and minerals</td>
<td>9.2</td>
<td>1.9</td>
<td>456</td>
<td>223</td>
<td>2.0</td>
<td>12</td>
<td>0.03</td>
</tr>
<tr>
<td>22</td>
<td>Mungbeans, spinach, rice, soy, lecithin, FOS. Fortificants: vitamins and minerals, omega-3 and -6 fatty acids</td>
<td>9.5</td>
<td>6.8</td>
<td>474</td>
<td>298</td>
<td>2.7</td>
<td>4</td>
<td>0.04</td>
</tr>
<tr>
<td>Based on mixed cereals and legumes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Tef, chickpeas, DSM, sugar, salt. Fortificants: calcium, phosphorus, vitamins and minerals</td>
<td>8.4</td>
<td>3.5</td>
<td>82</td>
<td>324</td>
<td>3.3</td>
<td>9</td>
<td>0.24</td>
</tr>
<tr>
<td>24</td>
<td>Oats (precooked), soybeans, sorghum, tef, wheat, peas, haricot beans, sunflower seeds, rice, maize, niger. Fortificants: vitamins and minerals</td>
<td>8.3</td>
<td>2.9</td>
<td>42</td>
<td>635</td>
<td>6.5</td>
<td>22</td>
<td>0.92</td>
</tr>
<tr>
<td>25</td>
<td>Oats, barley, wheat, peanuts, lentils, haricot beans, soybeans, red sorghum, bulla, sesame, linseed, tef, chickpeas. Fortificants: not specified</td>
<td>22.9</td>
<td>3.1</td>
<td>30</td>
<td>558</td>
<td>2.1</td>
<td>18</td>
<td>1.13</td>
</tr>
<tr>
<td>26</td>
<td>Wheat, oats, rice, barley, millet, sugar, maltodextrin, FOS, inulin. Fortificants: iron, zinc, calcium, vitamins</td>
<td>17.7</td>
<td>12.3</td>
<td>182</td>
<td>144</td>
<td>0.7</td>
<td>1</td>
<td>0.05</td>
</tr>
</tbody>
</table>

continued
TABLE 2. Iron, zinc, calcium, and hexa- (IP6)- and penta- (IP5)-inositol phosphate concentrations (mg/100 g dry weight) and phytate: mineral molar ratios of manufactured processed complementary foods from low-income countries (continued)

<table>
<thead>
<tr>
<th>Recipe no.</th>
<th>Ingredients</th>
<th>Iron</th>
<th>Zinc</th>
<th>Calcium</th>
<th>IP5 + IP6</th>
<th>Phytate: iron</th>
<th>Phytate: zinc</th>
<th>Phytate: calcium</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>Maize, sorghum, soy, millet. Fortificants: vitamins and minerals</td>
<td>22.1</td>
<td>5.2</td>
<td>145</td>
<td>585</td>
<td>2.2</td>
<td>11</td>
<td>0.25</td>
</tr>
</tbody>
</table>

DHA, docosahexaenoic acid; DWM, dried whole milk powder; DSM, dried skim milk powder; FOS, fructo-oligosaccharides

with corresponding phytate:mineral molar ratios, are presented (unpublished data). Most (93% [25/27]) of these processed complementary foods claimed to be fortified, most frequently, when details were supplied, with iron and/or calcium; only 22% (6/27) were fortified with zinc. In most cases, neither the level nor the form of the fortificants added was specified by the manufacturer (data not shown). Analyses of iron, zinc, and calcium were performed by AAS, and analyses of hexa- and penta-inositol phosphates were performed by HPLC using the procedure of Lehrfeld [46], as modified by Hotz and Gibson [47].

Again, the processed complementary foods based on unrefined cereals, oleaginous seeds, and/or legumes (recipes 4, 5, 24, 25, and 27) had the highest concentrations of IP5 and IP6, whereas those based on refined wheat flour (recipes 9 and 10), white rice flour (recipes 11 and 14), or rice flakes (recipe 18) had the lowest. Indeed, it is noteworthy that three of the processed complementary foods based on mixed cereals and legumes (recipes 24, 25, and 27) had concentrations of IP5 + IP6 that were as high as the values for the indigenous complementary foods based on unrefined maize (table 1).

In most cases, because of the addition of iron as a fortificant, the concentrations of iron in the processed complementary foods were consistently higher than those in complementary foods based on indigenous recipes, except for the indigenous recipes containing chicken liver (recipes 7 and 16). Fewer processed complementary foods (18% [5/27]) listed zinc as a fortificant, so not surprisingly, with few exceptions, those fortified with zinc had the highest zinc concentrations. In general, calcium concentrations were also consistently higher in the processed complementary foods that claimed to be fortified with calcium or an unspecified mixture of minerals (78% [21/27]) and/or that contained milk solids. Exceptions were three processed complementary foods (recipes 11, 17, and 25) that did not contain a calcium fortificant, minerals, or milk solids, and as a consequence, all had extremely low calcium concentrations (<3 0 mg/100 g dry weight), and one processed complementary food based on white rice flour, which had the lowest calcium concentration (9 mg/100 g dry weight), despite claiming to be fortified with minerals (recipe 14).

It is of interest that less than a third of the indigenous (27%) or processed (22%) complementary foods had phytate:iron molar ratios less than 1, even though 89% (24/27) of the processed complementary foods claimed to be fortified either specifically with iron (11/27) or with a premix of vitamins and minerals (13/27). In contrast, almost all of the processed complementary foods (82% [22/27]), as compared with 58% (15/26) of the indigenous complementary foods, had phytate:zinc molar ratios within the range indicative of an omnivorous diet or a vegetarian diet based on refined cereals (i.e., ratios of 5 to 18) with moderate zinc absorption [32]. Similarly, more of the processed complementary foods than the indigenous complementary foods had phytate:calcium molar ratios less than 0.17 (67% [18/27] vs. 50% [13/26]). In total, desirable molar ratios for phytate:iron (<1), phytate:zinc (<18), and phytate:calcium (<0.17) were achieved for 25%, 70%, and 57%, respectively, of the complementary foods presented in tables 1 and 2.

Despite fortification, almost none of the processed complementary foods itemized in table 2 met the World Health Organization (WHO) estimated needs for iron, zinc, or calcium for breastfed infants aged 9 to 11 months, when a daily ration of 40 g dry weight was assumed [48]. Clearly, manufacturers should fortify processed complementary foods appropriately to ensure they meet the WHO estimated needs for iron, zinc, and calcium for breastfed infants and young children. For the high-phytate, cereal-based, processed complementary foods available in low-income countries, the potential for using “protected” iron compounds such as NaFeEDTA should be explored, because this compound partially protects the fortificant iron from reacting with absorption inhibitors such as phytate (and polyphenols), as noted earlier [5]. Fortification guidelines are available in Allen et al. [49]. These same mineral deficits have also been reported earlier for infants and young children consuming the indigenous complementary foods itemized in table 1 [1] and elsewhere [2, 50]. Only one of the processed complementary foods analyzed in table 2 had an iron concentration with the potential to exceed the upper tolerable level for some age groups [51].
Use of phytate reduction strategies to enhance mineral bioavailability in plant-based complementary foods

In many low-income countries, the inhibitory effect of phytate on mineral bioavailability in cereal- and/or legume-based complementary foods is unlikely to be attenuated by the addition of expensive cellular animal protein- or ascorbic acid-rich foods, known enhancers of zinc, and nonheme iron absorption, respectively [3]. Instead, reducing the phytate content of these cereal- and/or legume-based complementary foods may be a more feasible alternative to enhance mineral bioavailability. Such an approach could also be used to improve the absorption of mineral fortificants in high-phytate processed complementary foods.

Food preparation and processing methods to reduce the phytate content of cereal- and/or legume-based complementary foods in the household include soaking, germination, fermentation, and pounding. Only a brief outline is given here; more details are available elsewhere [3]. Conventional heat treatments induce only moderate losses (5% to 15%) of phytic acid, depending on the plant species, temperature, and pH, whereas soaking cereal and, to a lesser extent, legume flours under optimal conditions can markedly reduce their IP5 and IP6 content, by a combination of passive diffusion of water-soluble sodium or potassium phytate [52] and hydrolysis of phytate by endogenous phytases. The extent of the IP5 + IP6 reduction after soaking varies, depending on the species, pH, and length and conditions of soaking; only modest reductions in IP5 + IP6 are achieved after soaking whole seeds or legumes [41]. Some loss of minerals, water-soluble vitamins, and possibly other antinutrients (e.g., polyphenols) may also occur with soaking [53].

Germination and fermentation also induce enzymatic hydrolysis of IP6 and IP5 to lower inositol phosphates through the action of endogenous or microbial phytase enzymes, respectively [3, 54]. For example, germination leads to an increase in phytase activity in certain cereals (e.g., maize, millet, and sorghum), most legumes, and oilseeds through de novo synthesis, activation of intrinsic phytase, or both. Egli et al. [55] observed that during germination, rice, millet, and mungbean had the largest reductions in phytate content, ranging from 50% for mungbean to 64% for millet. Germination also decreases the content of certain tannins and other polyphenols in legumes (e.g., *Vicia faba*) and red sorghum as a result of the formation of polyphenol complexes with proteins [56].

Fermentation of cereal- and/or legume-based complementary foods can be achieved in the household by adding starter cultures that contain microbial phytases such as molds or yeasts to the food. The organic acids produced during fermentation lower the pH, thus generating a pH that is optimal for the intrinsic phytases in the cereal and legume flours to further degrade the phytic acid. The extent of the reduction in higher inositol phosphate levels during fermentation varies; sometimes as much as 90% of the phytate can be removed when the conditions for fermentation are optimized [57]. In some circumstances, however, metal ions can inhibit the activity of certain phytases [58]. For example, calcium added as a fortificant to bread dough inhibits the activity of phytase in yeast [59].

Fermenting complementary foods has several other nutritional advantages. The low pH prevents the growth of pathogenic microorganisms, while the organic acids have the potential to form soluble ligands with iron and zinc, thus enhancing absorption. Improvements in protein quality have also been documented after fermentation, associated with the destruction by microbial enzymes of protein inhibitors that interfere with nitrogen digestibility, or from the ability of starter cultures to synthesize certain amino acids [3].

Home pounding can also be used to reduce the phytic acid content of unrefined cereals that have phytic acid localized in the outer aleurone layer (rice, sorghum, and wheat) or in the germ (maize) [11], as noted earlier, although the mineral content is also simultaneously reduced by this procedure. Removal of the hull or seed coat in legumes does not reduce their phytic acid content, however, because it is distributed throughout the cotyledons.

Dephytinization at the commercial level can be achieved by milling or the addition of exogenous phytase (*myo*-inositol hexakisphosphate phosphohydrolases) enzymes. When milling is used to remove the bran and/or germ from cereals, as much as 90% of the phytate can be lost. Several sources of phytase enzymes are available. Many are extracted from molds, which act over a broader pH range (2.5 to 5.5) than cereal phytases (4.5 to 5.6) and at the physiological conditions of the stomach and the small intestine. They include *Aspergillus ficium* (a genetically modified variety of *A. niger*), *A. oxyzae*, and *A. fumiatus*. *A. fumiatus* has the added advantage of resisting heat treatment at temperatures up to 100°C for 20 minutes [60]. These commercial phytase enzymes can degrade phytate completely in approximately 2 hours, provided the phytase enzyme is added to an aqueous slurry of the complementary foods held at the pH optimum of the enzyme. Iron absorption was reported to be significantly increased in women receiving an iron-fortified, whole-maize porridge meal (phytate:iron molar ratio ~ 8:1) containing added microbial phytase derived from a genetically modified culture of *A. niger* and active at the pH of the gastrointestinal tract [61]. However, the high cost of microbial phytases may preclude their use in low-income countries. Further, because some phytase enzymes (e.g., *A. ficium*) are derived from a genetically modified variety of *A. niger*, their use may also be restricted by national legislation in some countries.
Naturally occurring phytase enzymes in some whole-grain cereals (wheat, barley, and rye) have also been used to facilitate phytate hydrolysis in cereal-based complementary foods [55, 62]. Cereals with the highest phytase activity are whole wheat, whole rye, buckwheat, and barley, whereas sorghum, maize, and rice have low phytase activity. Legumes and oilseeds have lower phytase activity than cereals. When 10% whole wheat or rye flour was added to a complementary food slurry based on cereals and legumes, phytic acid was completely degraded after 1 to 2 hours when the mixture was maintained under optimum conditions for phytase activity [62].

Thus, complete degradation of phytate in cereal- and/or legume-based complementary foods can be achieved at the commercial level by using either exogenous or intrinsic phytases [63, 64], as long as optimal conditions for enzyme activity are maintained. Dephytinization by these methods has resulted in significant increases in the absorption of iron [17, 65] and zinc (but not copper [12]) in several isotope studies in adults. Studies on infants and young children are more limited; although there are some reports of significant increases (p < .05) in zinc (16.7% vs. 22.5%) [66] and iron (3.9% vs. 8.7%) [67] absorption after feeding infants commercial dephytinized soy formula compared with regular formula. Whether these commercial dephytinization strategies enhance calcium absorption from cereal- and/or legume-based complementary foods in infants and young children is less certain.

Unlike commercial dephytinization, household strategies such as soaking, germination, or fermentation can remove only about 50% of the phytate in cereal- and/or legume-based complementary foods [47]. Whether this level of phytate reduction can enhance mineral absorption from cereal- and/or legume-based complementary foods in infants and young children has not been investigated by in vivo isotope studies. In adults, significant increases in absorption of both zinc [18, 68] and calcium [19] have been achieved from test meals prepared with 60% phytate-reduced maize and administered over a whole day as compared with meals made from wild-type maize. Modest increases in absorption of intrinsic iron have also been reported in low-phytate versus wild-type maize [16].

These findings suggest that some improvement in mineral absorption is likely with a 50% reduction of phytate content in high-phytate complementary foods. Nevertheless, the magnitude of the increase in fractional absorption is difficult to predict and will vary depending on the composition of the complementary food and the dietary intake, age, and nutritional status of the target group [69, 70]. For example, even complete phytate degradation by commercial phytase enzyme improved iron absorption from cereal porridges prepared with water but not from porridges prepared with milk [17]. This finding is important, because manufacturers often recommend preparing fortified complementary foods with milk rather than water. The health status of infants and young children is also likely to have a major impact on mineral absorption, especially in settings where environmental enteropathy may be widespread [71, 72].

Conclusions and recommendations

There is an urgent need to address the problems associated with poor mineral bioavailability in both indigenous and commercially processed cereal-based complementary foods used in low-income countries. Many of these complementary foods have very high concentrations of phytate and phytate:mineral molar ratios at levels likely to inhibit absorption of iron, zinc, and calcium. Dephytinization strategies exist to reduce the phytate content of both indigenous and processed complementary foods, and some improvement in mineral absorption is likely if these strategies are implemented. The magnitude of the increase in fractional absorption, however, is difficult to predict and will vary, depending on the composition of the complementary food and the dietary intakes, age, health, and nutritional status of the target group. However, dephytinization alone is unlikely to be sufficient to overcome the shortfalls in iron, zinc, and calcium that have been consistently reported in cereal- and/or legume-based complementary foods used in low-income countries. Instead, dephytinization should be combined with enrichment strategies such as the addition of animal-source and vitamin C–rich foods, where feasible, in an effort to overcome, at least in part, these mineral deficits in indigenous complementary foods.

Cereal- and/or legume-based complementary foods can also be fortified with micronutrients, including minerals, in an effort to close the gap that may still remain between the level of absorbed minerals in high-phytate cereal- and/or legume-based complementary foods and the WHO recommendations. Use of “protected” iron compounds such as NaFeEDTA, which partially protects the fortificant iron from reacting with phytate or polyphenols, should also be explored. Manufactured fortified complementary foods can be provided through commercial markets or freely distributed in national government programs. Alternatively, resource-poor households can be supplied with fortificant premixes in single-dose sachets containing micronutrient powders or lipid-based nutrient supplements that can be added to home-prepared complementary foods. However, even when high-phytate complementary foods are fortified with minerals, the level and form of the mineral fortificants do not necessarily ensure that the fortified complementary foods meet the mineral needs of infants and young children. More effort should be made to ensure that fortified foods and the dietary intakes, age, and nutritional status of the target group. However, dephytinization strategies exist to reduce the phytate content of both indigenous and processed complementary foods, and some improvement in mineral absorption is likely if these strategies are implemented. The magnitude of the increase in fractional absorption, however, is difficult to predict and will vary, depending on the composition of the complementary food and the dietary intakes, age, health, and nutritional status of the target group. However, dephytinization alone is unlikely to be sufficient to overcome the shortfalls in iron, zinc, and calcium that have been consistently reported in cereal- and/or legume-based complementary foods used in low-income countries. Instead, dephytinization should be combined with enrichment strategies such as the addition of animal-source and vitamin C–rich foods, where feasible, in an effort to overcome, at least in part, these mineral deficits in indigenous complementary foods.

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cereal- and/or legume-based complementary foods in low-income countries meet the WHO recommendations for iron, zinc, and calcium for breastfed infants and children. Attention must also be given when setting fortificant levels to avoid antagonistic interactions between minerals and intakes that may exceed the tolerable upper intake levels.

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Phytate, iron, zinc, and calcium concentrations in plant-based complementary foods


Are peanut allergies a concern for using peanut-based formulated foods in developing countries?

Zhenyu Yang

Abstract

Background. Peanut allergy is relatively common among children in developed countries and may have severe outcomes, including anaphylaxis. However, few data about peanut allergy in developing countries are available. Meanwhile, formulated foods with peanuts as a major ingredient are being promoted to prevent and control malnutrition in developing countries.

Objective. The objectives of the paper are to review the existing epidemiologic data about peanut allergy, to determine whether the prevalence of peanut allergy is lower in developing countries, and to explore the possible reasons for onset of peanut allergy.

Methods. Publications relevant to peanut allergy were searched via Pubmed, and prevalence and etiological factors of peanut allergy were reviewed.

Results. Data about peanut allergy were scarce in most developing countries. The existing data support the conclusion that peanut allergy is not as common in developing countries as in developed countries and may not be a major concern for programs promoting formulated food containing peanuts for control of malnutrition. However, plans for treatment of individuals with peanut allergy could be incorporated into these formulated food supplementation programs. A few risk factors (late introduction of peanuts to children, peanut processing technology, non-oral peanut exposure, and maternal peanut exposure during pregnancy and lactation) have been hypothesized to be associated with peanut allergy. However, more conclusive data are needed to verify or disprove these hypotheses.

Conclusions. Peanut allergy is not as common in developing countries as in developed countries and may not be a major concern for programs promoting formulated food containing peanuts for control of malnutrition.

However, more research about prevalence of peanut allergy is warranted in developing countries.

Key words: Developing countries, formulated food, peanut allergy

Introduction

Peanut allergy is an IgE-mediated food allergy that is quite common in some developed countries (e.g., the United Kingdom, Australia, and the United States). Around 1% of children under 5 years of age are affected by the disease in these countries [1]. Peanut allergy can result in anaphylactic reactions that are potentially life-threatening; thus, special attention should be paid to peanut allergy when peanut consumption is promoted at scale. However, few epidemiologic data are available about peanut allergy in developing countries.

With the increasing use of formulated foods containing peanuts (e.g., Plumpy'nut, Nutributter) for the treatment and prevention of malnutrition, concerns have been raised about large-scale use of peanut-based formulated foods and risks associated with peanut allergy. To prevent and control malnutrition, supplying formulated foods is one of the most important strategies, and milk, eggs, soybeans, and peanuts are among the key potential ingredients. However, other potential replacements for peanuts (i.e., milk, eggs, and soybeans) have similar or even stronger allergenicity, so substituting these products does not necessarily reduce risk [2]. The purpose of this paper is to review the current evidence regarding the epidemiology of peanut allergy, especially in developing countries.

To elucidate intake of peanuts globally, data on per capita peanut consumption are shown in figure 1. The figure shows that peanut consumption per capita per year is highest in North America, lowest in Europe, and moderate in Africa, Asia and the Pacific region, and Central America and the Caribbean. By contrast, peanut oil consumption is highest in Africa, lowest in...
Central America and the Caribbean, and moderate in Asia and the Pacific, North America, and Europe (fig. 2) (The data were extracted from Food Balance Data Sheet 2003, from FAO website [3]).

**Definition of peanut allergy and peanut sensitization**

Reported peanut allergy is usually determined by a clinical history of allergic symptoms and the temporal association between peanut intake and these symptoms. Diagnosis of peanut allergy is based on general symptoms of the skin, gastrointestinal tract, and respiratory tract, the medical history of the temporal association between peanut consumption and the symptoms (generally seconds or minutes, but can be up to 2 hours), and evidence of peanut-specific IgE [1]. The gold standard for diagnosis is the double-blind, placebo-controlled food challenge test.

Peanut sensitization is determined by the peanut-specific skinprick test and/or serum peanut-specific IgE (peanut-sIgE) [4]. The majority of subjects with low positive peanut-specific IgE do not have peanut allergy [4, 5], just as most food sensitization may not lead to food allergy in most circumstances [6]. Thus, the positive predictive value of the skinprick test is usually low [7, 8]. The peanut sensitization test could be used more as a screening tool for peanut allergy rather than a diagnostic test confirming peanut allergy [4].

**Sources searched and search strategy for the review**

Publications relevant to peanut allergy were searched by PubMed with specific key words on 14 July 2009 and updated on 14 December 2009. All titles and abstracts were assessed for their relevance to peanut allergy. The phrase (“Peanut Hypersensitivity”[MAJR] AND “Humans”[MeSH Terms]) AND (“Child, Preschool”[MeSH Terms] OR “Infant”[MeSH Terms]) was used for the search. Only publications written in English were reviewed. The references were extracted from the search results based on the following criteria for inclusion: population-based studies with estimation of the prevalence of peanut allergy, etiologic studies of peanut allergy, reviews of peanut allergy, and case report studies. Ninety-three papers were found, of which 27 met these criteria. The phrase (“Food Hypersensitivity”[MAJR] AND “Humans”[MeSH Terms]) AND (“Africa”[All Fields] OR “Asia”[All Fields] OR “America”[All Fields]) AND (“arachis hypogaea”[MeSH Terms] OR (“arachis”[All Fields] AND “hypogaea”[All Fields]) OR “arachis hypogaea”[All Fields] OR “peanut”[All Fields]) was used to identify all potential peanut allergy studies in developing countries. Five additional papers met the criteria.

**Epidemiology**

**Age distribution**

The mean age for the diagnosis of peanut allergy based on clinical characteristics was 14 months in children [1], and the median age of first peanut reaction was 14 to 24 months in the United States [9–11]. A study in the United Kingdom also found that the median age of onset of peanut allergy symptoms was about 24 months [12]. The mean and median ages of first reaction were 12 and 15.1 months, respectively, in a population study in Australia. Later onset was associated with increased risk of anaphylaxis [13]. Peanut allergy developed before 6 months of age in 4.4% of these patients, before 24 months in about 68%, and before 72 months in about 90% [13]. In a study in France, the first symptoms of 46% of peanut allergy cases appeared before 1 year.
of age, 7% had symptoms before 6 months of age, and 80% of all cases occurred by 3 years of age [14]. The peak age for diagnosis of food allergy was 18 months in a Denmark study [6]. Most peanut allergy occurred by 72 months of age.

