

**MICRONUTRIENT SPRINKLES FOR
USE IN INFANTS AND YOUNG CHILDREN:
GUIDELINES ON RECOMMENDATIONS FOR USE
AND PROGRAM MONITORING AND EVALUATION**



Sprinkles Global Health Initiative

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TABLE OF CONTENTS

Preface.....	2
Introduction.....	3
Background.....	4
Magnitude of problem.....	4
Micronutrient Sprinkles.....	4
Advantages of Sprinkles.....	5
Recommendations.....	6
Sprinkles formulations.....	6
Schedule of administration.....	7
Distribution and storage instructions.....	7
Instructions for use.....	8
Sprinkles use in areas of high malaria transmission.....	9
Key messages.....	10
Monitoring and evaluation	11
Process evaluation.....	11
Impact evaluation.....	13
Where to access more information.....	15
References.....	15
Suggestions for further readings.....	16
Appendices.....	17



PREFACE

Home fortification of weaning foods with Sprinkles is an important advancement in the global challenge to reduce childhood anemia resulting from iron and other micronutrient deficiencies. The goal of the Sprinkles Global Health Initiative is to reduce the global burden of anemia and micronutrient deficiencies by advocating home fortification strategies to increase the micronutrient content of weaning foods. This can be achieved through the promotion of healthy weaning practices, and by making micronutrient Sprinkles widely available, particularly in developing countries. Sprinkles were developed at the Hospital for Sick Children, Toronto, Canada to improve the micronutrient status of infants and children in order to help meet their genetic potential for physical and intellectual growth and good health. This publication was written to help program planners and managers develop effective strategies for preventing and controlling anemia and micronutrient deficiencies in infants and young children using Sprinkles.

This document first provides a background on Sprinkles. It then provides guidelines on their recommendations for use, followed by recommendations for program monitoring and evaluation.

Action is urgently needed to help solve the problem of anemia and micronutrient deficiencies in infant and young children.

It is hoped that the information provided in this document will allow program planners and managers to implement Sprinkles programs that are country specific to aid in the reduction of anemia and micronutrient deficiencies among infants and young children worldwide.

Stanley Zlotkin

Head and Founder, Sprinkles Global Health Initiative



INTRODUCTION

Since 1997, the ‘Sprinkles project’ has progressed from an ambitious idea to a sustainable operational reality. With ongoing research and development, Sprinkles have shown to be a strategy that is both feasible and sustainable in real-life settings in the developing world. The development of Sprinkles has followed a pathway which includes three discrete components: (i) demonstrating proof of their efficacy and effectiveness at different doses, formulations and regimens through community-based research projects in different populations of children at risk; (ii) obtaining a sustainable, inexpensive supply and general support of the manufacturing of Sprinkles; and (iii) program development for country-wide distribution. There is growing recognition of Sprinkles by the international nutrition and health community as an intervention that holds great potential for reducing the prevalence of anemia and micronutrient deficiencies among young children worldwide. As a new goal has been set by UNICEF to significantly reduce the prevalence of anemia in women and children by 2010, it is hopeful that Sprinkles will make a significant contribution towards achieving this goal.



BACKGROUND

Magnitude of the Problem

Recent WHO/UNICEF estimates suggest that the number of children with iron deficiency and anemia is approximately 750 million (UNICEF 2003). Iron deficiency remains the most common preventable nutritional deficiency despite continued global goals for its reduction (WHO 2001). In developing countries, it is estimated that more than 40 to 50% of children less than 5 years of age are iron deficient, primarily due to a diet inadequate in bioavailable iron (UNICEF/MI 2004).

Micronutrient deficiencies are a form of malnutrition caused by deficiencies of vitamins and minerals (also known as micronutrients) from the diet that are essential for human health, growth and development. Among the populations most vulnerable to micronutrient malnutrition are infants, young children and pregnant women due to their higher dietary requirements. Vitamin and mineral deficiencies affect a third of the world's people and account for an estimated 7.3% of the global burden of disease. Children under two are particularly vulnerable to micronutrient deficiencies. This form of malnutrition is often a major public health problem in populations in the developing world where the availability of a diverse supply of foods is limited. Common deficiencies among children include those of iron (as mentioned above), vitamin A, zinc and iodine. Micronutrient deficiencies put people at increased risk of early mortality, disease, and disability.