**Geographic distribution**

Most of the prevalence data about peanut allergies are reported from studies in North America, Western Europe, and Australia (table 1). A recent study in Canada among children with a mean age of about 7 years found that the prevalence of peanut allergy was 1.63% [21]. A study in the United States showed that the prevalence of peanut allergy was 0.8% for children under 18 years of age [23]. The prevalence of peanut allergy was 1% for 3- to 4-year-old children [19], 1.8% for 4- to 5-year-old children [18], and 1.85% for 4- to 18-year-old children [16] in the United Kingdom and 1.15% to 2.1% for children under 6 years of age in Australia [13, 15].

The rates of peanut allergy are not consistent across Europe [24]. The prevalence of peanut allergy among young adults with a mean age of 22 years in Denmark was about 0.6% [25]. The estimated prevalence of peanut allergy was 0.3% to 0.75% in France [26]. Peanut is not a very common allergenic food in the eastern Black Sea region of Turkey [27]. In Spain, peanut allergy is also not a common food allergy [28].

The occurrence of peanut allergy may differ between Asian and Western populations [29]. Although prevalence data on peanut allergy are not available for most Asian countries, available data on the occurrence of peanut allergy also differed across countries in Asia (peanut hypersensitivity was low in Malaysia, Japan, and the Philippines and relatively high in Indonesia) [30, 31]. Peanut ranked only sixth among common food allergens in Asia [31]. A survey in China found that the prevalence of peanut sensitization, defined by skin prick test wheal diameter at least 3 mm greater than the saline control, was about 12.3% for 11- to 17-year-olds [7], which was much higher than the 3.3% reported in the United Kingdom [19]. However, the prevalence of self-reported peanut allergy was only about 0.3% for these Chinese populations (n = 2,118). Only one of the seven subjects who reported peanut allergy had peanut

<table>
<thead>
<tr>
<th>Region</th>
<th>Country</th>
<th>Year</th>
<th>Age</th>
<th>Peanut allergy (%)</th>
<th>Peanut sensitization (%)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia Pacific</td>
<td>Australia</td>
<td>2005</td>
<td>5 yr</td>
<td>2.1</td>
<td>—</td>
<td>Kljakovic [15]</td>
</tr>
<tr>
<td></td>
<td>Australia</td>
<td>2004</td>
<td>0–72 mo</td>
<td>1.15</td>
<td>1.53</td>
<td>Mullins [13]</td>
</tr>
<tr>
<td></td>
<td>Australia</td>
<td>2001</td>
<td>0–72 mo</td>
<td>0.73</td>
<td>0.84</td>
<td>Mullins [13]</td>
</tr>
<tr>
<td>Western Asia and</td>
<td>Israel</td>
<td>2004</td>
<td>4–18 yr</td>
<td>0.17</td>
<td>—</td>
<td>Du Toit [16]</td>
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<tr>
<td>Middle East</td>
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<tr>
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<td>Denmark</td>
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<td>22 yr</td>
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<td>—</td>
<td>Osterballe [17]</td>
</tr>
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<td>UK</td>
<td>2004</td>
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<td>2.8</td>
<td>Du Toit [16]</td>
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<tr>
<td></td>
<td>UK</td>
<td>2003</td>
<td>4–5 yr</td>
<td>1.8</td>
<td>2.8</td>
<td>Hourihane [18]</td>
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<tr>
<td></td>
<td>UK</td>
<td>1998</td>
<td>3–4 yr</td>
<td>1</td>
<td>3.3</td>
<td>Grundy [19]</td>
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<tr>
<td></td>
<td>UK</td>
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<td>4–5 yr</td>
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<td>1.1</td>
<td>Tariq [20]</td>
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<td>Canada</td>
<td>2005</td>
<td>7.1–7.6 yr</td>
<td>1.63</td>
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<td>Ben-Shoshan [21]</td>
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<tr>
<td></td>
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<td>2000</td>
<td>7.4 yr</td>
<td>1.50</td>
<td>—</td>
<td>Kagan [22]</td>
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<td></td>
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<td>0.8</td>
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<td>Sicherer [23]</td>
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<td></td>
<td>USA</td>
<td>1997</td>
<td>0–5 yr</td>
<td>0.4</td>
<td>—</td>
<td>Sicherer [23]</td>
</tr>
</tbody>
</table>

*a. Parent-reported allergic reaction to peanut with confirmed skin prick test (SPT) or elevated serum peanut-specific IgE.  
b. Peanut allergy was diagnosed as a history of acute allergic reaction within 2 hours of peanut exposure and a positive SPT.  
c. Peanut sensitization was diagnosed as a positive SPT, which was defined as a wheal size at least 3 mm greater than negative control.  
d. Self-reported peanut allergy confirmed by SPT and double-blinded, placebo-controlled, peanut challenge test (DBPCCT).  
e. History of allergic reaction (at least one of the symptoms: itchy rash, wheezing, vomiting, diarrhea, and swelling) within 2 hours of peanut ingestion, confirmed by positive SPT or peanut-specific IgE or both, or oral peanut challenge test.  
f. SPT, peanut-specific IgE, and DBPCCT.  
g. Parent-reported allergic reaction to peanut with confirmed SPT and open food challenge test.  
h. Parent-reported allergic reaction to peanut with confirmed SPT and peanut-specific IgE.  
i. Parent-reported allergic reaction to peanut with confirmed SPT or elevated serum peanut-specific IgE or DBPCCT.  
j. History of allergic reaction (skin with hives or angioedema; respiratory tract with trouble breathing, wheezing, or throat tightness; and gastrointestinal tract with vomiting or diarrhea) occurring within 2 hours of peanut ingestion.
sensitization, as assessed by the peanut allergen-specific skin prick test (mean wheal diameter > 3 mm), and four of the seven subjects had allergic symptoms. Thus, the prevalence of actual peanut allergy appears to be less than the reported prevalence of peanut allergy (0.3%). Peanut was one of the leading causes of adverse food reactions for 2- to 7-year-old children in Hong Kong, and peanut allergy was less common among those born in mainland China than those born in Hong Kong [32]. About 0.52% of these children had parent-reported and doctor-diagnosed adverse peanut reactions. In Israel, the incidence of peanut allergy is also quite low (~ 0.17%) for 4- to 18-year-old children [16]. Overall, peanut allergy is relatively rare in Asia, although data for many parts of Asia are lacking [33].

No data on the prevalence of peanut allergy are available for Africa. Some cases of peanut sensitization diagnosed using peanut-specific IgE concentration (> 0.35 kU/L) have been reported in South Africa [34]. However, in Nigeria, food intolerance was a relatively minor risk factor for atopic dermatitis (an allergic disease that can increase the risk of other allergic diseases) [35]. About 3.5% of atopic dermatitis patients in the Nigerian study had food intolerance, mainly for eggs, crayfish, and artificial milk. In a cross-sectional study in Mozambique, seafood, meat, and fruits or vegetables were common reasons for self-reported food allergy, and peanut was not reported as a reason for self-reported food allergy [36].

When peanut-based foods (such as Plumpy’nut and Nutributter, both of which contain peanut butter, milk powder, vegetable oil, and micronutrients) are used in research settings, children are first given a test dose to assess food intolerance. In published studies on a total of 1,262 children in Africa who consumed peanut-based supplements for at least 2 months, no cases of peanut allergy were observed. The children in these studies ranged in age from 6 to 60 months (personal communication, Drs. Kathryn Dewey and Ken Maleta).

Plumpy’nut has been widely used for treatment of severe acute malnutrition in more than 1 million children in Africa (e.g., Niger, Malawi, and Congo) during the last 10 years. No peanut allergy has been reported in these populations, although underreporting cannot be ruled out (personal communication, Dr. André Briend).

**Epidemiologic trends**

Several studies suggest that the incidence of peanut allergy has risen during the past several decades in some developed countries. For example, in Australia, the estimated minimum prevalence of peanut allergy for children by 72 months of age increased from 0.73% in 2001 to 1.15% in 2007 [13]. Self-reported peanut allergy increased from 0.4% in 1997 to 0.8% in 2002 among children less than 18 years old in the United States [23]. The prevalence of self-reported peanut allergy verified by the open food challenge test increased from 0.5% in 1989 to 1.0% in 1994 in the United Kingdom, but this change was not statistically significant. The overall prevalence of peanut allergy among 3- to 4-year-old children in the United Kingdom was 1.5% [19]. However, an increasing prevalence of peanut allergy has not been conclusively documented in other studies. For example, in one study in Canada, the prevalence of peanut allergy among 5- to 9-year-old children was 1.64% in 2007, versus 1.34% in 2002. The difference between these two surveys was not statistically significant [21].

**Theories about reasons for different levels of peanut allergy**

It is well accepted that allergic diseases are becoming more common in general, which may be due to cleaner environments. The “hygiene hypothesis” posits that lower exposure to infectious agents during childhood (related to smaller family size and greater affluence) increases susceptibility to allergic diseases [37, 38]. This may partially explain the differences in prevalence rates of peanut allergy between developing and developed countries. On the other hand, protein–energy malnutrition could result in weak immunologic function and lower the risk of allergic response [39], which may partially explain why no peanut allergy cases have been reported when Plumpy’nut is used widely for treating severely malnourished children (personal communication, Dr. André Briend).

A recent study compared the occurrence of peanut allergy among Jewish children with similar genetic backgrounds (Ashkenazi or Sephardic ancestry) living in the United Kingdom and in Israel [16]. The prevalence of peanut allergy among 4- to 18-year-old children was significantly higher in the United Kingdom (1.85%) than in Israel (0.17%). In this study, peanuts were introduced by 9 months of age to 69% of Israeli infants, compared with only 10% of UK infants, and the amount consumed was greater for the children in Israel (monthly median consumption, 7.1 g) than in the United Kingdom (monthly median consumption, 0 g during the first year. The authors suggested that avoidance of peanut consumption in early life could increase the risk of peanut allergy [16]. Thus, early exposure to peanuts could decrease the occurrence of peanut allergy [40], and delayed introduction of peanuts may not prevent it [41].

Another hypothesis for varying prevalence rates of peanut allergy is that peanut processing procedures could be related to the degree of allergenicity [42]. Roasting peanuts can induce the Maillard reaction, which is a chemical reaction between an amino acid
in proteins and an aldehyde or ketone group in sugar in carbohydrates, producing insoluble glycol-protein and related end products, which could become antigens and cause immunologic reactions [42]. The difference in the prevalence of peanut allergy between the United States and China could be due to different peanut processing procedures [42]. In China, peanuts are usually boiled or fried or used as peanut oil. In the United States, by contrast, peanuts are usually roasted by using dry heat [42]. The temperature used for roasting is high [43]. Moreover, peanut oil is commonly used for cooking in China, and small amounts of peanut antigens in the oil could be introduced into the diet during early childhood.

Nonoral peanut exposure could be another risk factor for peanut allergy. A recent case–control study found that household peanut consumption (peanut consumption by all family members during the first year of the subject's life) was associated with greater risks of peanut allergy [44]. Another nested case–control study by the same group showed that infants' epicutaneous exposure to creams containing peanut oil in the first 6 months of life may be related to an increased risk of peanut allergy, diagnosed by using clinical history, the skin prick test, and the double-blinded, placebo-controlled, food challenge test [45]. Low doses of peanut antigens, which were detected in refined peanut oil and can produce a positive skin prick test in peanut allergy patients, could pass through the skin barrier into the circulation and cause peanut allergy. By contrast, peanut protein when ingested is usually digested into single amino acids, which are absorbed from the gastrointestinal tract. In the United States, skin care products containing peanut oil either are not widely available or the peanut antigen level of peanut oil–containing cream is too low to cause peanut allergy [46, 47], so exposure to skin creams does not explain the relatively high rates of peanut allergy in the United States. Other factors may explain the similarity in allergy prevalence between the United Kingdom and the United States, such as environmental peanut exposure, maternal history of allergic diseases, or other food allergies among children.

Another hypothesis is that maternal peanut exposure during pregnancy and/or lactation is related to peanut allergy in the child, but the evidence is not convincing. In one study, peanut-specific IgE was not detectable in the cord blood, a finding that supports the assumption that peanut IgE antibody cannot cross the placenta to cause peanut allergy [45]. Another study found that peanut consumption during pregnancy was marginally associated with peanut allergy (OR, 3.97; 95% CI, 0.73 to 24; p = .063) [34], but this finding was not replicated in other studies [44, 45]. The major peanut antigens (Ara h1 and Ara h2) have been detected in breastmilk [48]. Breastfeeding was associated with an increased risk of peanut allergy in crude analysis in a few studies [18, 19, 44, 45]. However, the association became nonsignificant after controlling for other covariates in most of these studies [18, 44, 45]. An intervention trial that included peanut avoidance during the 3rd trimester of pregnancy, lactation, and infancy did not significantly prevent peanut allergy during the 7-year follow-up [49].

Summary

Data about peanut allergy are scarce for most developing countries. Based on the experience of using Plumpy’nut and Nutributter in Africa, peanut allergy does not appear to be a major concern in that region.

Early consumption of peanuts by infants (i.e., starting from 6 months of age) may decrease the risk of peanut allergy, but further research is needed.

There are several hypotheses regarding risk factors for peanut allergy (e.g., peanut processing technology, nonoral peanut exposure, and maternal peanut exposure during pregnancy and lactation), but additional evidence is needed to confirm or refute these hypotheses.

Acknowledgments

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References

Marketing complementary foods and supplements in Burkina Faso, Madagascar, and Vietnam: Lessons learned from the Nutridev program

Olivier Bruyeron, MirrDyn Denizeau, Jacques Berger, and Serge Trèche

Abstract

Background. Sustainable approaches to improving infant and young child feeding are needed. The Nutridev program worked in Vietnam, Madagascar, and Burkina Faso to test different strategies to improve complementary feeding using fortified products sold to families.

Objective. To review the experiences of programs producing and marketing fortified complementary foods and to report on the feasibility of local production and marketing of fortified complementary foods to increase usage of high-quality foods among children of low-income families in a self-sustaining manner.

Methods. Project documents, surveys of mothers, and production and sales reports were reviewed.

Results. Nutridev experience in Vietnam, Madagascar, and Burkina Faso demonstrates that it is possible to produce affordable, high-quality complementary foods and supplements locally in developing countries. Strategies to make products readily available to the targeted population and to convince this population to consume them yielded mixed results, varying greatly based on the strategy utilized and the context in which it was implemented.

Conclusions. In several contexts, the optimal approach appears to be strengthening the existing food distribution network to sell complementary foods and supplements, with the implementation of a temporary promotion and nutrition education network in partnership with local authorities (e.g., health services) to increase awareness among families about the fortified complementary food product and optimal feeding practices. In urban areas, where the density of the population is high, design and implementation of specific networks very close to consumers seems to be a good way to combine economic sustainability and good consumption levels.

Key words: Complementary foods and supplements, local production, marketing, consumer price, food consumption, nutrition intervention

Introduction

In most developing countries, malnutrition is related to deficits in birthweight, lack of exclusive breastfeeding in the first 6 months of life, and growth failure from 6 to 24 months of age [1]. The latter period coincides with the time when different foods are successively introduced to complement breastmilk. Malnutrition during this period is caused by inadequate intake of nutritionally appropriate complementary foods, which can cause food-borne diseases (diarrhea, parasitic infections) [2] or reduce micronutrient bioavailability.

Timely use of appropriate complementary foods and/or food supplements is generally recognized as a necessary condition to prevent malnutrition [3]. But encouraging mothers to buy or prepare appropriate food products at the appropriate time is a challenge that has often been undertaken without success in developing countries.

Since 1994, Gret and IRD (Research Institute for Development), in partnership with local institutions, have implemented Nutridev, a research-action program aimed at improving complementary feeding of children 6 to 24 months of age through a sustainable approach in order to prevent infant and young child malnutrition in developing countries.

In the initial stages, Nutridev tried to develop recipes from locally available products for complementary feeding of children over 6 months of age (in Madagascar). This method was abandoned because the price of the local commodities required to prepare a nutritionally well-balanced meal was prohibitive (to
provide sufficient iron would have required expensive animal products, such as meat or poultry); the time to prepare the meals was excessive for busy caregivers; improved recipes were often very difficult to explain to caregivers (specifically, proportions); and too many different recipes needed to be developed to take into account seasonality, local commodities, and variations in local contexts.

To address these issues, the Nutridev program instead developed strategies to manufacture easy-to-use fortified products marketed to low-income families with young children. Activities were implemented in three countries with very contrasting cultural, economic, and agroecologic contexts: Vietnam and Madagascar (both since 1994), and Burkina Faso (since 2003).

**Products developed**

The types of products developed included infant flours (instant or needing to be cooked for at least 10 minutes) to be prepared at home, porridges sold ready to eat, and complementary food supplements to be added to the child’s portion of traditional dishes (listed by type and by country in table 1).

An instant flour (*Favina*) was used in Vietnam, since it was determined that caretakers were aware of microbiologic risks and safe water was easily available. Ready-to-cook flours were made in Burkina Faso and Madagascar because easily available water is generally unsafe.

Prepared ready-to-eat porridges were also developed in Madagascar and Burkina Faso, since they are an easy way to feed children, require less time, and save fuel costs. *Koba Aina* porridge is prepared from the infant flour *Koba Aina* at central sites (restaurants for babies) in Madagascar. In Burkina Faso, a fermented porridge (*Ben-Songo*) is made in two producers’ own homes, using improved processes derived from traditional ones widely used in Central and West Africa [4]. Both types of ready-to-eat porridge are kept at temperatures above 50°C and sold to the children’s caretakers at the site of preparation. *Koba Aina* porridges are also sold by door-to-door saleswomen.

In Vietnam, a fortified amylase complementary food supplement (*Favilase*) was developed to reduce the viscosity of the meal in order to allow preparation of porridge with higher energy density and provide sufficient macronutrients and micronutrients. In Burkina Faso, *Dayeri n Yonma* was developed. This product is a base from which mothers can produce a complete infant flour at home. It contains amylase [5], soybeans, vitamins, minerals, and salt. In Madagascar, *Bo Salama*, a food supplement to be added to the meal of a child from the age of 1 year, was developed. This product contains peanuts, salt, vitamins, and minerals, but no amylase.

The nutrient composition of the products was based on recommendations for a breastfed child 6 to 24 months of age (from Lutter and Dewey [6]). All flours follow the recommended nutrient compositions presented in table 2. In addition, the ratio between calcium and phosphorus in the products is between 1 and 2. The products are designed for the preparation of porridge with a dry matter content of at least 25%, an energy density of at least 100 to 120 kcal per 100 mL of prepared gruel, and a flow rate near 100 mm/30 seconds at 45°C (measured with a Bostwick consistometer [7, 8]). All nutritional needs for the breastfed child (in addition to breastmilk) can be met from one to four servings, depending on the child’s age (two 35-g servings for a 6- to 11-month-old child, up to four servings

<table>
<thead>
<tr>
<th>Country</th>
<th>Infant flour</th>
<th>Ready-to-eat porridge</th>
<th>Complementary food supplement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vietnam</td>
<td><em>Favina</em> (instant) (made from rice, soy, sugar, sesame, powdered milk, vitamins and minerals, salt)</td>
<td><em>Koba Aina</em> porridge (made from infant flour)</td>
<td><em>Favilase</em> (containing soy, vitamins, minerals, salt, α-amylase)</td>
</tr>
<tr>
<td>Madagascar</td>
<td>Products ready to cook (made from corn, soy, rice, sugar, peanuts, vitamins and minerals, amylase, salt); <em>Koba Aina</em> (industrially produced), <em>Koba Mazika</em> (small-scale production)</td>
<td></td>
<td><em>Bo Salama</em> (containing peanuts, salt, vitamins and minerals)</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td><em>Yonhamna</em> (ready to cook) in rural areas (made from millet, cowpeas, peanuts, sugar, salt, vitamins and minerals, amylase) and 6 other ready-to-cook products in urban areas called <em>Cérèalor</em>, <em>Fanutri</em>, <em>Misola</em>, <em>Natavie</em>, <em>Nutrilac</em>, <em>VitaSojaMais</em> (products made from millet or corn, from cowpea or sesame or soybean, some with peanut, some with powdered milk, from sugar, vitamins and minerals, salt and amylase)</td>
<td><em>Ben-Songo</em> (a fermented porridge made from millet, peanuts, sugar, vitamins and minerals, salt, amylase)</td>
<td><em>Dayeri n Yonma</em> (containing soy, vitamins and minerals, salt, amylase)</td>
</tr>
</tbody>
</table>
for a child 18 to 24 months of age) (table 2).

Formulation of products was carried out using software (Alicom) developed by IRD to establish the proportions of available ingredients needed to minimize the cost of raw materials, while taking into account the predetermined nutritional objectives. Attention was also paid to processing methods, microbiologic and organoleptic characteristics, and sufficient bioavailability of nutrients. The development phase of a product included sensory evaluation tests to optimize its organoleptic characteristics.

**Strategies implemented to produce and market products**

The following sections describe the implementation of production, distribution, and marketing activities in the three countries. Table 3 summarizes these activities.

**Fasevie in Vietnam**

**Strategy**

The Fasevie program started in 1994 and was focused in its early stages on the local production of equipment necessary to produce instant infant flours (e.g., a very-low-cost cooker-extruder [9], a roaster, and a blender), the development of two different product formulations (instant infant flours and food supplement), and the production of infant foods by local enterprises [10]. Later, a ready-to-cook infant flour was also developed [11] (primarily targeted to mountainous areas), and the capacity of the production unit of the National Institute of Nutrition was improved in order to supply the National Program of Nutrition, which distributes this flour free to the poorest families with young children in Vietnam. Production was decentralized and carried out by medium and small enterprises with locally purchased equipment. Four enterprises were supported: two public, one semiprivate, and one private. One public and the private enterprise stopped their activity within a few years after the launch of the production. Their main reasons for ceasing production were insufficient support from the local authorities and insufficient sales volume of the infant flour, according to the results of the first marketing activities, to justify the mobilization of resources from their enterprises.

The strategy to market infant foods was tested in depth with the medium-scale, semiprivate production company. The company was founded partially with public funds but was managed privately. The strategy was implemented in two central rural areas of Vietnam between 2000 and 2008. Since the end of funding and support from Gret and IRD, some activities have been modified by local organizations (the Women’s Union, People’s Committee, and Health Services). The distribution and marketing strategy described below corresponds to the strategy implemented until 2008 [10].

The instant infant flour (Favina) was packed in plastic 400-g boxes containing 11 servings of 35 g each. In 2008, the consumer price was around 17,000 VND (US$1.06 per box and 1,487 VND (US$0.09) per serving of infant flour. This price included all costs (i.e., ingredients, packaging, and distribution). The complementary food supplement Favilase was packed in 150-g bags. Its consumer price was 6,000 VND (US$0.38) per bag containing 13 servings of 11 g each. This product has been sold in only a few areas and for only a short time because people prefer to buy the infant flour Favina.

The distribution system at the village level was based on a network of volunteers from the Vietnamese Women’s Union. The Union is a public organization founded in 1930, with a history closely linked to Vietnam’s history of national independence and development. The Union has a network that operates throughout Vietnam at four administrative levels—central, provincial,
district, and commune—with a total membership of about 13 million women. Since its foundation, the Union has transformed into a developmental organization that is mandated to protect women's rights and strive for gender equality.

Each volunteer from the Women's Union sold products door-to-door to mothers of children over 6 months of age and reinforced mothers’ awareness about infant nutrition through home visits. A program of seven home visits was developed, with visits from the third trimester of pregnancy until the child reached the age of 24 months. Women were visited during pregnancy to increase their awareness about nutrition. Use of the product Favina was proposed only to mothers with children over 6 months of age. During the visits, the volunteers also gave the mothers information about breastfeeding, hygiene, vaccination, etc. Each community-level volunteer was in charge of 20 to 30 pregnant women or mothers. They were managed by a chief volunteer at the municipality level. A paid program manager supervised the activities of the chief volunteers at the district level, and a coordinator supported the activities of the district managers at the province level. All staff was from the Women's Union except at the provincial level, which included staff from the Faseviet team. From 2006 to 2008, activities were implemented in two provinces (out of 63 in Vietnam) and included a population of 2.6 million. Around 4,000 chief or community volunteers were involved, and 50,000 children were targeted by the activities each month. Attempts were also made to market the product through the existing distribution network of food products.

In addition to the infant flour manufacturer and the Women's Union, several other institutions were involved in the implementation of the strategy. At the national level, these included the National Institute of Nutrition within the Ministry of Health. At the province, district, and municipality levels, the Peoples Committees and Health Services played an important role in the social and political mobilization of the population.

Results

Favina has been exclusively sold through the Women's Union. The attempts to sell Favina through the distribution network of food products were ultimately unsuccessful, for a variety of reasons, including lack of interest from product wholesalers, insufficient sales volume to interest grocery shops over the long term, the costs of promoting a new product, and, probably most importantly, the unwillingness of the Women's Union to allow others to sell the product.

According to a survey in different districts conducted in 2007, 80% of mothers with young children reported that they had ever given the product Favina to their child. Based on data from sales reports and on data from Health Services from January 2006 to May 2007, the monthly penetration rate (monthly percentage of target families who purchase the product at least one time) was 13% on average in all 338 intervention municipalities, and 30% or higher in 10% of these intervention municipalities. Among those families with a 6- to 24-month-old child who purchased products at least once a month, the average number of 400-g boxes bought per month was about 1.2 (14 servings of 35 g each). Therefore, in households that purchased Favina, the child was receiving roughly three servings on average per week.

The relatively low purchase rate may be related to the large container size and thus the relatively high cost for a one-time purchase. However, this price was only half that of the cheapest fortified infant flour available on the market. Compared with the mean per capita income, estimated at 446,000 VND (US$28) per month in the intervention provinces in 2007, the price was relatively low (only 4% of per capita monthly income); however, the large up-front payment for multiple servings may be difficult for poor families.

Another reason for the low purchase rate is limited distribution. Although the community volunteers successfully implemented home visits (nearly 100% of mothers received at least one home visit, with a mean number of between four and five home visits per targeted woman), they were less successful in selling products. Each month, the products were not available for sale, on average, in 34% of the 338 intervention municipalities targeted by the intervention. This appears to have been due in large part to the deficiency of the distribution network, particularly the supply chain. Although producers rented trucks to dispatch the product to the district level, the management of the supply chain (notably the management of money from volunteers to the production unit) was done by the Women's Union. This was quite difficult on the large scale (4,000 volunteers), and a great amount of time was needed to collect funds and provide payment to the production unit. It is probable this was also not considered a priority by the Women's Union chiefs and volunteers, who were very focused on nutrition education. Thus, the production unit was not paid on time, and as a consequence the unit limited production and did not deliver the product to the Women's Union.

Nutrimad in Madagascar

In Madagascar, three different strategies to market complementary foods and/or food supplements have been tested: one in urban areas and two in rural areas.

Urban strategy

In the urban areas, the strategy is based on the sale of two products: a ready-to-cook infant flour called Koba Aina, which is wrapped in bags of 35 g, and a ready-to-
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Madagascar</th>
<th>Burkina Faso</th>
<th>Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Products</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ready-to-eat porridge, ready-to-cook infant flour</td>
<td>Ready-to-cook infant flour</td>
<td>Ready-to-eat infant flour, food complement</td>
<td>Instant infant flour, food complement</td>
</tr>
<tr>
<td>Selling units</td>
<td>120-g ladle; 35-g single-dose bag</td>
<td>35-g single-dose bag; 13-g single-dose bag</td>
<td>100-g to 1-kg plastic bags; 400-g to 650-g plastic boxes</td>
</tr>
<tr>
<td>Production</td>
<td>Big private company; industrialized and centralized production</td>
<td>Production at household and community levels</td>
<td>Small and medium private enterprises</td>
</tr>
<tr>
<td>Distribution network</td>
<td>Door-to-door sales by saleswomen and in <em>Hotelin-jazakely</em> (sale of flour and porridge)</td>
<td>Sales by community volunteers on door-to-door visits (sale of flour)</td>
<td>Sales through grocery shops, supermarkets, and pharmacies (sale of flour)</td>
</tr>
<tr>
<td>Price</td>
<td>Includes real salary of saleswomen</td>
<td>Includes financial compensation of community volunteers</td>
<td>Includes conventional profit margin (e.g., for groceries and pharmacies)</td>
</tr>
<tr>
<td>Promotion</td>
<td>Not coupled with nutrition education; promotion by saleswomen at <em>Hotelin-jazakely</em> and during door-to-door sales</td>
<td>Coupled with nutrition education; promotion by community volunteers at village level</td>
<td>Not coupled with nutrition education; promotion by saleswomen during door-to-door sales; point-of-sale promotion (in marketplaces, health centers, and grocery shops); promotion by health community volunteers at village level; local broadcasting</td>
</tr>
</tbody>
</table>

TABLE 3. Main characteristics of Nutridev programs developed in Madagascar, Burkina Faso, and Vietnam
Marketing complementary foods and supplements

Eat porridge made from *Koba Aina* served with ladles with a volume of 120 mL. The production of the flour is carried out by a private company at industrial scale. The consumer price is around $US0.05 (100 ariary) per bag or per ladle. The distribution system is based on a network of 39 baby restaurants, called *Hotelin-jazakely* Nutrimad, implemented in the poorest areas of the four principal towns and two secondary towns of the country. Each *Hotelin-jazakely* is managed by one or two saleswomen who sell the products inside the *Hotelin-jazakely* and door-to-door in a limited area around it, and sometimes through small grocery shops in the same area. Product promotion is carried out at the *Hotelin-jazakely* (e.g., by advertisements and specific activities, such as infant weighing sessions) and during the door-to-door visits by saleswomen who are specially trained to identify, approach, and convince mothers of 6- to 24-month-old children to use the product. Every day, around 15,000 6- to 24-month-old children are targeted by the distribution network.

At the early stages of implementation, product promotion was coupled with nutrition education activities; this, however, is no longer the case because of the significant cost of these additional activities. The priority of the strategy is to develop a sustainable distribution network, and the cost of additional education cannot realistically be absorbed in the selling price.

Various partners have been involved in implementing the urban strategy. These include the private company producing *Koba Aina* and public institutions, including the National Office of Nutrition and the Ministry of Health, which authorize activities. Municipal authorities facilitate the installation of new *Hotelin-jazakely*, and Antananarivo University is involved in scientific aspects of the project.

**Rural strategies**

In rural areas, a first strategy to improve complementary feeding was tested between 1998 and 2001 [12]. It was integrated in a nutrition program called Community-Based Nutrition, implemented by the Ministry of Health and local nongovernmental organizations, with support from UNICEF. Within the framework of the Community-Based Nutrition Program, community volunteers were in charge of mobilizing inhabitants at the village level to increase maternal awareness about infant nutrition and care and to deliver some general nutrition messages. The Nutrimad contribution consisted in reinforcing activities aimed at improving infant and young child feeding. This was done by providing additional training and assistance to Community-Based Nutrition volunteers from fieldworkers remunerated by the project, and by making accessible an appropriate complementary food for children over 6 months of age.

After preliminary studies, it was concluded that it was not feasible for mothers to carry out all the
necessary tasks to prepare porridges with the required nutritional and hygienic characteristics entirely by themselves. Consequently, during the first year of the intervention, the Nutrimad program trained and supported community volunteers to produce a ready-to-cook infant flour at the community level based on local raw materials and traditional techniques and to sell it to the mothers living in their villages.

After several months, it was determined that producing flours with consistent qualities required too much time from the community volunteers and that production therefore needed to be centralized. A small enterprise was set up and equipped with basic devices. Some of the project fieldworkers were trained to produce ready-to-cook infant flour with the required characteristics. Initially, the flour was produced using processes derived from local techniques (e.g., germination of seeds) and a minimum of nonlocal products (only mineral and vitamin complex). Later, more cost-effective options were adopted, including incorporation of industrial amylases instead of malted leguminous seeds as sources of amylases. Currently, the production unit produces a ready-to-cook infant flour called Koba Mazika, sold in a 35-g bag.

With centralized production, the role of community volunteers was reduced to the promotion and sale of the product in their own communities, and a small margin was added to the sales price to motivate them. But in spite of training, supervision, and tools placed at the community volunteers’ disposal to support nutrition education and product promotion activities, the number and quality of the activities implemented by community volunteers did not meet expectations. Thus, this strategy was significantly modified at the end of 2001.

The second strategy implemented in rural areas is based on the sale of two kinds of products: ready-to-cook infant flours sold in 35-g bags (Koba Aina or Koba Mazika, depending on the area) and a food supplement, called Bo Salama, sold in a 12-g bag and designed to be added to the child’s usual dish. Production is carried out by three private companies, one at the industrial level and two at the small-scale level. The consumer price is around US$0.05 (100 ariary) per bag for both products.

The distribution system is based on a network of municipal facilitators, community volunteers, and small grocery shops. Product promotion is carried out in a variety of ways at the village level: by community volunteers, by advertisements in grocery shops and sometimes by mothers who give the lead to others. In marketplaces and in health centers, project fieldworkers and municipal facilitators promote the products. Promotion is carried out at larger scale through local broadcasting. Every day, around 43,000 older infants and young children of 41 municipalities are targeted by the distribution network.

Three types of partners are involved. First are private companies that manufacture the products. Second are public institutions. These include institutions at the national level (the National Office of Nutrition and the Ministry of Health, which authorize activities, and Antananarivo University, which supports research-action activities) and at the local level (municipal authorities that contribute to the salaries of municipal facilitators and health agents providing nutrition education). The third group of partners is made up of local nongovernmental organizations (ASOS-Action Santé Organisation Secours and Tsihatava) involved in implementation of nutrition activities.

**Results**

Sales figures and survey data on consumption indicate varying levels of success for the strategies used in urban and rural areas of Madagascar. In the urban area of Antananarivo, the levels of consumption were high, even though the strategy was implemented in the poorest parts of the city. The monthly penetration rate, defined as the rate of 6- to 24-month-old children consuming at least one serving of Koba Aina (120 g of porridge made from 35 g of flour) per month, was around 57% (data from July 2009). These children consumed on average 18 servings per month. About 17% of children ate at least 25 servings per month.

Several factors have been identified by program implementers and through surveys to explain these positive results. The first is the affordability of the ready-to-cook Koba Aina flour and the ready-to-eat Koba Aina porridge. Their selling units are small (a 35-g bag of flour or a ladle of porridge), and thus the consumer price is adapted to the local purchasing power (100 ariary per pack or per ladle), where 42% of people live under the poverty line (fixed at 305,300 ariary per person per year, i.e., 836 ariary per day [13]), and more than 80% live with less than 2,000 ariary (US$1) per person per day [14] in Antananarivo City.

A second factor contributing to high consumption in urban areas is that products are available very close to the families. The effort to prepare and sell Koba Aina porridge 6 days per week door-to-door facilitates the use of this complementary food in a context where many families do not have the facilities to prepare a complementary food in addition to the family dish, and where some meals, such as breakfast, are usually eaten at home. Porridge represents 60% of sales volumes in urban areas.

Although this distribution network is efficient, it has limitations. These limiting factors include the additional costs supported by the consumers, which consist of the cost of door-to-door distribution (around 20 ariary per serving as margin to saleswomen), the cost of cooking (around 5 ariary per serving), and the cost of the monitoring system necessary to manage the quality of porridge and conditions of sales (around
appropriate use of clients and increasing awareness of families about the
appropriate use of Koba Aina. Even though survey results indicate that after few months of intervention the awareness of Koba Aina products is close to 100% among mothers with 6- to 24-month-old children, it is possible that this approach of implementing only a few neighborhood marketing activities limits the development of a good brand image and consequently the development of sales.

In the rural areas of Madagascar (the Androy and Atsimo Atsinanana areas in the south and southeast), where two products have been promoted in each area (ready-to-cook Koba Aina flour and Bo Salama food supplement), sales and consumption have been a little bit lower than in the urban area. For the moment, sales are significant only for Koba Aina flour, since the Bo Salama food supplement has only been promoted for a few months. According to recent surveys conducted after 18 months (Androy area) and 12 months (Atsimo Atsinanana area) of intervention, the monthly penetration rates of Koba Aina flour were 69% and 55%, respectively, with 30% and 15% of 6- to 24-month-old children consuming at least 12 servings per month, and 12% and 5% of these children consuming at least 25 servings per month.

Three main points have been identified to explain these encouraging results. The first is the relative affordability of Koba Aina flour. According to a survey conducted in the Androy area, the consumer price (100 ariary per serving) is considered cheap, normal, or expensive, respectively, by 50%, 23%, and 27% of mothers with a 6- to 24-month-old child. Even though the consumer price is considered cheap by 50% of mothers, the level of poverty in these areas is very high (83% of population in Androy area and 84% of population in Atsimo Atsinanana area live under the poverty line [13]), and thus the price of Koba Aina undoubtedly limits its consumption.

The promotional activities conducted in rural areas appear to have been efficient in informing mothers and convincing them to test the product, but generally not to sustain use at high levels, as promotions are not done for a long-enough period. In the Androy and Atsimo Atsinanana areas, 99% and 98% of mothers, respectively, remembered having received information about Koba Aina, and 76% of mothers in the Androy area had used Koba Aina flour at least once. As a result of nutrition education activities implemented at the same time that promotional activities, mothers were also able to explain the preventive role of the product (99% of mothers wanted to give Koba Aina when their children were in good health, versus 54% when their children were sick). It is possible that additional promotional activities could encourage continuous use and increased consumption; however, it must be noted that the cost of this promotion is too large to be added into the consumer price.

The distribution network in the rural areas, consisting of sale of the product in the marketplace and at the village level, has guaranteed good availability of the product close to the family, but this network is also expensive and difficult to manage. If sales were limited to the marketplace, it is estimated that only about 60% of current sales would be realized.

**Nutrifaso in Burkina Faso**

Three different strategies are currently being implemented in Burkina Faso: two in urban areas and one in rural areas.

**Urban strategies**

The first strategy consists in making different ready-to-cook infant flours available to urban families by supplying technical support for production [15], promotion, and distribution activities of small and medium-sized enterprises established in the two main cities (Ouagadougou and Bobo Dioulasso) and a secondary town (Fada N’Gourma). These enterprises deliver their products mostly locally, but sometimes in more remote areas, in packaging of various types (bag or plastic box) and sizes (from 100 g up to 1 kg) in supermarkets, grocery shops, and pharmacies.

Promotion of infant flour is organized at retail sites and in crowded locations (markets and health centers). Promotion activities include advertisements, displays, free tastings, distribution of free samples, “buy one, get one or two free” offers, etc. Promotional messages are broadcast on local radio stations. Every 6- to 24-month-old child in the intervention city is targeted. The main partners involved in this strategy are the enterprises and the retailers.

The second strategy implemented in an urban area consists in supporting very small-scale production and distribution of a fermented ready-to-eat porridge called Ben-Songo. Presently, this porridge is prepared at home by two female producers who have been trained in improved processing techniques developed within the framework of a former research program supported by the European Union [16, 17]. The porridge is marketed door-to-door by saleswomen and served in ladles with a volume of 120 mL to every child living around the production units located in two suburbs of Ouagadougou. Promotion activities are organized in marketplaces and close to health centers (advertisements, free tastings). Producers, health agents, and the Direction of Nutrition are the principal partners.

**Rural strategy**

The strategy being implemented in rural areas consists of making available a ready-to-cook infant flour
called Yonhanma and a food supplement called Dayeri n Yonna for children over 1 year of age. These two products are manufactured in six small-scale production units managed by women’s associations. They are made available in the villages in grocery shops and by a network of community health workers who are allowed to charge a profit margin on the consumer price. Yonhanma is sold in bags of 400 g for US$0.57 (250 FCFA) and Dayeri n Yonna in bags of 76 g for US$0.34 (150 FCFA).

These sizes correspond to the quantities necessary to prepare porridge or fortified meals for 1 or 2 weeks, respectively. Product promotion is performed in marketplaces and health centers by project fieldworkers, at the village level by health community workers and grocery shops, and at larger scale through broadcast messages. Product promotions organized by project fieldworkers and community health workers in health centers, marketplaces, and the customers’ homes are always associated with nutrition education activities. Three kinds of partners are involved with the implementation of this strategy: small production units, public institutions at the national level (Direction of Nutrition of the Ministry of Health) and the local level (municipal authorities), and a local nongovernmental organization called IcoDev that provides field supervisors responsible for supervision of project fieldworkers and health community workers.

Results

Consumption data for Burkina Faso are available only for the rural strategy. In a survey conducted in 2008 to evaluate our activities, the percentage of mothers with 6- to 24-month-old children who said they used the product at least once per month was around 44% for Yonhanma and 32% for the food supplement. Compared with the monthly volume of sales, these rates overestimate consumption, since sales figures by area indicate a monthly penetration rate of 30% and 44% for Yonhanma supplements locally in developing countries [19].

After 2 years of intervention, Yonhanma flour was known by 80% of mothers, which confirms the ability of the community health workers to inform families about the product. Information on the opinions of mothers about the products and the brand image is limited. According to a survey conducted in 2009, the buying motivations of mothers who used Yonhanma were the vitamin contents (84%), the consistency of the porridge (28%), and that the children liked it (28%). The mothers reported that the products were easy to use, but the cooking instructions needed to be explained because they did not exactly correspond to their usual cooking practices for preparation of porridge. After they had been explained, the cooking instructions were considered easy to follow, and preparation only required kitchen utensils generally available at home. At present, the main factor limiting sales volume seems to be the capacity to persuade fathers (who manage the bulk of family funds) to spend money on special foods for children (children usually eat the family meal made from few staple foods produced by the household). Community workers report that it is more difficult to persuade fathers than mothers to use the product. More effort is required to mobilize key opinion leaders to address this issue.

Lessons learned

Products and promotion

Nutridev experience in Vietnam, Madagascar, and Burkina Faso demonstrates that it is possible to produce high-quality complementary foods and/or food supplements locally in developing countries [19]. As shown in table 4, the actual characteristics of the products correspond to the required characteristics. Regular microbiologic controls of the finished products demonstrated that it is easy to obtain safe products when production is done at the industrial-scale level (Koba Aina in Madagascar) or the medium-scale level (Favina in Vietnam). In the case of production on a smaller scale, the microbiologic quality of the flours is less constant and mainly depends on the entrepreneurs’ awareness of the importance of safety aspects: the microbiologic quality is better and more constant in production units with long-term experience in food processing (Burkina Faso) than in recently created production units with no previous experience (Koba Mazika in Madagascar).

Whatever the context, if designers of foods for infants and young children take the time to identify food taboos and to study local food habits, it is
generally easy to comply with the cultural preferences of the child caregivers. In some contexts in which the population has very strong links with a staple food (e.g., rice in Madagascar), its incorporation into infant flours may be compulsory even if other foods have a higher nutrient content and are cheaper.

The sensory acceptability of products is achievable if it is addressed at multiple steps in the development process and if acceptability studies and comparison tests are performed. Ease of use is also an important aspect to consider and address. Depending on their lifestyle, culinary habits, and awareness of the existence of sophisticated products, caregivers of infants and young children will or will not accept products requiring more effort to prepare. To surmount this difficulty, the Nutridev program provided different kinds of products, such as ready-to-cook flours, ready-to-eat porridges, and instant flours. Each has advantages (instant infant flours and ready-to-eat porridges save caregivers’ time and do not require kitchen, small saucepan or fuel) and drawbacks (microbiologic risk for instant flour due to uncertainty about the quality of the water that will be used to prepare the porridge, constraints on developing a distribution network for ready-to-use porridge).

One of the main factors that determine the feasibility of their local production is the factory price (including all production charges and a profit margin for the producer) at which it is possible to produce complementary foods and/or food supplements locally. Calculations of the ratio between the factory price and the price of the same quantity of the local staple food (rice or millet flour) confirm that it is possible to put fortified infant flours with all the required characteristics on the market at a price approximately 2.5 times the price of the local staple food (except in Vietnam, because of the high packaging costs to attract Vietnamese clients and the cost of using milk powder and sesame in Favina). Even if the factory price does not include the costs of distribution and promotion or nutrition education campaigns, the cost of the products should not be considered as the limiting factor for their large-scale utilization. Thus, it appears that the challenge of marketing infant flours lies above all in the subsequent (postproduction) steps.

Regarding production of the three food supplements (Bo Salama in Madagascar, Dayeri n Yonna in Burkina Faso, and Favilase in Vietnam), the main conclusions that can currently be drawn from the Nutridev experience are mixed. These types of product have a simpler composition than infant flours, are easier to produce, and have an efficacy that is at least as good as that of infant flour [19]. But these products are more difficult to design, since they require more detailed diagnostic studies and tests with the population, which often yield results that are inconsistent. In addition, even if the factory price for a quantity corresponding to one serving is lower than the corresponding price for one serving of infant flour, interviews with mothers show that the low quantity of product with regard to its price tends to discourage target consumers from buying the product.

**Sales and consumption**

Nutridev’s efforts in Vietnam, Madagascar, and Burkina Faso to make products readily available to the targeted populations and to convince the target population to consume them yielded mixed results. The results varied greatly according to the strategy utilized and the context in which it was implemented. Relatively affordable, small product units available close to the families contributed to high consumption. This was facilitated by the high population density found in urban settings. Promotion was often limited, since the costs of promotion are often too high to be added to the consumer price. Sale of the product in marketplaces and at the village level guaranteed good availability, but the network of distributors required for this was often found too expensive and difficult to manage.