Micronutrient Sprinkles

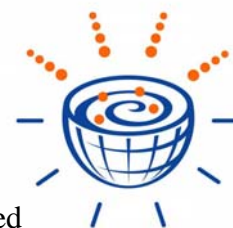
Sprinkles is an innovation in 'home-fortification' to address vitamin and mineral deficiencies. Sprinkles are a unique delivery system to provide micronutrients to vulnerable populations enabling families to fortify many different semi-solid foods in the home.

Sprinkles are sachets (like small packets of sugar) containing a blend of micronutrients in powder form, which are easily sprinkled onto foods prepared in the home. Any homemade food can be instantly fortified by adding Sprinkles. Coating of the iron prevents changes to the taste, colour or texture of the food to which Sprinkles are added. Sprinkles were developed by the Sprinkles Global Health Initiative to prevent and treat anemia and micronutrient deficiencies among young children and other vulnerable groups at risk.



Advantages of Sprinkles

1. Sprinkles can provide the Recommended Nutrient Intake (RNI) of micronutrients to each child.
2. Aside from iron, essential micronutrients such as vitamins A, C and D, folic acid, iodine and zinc can be added to the sachets to prevent and treat micronutrient deficiencies and improve overall nutritional status.
3. Lipid encapsulation of the iron prevents its interaction with food and masks its taste, thus there are minimal changes to the taste, colour or texture of the food to which Sprinkles are added. Encapsulation may also reduce gastrointestinal discomfort and interaction of iron with other nutrients.
4. The sachets are easy to use and convenient. No special measuring utensils or handling is required and they can be given at any mealtime during the day. One does not have to be literate to learn how to use them.
5. The use of Sprinkles does not require any change in food practices as it can be mixed with home-made foods. They do not conflict with breast-feeding and can help promote the timely transition from exclusive breast-feeding to complementary foods at 6 months of age as recommended by the WHO.
6. Sprinkles are a food-based rather than a medical intervention and thus can be easily incorporated into any feeding schedule.
7. The potential for overdose is unlikely because numerous individual packages would have to be opened and ingested for this to occur (an infant would need to consume many packages (approximately 20) to reach toxicity levels).
8. The sachets are lightweight and thus are simple to store, transport and distribute. Sprinkles have a long shelf-life, even in hot or humid conditions (2 years).
9. The cost of Sprinkles is not excessive (0.015-0.035 US \$ per sachet depending on volume produced and site of production). The packaging of Sprinkles is attractive and thus is easily accepted.



One of the greatest benefits of the Sprinkles concept is that it can be easily incorporated into currently recommended complementary feeding practices for infants after 6 months of age. In many developing countries, poor infant weaning practices are common, such as prolonged exclusive breastfeeding, delayed introduction of semi-solid foods and feeding of poor quality complementary foods with low iron bioavailability. Aside from providing iron and other micronutrients, the Sprinkles intervention can contribute to healthy infant weaning practices through the concurrent promotion of appropriate weaning practices, since Sprinkles can only be used with complementary foods.

Program planners and managers may choose to use Sprinkles in a ‘stand-alone’ type program, or as a part of a more comprehensive approach including the promotion of the essential nutrition information for child development as described in ‘Facts for Life’ documents published by United Nations Agencies. These essential nutrition messages are meant to be given to parents, caregivers, health workers, government officials, journalists and teachers to promote the normal growth of young children (**Appendix A**).

RECOMMENDATIONS

Sprinkles formulations

Sprinkles has two standard formulations: the Nutritional Anemia Formulation and the Multi-Micronutrient Formulation.