**Sustainability**

For financial sustainability, it will be necessary to build a profitable business that includes all production, distribution, and promotion costs in the consumer price, or alternatively to obtain a long-term grant to offset costs. In urban areas of Madagascar, it may be possible to use a social-business approach. According to sales volumes obtained per area, it is possible to maintain low prices and expect a balanced budget above a certain scale. In Burkina Faso, the strategy based on the support of producers to independently develop their own distribution network could be the easiest and most sustainable of the approaches tested. But major disadvantages of this strategy are that a constant consumer price is difficult to guarantee and that this business approach does not encourage implementation in the poorest areas. It is therefore difficult to guarantee that affordable products will be available to the poor through this strategy unless it is combined with strong incentives to develop a large part of the business in the poorest areas.

To sustain a business approach in rural areas, it will be necessary either to obtain a long-term public grant or to noticeably increase the prices of the products, which would lead to a reduction of their affordability. In Burkina Faso, the strategy aims to introduce products into the common food distribution network existing in rural areas. This approach can be sustained if sales volumes are sufficient to maintain the interest of producers and shopkeepers.

The strategy in rural Vietnam is to distribute the product during home visits by community volunteers, who have to combine this with their usual activities.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Madagascar</th>
<th>Burkina Faso</th>
<th>Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Koba Aina</td>
<td>Koba Aina porridge</td>
<td>Koba Mazika</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of product</td>
<td>Ready-to-cook flour</td>
<td>Ready-to-eat flour</td>
<td>Instant flour</td>
</tr>
<tr>
<td>Production unit characteristics</td>
<td>Industrial level</td>
<td>Industrial level</td>
<td>Medium-scale level</td>
</tr>
<tr>
<td></td>
<td>Small-scale level</td>
<td>Small-scale level</td>
<td>Very small-scale level</td>
</tr>
<tr>
<td>Type of packaging/selling unit</td>
<td>35-g plastic bag</td>
<td>120-g ladle</td>
<td>400-g plastic bag</td>
</tr>
<tr>
<td></td>
<td>Made from safe flour and water and stored at &gt; 50°C</td>
<td>Satisfactory for 11 of the 19 last controls</td>
<td>Fermented gruel made from safe flour and water and stored at &gt; 50°C</td>
</tr>
<tr>
<td>Microbiologic quality as sold</td>
<td>Satisfactory for the 11 last controls</td>
<td>Satisfactory for 95 of the 102 last controls</td>
<td>Satisfactory for last controls</td>
</tr>
<tr>
<td>Humidity of the flour</td>
<td>108 last controls &lt; 8%</td>
<td>8 of the 22 last controls &lt; 8%</td>
<td>120 last controls &lt; 8%</td>
</tr>
<tr>
<td>Nutrient content and bioavailability</td>
<td>Taking into account the proportion and nutrient contents of the raw materials and mineral and vitamin complement, the estimated nutrient contents of flours or porridge match with the recommendations given by Lutter and Dewey [6]. Processing methods are chosen to reduce antinutritional factor activities</td>
<td>Optimization of the organoleptic characteristics of the products by sensorial evaluation during the development phase</td>
<td></td>
</tr>
<tr>
<td>Cultural acceptability</td>
<td>No refusal to consume because of the ingredients or the type of food</td>
<td>Optimization of pre-existing products</td>
<td>Without apparent lumps</td>
</tr>
<tr>
<td>Sensorial acceptability</td>
<td>Validation of the product 5 yr after launching by a huge study involving a sensory analysis laboratory</td>
<td>The 102 last controls with 98% of the flour passing through a 500-µm sieve</td>
<td>The last 43 tested samples had FR &gt; 85 mm/30 s when prepared at ED between 80 and 110 kcal/100 mL</td>
</tr>
<tr>
<td>Particle size</td>
<td>107 of the 108 last controls with 98% of the flour passing through a 500-µm sieve</td>
<td>1 of the 22 last controls with 98% of the flour passing through a 500-µm sieve</td>
<td>The last controls with 98% of the flour passing through a 500-µm sieve</td>
</tr>
<tr>
<td>Porridge consistency when prepared at an appropriate ED</td>
<td>Without apparent lumps</td>
<td>13 of the 22 last tested samples had FR &gt; 60 mm/30 s when prepared at ED &gt; 80 kcal/100 mL</td>
<td>The last 22 tested samples had FR &gt; 60 mm/30 s when prepared at ED &gt; 80 kcal/100 mL</td>
</tr>
<tr>
<td></td>
<td>71% of the last 371 tested samples had appropriate ED (90–120 kcal/100 mL) and FR (80–160 mm/30 s)</td>
<td>33 of the 37 last tested samples had appropriate ED (90–110 kcal/100 mL) and FR (90–150 mm/30 s)</td>
<td>The last 43 tested samples had FR &gt; 85 mm/30 s when prepared at ED between 80 and 110 kcal/100 mL</td>
</tr>
<tr>
<td></td>
<td>13 of the 22 last tested samples had FR &gt; 60 mm/30 s when prepared at ED &gt; 80 kcal/100 mL</td>
<td>33 of the 37 last tested samples had appropriate ED (90–110 kcal/100 mL) and FR (90–150 mm/30 s)</td>
<td>The last 43 tested samples had FR &gt; 85 mm/30 s when prepared at ED between 80 and 110 kcal/100 mL</td>
</tr>
</tbody>
</table>
Although delivery is carried out by unpaid volunteers, funding is needed for training sessions, motivational activities, newsletters, nutrition education supports, and other related expenses. The Women’s Union is dependent on external resources, which are often limited. Staff and the means available to oversee the project are often insufficient. In addition, the Women’s Union mandate requires maintaining flour sales together with nutrition education, which is quite expensive because of the time needed for nutrition education activities. Thus, the self-sustainability of this effort is questionable.

For sustainability, institutional partnerships will need to be maintained. In urban areas of Burkina Faso, the strategy is mainly based on partnership between private producers and shopkeepers—a preexisting and stable relationship. The challenge for this strategy will instead be to maintain the quality of products (specifically the nutritional quality). In urban Madagascar, the distribution network implemented through the *Hotelin-jaza-kely* could be managed and sustained as a social private enterprise, in partnership with public authorities. The situation will be even more challenging in rural areas of Madagascar and Burkina Faso, because even if sales volumes are sufficient to maintain the interest of producers and the existing food distribution network, an important proportion of the products are sold by actors from the public sector (e.g., the community health workers) who benefit from external funding (e.g., Gret project funds). These institutional partnerships must be maintained for the foreseeable future. Following promotion activities to increase awareness of and demand for complementary foods and/or food supplements, the challenge will be to progressively change the strategy to make it self-sufficient and require a smaller and more sustainable coalition of institutional partners.

### Conclusions

The objective of Nutrivel interventions is to enable underprivileged families to feed their children optimally, with the ultimate aim of preventing malnutrition without being dependent on external assistance. To reach this objective, strategies were conceived and implemented to support the local production and marketing of high-quality and affordable complementary foods and/or food supplements. Depending on the specific features of each area and the strategies implemented, the results are mixed. Generally, it has been possible to develop the local production of quality complementary foods and/or food supplements and to sell these products to poor families, but the levels of sales are not always as good as expected. Marketing of the products remains a challenge.

In many cases, the selling of products by community volunteers brought about quick improvements in mothers’ awareness of complementary foods and/
or food supplements, but sustainability of this kind of network is difficult to achieve. Mobilization of the existing food distribution network seems to be a more sustainable option. The optimal approach appears to be mobilization and strengthening of the existing food distribution network, with the implementation of a temporary promotion and nutrition education network in partnership with local authorities (e.g., health services) to increase awareness among families about optimal feeding practices and build demand for complementary foods and/or food supplements. Without promotion, sales volumes will probably be insufficient to interest retailers over the long term and bring about improvement in feeding practices.

Good results can also be obtained through innovative sales practices. In urban areas of Madagascar, door-to-door selling of a ready-to-eat porridge achieved satisfactory results in terms of consumption and costs. This activity could be formalized into a durable social business, which could be managed by a private company. This company would need to be financially sustainable, with the objective of facilitating the consumption of quality complementary foods and/or food supplements by underprivileged families rather than maximizing profits. Supporting such companies will be a challenge for Nutridev in the coming years.

Based on experiences in Madagascar, Burkina Faso, and Vietnam, it appears that even if it is possible to convince families to give their children a meal prepared with a specific complementary food and/or food supplement every day, it probably will not be possible to persuade them to give these products two or three times per day in order to meet all nutritional needs not covered by breastfeeding, in accordance with international recommendations. The development of new products to be consumed once per day (as a meal or not) that meet some daily nutritional needs should be further explored. New products that meet all micronutrient needs of 6- to 24-month-old children when consumed only once per day in addition to breastmilk and other local complementary foods (e.g., an infant flour with high contents of micronutrients) could aid in the challenge of finding ways to reduce malnutrition in a sustainable way.

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References


Monitoring the marketing, distribution, and use of Sprinkles micronutrient powders in rural western Kenya

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Abstract

Background. In 2007, the US Centers for Disease Control and Prevention partnered with local Kenyan institutions to implement the Nyando Integrated Child Health and Education Project, an effectiveness study that used social marketing and a community-based distribution program to promote the sale of Sprinkles and other health products.

Objective. To describe monitoring of wholesale sales, household demand, promotional strategies, and perceived factors influencing Sprinkles sales among vendors.

Methods. Ongoing quantitative and qualitative monitoring of Sprinkles sales began in May 2007 in 30 intervention villages. Data sources included baseline and follow-up cross-sectional surveys; office records of Sprinkles sales to vendors; biweekly household monitoring of Sprinkles use; and qualitative data collection, including vendor focus groups and key informant interviews.

Results. A total of 550 children aged 6 to 35 months were enrolled at baseline, and 451 were available at 12-month follow-up. During this period, nearly 160,000 sachets were sold wholesale to vendors, with variability in sales influenced by the social, political, and economic context. Vendors living closer to the wholesale office purchased more Sprinkles, so a second office was opened closer to remote vendors. On average, 33% of households purchased Sprinkles during household monitoring visits. Training sessions and community launches were important for community support and raising awareness about Sprinkles. Vendor incentives motivated vendors to sell Sprinkles, and consumer incentives promoted purchases.

Conclusions. Sprinkles program monitoring in Kenya was critically important for understanding sales and distribution trends and vendor perceptions. Understanding these trends led to strategic changes to the intervention over time.

Key words: Delivery strategies, home fortification, Kenya, multiple micronutrient powders, program monitoring, Sprinkles

Background

Vitamin and mineral deficiencies affect over 2 billion people worldwide [1]. Although there is evidence on the efficacy and cost-effectiveness of micronutrient interventions in improving vitamin and mineral status, research on intervention delivery and utilization remains an important research gap [1, 2].

Iron-deficiency anemia is the most common preventable nutritional deficiency worldwide [3]. Despite the well-recognized benefits of iron supplementation for control of anemia, implementation is hindered by poor adherence to daily dosing, inadequate iron supplies, low coverage, dose-related gastrointestinal side effects, and possible increased risk of malaria morbidity [4]. In response to these operational constraints, home fortification with micronutrient powders (Sprinkles) was developed as a novel approach for delivering iron and other micronutrients. Sprinkles are single-dose packets of dry powder containing lipid-encapsulated...
iron and other micronutrients that can be added to any semi-solid home-prepared complementary food [5]. Multiple studies have demonstrated the efficacy of Sprinkles in preventing and treating anemia [5, 6].

Because home-fortification products usually have high acceptability and fewer side effects than iron drops, their approach to treating anemia is considered the preferred strategy for programs in developing countries [7]. Sprinkles programs are currently at national scale in several countries, including Bangladesh [8], Mongolia [9], and Haiti [10]. However, few studies have documented experiences with specific delivery systems for effectively distributing Sprinkles in resource-poor communities [2]. This paper describes the monitoring system of a market-based Sprinkles delivery system in western Kenya and how the monitoring system was used to make strategic changes in program implementation.

Community-based distribution programs

Community-based distribution programs and social marketing techniques have been used in resource-poor settings since the 1970s to promote the use of public health products such as contraceptives, oral rehydration salts, and nutritional supplements [11–15]. A community-based distribution program is a nonclinical, health outreach and program delivery method that uses trained volunteers or paid health workers to provide health services, information, and/or promotion of health products to community members [16–18]. Community-based distribution programs are one of the best ways to reach people in rural, resource-poor settings where health facilities are scarce [15].

Community-based distribution programs provide easy access to essential services and products and do not require customers to spend resources on transportation [15]. Supplementation programs have used community-based distribution programs and social marketing techniques in multiple countries [19–22]. Providing multiple services and products in one visit is often more cost effective [15] and can help facilitate a community’s acceptance of new products [23].

Study site

This study was conducted in Nyanza Province, which has the highest rates of infant and childhood mortality and HIV prevalence in Kenya [24, 25]. The burden of disease in western Kenya is further characterized by endemic malaria transmission, diarrheal diseases caused by poor access to safe water, and anemia [26]. In addition, limited communication and transportation infrastructure makes access to health interventions difficult, particularly during the two rainy seasons from March to May and from October to December.

The Safe Water and AIDS Project (SWAP) has been delivering health products through a community-based distribution program in Nyando Province for 7 years. The SWAP approach is based in an ecologic framework that mobilizes formal and informal community institutions to support community vendor groups who sell health products to their neighbors. This system combines household, clinic, school, and local commercial distribution and promotion approaches to increase access to various evidence-based health products. Examples of SWAP health products include water storage containers, water disinfectant products, soap, bednets, contraceptives, and deworming tablets. Community-based groups and HIV groups within the project area are encouraged to register to become SWAP vendor groups. SWAP groups then receive training on the purpose and use of health products, business practices, and microcredit. There are approximately 775 active SWAP groups in Nyanza Province.

In March 2007, the US Centers for Disease Control and Prevention (CDC) joined with SWAP and other partners to implement the Nyando Integrated Child Health and Education Project (NICHE), an effectiveness study of SWAP’s health product delivery system. A brief overview of NICHE has been given elsewhere [26]. This paper describes the quantitative and qualitative monitoring of the Sprinkles intervention delivery system during the first 12 months of implementation and illustrates how this monitoring system led to strategic changes and improvements in the intervention. We specifically describe the process monitoring of wholesale Sprinkles sales to vendors and household demand, promotional strategies, and perceived factors influencing Sprinkles sales among vendors.

Methods

Study setting

NICHE was implemented in Nyando Division, located in rural Nyanza Province in western Kenya. The Division has approximately 80,000 people and 15,000 households. Ahero, the capital of Nyando Division, houses the district hospital; community clinics also provide routine vaccinations, growth monitoring, and nutrition counseling for children. The majority of the Luo population consists of subsistence farmers who cultivate maize, sorghum, cassava, and millet, carry out animal husbandry, and engage in migrant labor. Families in this polygamous society live in compounds (dalas) that consist of a single main house surrounded by one to three additional households. These compounds are often multigenerational.

To monitor program effectiveness, a study was conducted in 2007 and 2008 in 60 rural villages in
Nyando Division, where 30 intervention villages and 30 comparison villages were selected to compare the effects of SWAP interventions.

**Study design and data sources**

This study was a cluster-randomized, longitudinal, cohort trial with two primary objectives—to measure the effectiveness of Sprinkles distribution through an integrated health promotion and income-generating program, and to measure the impact of Sprinkles sales on iron deficiency and anemia among young children. Monitoring of sales, use, and biologic impact took place in both arms of the study. The results are presented here from the first year of the study, when Sprinkles were marketed and distributed only in the 30 intervention villages.

Sources of monitoring data are presented in **table 1** and included cross-sectional baseline and follow-up surveys, including measurement of selected biomarkers and anthropometry; SWAP office records of Sprinkles sales to vendors; biweekly household monitoring of the selected cohort to determine Sprinkles use and health status; and qualitative data collection, including focus groups and key informant interviews with vendors. Quantitative and qualitative data monitoring were integrated to increase understanding of intervention delivery and utilization as well as confidence in the validity of the findings.

**Sample size calculation**

Sample size estimates were based on predicted change of hemoglobin levels among households consuming Sprinkles. Based on prior efficacy trials, we estimated that Sprinkles would decrease anemia in this population of children aged 6 to 35 months from 60% to 50% over a 12-month period [5, 6]. At a confidence level of 95%, a power of 80%, and a design effect of 1.5, it was determined that a minimum of 583 children would need to be followed in the intervention and comparison groups at baseline and follow-up. The sample size was then adjusted for an estimated 20% rate of nonresponse and loss to follow-up to produce a final estimated sample size of 729 children per arm.

**Selection of subjects for quantitative data collection**

A two-stage, cluster-sampling strategy was used to select 30 intervention and 30 comparison villages from Nyando Division. The villages were chosen from separate political jurisdictions (sublocations) to inhibit interventions in one village from influencing conditions in the other. Villages in and near the urban centers of Ahero and Awasi (n = 38) and villages with preexisting SWAP groups (n = 4) were excluded from selection.

In the first stage of sampling, 30 intervention and 30 comparison villages were randomly selected, with probability proportional to size, using the 1999 Nyando Division census. A household census was performed in all 60 villages selected to be in the study. Village maps with geographical positioning system (GPS) coordinates of all households, and important landmarks were created. In the second stage of sampling, 25 children aged 6 to 35 months were randomly selected from each intervention and comparison village. In villages with less than 25 children, all children in the target age group were sampled.

The selection of the cohort is described in **figure 1**. Of 1,420 sampled children, 1,079 were enrolled, for an enrollment rate of 75.9%. There were no differences in enrollment rates between intervention and comparison areas. Among the 341 excluded from the study, 33.3% of children were outside of the age range (due to discrepancies in dates of birth reported during the census), 2.9% of parents did not give consent, and 63.8% of children were unavailable for enrollment on

<table>
<thead>
<tr>
<th>Data source</th>
<th>Target participants</th>
<th>Type of research</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Household Survey</td>
<td>Mothers of children 6–35 mo of age (n = 550)</td>
<td>Quantitative</td>
<td>Mar 2007</td>
</tr>
<tr>
<td>Follow-up Household Survey</td>
<td>Mothers of children selected at baseline available for follow-up (n = 451)</td>
<td>Quantitative</td>
<td>Mar 2008</td>
</tr>
<tr>
<td>Office records of sales and distribution of incentives</td>
<td>Vendors (n = 243)</td>
<td>Quantitative</td>
<td>Jun 2007–May 2008</td>
</tr>
<tr>
<td>Biweekly household monitoring</td>
<td>Mothers of children 6–35 mo of age (n = 550)</td>
<td>Quantitative</td>
<td>Jun 2007–May 2008</td>
</tr>
<tr>
<td>Focus group discussions (FGDs), key informant interviews (KIIs) with vendors</td>
<td>Vendors (n = 7 FGDs; n = 39 KIIs); additional sample of high-selling vendors (n = 11) and low-selling vendors (n = 8) interviewed at 2 time points</td>
<td>Qualitative</td>
<td>Aug 2007–Jun 2008</td>
</tr>
<tr>
<td>Observations of vendor training and launches</td>
<td>Trainers (n = 14) and vendors (n = 14)</td>
<td>Qualitative and quantitative</td>
<td>Jun, Jul, Oct, Nov 2007</td>
</tr>
</tbody>
</table>
three separate household visits. This resulted in an enrollment of 567 children in the intervention villages and 512 children in the comparison villages. During the course of the study, any person found to be ill, severely anemic (hemoglobin < 7 g/dL), or febrile was referred for treatment to the nearest hospital or clinic.

The data reported here are only from children with data from both the baseline and the 12-month follow-up surveys from households in the intervention villages. A total of 550 children aged 6 to 35 months had complete data at baseline (fig. 1). Approximately 18% were lost to follow-up, mainly due to respondents moving from the study area during the political violence following the Kenyan elections, as well as some deaths. This left 451 children aged 18 to 47 months for whom data were collected in the follow-up survey. The mothers (or primary caretakers) of these children were the respondents of the administered survey questions.

**Overview of SWAP implementation of Sprinkles**

Sprinkles were stored at the SWAP headquarters and were available for wholesale purchase through SWAP field offices. The vendors came to the field offices from their villages to purchase Sprinkles as needed. The vendors purchased Sprinkles at wholesale for 1 Kenya shilling (KES) (≈ 1.3 US cents) if they purchased 50 sachets or more. They were instructed to resell them at retail in their village and surrounding areas for 2 KES (≈ 2.7 US cents) per sachet. The profit was an incentive that either was kept by individual vendors for their personal use or contributed to the activities of their affiliated community groups. The vendors could buy any quantity of sachets, although they typically purchased 100 or more.

Vendor groups, hospital and clinic staff, and community leaders participated in Sprinkles training or orientation meetings prior to the start of the intervention to increase their knowledge of Sprinkles and build support for the intervention. Trained vendor groups were registered by SWAP, and only members of trained groups were supposed to have access to wholesale Sprinkles at the SWAP field offices. A special social mobilization event, or promotional launch, took place in each village (or at the border between two

![FIG. 1. Selection of study subjects](image-url)
villages) to introduce vendor groups and Sprinkles to community members. Skits and songs performed by a local theatre group encouraged audience participation and informed community members about Sprinkles. Sprinkles promotional songs were also played on a vehicle loudspeaker, testimonials and demonstrations were provided by mothers who gave Sprinkles to their children during the formative research phase [27], and free samples of Sprinkles were distributed to participants who attended the launches. Additional promotional materials with visual and written instructions describing correct Sprinkles preparation were also distributed (fig. 2). After the launches, repeated peer-to-peer communication among vendors and community members reinforced the rationale, benefits, and appropriate use of Sprinkles. It also provided opportunities for neighbors to follow up with vendors if there were problems or concerns. SWAP field officers also supported vendors by conducting regular site visits to all villages throughout the study period.

Incentives were provided to vendors and consumers. Vendor incentives, which included T-shirts, promotional stickers, and free sachets, were distributed during vendor meetings and training sessions. A T-shirt was given to every vendor who purchased 200 sachets wholesale. The vendors received promotional stickers to post on their houses to identify them as vendors. First-time vendors were given a loan of 200 sachets of Sprinkles as start-up stock, given the low cash supply. In early 2008, an additional set of 200 sachets was distributed at no cost to each active vendor to enable them to mitigate the effects of the political and economic crisis after several weeks of postpresidential election violence.

Incentives for consumers were also developed and distributed to both educate and incentivize the purchase of Sprinkles. These materials included a calendar and leaflet with visual and written instructions on use, a plastic cup, an initial two free sachets to introduce Sprinkles, and periodic promotions, such as a “buy one, get one free” sachet to boost sales. When purchasing Sprinkles wholesale, vendors received consumer incentives for free and were instructed to give them to consumers to motivate sales. Consumers were expected to receive the incentives free of charge from vendors after purchasing the specified quantity of Sprinkles, for example, a free calendar after the consumer purchased 10 sachets.

Quantitative data collection and analysis
The study team oversaw all field operations, including enrolling subjects and monitoring Sprinkles use and health outcomes. A personal digital assistant (PDA) device was used for all household quantitative data collection, including the cross-sectional surveys and biweekly household monitoring. PDAs were mounted with GPS, which were used to map a variety of locations, including the wholesale SWAP sales office, vendors’ houses, and households of study participants. Data were automatically saved in PDA memory in the field and uploaded onto a centralized MS Access database on a daily basis. A master list of all people living in the survey households (including respondents, children and their siblings, and anyone else residing in the home) was updated at each household monitoring visit.

Wholesale purchases of Sprinkles by vendors were recorded in SWAP office record books, which documented the date, the name of the vendor, the name of the SWAP group, the village of origin, the quantity purchased, and the number of vendor and/or consumer incentives received, including free Sprinkles sachets. These data were double-entered into an Excel database.
During the first year of NICHE implementation, data were collected from 17 biweekly household monitoring visits to measure household purchases of Sprinkles, individual use, and reported illness. Individual use of Sprinkles sachets was estimated by dividing the reported number of biweekly household Sprinkles purchases or gifts by the number of children aged 6 to 59 months living in that household (the population to which Sprinkles were promoted). Because of problems with a skip pattern on the PDA questionnaire, the questions on individual Sprinkles use were not available for all monitoring rounds; furthermore, it was later determined that there were also translation and comprehension issues with those questions. However, the correlation between estimates of individual Sprinkles use and reported use was good (correlation coefficient, 0.48; \( p < .01 \), using available data from rounds 6 to 17), so household purchases were used as a proxy for use. Data on Sprinkles use in the past 24 hours and the past 7 days were also collected during the 12-month follow-up survey.

Socioeconomic status was assessed with the use of a principal components analysis wealth index developed by the World Bank to allocate the study population into socioeconomic quintiles of Kenya as a measure of relative poverty [28].

Qualitative methods

Vendors were identified through SWAP staff and office lists of SWAP vendors. Between August and October 2007, the vendors were interviewed across all intervention villages in either focus group discussions (\( n = 7 \)) or key informant interviews (\( n = 14 \)). Additional key informant interviews with vendors (\( n = 25 \)) were conducted across intervention villages between January and June 2009. In addition, SWAP office records were used to identify vendors with higher sales (\( n = 11 \)) and lower sales (\( n = 8 \)) to participate in key informant interviews between November 2007 and January 2008. Higher-selling (\( n = 9 \)) and lower-selling (\( n = 6 \)) vendors were then followed up for an additional key informant interview in May and June 2008.

Qualitative data were collected by two Luo research assistants. The structured interview guides focused on vendor experiences, knowledge of Sprinkles with a focus on appropriate use, motivations, barriers, and their perceptions of the factors influencing Sprinkles sales. Focus group discussions and key informant interviews were conducted in Dholuo and usually took place at vendors’ homes or at a central location in the villages. Vendors received refreshments after the interview. The research assistants also carried out structured observations of all vendor training sessions and promotional launches. Handwritten verbatim notes documented the interviews. Notes were reviewed in the field, and in the evening they were transcribed and translated into English. Data were imported into NVIVO 8 (QSR International Pty Ltd, 2008) for data management and analysis. The qualitative data were reviewed, coded, and analyzed by one coauthor (Maria Elena D. Jefferds). The analysis presented here focused on identifying concepts, dominant themes, variability in the responses, and changes over time.

Ethical considerations

All study protocols were approved by the Scientific Steering Committee and the Ethical Review Committee of the Kenyan Medical Research Institute in Nairobi (protocol number SSC 1176) and the CDC Institutional Review Board (protocol number 5039). This trial is registered by clinicaltrials.gov, identifier NCT01088958.

Authors’ contributions to the study

The contributions of the authors to the study were as follows: Parminder S. Suchdev—design, data analysis, interpretation and writing of manuscript; Laird Ruth—design, data collection, interpretation and writing of manuscript; Alfredo Obure—data collection, interpretation of manuscript; Vincent Were—data collection and cleaning; Cliff Ochieng, Lorraine Ogange, Mercy Owuor, and Frances Ngure—data collection; Robert Quick—design, interpretation of manuscript; Patricia Juliao—design, data collection; Christina Jung and Kathryn Teates—data analysis; Kari Cruz—literature review; Maria Elena D. Jefferds—design, interpretation and writing of manuscript. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Results

Description of population at enrollment: Quantitative data collection

A total of 550 children were enrolled at baseline in the intervention villages; the mean (± SD) age was 19.9 ± 8.5 months, and 51.1% were male (table 2). The mean age of the mothers was 26.9 ± 7.6 years; less than 50% had completed primary school education. Approximately 96% of the households had mud or dung walls, and 98% lacked electricity. There were no significant demographic or socioeconomic differences between the intervention and comparison villages (data
Description of SWAP vendors: Qualitative data collection

A total of 118 vendors participated in focus group discussions or key informant interviews; only 6 were men. The vendors ranged in age from 20 to 74 years and had from 0 to 12 years of education. The majority were married or widowed, and their primary way of making a living was through petty trade and farming.

Sprinkles marketing and promotion

The follow-up survey found that 43% of the mothers attended the initial training sessions or promotional launches. Initially, 14 vendor groups received training; observations documented that 75% of the vendors were women, with 10 to 113 vendors attending each session. The initial 14 Sprinkles promotional launches reached approximately 2,400 people. As many as 198 adults attended each launch, and 75% of the audiences were women. Schoolchildren also attended each launch (range, 250 to 500), and this helped spread information about Sprinkles in the community and in the children's households. Qualitative monitoring with vendors during the first 3 months of implementation suggested low Sprinkles awareness and low Sprinkles sales in some of the smaller villages in the more remote locations. As a result, an additional four launches and training sessions were held in or near these villages.

Qualitative data from vendors demonstrated that interpersonal promotion of Sprinkles occurred both formally and informally by the vendors. The vendors reported that formal training was important in order to talk about Sprinkles effectively and that untrained vendors communicated incorrect information:

I have to spend so much time clarifying the wrong information.

Only trained vendors were supposed to sell Sprinkles in this distribution system; however, soon after implementation, an unknown number of untrained vendors entered the market selling Sprinkles. Vendors reported in qualitative interviews that some of these untrained vendors gained access to wholesale Sprinkles through family and friends, while others misrepresented themselves as members of registered community groups. In some villages, this resulted in many vendors competing for the same customers, which negatively affected the motivation of some trained vendors because securing sales was more difficult:

There were so many people who used to buy it [wholesale Sprinkles], including those who were never trained. They used to purchase it and sell it in the community; some also sold it from their shops. We asked [the field officer] to look into it and make them stop.

Incentives to promote Sprinkles had a broad reach, with more than 70% of mothers reporting receipt of a calendar at the follow-up survey. In addition, 38% reported receiving free Sprinkles at launches, and 19% received free sachets at training sessions. Approximately 10,000 promotional leaflets, 7,000 calendars, 400 stickers, 500 T-shirts, and 10,000 cups were distributed in the study area as part of Sprinkles marketing.

Vendors reported that vendor incentives were critical to keep vendors motivated, especially because sales varied over time. Many vendors were engaged in other petty trade and farming, so incentives were important to maintain interest and enthusiasm for specifically selling Sprinkles:

Bring back the Sprinkles T-shirts. Vendors need to be motivated because it is very hard to do this work. Convincing someone to buy a product is not easy at all.

Unfortunately, the Sprinkles cups were of unexpectedly low quality, which made them less effective than anticipated:

The cup doesn't really please them much...they say they have many Sprinkles cups that are not durable because the Sprinkles sticker falls off.

Furthermore, vendors reported that consumer incentives affected confidence in Sprinkles among some families. The vendors explained that some of the regular Sprinkles users expressed concern and questioned why the consumer incentives were happening and that this negatively affected Sprinkles use:

People who had faith in Sprinkles and were serious with it to improve the health of their children started to doubt Sprinkles because of the promotions. Some of them stopped buying it because they don't understand why it became so cheap suddenly [after the buy one, get one free promotion] and getting free cups too.
Qualitative data also showed that vendors often did not follow consumer incentive guidelines. For example, they reported practices such as selling consumer incentives, holding back an incentive if a customer had previously received one, and holding back the free sachet in the buy one, get one free promotion in order to give it to another potential customer:

“These promotions are very good. When we are selling, some people are really willing to buy and use Sprinkles, but they lack the money so we give them [another consumer’s] free sachets to start giving to the child as they are looking for money.”

Sprinkles awareness

During the follow-up survey, almost all mothers (98%) reported having heard about Sprinkles, most commonly from SWAP vendors (49%), promotional launches (30%), and training sessions (27%). More than one-fourth of the mothers (28%) reported that their household was visited by a SWAP vendor at some point. Among these 124 households visited by a vendor, the most commonly purchased health product was Sprinkles (76% of households), followed by Waterguard (41%) and soap (19%).

Vendor access to wholesale Sprinkles

Qualitative monitoring data from vendors suggested that access to wholesale Sprinkles varied among vendors and that the cost of transportation to the field office was a limiting factor. Analysis of GPS coordinates found that vendors who lived closer to the wholesale SWAP office purchased more Sprinkles (fig. 3). Vendors living less than 4 km from the office sold seven times more sachets than vendors living 8 to 12 km from the office. However, this pattern changed among those vendors living 16 to 24 km from the office, who sold nearly the same numbers of sachets as vendors living between 4 and 8 km from the office. The field officers determined that a vendor who lived in a village between 16 and 20 km from the office had become a supplier for vendors who lived farther away. In response, a second SWAP distribution office was opened closer to the remote vendors to improve access to wholesale Sprinkles.

Coverage of Sprinkles distribution

From July 2007 to June 2008, nearly 160,000 sachets were sold by SWAP to vendors (fig. 4). The majority of the sachets (74%) were purchased by vendors who came from the 30 intervention villages within the study cohort. During this same period, data from 6,880 biweekly household visits to intervention villages found that 33% of visits were to households that had purchased Sprinkles in the preceding 2 weeks.

The social, political, and economic context influenced Sprinkles sales during the first year (fig. 4). Sales were highest in the first 4 months of program implementation. In qualitative interviews several months following implementation, vendors nostalgically referred to the initial popularity of and interest in Sprinkles in
the early months of the intervention. In addition to the excitement about the new Sprinkles product, there was also increased availability of cash from seasonal crop sales in the community. In November and December, sales declined as the Kenyan presidential elections and holiday season distracted vendors and consumers. In January 2008, the postelection violence closed roads, shut down the economy, and limited people’s ability to work and access cash, all of which further depressed sales. Because of the drop in sales, additional incentives for vendors and consumers were provided to catalyze sales. For example, vendors were given a supply of free sachets, since many lacked capital to purchase Sprinkles. Consumer incentives included a buy one, get one free promotion, as well as a free cup with the purchase of 10 sachets. As a result of these incentives, the number of Sprinkles sales rose dramatically in February; however, vendor wholesale purchases declined dramatically the following month as the market became saturated. Qualitative data from vendors confirmed that the free sachet promotion flooded the market and undermined vendor sales:

*We want to earn a living from the products we sell, and if people take too long to buy them, life becomes difficult for us.*

Because of vendor concerns and threats to program viability, SWAP terminated the consumer incentive buy one, get one free. In June 2008, sales came to a complete halt when the stocks of Sprinkles were exhausted and a new supply was being manufactured and imported into Kenya to replace expired sachets.

The trends in wholesale Sprinkles sales were generally similar to the trends in household purchases between July and February (fig. 4). However, in March and April 2008, when wholesale Sprinkles sales plummeted due to market saturation, more than 35% of households continued to purchase Sprinkles, indicating that demand was still strong despite the decline in wholesale sales and the limited Sprinkles supply.

**Sprinkles use**

Sprinkles use was further characterized using the biweekly household monitoring data. To estimate average weekly consumption, the total number of sachets consumed between June 2007 and May 2008 was divided by the number of times the household was visited. Nearly 9 of 10 children ever used Sprinkles (89%). However, most children were infrequent users, consuming less than one sachet per week (fig. 5). During the follow-up survey, 35% of the mothers reported that their child had used Sprinkles in the past 24 hours, and 61% reported use in the past 7 days. Median use was three sachets over the past week. In the follow-up survey, children in the lowest socioeconomic status quintile were just as likely to have ever used Sprinkles as children in the highest quintile (83% vs. 85%, \( p = .8 \)). Similarly, there was no association between socioeconomic status quintile and Sprinkles use in the past 7 days or 24 hours. There was no effect of maternal education on Sprinkles use.

**Discussion**

Market-based Sprinkles distribution through a multifaceted, community-based program using local vendors was successfully implemented in western Kenya. Program monitoring was important for understanding promotion and sales trends. Understanding these trends made the program implementation more strategic and led to important modifications, such as carrying out more training sessions and launches, opening up a new Sprinkles distribution office, and revising incentive strategies.

Quality training sessions and launches, repeated periodically with wide access, were necessary for promotion, raising awareness, and building a knowledge base about Sprinkles among vendors and community members. When monitoring data showed low awareness and sales in some of the more remote villages, conducting additional training sessions and launches helped increase Sprinkles access and demand, and the follow-up survey results showed very high Sprinkles awareness among mothers. Data showing reduced access to wholesale Sprinkles among vendors who lived farther from the SWAP field office resulted in the opening of a second office, which improved access to supplies among remote vendors.

Given that inappropriate incentives can lead to low motivation and sales [20], changes in vendor and consumer incentives were also made when monitoring data suggested that they were no longer effective. Flooding the market with free Sprinkles sachets after the postelection violence decreased product value among some regular Sprinkles users and undermined vendors’ ability to sell Sprinkles. SWAP vendors were not paid...
Marketing, distribution, and use of Sprinkles MNP

a salary, so incentives to ensure adequate compensa-
tion from selling Sprinkles and to gain community
recognition were important to them. The Sprinkles
calendars were regarded as valuable consumer inen-
tives, and Sprinkles T-shirts were particularly coveted
as a vendor incentive. Sprinkles sales were influenced
by the social, political, and economic context, and most
of these factors were out of the control of the SWAP
program yet reflected typical real-life events that all
programs face. However, monitoring allowed program
staff to examine the influence of these contextual
factors on the intervention and to be strategic and
responsive to these conditions in a timely way to reduce
their effects.

The reasons for the success of the Sprinkles program
using the community-based distribution approach are
similar to those documented in other studies [15, 16,
23]. For example, the program focused on common
and important problems in the community, such as
nutrition and anemia. Also, Sprinkles themselves were
easy to market, distribute, and use, which resulted in
high demand among the study population, including
households in the lowest socioeconomic status quintile.
Conducting formative research and qualitative moni-
toring was essential for developing communication
and promotion strategies and better understanding
the nexus of intervention and community processes
that developed during project implementation. Because
of the study design and limited resources, there was
no mass media marketing as a component of this
intervention. Radio campaigns, however, are regularly
used in Kenya as an important strategy to increase
awareness and knowledge in programmatic settings
[29]. Therefore, the addition of mass media marketing
could have a pronounced impact on the scalability of
this intervention. Finally, NICHE utilized an integrated
approach that provided multiple health products
through multiple community-based delivery channels,
which probably facilitated community acceptance.

Limitations

This study had limitations. First, the study was limited
to one division in one district in Nyanza Province, so
the results are not representative of the province or
Kenya as a whole. It would be important to attempt to
evaluate a scaled-up Sprinkles program to determine
whether the findings from this study are applicable to
a broader population. Second, because the Sprin-
bles intervention could not be blinded, SWAP staff
may have introduced bias by making special efforts
to ensure that selected households were exposed to
Sprinkles. Third, the Hawthorne effect [30] may have
been responsible for the magnitude of use of Sprinkles,
as biweekly scrutiny of buying habits by the NICHE
team during home visits may have motivated mothers
to purchase Sprinkles. To address this potential bias,
data were also collected in comparison villages and
in a subsample of households that did not participate
in biweekly monitoring (data not shown). Finally, we
were unable to assess the Sprinkles intervention under
conditions of optimal access, because Sprinkles were
produced in another country, which required ordering,
shipping, entry through customs, and predetermined
packaging and labeling.

Conclusions

Marketing health products through community ven-
dors to some of the poorest people in Kenya can be
an effective way to distribute micronutrient Sprinkles.
The study findings demonstrated how routine pro-
gram monitoring was necessary for strategic program
changes. Program monitoring of Sprinkles interven-
tions is essential to effectively market this product to
populations in greatest need and to evaluate ongoing
program success.

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Formative research exploring acceptability, utilization, and promotion in order to develop a micronutrient powder (Sprinkles) intervention among Luo families in western Kenya

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Abstract

Background. There is a lack of peer-reviewed literature describing in detail the formative research to develop Sprinkles interventions.

Objective. To describe community members’ reactions to and experiences using Sprinkles, with an emphasis on acceptability, utilization, and promotion.

Methods. Fourteen initial focus group discussions on Sprinkles and a 25-family home study were conducted. For the home study, each child 6 to 59 months of age in the household received 30 sachets (1 per day). The initial 14 focus group discussions included mothers, grandmothers, vendors, women who purchased from vendors, and adults in the general population. Home study families were recruited from participants in the initial 14 focus group discussions who had at least one child 6 to 59 months of age.

Results. Sprinkles were highly acceptable to adults and most children; some children thought Sprinkles were sugar. Most home study families prepared and used Sprinkles correctly. All families reported positive effects, particularly increased appetite, and recommended Sprinkles; none experienced major problems. Potential barriers identified were lack of knowledge of and experience with Sprinkles, availability of Sprinkles, and cost. Promotional messages targeted to mothers, fathers, all child-care providers, and doctors focused on the positive health effects of Sprinkles.

Conclusions. Issues related to Sprinkles preparation, use, and barriers required attention before implementation. Locally appropriate visual and written instructions were developed for dissemination. Intervention training sessions and promotions were tailored to answer frequently asked questions, increase knowledge of Sprinkles, and provide tangible evidence of health benefits. Information needs and perceptions changed quickly after use of Sprinkles. Existing levels of Sprinkles awareness and knowledge should be considered when designing interventions.

Key words: Formative research, Kenya, micronutrient deficiency, multiple micronutrient powders (MNP), qualitative research, Sprinkles, acceptability, utilization, promotion

Introduction

Sprinkles are single-serving sachets of powder containing micronutrients used for home fortification of foods [1]. Micronutrient powders such as Sprinkles have emerged as important public health interventions, with many countries developing pilot programs with plans to scale up to subnational or national levels. A 2009 survey found over 30 projects distributing micronutrient powders in 14 Asian countries.* Formative research is necessary to effectively develop and implement a Sprinkles intervention in a new setting. Although the efficacy of Sprinkles has been described in peer-reviewed literature [2–5], only two reports [6, 7] and no

* Codling, Karen. Status of MNP Distribution in Asia: Questionnaire Responses. 4-28-2009. Workshop on Scaling Up the Use of Multiple Micronutrient Powders to Improve the Quality of Complementary Foods for Young Children; Bangkok, Thailand, 28 April to 1 May 2009.
journal articles were identified describing in detail the formative research to develop Sprinkles interventions. The dearth of published formative literature creates inefficiencies for implementers because it limits the ability to learn from the experience of others.

In 2007, a Sprinkles effectiveness study was initiated in Nyanza Province in western Kenya. The study intervention combined social marketing with community-based distribution of Sprinkles by vendors who sell health products to neighbors. The study population was predominantly of Luo origin, who are patrilinear, practice polygamy, and engage in subsistence agriculture, animal husbandry, petty trade, and migrant labor [8]. Luo families usually live in homesteads (compounds or “dalas”) which include the household of the senior family member and additional households of other family members; these are often multigenerational. The study site was a rural, marginal area with poor infrastructure. The study began with 4 months of qualitative formative research designed to understand the social and cultural context of child feeding, micronutrient deficiencies, iron supplementation, household decision-making, health-seeking behavior, and reactions to and experiences with Sprinkles. During the first 3 months of formative research, 14 initial focus group discussions were conducted on Sprinkles. This was followed by a 1-month home study of Sprinkles use among 25 families, which included household interviews, observations of child feeding, and three final focus group discussions. The purpose of this paper is to describe the results of the formative research exploring community members’ reactions to and experiences using Sprinkles, with an emphasis on acceptability, utilization, and promotion.

Methods

Ethical approval

The research ethics committees of the US Centers for Disease Control and Prevention and the Kenya Medical Research Institute, Kisumu, approved this study.

Sample

Purposeful sampling was used to recruit participants who were typical of the primary and secondary audiences for the intervention. Of the initial 14 focus group discussions, 3 were conducted with mothers of children 0 to 59 months of age, 3 with grandparents with children 0 to 59 months of age living in their homesteads, 2 with vendors, 3 with women who purchased Sprinkles from vendors, and 3 with adults in the general population. Most focus group discussions had seven or eight participants (range, five to nine).

For the home study, 25 participants from the 14 initial focus group discussions who had at least one child 6 to 59 months old were recruited. Each child 6 to 59 months of age living in the household received a 30-day supply of Sprinkles sachets, and their caregivers were instructed that each child should consume one sachet per day. The mothers or primary caregivers of the children, designated as key informants, were interviewed in their households and participated in one of three final focus group discussions.

Data collection

Focus group discussions were conducted at a location central to the villages; the participants received a small travel allowance. Focus group discussion and key informant participants received refreshments after the interviews.

Data were collected in Dholuo by Luo research assistants. Verbatim notes were handwritten during interviews. Debriefing and review of notes occurred in the field. The research assistants transcribed the notes the same day and translated them into English, and they were then entered into Word (Microsoft, 2007) and imported into NVivo 8 (QSR International Pty Ltd, 2008) for data management and analysis.

The initial 14 focus group discussions focused on immediate reactions to Sprinkles, acceptability, promotion, cost, and potential barriers. The participants were given a sachet of Sprinkles to examine, open, and taste. The moderator described Sprinkles as a single-dose sachet of powder with vitamins and minerals shown to prevent anemia in young children 6 to 59 months old. They were also told that Sprinkles should be mixed into a child’s serving of food, such as uji porridge (a staple food), and eaten immediately.

During the home study, data were collected at three points: enrollment, midway at 2 weeks, and finally at 4 weeks. The enrollment and midway data collections occurred in the households, and the three final focus group discussions occurred at a central location. At enrollment, the caretakers were given detailed oral instructions on how to prepare and serve Sprinkles, the dose, and possible side effects, including stool changes (dark or loose). The enrollment structured interview guide explored expectations and potential problems and included a household census. The midway and final structured interview guides examined use, acceptability, problems, and pricing. At midway, the research assistants observed eight child feedings with Sprinkles. The families were asked to keep all used sachets; at midway, the research assistants documented used and unopened sachets.

Analysis

Through content analysis, the interviews were first
coded for concepts, dominant themes, and variability [9, 10]. For this analysis, the data were initially segmented by target population and component (collection during the initial 14 focus group discussions or the home study) and then the data were compared across target populations and components (when possible). The findings reported here were similar across target populations and often across components, so that the findings are reported together. Only differences identified between the initial 14 focus group discussions and the home study interviews are reported in the text.

Results

There were 102 participants in the 14 initial focus group discussions. The majority were female, married, 20 to 49 years old, had 6 or more years of education, and worked in petty trade/small business or farming.

There were 25 families enrolled in the home study. The majority had fewer than three children 0 to 59 months of age living in the household and two to four additional children in this age group living in the homestead. The majority of families owned their homesteads; the parents were married with no more than two wives in the family; and the husband was the head of the household. One family moved before the midway data collection; 24 families with 47 children 6 to 59 months of age completed the study. The three final focus group discussions included 21 families.

Initial 14 focus group discussions: Immediate reactions and purchasing preferences

Almost all the participants’ immediate reactions to Sprinkles were positive. The participants reported that the key benefits of Sprinkles were prevention of anemia and avoidance of treatment for anemia, such as blood transfusions. Blood transfusions were reported not only as expensive, but as a way to acquire HIV. They also reported that Sprinkles could improve the quality of their children’s diets without the need to pay for costly foods:

The information about it preventing anemia is good, we are usually advised from the clinics to give our children certain foods which we sometimes cannot afford. This will help our children to become healthy and strong to fight illnesses. (Mothers of children 0 to 59 months, initial 14 focus group discussions)

Participants across all interviews reported that Sprinkles were similar to regularly used products, such as oral rehydration solution, sugar (glucose) packets, and spice sachets used in cooking. They reported they would expect to find Sprinkles for sale in pharmacies and clinics similar to drugs, but Sprinkles were also widely regarded as appropriate for food because of the similarity to sugar and cooking spices, the fact that they dissolved quickly in their mouths when tasted, and the finding that for some the Sprinkles had a salty (or other foodlike) taste.

Despite the fact that the Sprinkles sachets (fig. 1) used in this study were donated, with no possibility of altering the packaging, it was important to explore reactions to the packaging prior to implementation. The sachets had a light blue background with a white border. The outline of the child’s face was dark blue, and the cheeks and lines around the head were red. Overall, the participants reported that the child looked healthy. The colors were generally described as attractive; various participants said the red colors meant it would improve blood. The bowl was identified as a family pot and not a child’s serving vessel, leading to misunderstandings about preparation. Participants across all interviews reported that they were confident in the quality of the packaging and that the size and durability made it easy to carry. Across interviews, they reported preferences for both single sachets and bulk purchasing (e.g., bag of 15). Single sachets were described as easier to acquire with small sums of money. Bulk purchasing was identified as a way to overcome unreliable availability in local villages and to lower travel costs to purchase. Participants across all interviews asked questions about Sprinkles use, while far fewer raised concerns (table 1).

Home study: Experiences with Sprinkles preparation and use

The home study families reported that Sprinkles were generally easy to prepare and use. The research assistants documented correct preparation and use during observations of child feedings, with mothers preparing and serving Sprinkles in four households and female relatives or helpers doing so in four other households. Most families reported always mixing the entire sachet

FIG. 1. Back and front of the Sprinkles sachets used in the study
into food. One family reported initially giving only half a sachet per day to check for adverse effects; once satisfied, they gave the entire sachet. Another family reported their child consumed *uji* twice a day; thus, the sachet was split between meals.

At midway, observations of sachets in 24 households showed an average of 15 sachets used per child per household (range, 5 to 25). Five families reported giving away Sprinkles to children living in other households or older children taking and consuming Sprinkles without permission. In one household, one enrolled child reportedly consumed one Sprinkles sachet daily, while the other child stopped because of adverse effects (vomiting).

At midway, a 3-day recall of Sprinkles use was collected for each enrolled child; 18 families reported giving one sachet per day per child. Two families reported giving three sachets per day per child. Four families reported missing days. One participant explained that because she forgot one day, she gave two sachets the next day to catch up. Families reported that changes to their routine affected adherence, and few reported problems remembering to give Sprinkles:

> I was sick and during this time I could not give them Sprinkles. (Home study, midway)

### Home study: Acceptability

Among the home study families, Sprinkles acceptability was high for both children and families. Most families reported that the children ate food with Sprinkles without problems and some children even requested Sprinkles:

> They like it so much; they are the ones who remind me all the time to add Sprinkles to their food. (Home study, midway)

Several families reported that children requested Sprinkles because they thought it was sugar (glucose) because of the white powdery contents and the package size and coloring; this increased acceptability to the children. This misperception was documented during a child feeding observation:

> Both children murmured “glucose” when the sachets were brought out. (Child feeding observation, midway)

Some families said that the children never noticed Sprinkles in their food. A few families reported some initial reluctance of the children to consume food with Sprinkles, but after a few days it was overcome, in some cases by adding it without the child’s knowledge. Families said that all household members approved of Sprinkles:

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**TABLE 1. Frequently asked questions about Sprinkles in the initial 14 focus groups**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sprinkles are for children 6 months to 5 years of age; can older children and adults use them too?</td>
<td>Why should I give my child Sprinkles?</td>
</tr>
<tr>
<td>How often should I give my child Sprinkles?</td>
<td>For how long should I give my child Sprinkles?</td>
</tr>
<tr>
<td>Is it dangerous to give Sprinkles as a preventive measure for many months in a row?</td>
<td>How will I know Sprinkles are working?</td>
</tr>
<tr>
<td>Are there any side effects from using Sprinkles?</td>
<td>Will my child experience side effects if he/she stops taking Sprinkles?</td>
</tr>
<tr>
<td>How do I know if my child needs Sprinkles?</td>
<td>The sachet says it contains folic acid. Is this acid harmful to my child?</td>
</tr>
<tr>
<td>Can a child who is seriously ill take Sprinkles safely?</td>
<td>Will Sprinkles increase my child’s appetite?</td>
</tr>
<tr>
<td>Is it only used for prevention of disease, or also for treatment?</td>
<td>Why is the package so small?</td>
</tr>
<tr>
<td>Do I need to use the entire sachet at once?</td>
<td>Can I put the Sprinkles into a large container of food early in the day and serve portions to my child throughout the day?</td>
</tr>
<tr>
<td>Can I add Sprinkles to the pot of food while it is cooking?</td>
<td>To what foods can I add Sprinkles?</td>
</tr>
<tr>
<td>Into what amount of food do I mix Sprinkles?</td>
<td>Can someone eat the Sprinkles directly without putting it in food?</td>
</tr>
</tbody>
</table>
My husband was very happy; at mealtime he would ask, “Where is the baby’s drug?” (Home study, final)

Across interviews, household members largely embraced Sprinkles because of the perceived positive effects observed in children and because they knew that vitamins and minerals are important for health and development:

The other household members were asking why they do not have Sprinkles so that they can also eat them. (Home study, final)

Most home study participants reported no major problems with Sprinkles use and said they would recommend Sprinkles to others or had already done so. No participants suggested they would not recommend Sprinkles.

Home study: Effects of Sprinkles

All families reported observing positive health effects of Sprinkles in their children, including increased appetite and perceived improvements in immunity, strength, activity levels, and weight gain. Some families reported that preexisting health problems, such as diarrhea, vomiting, or swollen stomach (kwashiorkor), resolved after using Sprinkles:

Sprinkles make his mouth sweet, he used not to eat well but now he eats well. (Home study, midway)

Less commonly mentioned by some were initial adjustments to Sprinkles, including diarrhea, softer stool, dark stool, vomiting, or children disliking Sprinkles. Overall, changes to the stool were anticipated and not worrisome:

Its benefits are what we are seeing. The child used to be sickly but now she is stronger. She had diarrhea for the first few days but that stopped. The child eats Sprinkles and is very active, she likes it. (Home study, final)

Some families mentioned that children’s increased appetites stressed household finances because of increased food costs, thus turning a positive and valued effect into a potential problem. However, none suggested stopping Sprinkles:

The only problem is that they have become gluttons. (Home study, midway)

Initial 14 focus group discussions and home study: Reported potential barriers

Three main potential barriers were reported across all initial 14 focus group discussions: inadequate knowledge about Sprinkles and use, the need for tangible evidence that Sprinkles improves health (no negative effects), and cost:

Participant 4: They will only agree after getting proper education about Sprinkles.

Participant 7: Mothers will only use it after getting free samples to try and if low price.

Participant 3: People like what they can see; they will only use it after they see children using it have improved health.

(Women who purchased from vendors, initial 14 focus group discussions)

During the home study focus group discussions, potential barriers identified were primarily cost and lack of availability.

Initial 14 focus group discussions: Targeting promotional messages

Participants identified four main groups for targeting Sprinkles promotional messages: mothers, who are primarily responsible for child care; fathers, because they provide cash for purchases and may deliver child care; all other household members involved in child care; and doctors, because they diagnose disease and counsel families.

Initial 14 focus group discussions and home study: Content of promotional messages

The initial 14 focus group discussion and home study participants reported that the positive health effects of Sprinkles are the most important message for promotion. However, the initial 14 focus group discussions and the home study participants differed regarding the content of the suggested health messages. Across the initial 14 focus group discussions, prevention of anemia and iron deficiency was the primary message. Some participants also mentioned preventing disease, improving child growth, and increasing strength as important:

Participant 5: I think what you just told us, that it prevents iron deficiency is good enough.

Participant 6: Tell them that it prevents diseases and therefore they should use it.

(Grandmothers with children 0 to 59 months of age in the homestead, initial 14 focus group discussions)

In contrast, the key messages that home study participants identified included increased child appetite, disease prevention, reduced illness severity, healthier children, and strengthened immunity. Few home study participants mentioned the prevention of anemia or iron deficiency as an important message:
Participant 4: It improves appetite

Participant 7: It helps prevent diseases. If a disease attacks, it helps in reducing the severity.

Participant 2: It’s a drug that helps in preventing diseases; it is easy to use and improves appetite.

Participant 5: Tell them it’s good

(Home study, exit)

The participants also mentioned other topics, such as providing instructions on use, avoiding costly disease treatments, and avoiding costly foods.

Discussion

This formative study found high acceptability and utilization of Sprinkles among Luo peoples in western Kenya, and the findings contributed to the development of promotional messages. The study also identified priority issues related to preparation and use of Sprinkles and potential barriers that required attention before and during implementation of the intervention.

As in other studies [5, 7, 11, 12], the reactions of the participants in the initial 14 focus group discussions and the home study to Sprinkles were positive, with high acceptability among adults and the majority of the children. The perceived familiarity of Sprinkles to regularly used products did not raise concerns, which could have been a problem if Sprinkles were perceived as similar to a product that could potentially inhibit use of Sprinkles, such as condoms or powder used in black magic. Vitamins and minerals were already valued for healthy growth and development among the population. These factors all likely contributed to the high acceptability expressed across interviews. Other studies have documented children enthusiastically eating food with Sprinkles [6] or initially refusing food with Sprinkles [2, 3, 13], but none have reported children confusing Sprinkles with sugar. This confusion was due to the white, powdery consistency of Sprinkles and packaging size and color similar to that of locally available sugar. This confusion might also partly explain why some older children took and consumed Sprinkles without permission during the home study. Used as directed, Sprinkles do not change the taste of food [1], and when tasted directly the powder is not sweet. Caretakers may sweeten uji with sugar for young children, and this probably contributed to their confusion as well.

Overall, Sprinkles were described as easy to prepare and use, and parents reported observing positive effects, as in other studies [6, 12–14], but issues were identified related to preparation and use, as well as potential barriers, requiring follow-up. The bowl on the package instructions was misunderstood as a family pot. Also, the participants in the initial 14 focus group discussions and the home study families received information on preparation and use similar to or in more detail than would occur in a real program setting (e.g., 10 to 15 minutes of detailed oral instructions with opportunities for questions). Despite this, among the participants in the initial 14 focus group discussions, many of the frequently asked questions were about preparation and use, and reported potential barriers centered on inadequate knowledge of Sprinkles, including use. Also, various home study families reported utilization inconsistent with instructions. For example, two families reported giving three sachets a day (one at every meal), one reported giving two sachets in one day when they missed a day, and another reported splitting the sachets among meals. Although all available caretakers received training during enrollment into the home study, many household members may perform child care, and it is possible that not everyone was trained, similar to what would happen in a real-world setting. Finally, although the majority of home study families reported observing positive effects in their children, some reported adverse effects and stool changes. As suggested by others [6,13], this study warned the participants about potential stool changes, and they were told that dark stools are one sign that Sprinkles are working. Stool changes were generally anticipated and were not upsetting.

Documentation of reactions and everyday experiences using Sprinkles informed the development of the intervention. This information highlighted the need during implementation to provide training and appropriate information and materials that vendors and families can refer to repeatedly on correct preparation, usage, and doses; positive and negative effects; and how to respond if a family forgets to give Sprinkles. Vendors and community leaders received Sprinkles training prior to implementation. Instructional promotion materials (leaflets and calendars) were developed for widespread, repeated distribution in all intervention villages. They were pretested with mothers and grandmothers for comprehension and feedback and provided locally appropriate visual and written directions of how to prepare and serve Sprinkles. Intervention training sessions and Sprinkles promotions were tailored to answer the frequently asked questions specifically and increase knowledge of Sprinkles. Home study participants gave testimonials during promotional events about their experiences and the tangible effects observed in their children, providing locally compelling evidence that Sprinkles improves health.

Potential messages drawn from the findings were tested for resonance and comprehension and were ranked during focus group discussions with mothers, grandmothers, fathers, and adults in the general population. Final intervention messages promoted improved appetite and immunity, with the tagline “Healthy Child, Happy Family.”
Comparison of the initial 14 focus group discussions with the home study findings showed that information needs and perceptions changed after Sprinkles had been used for only a few weeks. Existing levels of Sprinkles awareness and knowledge, and changes over time should be taken into consideration when designing interventions.

During 4 months of formative research, critical information was collected to implement the study intervention in a locally relevant and appropriate way. Potential problems identified in the formative work were addressed prior to the study and continued to be examined during ongoing qualitative monitoring carried out during implementation.

Acknowledgments

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References

Growing children’s bodies and minds: Maximizing child nutrition and development

Patrice Engle and Sandra L. Huffman

Abstract

For their optimal growth, and for greater long-term human capital development, children profit not only from improved nutrition but also from improved learning opportunities in the earliest years of life. This paper describes how actions to enhance optimal infant and young child nutrition can be linked with child development interventions for children under 3 years of age. In countries with high rates of malnutrition, linking these two components will result in synergies of program activities, and will bring about a greater impact at reduced cost than either activity conducted separately. New understanding of social marketing and communication strategies can increase effectiveness of linked interventions. Public–private partnerships to improve both child development and nutrition offer promise for sustainable interventions.

Key words: Child development, nutrition, developing countries, infant and young child feeding, social marketing

Introduction

It is well recognized that the first few years of life are critical both for a child’s nutrition and for his or her physical, social, cognitive, and emotional development, and that interventions during this period have maximum impact. Therefore, combining programs to improve nutrition with those for early childhood development would seem to be a reasonable approach.

However, there is as yet no clear model of the best ways of combining nutrition and early child development programs. This paper examines proposed mechanisms for the link between nutrition and early child development and models of programs that combine the two interventions.

From conception through the first few years of a child’s life is the period of greatest risk and greatest opportunity for making a difference for children. Rapid brain development affects cognitive and socioemotional development, which is critical for long-term economic productivity, for meeting the challenges of a workforce in a global marketplace, and for ensuring every child’s right to survival and development.

Poverty, poor health, undernutrition, and lack of early stimulation undermine children’s development early in life when brain development is most rapid and the architecture of the brain is most sensitive to the influences of the external environment—prenatally through 3 years of age.

As a result, it is estimated that at the current time more than 200 million children under 5 years of age fail annually to reach their full potential in cognitive, language, and socioemotional development [1, 6]. Many of these children will do poorly in school, resulting in lowered incomes and productivity. Given lower levels of education, they will be likely to provide their children with poorer-quality health care, nutrition, and stimulation, thus contributing to the intergenerational transmission of poverty [1, 6].

Malnutrition under the age of 2 years results in long-term impacts on adult size, IQ, school attainment, and adult wages. Micronutrient deficiencies (especially iron and iodine) also affect IQ and development. Suboptimal parental care (lack of stimulation, social interaction, and emotional support) during the first 3 years of life has long-lasting cognitive and emotional effects on children. The time between 2 and 3 years of age is especially critical for developing language skills. Thus, efforts to improve nutrition and parenting behavior should optimally start prenatally and continue throughout the first 3 years of life. We review evidence...
on the impact of nutrition on child development, stimulation and responsive care on child development, as well as mechanisms for the interaction, and suggest innovative approaches to programming for both nutrition and early child development.

**Role of infant and young child nutrition in early child development**

It is well known that nutrition of young children affects their health and their physical, cognitive, and emotional development. It is also well recognized that children who are malnourished do not learn well and have more social and emotional problems than those who are healthy and well nourished [1, 2].

Poor maternal nutrition, inadequate child feeding practices, and high rates of infection cause stunting (reduced linear growth), which is difficult to reverse after the age of 2 years. Breastfeeding is a critical factor for improving nutritional status, reducing illness, and improving cognitive and social development in young children. Exclusive breastfeeding for the first 6 months of life and continued breastfeeding for 2 years and beyond are closely associated with improved health. Nutrients in breastmilk have been shown to facilitate brain development. Breastfeeding also enhances maternal–infant bonding, which is associated with improved maternal care and enhanced emotional development in the infant. Improvements in complementary feeding from 6 months of age enhance linear growth and micronutrient status [3–5]. Suboptimal feeding practices and poor-quality complementary foods result in micronutrient deficiencies and stunting among children 6 to 24 months of age.

The critical role of nutrition for the development of cognitive skills has been well documented [2, 6]. For every 10% increase in stunting (≤ −2 SD height-for-age), the proportion of children reaching the final grade of primary school drops by 7.9% [2]. Moreover, stunted children learn less in school, with lower reading and math scores that are equivalent to two fewer years of schooling [6].

Poor cognitive development is also related to iron-deficiency anemia and iodine deficiency [1, 7]. The critical role played by several other nutrients in cognitive development is only beginning to be recognized [1]. Malnutrition directly causes central nervous system damage, which results in impacts on cognitive and emotional development. Victora et al. [2] conclude that “the damage suffered early in life leads to permanent impairment, and might also affect future generations.”

Malnutrition also affects emotionality, irritability, and attention in young children and social and emotional responses in older children. Underweight and stunted children demonstrate a variety of affective variations, including irritability, apathy, less play, more insecure attachment patterns, and poorer social relations in school [1]. Such children have poorer social functioning and more anxiety, depression, and inattention in adolescence [1, 7]. Anemic children have been found to be more easily upset and more fearful than nonanemic children [8].

**Role of a responsive and stimulating environment and opportunities for learning in early child development**

The effects of nutrition on child development described above are now accepted, but it is less well known that a more stimulating and responsive interaction with caregivers has an equally important role in children's long-term cognitive and socio-emotional development. Psychosocial risk factors for poor child development include lack of responsive caregiver–child interaction, lack of learning opportunities in the home environment, and exposure to excessive stress, which may result from extreme poverty, maternal depression, or conflict and emergencies. Interventions to reduce these risks have an effect on child development in both malnourished and well-nourished populations; they have an independent and equally important effect.

**Definition of child development**

Child development refers to the gradual emergence of increasingly complex patterns of thinking, perceiving, moving, speaking and understanding, and relating. In addition to more commonly measured skills of language and cognitive understanding, children also develop their ability to control themselves and regulate their emotions (self-regulation) and to learn how to focus their attention and shift this focus of attention, prioritize, and plan (executive function). Methods are being developed to measure these latter capacities. These “domains” of development—cognitive, language, executive function/self-regulatory, motor, and social/emotional—all contribute to long-term well-being, including learning, school performance, economic productivity, and responsible citizenship throughout life. Many aspects of a child’s development are affected by the quality of the relationship with a caregiver, often called the child’s attachment to the caregiver.

**Interventions for child development**

Children’s cognitive development can be improved through adult support in a process called “scaffolding,” in which a child is encouraged to consider new options or extend her thinking through adult (usually parental) facilitation and joint attention (both adult and child attending to the same task). The amount and quality of
language exposure are strongly associated with better language development, which in turn affects school performance and success [9]. Learning materials that provide children with opportunities for manipulation and control, whether home-made or purchased, and books are important supports for learning [10].

Programmatic interventions have been able to improve a child's developmental level by changing patterns of interaction between caregivers and young children and by increasing children's access to stimulating learning opportunities.

Parenting education on how to support young children's learning through stimulation, encouragement, and interaction (such as through reading, telling stories, playing with children) has been successful in helping enhance child development [11–16]. Some of the most successful interventions in low-resource settings were increased play, reading to children, and possibly massage [17]. Many studies demonstrate that psychosocial interventions have effects on cognition even in well-nourished populations [10, 16, 18].

**How nutrition and child development influence each other**

*Figure 1* illustrates pathways through which malnutrition affects a child's development. Three main kinds of influences have been identified. Malnutrition poses a biological risk and affects the central nervous system and children's cognitive development. Experience and stimulation also affect brain structure and function, resulting in biological risk [19].

A second pathway through which malnutrition affects child development is that changes in child behavior as a function of malnutrition impact the development of mother–child relationship or attachment. A child who is stunted is likely to be more apathetic or less responsive [17]. The infant's first line of defense is the smile emerging around 6 weeks, which builds the attachment bond with the caregiver that is so necessary to the child's survival, growth, and development. If malnutrition reduces the emergence or frequency of these smiles and laughs, the critical attachment bond may be weaker [20]. Caregiving quality depends on this strong bond or attachment, and if it does not develop the child will be at risk of neglect or less responsive care. Thus a child's behavior (“cuteness”) can affect the care that she/he receives, resulting in higher risk of malnutrition for difficult children [21, 22]. The emotional characteristics of the child have been shown to interact with aspects of the child-rearing situation (such as maternal depression), leading to changes in care patterns and resulting in more negative growth patterns for these children [21]. In other words, a child who is fussy or irritable is more at risk for receiving poor care than one who is easier to parent, and poor physical or mental health of the caregiver increases the risk.

Responsive care can impact not only play but also feeding, particularly responsiveness during complementary feeding. The quality of care the main caregiver provides, in terms of responsiveness to cues of child hunger and feeding, has been shown to relate to children's nutrient intake from complementary foods [23, 24].

Third, the caregiver's health and mental well-being influence her or his caregiving behavior. The mother's well-being, either nutritional (e.g., anemia, short height, low weight) or psychological (e.g., depression) can affect the young child's nutrition and development. A woman who was born with low birthweight will be more likely to have a low-birthweight child herself, and a woman's height-for-age when she was less than 3 years old will have a significant association with the birthweight of her child [2]. A mother with a compromised state will be less likely to provide responsive, sensitive care and feeding for an infant. For example,
a woman's iron status has been shown to be associated with the quality of the mother–child interaction [25]. Maternal depression has a significant influence on caring practices. It is associated with reduced likelihood of breastfeeding, greater probability of stunting, and lower developmental levels in the child [26]. Improving the mother's nutrient status (through reductions not only in anaemia but in other micronutrient deficiencies as well) can improve her ability to interact with her child. Recent evidence illustrates high rates of postpartum depression in women in developing countries, which may be caused in part by essential fatty acid deficiencies [27].

Finally, malnutrition is often seen in conditions of poverty, when there is not only food scarcity, but also lack of adequate services, poor living conditions, and various other threats.

Interventions to improve both nutrition and child development should focus not only on food intake, but also on parenting and the quality of the mother–child interaction, and on the broader social and economic context. An intervention that includes both infant and young child nutrition and child development could also increase the caregiver's motivation and commitment, since the focus is on not only the child's problems (e.g., undernutrition) but also the caregiver's hopes and aspirations for the child and the possibilities that the child may develop well.

Programmatic strategies for linking nutrition and early child development

Additive and synergistic effects

A number of studies have shown that improvements in nutrition and psychosocial stimulation together have additive effects on growth or on development. Pelto, Dickin, and Engle's 1999 review of studies in the 1980s and 1990s found examples of additive effects on nutrition and development, but not synergistic effects [11].

However, in some early studies children were beyond the most critical age when the supplementation began. For example, Grantham-McGregor et al. provided stimulation and food supplementation to stunted children aged 9 to 24 months in a 2 × 2 design [28]. Both interventions had an impact on cognitive development. However, Walker et al. found that there were long-term effects of stimulation on cognitive and socioemotional development at age 17 to 18 years, but not of food supplementation [29]. We now know that nutrition interventions have to begin in the first 12 months of life to have maximum impact. Because children were already stunted and some were older than 12 months when the intervention began, food supplementation probably began too late for some children to have a long-term impact on growth.

Therefore, in current work, impacts on growth are likely to be greater than previously observed, since older studies included children over 18 months of age and the nutritional supplements provided were often incomplete (e.g., they lacked micronutrients, essential fatty acids or milk). Only recently have studies examined impacts of responsive complementary feeding interventions among children beginning in the first year of life, and these results suggest benefits on dietary intake, growth, and, in a few cases, development in India, Bangladesh, and Malawi [30–34].

Additionally, recent studies have shown that the impact of a stimulation intervention on cognitive development is often greater in more malnourished and poorer families, suggesting that there may be interactive or synergistic effects on child development [35]. Watanabe et al. combined a food supplementation program for children 4 to 5 years of age with an improved preschool experience in Vietnam and found that the effects on cognitive development were greater in the combined intervention than the nutrition-only group, and that they were much larger for stunted children (effect size = .61 SD) than for nonstunted children (effect size = .06 SD) [36]. One would expect even larger impacts if supplementation were done when the children were under 2 years of age.

Combining infant and young child feeding interventions with child development stimulation has shown benefits for both. Combining the two can increase impact and increase efficiency of service delivery.

Early child development in health and nutrition programs

In a number of countries, including India, Kazakhstan, Malawi, Moldova, Nepal, Sri Lanka, and South Africa, efforts have been made to develop an integrated approach to early child development and nutrition through IMCI (Integrated Management of Child- hood Illnesses). The Care for Development module combines infant and young child nutrition counseling with recommendations for play and communication with the child.

In Malawi, an evaluation of the implementation of Community IMCI in five districts found significant increases in rates of exclusive breastfeeding, initiation of complementary feeding, number of meals per day, and some responsive feeding behaviors. Changes in maternal attitudes and reports of behavior regarding psychosocial stimulation were also found, including an increase in parents responding when a child tries to speak (increasing to 34%) and providing children with toys (increasing to 31%), but reading and storytelling remained low at 5% and 8%, respectively [37, 38].
Early child development in parenting programs

Parenting programs through group classes or home visits that combine nutrition and development have been shown to improve parenting skills related to both nutrition and child development in Bangladesh [39, 40], Indonesia [41], Jamaica [42], Kenya [43], Peru [44], the Philippines [45], South Africa [46], and Uganda [47, 48].

The Philippines developed a slogan of “mental feeding” to encourage families to both feed and read to children. Brazil launched a major awareness campaign urging families to adopt 28 key behaviors that would improve the health, nutrition, and well-being of their children [49].

Child-care programs

In combination with community-based child care for children under 3 years of age, parenting education also was successful in Bolivia in the Wawawasi [50] and Integrated Program of Infant Development (PIDI) programs [51], with the Comprehensive Childcare Program (Spanish acronym PAININ (Programa de Atención Integral a la Niñez) in Nicaragua [52] and with the Bangladesh Integrated Nutrition Program (BINP) [53]. Additionally, educating caregivers was beneficial in nutrition rehabilitation units in Bangladesh [54] and Uganda [55] and with caregivers of HIV-affected children in South Africa [56, 57].

Using social marketing strategies

Social marketing of key messages on child development has also been shown to improve caregiving behaviors in both developed and developing countries through nutrition and health programs. A social marketing campaign conducted in the state of West Virginia educated parents and caretakers about the importance of love, talk, rhyme, reading, and playing for children from birth to age three. The program targeted women participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which serves low-income women, infants, and children up to age five who are at nutritional risk. Based on formative research, an audience-driven intervention was developed that consisted of a toolkit for parents and child-care providers reminding them to work early literacy concepts into their everyday routines. The toolkits contained a tote bag, bib, activity mat, snack holder, and rhyming book, all of which emphasized the importance of working love, talk, rhyme, reading, and playing into everyday activities with young children. Evaluation of the project showed significant gains in the amount of time parents and child-care providers spent reading to, rhyming with, and asking questions of young children. The project also demonstrated significant positive shifts in attitudes about talking at mealtimes, playing with everyday items, and giving children hugs and kisses [58].

The Reach Out and Read [59] program in the United States and other countries has used pediatricians to provide a small, inexpensive book to children 6 months of age and older and has reported significant increases in parental reading to children [60]. Studies found an association between the intervention and statistically significant improvements in preschool language scores and how often parents read to children, a good predictor of later literacy success [59].

Read to Grow uses trained volunteers to work with parents in the hospital when a baby is born, linking health to the importance of early literacy, language development, and attachment [61]. Parents are encouraged to begin reading aloud to their infants right from birth. They are given a “literacy bag” containing a free new children’s book and informational guide.

Social marketing programs focused on early childhood development have also been successfully implemented in developing countries. In the Maldives, UNICEF initiated a project called “First Steps Maldives” with a goal of securing every child’s full physical, cognitive, and psychosocial development in a stimulating environment. One of the main objectives was to ensure that parents and grandparents were aware that it is important for both fathers and mothers to be actively involved in nurturing and stimulating their children. A multimedia campaign was conducted using radio, television, and posters to reach out to families for early childhood care and development. An evaluation of the First Steps project found improved child care in most families observed in terms of breast feeding, vaccination, the caring role of fathers, and children’s psychosocial and cognitive needs [62].

The Equal Access Initiative uses low-cost technology and community outreach to disseminate information on early childhood development and other issues to families living in remote rural areas in Nepal [63]. An early child development radio program called Kheldai Sikdai (“Learning While Playing”) is broadcast in Nepal via FM and satellite radio to early child development centers and a broadcast audience of millions. In Kyrgyzstan, promotion of exclusive breastfeeding and early child development messages are combined with the distribution of micronutrient powders for use among children 2 to 24 months of age in a pilot study in one district in the country. The project is just beginning, but early results suggest that the combination may be effective and should be scaled up (personal communication, M. Serdula, CDC).

Effective social marketing

Based on these experiences, we have much better evidence for what makes social marketing programs
effective, which can be helpful for early child development and infant and young child nutrition interventions. A review of breastfeeding media promotion in 25 countries found that few of the early media campaigns analyzed the psychological, social, and cultural barriers to behavior change [64]. In recent years, many breastfeeding media campaigns have followed social marketing principles of research and planning and have developed programs with frequent messages on specific behaviors directed to targeted audiences. Mass media have increased coverage and awareness, and interpersonal contact at the community, family, and individual level has influenced behavior change [65].

Comprehensive social marketing strategies that include interpersonal communication, mass media, and traditional media have been shown to improve infant feeding behaviors at scale within a relatively short period of time in Bolivia, Ghana, and Madagascar. All three programs reached sizable populations (Bolivia, 1 million; Ghana, 3.5 million; and Madagascar, 6 million). Partnerships were used to harmonize nutrition messages and field approaches and to develop materials. Targeted, concise messages were used to promote doable actions. Consistent messages and materials were used across all program communication channels to address critical behaviors, and primary audiences were saturated with messages through appropriate media (electronic, print, interpersonal, events, traditional). Fathers and grandmothers were also included as secondary audiences to promote behaviors supporting mothers to optimally breastfeed. The programs also included training for health workers and community workers and peer group support. As a result of the interventions, the rate of timely initiation of breastfeeding increased from 56% to 74% in Bolivia, from 32% to 40% in Ghana, and from 34% to 78% in Madagascar. Increases in the rate of exclusive breastfeeding (age 0 to 6 months) were also documented: from 54% to 65% in Bolivia, from 68% to 79% in Ghana, and from 46% to 68% in Madagascar [66].

Thus, the best strategies to use in linked early child development and nutrition programs are a variety of modes of intervention, addressing cultural, psychological, and economic barriers to change, careful targeting, concise messages, and doable actions addressed to all relevant audiences.

**Sustainability**

But as with many programs, when funding ends, the program often ends as well, unless a means of self-sustainability can be found. The Step by Step program operating in several developing countries provides books in local languages and sustains itself through the sale of these low-cost books. Sesame Street (operating in more than 100 countries) receives funds for programming in part from sales of toys and dolls associated with the show. Building more of these self-financing strategies into programs should increase sustainability, and the link with early child development offers new opportunities for these strategies.

**Other programming options for nutrition and early child development**

One of the difficulties in addressing young child nutrition together with early child development programs is that most early child development programs are focused on children 3 years of age or older and function through preschool education centers. Ministries of Education take the lead and work through channels such as community-based child-care centers and school-related programs. Yet in order to be effective, nutrition interventions need to focus on earlier ages, specifically children under age two. Therefore, a combined program of nutrition and early child development needs to link with early child development interventions for children from 0 to 2 or 3 years of age.

Research suggests that interventions that begin with younger-aged children are likely to be more effective [14]. Currently such programs are often found under the auspices of Ministries of Health, such as in Community Integrated Management of Childhood Illnesses (CIMCI) programs. But such health programs are often overburdened and focused on treating sick children, with little staff time or resources left for encouraging improvements in child nutrition or parenting skills.

Child-care centers for very young children are usually limited to children whose caregivers need support in caring for them daily (e.g., while they are at work). Where they exist, they provide excellent platforms for linked nutrition and early child development, but coverage tends to be extremely limited in low-resource settings. Early child development interventions that reach young children by providing parenting education and support through home visits, communication campaigns, group sessions, or providing learning materials could provide a good platform, and these programs usually include infant and young child feeding messages. The coverage of these programs is slowly increasing, but it is still low.

Thus, there is a need for approaches to extend actions outside these traditional modes of intervention. Public–private partnerships can be used to reach groups who do not have access to these more traditional delivery channels, or when the health care system does not provide this support. They provide an opportunity to reach target populations more frequently than can be done through health center contacts. Private companies producing complementary foods and supplements used for home fortification can work with mass media and nongovernmental organizations (NGOs) to enhance both nutrition and early child development messages.
Social marketing can be used to promote both nutrition and improved parenting messages, monitoring and evaluation of activities to show impacts, and advocacy and communication to increase support for linking nutrition and early child development at international and national levels. Links with existing public sector interpersonal activities for early child development can be employed so that these activities and messages will be coordinated and reinforce one another.

When there is little existing early child development activity in the public sector, then the qualitative work, message development, and advocacy will be an important component of the work with the public sector (for example, through coordinating committees). This will inform any public sector work on early child development and increase the chance of interpersonal reinforcement, which increases success both in improving feeding practices and in enhancing parenting skills.

In summary, while there are many actions to address these issues, public–private partnerships can improve both nutrition and early child development. Some examples of these combinations are:

» Promotion of early initiation of and exclusive breastfeeding for the first 6 months and continued breastfeeding until 2 years and beyond, plus recommendations on play and communication for improved parent–child interaction;

» Promotion of optimal complementary feeding practices, with a strong focus on responsive interactions during feeding;

» Distribution/sale and marketing of products for home fortification of complementary foods with messages on appropriate use combined with distribution/sale of learning materials (books, simple toys, and guidance for their use);

» Promotion of optimal parenting interactions for feeding, health care, and child development.

NGOs, media, and private and public sector companies can facilitate these actions. Different approaches include:

» Consumer research to understand consumer behavior and to develop effective education and awareness campaigns;

» Government- or private sector-sponsored nutrition and early childhood awareness programs;

» Promotion of government sponsored/endorsed seals and logos;

» Partnerships to launch information, awareness and communication programs;

» Social marketing campaigns involving NGOs;

» Traditional product advertising campaigns by firms targeted to different consumer segments;

» Linking products together to improve both child development and nutrition;

» Demonstrations of products and skill-building activities for both nutrition and early child development.

To reach lower-income-level consumers, it is clear that it will be necessary not only to focus on traditional distribution channels but also to include alternative channels. There are a range of channels that can be utilized:

» Retail (e.g., chain groceries or convenience stores, local shops);

» Private company channels (e.g., company-owned, wholesalers, distributors);

» Government or private healthcare systems (e.g., perinatal clinics, mother/child health clinics, primary health care center, immunization clinics);

» Public feeding programs (e.g., public distribution system, schools);

» Humanitarian aid, emergency, and health efforts run by NGOs or nonprofits;

» Nontraditional channels (e.g., women's associations, direct-to-home sellers, pediatricians and family doctors);

» Microfinance and microenterprises, such as incorporating toys, children's books, and learning materials with sales of products to improve child health and nutrition.

**Messages on nutrition and early child development**

The messages on infant and young child nutrition and early child development should be developed locally with Ministries of Education, Health and Nutrition, and local experts, and can include items similar to those shown in box 1.

<table>
<thead>
<tr>
<th>BOX 1. Possible messages on infant and young child nutrition and early child development</th>
</tr>
</thead>
<tbody>
<tr>
<td>» Exclusively breastfeed your infant until she/he is 6 months of age and continue breastfeeding to help her/him be as smart as she/he can be</td>
</tr>
<tr>
<td>» Feed your child nutritious foods (such as meat, fortified complementary foods) to help him grow well and be able to learn</td>
</tr>
<tr>
<td>» Feed your child with patience, love, and good humor to help your child grow well and be able to learn</td>
</tr>
<tr>
<td>» Read to your young child and tell stories as often as you can</td>
</tr>
<tr>
<td>» Play with your young child so that she will learn and later do well in school</td>
</tr>
<tr>
<td>» Take your child outside your home</td>
</tr>
<tr>
<td>» Sing to your child</td>
</tr>
<tr>
<td>» Teach your child simple things every day, including words, numbers, and drawing</td>
</tr>
<tr>
<td>» Get a conversation going with your child with words or gestures; children can understand long before they can talk</td>
</tr>
<tr>
<td>» Praise your young child for what he/she manages to do</td>
</tr>
</tbody>
</table>
Measurement of outcomes

For the evaluation of public health and child development outcomes, variables to be measured could include nutritional status (anthropometric measures of weight, length, arm circumference, knee–heel length), biochemical data (anemia, iron deficiency), feeding practices, parenting practices, and child development indicators (language development, problem-solving, attention, and motor development).

Valid measurement of child development in children less than 3 years of age is challenging because different domains develop at different rates, characterized by developmental spurts and plateaus, with a continuing interplay between biological and psychological development. At this age, domains of development (e.g., motor, mental, socioemotional) are difficult to separate. For all of these reasons, assessments in the first year of life tend not to be highly predictive of later development except for children in the lower percentiles. It is thus advisable to capture effects of early intervention programs on several domains of child development to assess the possibility of impact most effectively, and to assess children at older ages, if possible.

A consensus on how to measure early child development with a global scale is slowly emerging. A series of child development questions will be included in the UNICEF Multiple Indicator Cluster Survey (MICS) in 2010. The World Health Organization (WHO) developed motor milestones appropriate for motor development for children 6 to 18 months of age. In the meantime, a good proxy for child development indicators is the quality of the home environment (learning materials available, parent's report of activities with children, children's opportunities for daily stimulation), which is strongly related to child development outcomes in many cultures and is easier to measure [10]. The most common measure is the HOME scale (Home Observation for Measurement of the Environment) to assess family care patterns and interactions with young children. The HOME scale correlates well with later IQ even after controlling for socioeconomic status [10].

Bradley and Corwyn found three key dimensions of the HOME along which most cultures vary: warmth and responsiveness, discipline/harsh punishment, and stimulation/teaching [10]. They found that both warmth/responsiveness and stimulation/teaching showed strong associations with child development outcomes in almost every cultural context, the former more consistently with social and emotional development, and the latter with child competence.

Because the HOME requires an hour of skilled observation, it cannot be used in a household survey. Therefore, UNICEF derived two measures of the home environment to be used in its household survey (Multiple Indicator Cluster Survey, or MICS): the Family Care Index, which assesses activities family members over age 15 do with children, and a description of learning materials in the home (children's books and number of types of toys). The major scale used is the Family Care Index, because most do not require any funds. These activities are coded in terms of activities of mothers, fathers, and other family members, so that these three scales can be compared. The activities in the scale include:

» Reading to the child
» Singing to the child
» Telling stories to the child
» Taking the child outside the home
» Playing with the child
» Teaching the child names, counting, or drawing

In Bangladesh, these indicators correlated well with the HOME scale, with Bayley tests (measuring IQ), and with nutritional status of young children [67]. They correlated with parental reports of "doing something to help prepare children for school" and "doing something to help increase children's IQ."* These indicators were collected in 31 countries in 2005, and will be assessed again in 2010. Specific questions are in box 2.

In addition, in some countries there are questions about the presence of children's toys and books, including not only purchased toys, but also homemade toys, and materials for play that are not household or outside objects. These questions provide a context for understanding the family activities and assessing the quality of the environment. The two most used measures are the number of children's books and whether or not there are purchased or homemade toys, used as individual scores. With the use of these measures, it is possible to determine whether there are resources that families have for children's learning. These measures are clearly more associated with income level, as well as with the education level of the mother [67]. However, there is an important reason for including them for purposes of advocacy. These measures allow us to describe the differences in children's opportunities for learning across a range of economic levels. The absence of books for children in the home, for example, not only suggests that the family may not have the means to purchase a book but also that the government has not prioritized low cost children's books in its policy options.

Of course, we know that having books in the house is not enough. Using the MICS data from 87,231 children, we find that when the family reports no children's books at home, only 8% of mothers, and 3% of fathers report reading to their child. On the other hand, among families that have from 1 to 9 children's books, 57% of mothers did not read to their young children in the past 3 days, and 84% of fathers did not read to their young

children in the last three days.* Thus not only the shortage of books, but also parental habits are limiting reading to children.

**Conclusions**

Linking nutrition with early child development programs can have long-term benefits for children’s health and their psychosocial and intellectual development. Health programs with access to young children through IMCI and well-child activities, such as immunizations, growth monitoring and promotion, and child health days, can be one means to do so, as can social marketing of messages to encourage improved feeding and parent–child interaction. Public–private partnerships to improve both child development and nutrition offer the promise of sustainable interventions.

* Analysis of 87,231 families in the MICS3 data set with complete information on family care and ownership of books.

**References**

4. Rivera JA, Sotres-Alvarez D, Habicht J, Shamah T, Villapando S. Impact of the Mexican program for education, health, and nutrition (Progresa) on rates of growth and anemia in infants and young children: a randomized
BOX 2. Child development questions in MICS 2005 module (continued)

<table>
<thead>
<tr>
<th>MICS Optional Module</th>
<th>Question CE1 is to be administered only once to each caretaker</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Child development</strong></td>
<td><strong>CE</strong></td>
</tr>
</tbody>
</table>
| CE1. How many books are there in the household? Please include schoolbooks, but not other books meant for children, such as picture books  
*If ‘none’ enter 00* | Number of non-children’s books........0 __  
Ten or more non-children’s books........10 |
| CE2. How many children’s books or picture books do you have for (name)?  
*If ‘none’ enter 00* | Number of children’s books .................0 __  
Ten or more books ................................10 |
| CE3. I am interested in learning about the things that (name) plays with when he/she is at home.  
What does (name) play with?  
Does he/she play with  
Household objects, such as bowls, plates, cups or pots?  
Objects and materials found outside the living quarters, such as sticks, rocks, animals, shells, or leaves?  
Homemade toys, such as dolls, cars and other toys made at home?  
Toys that came from a store?  
*If the respondent says “YES” to any of the prompted categories, then probe to learn specifically what the child plays with to ascertain the response*  
*Code Y if child does not play with any of the items mentioned.* | Household objects  
(bowls, plates, cups, pots) .....................A  
Objects and materials found outside the living quarters (sticks, rocks, animals, shells, leaves) .....................B  
Homemade toys (dolls, cars and other toys made at home) .....................C  
Toys that came from a store .....................D  
No playthings mentioned .....................Y |
| CE4. Sometimes adults taking care of children have to leave the house to go shopping, wash clothes, or for other reasons and have to leave young children with others. Since last (day of the week) how many times was (name) left in the care of another child (that is, someone less than 10 years old)?  
*If ‘none’ enter 00* | Number of times....................................____ |
| CE5. In the past week, how many times was (name) left alone?  
*If ‘none’ enter 00* | Number of times....................................____ |

46. Magwaza A, Edwards S. An evaluation of an integrated


Validity and reliability of mothers’ reports of language development in 1-year-old children in a large-scale survey in Bangladesh

Jena D. Hamadani, Helen Baker-Henningham, Fahmida Tofail, Fardina Mehrin, Syed N. Huda, and Sally M. Grantham-McGregor

Abstract

Background. In developing countries, it is often important to have measures of development in children under 3 years of age in large-scale surveys or evaluations of nutrition and stimulation programs. However, there is a lack of suitable instruments with established validity.

Objective. To develop a language test for children aged 12 to 18 months based on mothers’ report, suitable for use in large-scale surveys, and examine its concurrent and predictive validity. To determine whether the test is sensitive to home stimulation and nutritional status and compare the test with the Bayley Scales of Infant Development (BSID).

Methods. A subsample of participants in a large, prospective cohort study in rural Bangladesh (MINIMat) was selected for a study of child development (n = 2,852). A total of 2,418 participants were interviewed concerning their children’s expressive and receptive vocabulary, and children were tested using the BSID.

Results. The language test had reasonable short- and long-term reliability between 12 and 18 months (r = 0.50) and concurrent validity with the Bayley Mental Development Index (MDI) (r = 0.32 language comprehension to 0.41 language expression). Its predictive validity with IQ at age 5 years was similar to that of the Bayley MDI (r = 0.37 to 0.41 for language and r = 0.37 for MDI). Child language was independently associated with postnatal growth, stimulation in the home, gestational age, and socioeconomic status, and a similar set of variables predicted the Bayley MDI.

Conclusions. The language test was reliable, had acceptable concurrent and predictive validity, and was sensitive to environmental and child characteristics. Mothers’ reports of language could be useful in large-scale programs.

Key words: Bangladesh, child development, child language, measurement

Introduction

It is often helpful to measure the developmental levels of large numbers of young children, particularly in developing countries. Assessments of representative samples of populations can be used to monitor progress over time and identify areas with problems of poor child development. Both psychosocial stimulation and nutritional interventions in children under 3 years of age usually aim to improve their motor, cognitive, and language development. Unfortunately, assessment of the children’s development is rarely done. One reason is the difficulty in identifying available tests that are suitable for large-scale programs. In this paper, we describe the reliability and validity of a language test that could be used as an outcome measure for large-scale integrated programs of early childhood stimulation and nutrition.

Full developmental assessments with infant tests such as the Bayley Scales of Infant Development take at least 1 hour, and the test kits are expensive. Trained psychologists are needed to conduct the assessments and a quiet controlled environment is also needed, which usually precludes testing at home. There is a great need to identify measures of development that can be used in the field by relatively low-skilled people and are suitable for use in large-scale early child development programs. Assessment of attained milestones has been used to assess motor development in several...
studies in developing countries, such as Pakistan [1], Indonesia [2], and Ghana [3]. However, there is limited information on their predictive validity. There are very few data on suitable measures for cognitive and language development.

Assembling the language development of young children in developing countries presents particular problems, because children tend to be inhibited with strange testers and rarely speak spontaneously. Mothers' reports provide an alternative way of assessing children. Mothers are usually with their children most of the time and have a good idea of their language ability in all situations. One limitation is that in many developing countries mothers are not sufficiently literate to complete a questionnaire and have to be interviewed. However, the interview can be done at home, it is quicker than a formal assessment, and the interviewer requires lower skills than a tester. Several investigators have found maternal report reliable and valid [4]; however, others have questioned it [5]. Recognition (when the mother is asked about specific words) is likely to be quicker and more valid than recall (when the mother is asked what words the child uses) [6].

We developed a language test for children 12 to 18 months of age based on mothers' reports to be used in large-scale evaluations or surveys in Bangladesh. We took the opportunity of an ongoing cohort study (MINIMat) [7] to assess the validity of the test. The specific aims were to examine the short- and longer-term reliability of the test; to determine the association between the children's language scores at 18 months of age and concurrent scores on the Bayley Scales and future IQ at 63 months; to examine the associations between the language scores and the children's nutritional status, socioeconomic background, and stimulation in the home; and to compare the Bayley Scale and the language test for their predictive ability and the above associations.

Methods

Location

The study was located in Matlab, a poor rural subdistrict in the east-central plain of Bangladesh. Farming and fishing are the main occupations, and about 85% of the population are Muslim. The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) has a Health and Demographic Surveillance System (HDSS) that has recorded vital demographic information in the area since 1966.

MINIMat study

The study piggybacked a large cohort study run by ICDDR,B concerning the effects of nutritional supplementation in pregnancy. In that study, using the HDSS, all pregnant women in the area were enrolled in early pregnancy and randomized twice, first to early (E) or usual (U) food supplementation and then to a) multiple micronutrients, b) iron (60 mg) and folic acid, or c) iron (30 mg) and folic acid supplementation, making six groups i.e. E+a, E+b, E+c, U+a, U+b and U+c. There was no overall benefit from any of the supplements on children's development; however, children of mothers who were undernourished on enrollment (body mass index [BMI] < 18.5 kg/m²) showed small benefits at 7 months of age from early food on problem-solving ability and from multiple micronutrients on motor development [7]. However, no benefits remained at 18 months (Hamadani, unpublished results).

Sample

We selected a subsample to study child development, consisting of all live, singleton babies born between 20 May 2002 and 20 December 2003 (n = 2,853). We followed the children to 18 months of age, when all children were visited and weighed and 2,418 (85%) of the 2,853 mothers were interviewed at home concerning their children's language ability. Among the losses, 15.6% refused to participate, 11.5% migrated, 6.2% were sick at the time of interview, 20.5% had died, 0.7% were disabled, and 42.3% were absent for a long time and were not found on repeated visits to the home. In addition, the language test was only ready for use after the home visiting had started, and a further 3.2% of mothers who were visited before the test was ready were not given the test.

The main focus of the study was children around 18 months of age. However, a subsample of 1,429 children who reached 12 months after the language test was introduced with the 18-month children were also given the language inventory at 12 months of age. These data were only used to assess the long-term test–retest reliability of the scores over time.

Measurements and procedure

Socioeconomic status

On enrollment, mothers were interviewed and information was obtained about the number of household possessions (e.g., television, radio, domestic animals, chairs, tables, beds, bicycles, rickshaws, etc.), land ownership, and construction materials of the walls of the house. A wealth index was created using principal components analysis by giving weight to each of the items above, and the households were divided into socioeconomic status quintiles based on this wealth index [8]. In addition, deficits between income and expenditure (occasional or constant deficit: yes/no), family structure, and parental age, education, and occupation were recorded.
**Anthropometry**

Maternal weight and height were measured on enrollment, and mothers' BMI was calculated as weight (kg)/height (m)$^2$. Length and weight of children were measured at birth and 18 months, using standard procedures [9]. The 18-month heights and weights were converted to standard scores using the new World Health Organization (WHO) growth chart [10].

**Home stimulation**

At 18 months, the mothers were interviewed with a modified version of Home Observation for Measurement of Environment (HOME) [11] that measures the quality of stimulation in the home through a combination of observations and maternal report. Each item was scored as 1 for a correct response and 0 for an incorrect or absent response. One of four research assistants who were extensively trained and had achieved good interobserver reliabilities with the trainer [12] interviewed the mothers and observed the children in their homes. A total HOME score was computed by summing the scores of all maternal report and observation items, and this score was used in the analysis.

**Developmental assessment**

At 18 months, the revised version of Bayley Scales of Infant Development (BSID-II) was used to assess the children's mental (MDI) and psychomotor (PDI) development indices [13]. The Bayley test was standardized in the United States. It has not been standardized for Bangladesh, but it has been used in several previous studies there [14–16]. It has also been used in many other developing countries, including Indonesia [17], Guatemala [18], and India [19]. One of the five psychologists tested the children at a local clinic near their residence. Before the study began, the psychologists were extensively trained and achieved good interobserver reliabilities with the trainer [12]. The same cohort of children was recently tested at 5 years 3 months (63 months) of age using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI) [20], which measures children's intelligence quotient (IQ). The scale has three subtests—verbal (VIQ), performance (PIQ), and processing speed (PSIQ)—and a full-scale IQ (FSIQ). Only the PIQ and VIQ were assessed.

The test was translated and piloted in the same population, and minor modifications were made to make it culturally appropriate for use in rural Bangladesh. Test–retest correlations for FSIQ, VIQ, and PIQ were $(r = 0.93, r = 0.89, and r = 0.84$, respectively; $p = 0.01$ for all) [Shiraji, personal communication].

**Language inventory**

We based our inventory for Bangladesh on the principles of the MacArthur Communicative Development Inventories: Words and Gestures [6]. The MacArthur Inventories were developed in the United States and depend on the mothers recognizing the words and actions that their child comprehends or uses to communicate. There is a short version of 89 words based on the long version, which contains only nouns, verbs, and sounds but no gestures [21].

To develop an inventory for Bangladesh, it would not have been valid to translate the MacArthur Inventory, because the language environment of the children is very different. We therefore began by interviewing 50 mothers of children aged 12 to 36 months, seeking information on the words their children understood or used. We probed specific categories taken from the MacArthur Inventory, including words for animals, vehicles, toys, food and drink, clothing, body parts, furniture, small household items, outside things and places to go, people, verbs, sounds (animal noises, etc.), phrases, games and routines, descriptive words, pronouns, question words, words about time, quantifiers, and prepositions and locations. We obtained 495 words and listed them by category and interviewed a further 100 mothers of children aged 11 to 19 months, first asking about the words listed, then probing for more words. The words mentioned were then arranged in order of frequency mentioned and by category. From the 495 words, we then selected 60 words across 15 categories, using 40 words of moderate difficulty (known by 40% to 60% of the children) and 10 easy and 10 more difficult words. We dropped five categories, as there were insufficient suitable words (pronouns, question words, words about time, quantifiers, and prepositions and locations). The final inventory had two subscales; words comprehended and words expressed. We assessed short-term test–retest reliability by interviewing 20 mothers of children aged 12 months and 15 mothers of children aged 18 months twice, 7 to 14 days apart.

**Statistical analysis**

All data were checked for normality. The language expression score was skewed, and a log-10 of the variable was used to normalize the data. The long-term reliability of the language subscales from 12 to 18 months was assessed using intraclass correlation coefficients. To investigate the concurrent and predictive validity of the language subscales, partial correlations, controlling for child's age, were computed between the language expression and comprehension and the Bayley MDI and PDI scores at age 18 months and the WPPSI, VIQ, PIQ, and FSIQ at age 5 years.

The relationship of the child development outcomes at 18 months—language expression and comprehension and Bayley MDI and PDI—with family and child characteristics was examined by partial Pearson's correlations controlling for child's age.

Growth in length since birth was computed by regressing birth length, age, and sex on child length at
Results

The test–retest reliability for comprehension and expression over 7 to 14 days was $r = 0.78$ and 0.84, respectively, at 12 months, and $r = 0.67$ and 0.99, respectively at 18 months. This compares reasonably well with the short-term reliability of the full infant form of the MacArthur Inventory of $r = 0.8$ to 0.9 for each month of age, except for 12 months, which was $r = 0.6$ [6].

We gave the language inventory test to 2,418 mothers of infants around 18 months of age. Complete datasets with all relevant covariates were available for 2,098 children (87%) 18 months of age (range, 17 to 22 months), and data for these children were used in the analyses. Of these, 2,098 children, 1,803 (75%) were also assessed on the Bayley Scales of Infant Development. There were significant differences between children included in the analyses and those not included in several enrollment variables, including maternal education (included mean [± SD] = 4.7 ± 4.1, not included mean = 5.6 ± 4.9, $p < 0.0001$), paternal education (included mean = 5.2 ± 4.1, not included mean = 6.1 ± 4.7, $p < 0.0001$), wealth (included mean = 2.9 ± 1.4, not included mean = 3.2 ± 1.4, $p < 0.0001$), birthweight (included mean = 2,702.1 ± 365.7, not included mean = 2,614.4 ± 452.3, $p < 0.0001$), and birth order (included mean = 2.4 ± 1.4, not included mean = 1.9 ± 1.1, $p < 0.0001$). Except for birthweight, the lost children tended to be better off.

Family and child characteristics of the tested sample are given in Table 1. The children came from very poor homes. The average child was moderately stunted, and their mean birthweight was only 2.7 kg. The parents had low levels of education, and nearly 20% reported deficits between income and expenditure.

### Table 1. Family and child characteristics of children given the language test ($n = 2,098$)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family</strong></td>
<td></td>
</tr>
<tr>
<td>Mother's age (yr)</td>
<td>26.7 ± 6.0</td>
</tr>
<tr>
<td>Mother's education (yr)</td>
<td>4.7 ± 4.1</td>
</tr>
<tr>
<td>Mother's BMI (kg/m(^2))</td>
<td>20.1 ± 2.7</td>
</tr>
<tr>
<td>Father's education (yr)</td>
<td>5.2 ± 4.5</td>
</tr>
<tr>
<td>Income–expenditure: occasional or constant deficit (%) ($n = 425$)</td>
<td>19.5</td>
</tr>
<tr>
<td>Assets (factor score)</td>
<td>−0.13 ± 2.35</td>
</tr>
<tr>
<td>Stimulation in the home (HOME)</td>
<td>83.5 ± 7.0</td>
</tr>
<tr>
<td><strong>Child</strong></td>
<td></td>
</tr>
<tr>
<td>Age (mo)</td>
<td>18.2 ± 1.0</td>
</tr>
<tr>
<td>Weight-for-height z-score at 18 mo</td>
<td>−0.9 ± 1.0</td>
</tr>
<tr>
<td>Height-for-age z-score at 18 mo</td>
<td>−2.0 ± 1.1</td>
</tr>
<tr>
<td>Weight-for-age z-score at 18 mo</td>
<td>−1.6 ± 1.1</td>
</tr>
<tr>
<td>Birthweight (g)</td>
<td>2,702.0 ± 396.0</td>
</tr>
<tr>
<td>Birth length (cm)</td>
<td>47.8 ± 2.1</td>
</tr>
<tr>
<td>Gestational age at birth (wk)</td>
<td>39.1 ± 1.6</td>
</tr>
<tr>
<td>Birth order</td>
<td>2.43 ± 1.42</td>
</tr>
<tr>
<td>Bayley MDI ($n = 1,803$)</td>
<td>78.9 ± 12.4</td>
</tr>
<tr>
<td>Bayley PDI ($n = 1,803$)</td>
<td>93.8 ± 13.4</td>
</tr>
<tr>
<td>Language comprehension at 12 mo</td>
<td>22 (18–27)</td>
</tr>
<tr>
<td>Language expression at 12 mo</td>
<td>4 (3–6)</td>
</tr>
<tr>
<td>Language comprehension at 18 mo</td>
<td>38 (33–44)</td>
</tr>
<tr>
<td>Language expression at 18 mo</td>
<td>10 (6–15)</td>
</tr>
</tbody>
</table>

BMI, body mass index; HOME, Home Observation for Measurement of Environment; MDI, Mental Development Index; PDI, Psychomotor Development Index

\(^a\) Plus–minus values are means ± SD. Values followed by parentheses are medians (interquartile range)

Reliability and validity of the language inventory

The long-term reliability of the language expression and comprehension measures, between 12 and 18 months of age in 1,429 children was $r = 0.51$ for comprehension and $r = 0.50$ for expression.

The correlations of the language inventory with the
Bayley test at age 18 months ranged from 0.20 (with the Bayley PDI) to 0.41 (with the Bayley MDI) (table 2). With the WPPSI full-scale IQ at age 63 months, the correlations ranged from $r = 0.37$ to 0.41 (table 2). This is very similar to those of the Bayley MDI scores ($r = 0.37$) and slightly better than the PDI ($r = 0.28$).

**Associations between developmental outcomes and other variables**

We then examined whether the language and Bayley scores were associated with the child and family characteristics given in table 1. Nearly all the variables were significantly correlated with the developmental outcomes; however, the correlations were generally small. The highest correlations were between stimulation in the home and the language scores (table 3).

The multiple regression analyses (table 4) show that children’s language and Bayley scores were independently associated with a similar set of variables. Both language scales and the MDI and PDI were predicted by child’s age, stimulation in the home, gestational age, and postnatal growth in length. The standardized effect sizes for stimulation in the home were 0.12 for the Bayley PDI, 0.15 for the MDI, 0.40 for language expression, and 0.55 for language comprehension. The standardized effect sizes for gestational age were 0.16 for the PDI, 0.09 for the MDI, 0.06 for language expression, and 0.05 for language comprehension. The standardized effect sizes for growth in length were 0.24 for the PDI, 0.14 for the MDI, 0.10 for language expression, and 0.07 for language comprehension. Child sex predicted child language scores only (the effect sizes were 0.24 for language expression and 0.08 for language comprehension), with girls having higher scores. Other significant independent predictors were mother’s age (language comprehension), mother’s education (language expression), wealth index (MDI), income–expenditure ratio (language comprehension), and birth order (MDI). More of the variance in the scores was explained for children’s language scores (25.4% for expression and 36.6% for comprehension) than for children’s Bayley scores (15.9% for the MDI and 12.9% for the PDI). We reran the regressions entering weight residuals instead of height residuals. There was little difference in the results, and the weight residuals were significant in all four regressions (data not shown).

**Discussion**

We developed a language test based on mother’s reports and using the constructs of the short form of the MacArthur Communicative Development Inventory. The test was easy to give and took no more than 15 minutes. No equipment except a record form was needed. The concurrent correlations of the language scores with the Bayley MDI were moderate and better than those with the PDI. This difference was expected, because the MDI includes some language items, whereas the PDI contains predominantly motor items.

Long-term reliability over time between 12 and 18 months of age was $r = 0.51$ for comprehension and $r = 0.50$ for expression. This compares with a reliability of $r = 0.39$ for verbal expression for the full MacArthur Inventory from 12 to 24 months of age in 2,156 children [23] and $r = 0.69$ for just over 6 months from 13.5 to 20.2 months in 217 children [24]. The spread of ages was narrower in the Bangladeshi study than in the full Mac Arthur Inventory.

The untested children were significantly different from the tested children in several variables. However, this should not affect the findings to any extent, because we were not interested in the absolute level of the scores but in their relationship with other concurrent and future variables. There is no obvious reason why the relationship should be different in the untested and tested children. Also, many of the differences were small and were significant only due to large sample

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**TABLE 2. Validity of the language test: Partial correlations after controlling for child’s age at 18 months**

<table>
<thead>
<tr>
<th>Test</th>
<th>Expression</th>
<th>Comprehension</th>
<th>Bayley MDI</th>
<th>Bayley PDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayley MDI at 18 mo</td>
<td>0.41</td>
<td>0.32</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>(n = 2,038)</td>
<td>(n = 2,038)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayley PDI at 18 mo</td>
<td>0.20</td>
<td>0.24</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>(n = 2,038)</td>
<td>(n = 2,038)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPPSI verbal IQ at 5 yr</td>
<td>0.32</td>
<td>0.37</td>
<td>0.37</td>
<td>0.25</td>
</tr>
<tr>
<td></td>
<td>(n = 2,110)</td>
<td>(n = 2,111)</td>
<td>(n = 1,882)</td>
<td>(n = 1,882)</td>
</tr>
<tr>
<td>WPPSI performance IQ at 5 yr</td>
<td>0.30</td>
<td>0.35</td>
<td>0.29</td>
<td>0.24</td>
</tr>
<tr>
<td></td>
<td>(n = 2,110)</td>
<td>(n = 2,111)</td>
<td>(n = 1,882)</td>
<td>(n = 1,882)</td>
</tr>
<tr>
<td>WPPSI full-scale IQ</td>
<td>0.37</td>
<td>0.41</td>
<td>0.37</td>
<td>0.28</td>
</tr>
<tr>
<td></td>
<td>(n = 2,110)</td>
<td>(n = 2,111)</td>
<td>(n = 1,882)</td>
<td>(n = 1,882)</td>
</tr>
</tbody>
</table>

MDI, Mental Development Index; PDI, Psychomotor Development Index; WPPSI, Wechsler Preschool and Primary Scale of Intelligence
The ability of tests of infant development to predict later IQ is generally limited and increases with age [25]. In a review of longitudinal studies using any infant development test, the average correlation between tests given between 13 and 30 months of age with IQ between 5 and 7 years was $r = 0.34$ to $0.39$ [25]. The ability of language scores to predict future IQ was similar.

The mean MDI scores in this study were particularly low. Nearly all children were extremely disadvantaged, and many were at least moderately stunted, which would account for their generally low scores. In another Bangladeshi study, less disadvantaged urban children at 10 months of age had mean MDI and PDI scores around 100, which is the mean of the standardization sample [14]. Furthermore, the MDI scores had very similar predictive ability with IQ at 63 months ($r = 0.37$) to that reported by Colombo from studies elsewhere [25].

The language scores were related to most of the same variables that the MDI was related to, including nutritional status, home stimulation, and socioeconomic background, and more of the variance in language was explained. The association with HOME was particularly strong with language. The HOME also depends on mothers’ reports to some extent. It is possible that better-educated and more intelligent mothers report better performance on both the HOME and their child’s language. However, when we controlled for maternal education and socioeconomic background, the HOME effect remained large. It appears that language is particularly sensitive to the home environment.

The effect of postnatal growth was stronger for motor development than for mental and language development. This has been found before [18], and it is well recognized that motor development is the first to benefit from supplementation with protein and calories [31] in children under 2 years of age.

Child’s age was positively related to language scores...
The language scores are not corrected for age, and the children ranged in age from 17 to 22 months, so an improvement with age is expected, whereas the Bayley scores are corrected for age, and the decline with age represents a decline compared with the average child in the standardization sample. Such declines, even over the small age range in this study, are expected in children as disadvantaged as these very poor Bangladeshi children [32].

This language test should be suitable for other rural areas in Bangladesh but would need to be piloted before use in urban Bangladesh. We have recently extended the test to 30 months of age. Similar tests could be developed in other developing countries.

In conclusion, we designed a language test based on mothers’ reports that was given to 18-month-old children. It proved easy to give and reliable, had acceptable predictive validity with IQ, and compared favorably with the Bayley Scales MDI. It was also sensitive to stimulation in the home and postnatal growth. The results suggest that mothers’ reports of language could be useful in large surveys or in evaluations of early childhood intervention programs when the aim is to improve language or cognitive development.

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**TABLE 4. Multiple regression analyses on children’s language expression and comprehension (n = 2,098) and Bayley MDI and PDI (n = 1803) at age 18 months**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Expression B (95% CI)</th>
<th>Comprehension B (95% CI)</th>
<th>MDI B (95% CI)</th>
<th>PDI B (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s age</td>
<td>0.02*** (0.01, 0.02)</td>
<td>0.50** (0.18, 0.82)</td>
<td>-2.14*** (-2.64, -1.64)</td>
<td>-1.75*** (-2.30, -1.19)</td>
</tr>
<tr>
<td>Child’s sex</td>
<td>0.03*** (0.02, 0.04)</td>
<td>0.66* (0.12, 1.21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother’s age</td>
<td>0.07** (0.03, 0.12)</td>
<td>0.63*** (0.59, 0.67)</td>
<td>0.27*** (0.18, 0.36)</td>
<td>0.24*** (0.15, 0.32)</td>
</tr>
<tr>
<td>Stimulation in the home</td>
<td>0.007*** (0.007, 0.008)</td>
<td>0.63*** (0.59, 0.67)</td>
<td>0.27*** (0.18, 0.36)</td>
<td>0.24*** (0.15, 0.32)</td>
</tr>
<tr>
<td>Mother’s education</td>
<td>0.002** (0.001, 0.004)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wealth</td>
<td></td>
<td>0.89*** (0.43, 1.34)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age</td>
<td>0.004** (0.001, 0.007)</td>
<td>0.25** (0.08, 0.42)</td>
<td>0.67*** (0.34, 1.00)</td>
<td>1.32*** (1.00, 1.68)</td>
</tr>
<tr>
<td>Growth in length</td>
<td>0.014*** (0.008, 0.02)</td>
<td>0.59*** (0.28, 0.90)</td>
<td>1.85*** (1.24, 2.47)</td>
<td>3.39*** (2.73, 4.06)</td>
</tr>
<tr>
<td>Birth order</td>
<td></td>
<td>1.83*** (1.11, 2.55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R² = 25.4%, F = 119.11***</td>
<td>R² = 36.4%, F = 171.51***</td>
<td>R² = 15.3%, F = 55.20***</td>
<td>R² = 12.4%, F = 64.77***</td>
<td></td>
</tr>
</tbody>
</table>
Canadian International Development Agency (CIDA), Embassy of the Kingdom of the Netherlands (EKN), Swedish International Development Cooperation Agency (Sida), Swiss Agency for Development and Cooperation (SDC), and Department for International Development, UK (DFID). The authors thank all the mothers and children who participated in the study, the members of the MINIMat team, the testers (Shamima Shirazi, Musarrat Rubina Mannan, Mahfuza Rahman, Qamrun Nahar, and Zohura Parveen), and interviewers (Fatema Khatun, Shiuli Rani Das, Saleha Begum, and Nasima Akhtar).

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