Composition of Nutritional Anemia Formulation Sprinkles

Micronutrient	Amount
Iron	<i>12.5 mg</i>
Zinc	<i>5 mg</i>
Folic Acid	<i>160 µg</i>
Vitamin A	<i>300 µg RE</i>
Vitamin C	<i>30 mg</i>

Composition of Multi-Micronutrient Formulation Sprinkles

Micronutrient	Amount
Vitamin A	<i>400 µg RE</i>
Vitamin C	<i>30 mg</i>
Vitamin D	<i>5.0 µg</i>
Vitamin E	<i>5 mg a-TE</i>
Vitamin B1	<i>0.5 mg</i>
Vitamin B2	<i>0.5 mg</i>
Vitamin B6	<i>0.5 mg</i>
Vitamin B12	<i>0.9 µg</i>
Folic Acid	<i>150 µg</i>
Niacin	<i>6 mg</i>
Iron	<i>12.5 mg</i>
Zinc	<i>4.1 mg</i>
Copper	<i>0.56 mg</i>
Iodine	<i>90 µg</i>



The Sprinkles formulations contain iron and other micronutrients as a means to control the development of nutritional anemias and/or other common micronutrient deficiencies. Aside from iron, the formulations include micronutrients needed for increased iron absorption (vitamin C), for proper iron metabolism and/or maintenance of an anemia-free state (vitamin A and folic acid) and for proper growth and immune function (zinc and vitamin A). The level of nutrients used in the formulations are based on bioavailability and dose response studies using Sprinkles as well as the Recommended Nutrient Intakes published by the WHO (2002) and the Dietary Reference Intakes of the North American Institutes of Medicine (a private, non-profit organization that provides health policy advice under government funding to the National Academy of Sciences).

Schedule of administration (time and duration of use)

The schedule of administration for Sprinkles will depend on the country, the target population, and the chosen distribution model and channel.

The current INACG/WHO/UNICEF recommendation is to provide daily iron supplementation to all infants 6-24 months of age where the prevalence of anemia is at least 40% (Stoltzfus and Dreyfuss 1998). From previous studies on the Sprinkles intervention, there is evidence that the administration of 60 Sprinkles sachets is adequate to rapidly improve hemoglobin concentrations and iron stores in a large proportion of young children. After ingestion of 60 sachets, hematologic benefits have shown to be sustained over a period of 6 months. Thus, Sprinkles may not be required for a prolonged period of time. For public sector distribution (free distribution), it is therefore suggested to use age milestones which are clear and easy to remember. For example, a possible schedule of administration would be to give 60 Sprinkles sachets over 60-120 days starting when complementary foods are introduced at 6 months of age, and repeated at 12 and 18 months of age. In this case, Sprinkles distribution can be integrated into already existing programs targeted at infants and young children such as complementary feeding programs, immunization days or vitamin A campaigns.

Distribution and storage instructions

After delivery to a central distribution centre, Sprinkles should be stored or warehoused properly. Storage areas should be hygienic, free of pests and contamination from chemical or other residues and ideally protected from undesirable climatic conditions.

It is recommended that Sprinkles sachets be distributed to individual families in a secondary package, such as a polyethylene bag or a small box, so they can be easily stored within the homes of families. Even though Sprinkles are stable in both hot and cold climates, it is recommended whenever possible to store the Sprinkles sachets in a cool, dry, and clean place within the home.



Instructions for use

1. Who should use Sprinkles

Sprinkles should be used by young children 6–24 months of age.

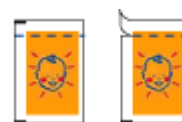
2. Who should not use Sprinkles

Iron-containing supplements should be withheld from severely malnourished children during the first 7 days of acute rehabilitation (according to WHO guidelines). Sprinkles can be used effectively and safely after the child has received adequate nutritional rehabilitation.

Until further evidence becomes available on the safety of iron supplements during infectious episodes, it would be prudent to withhold giving any iron intervention (including Sprinkles) to a child presenting with fever to minimize the potential that iron could exacerbate the infection.

3. Standard guidelines for using Sprinkles

Tear open the top of the package



Pour the entire contents of the package into any semi-liquid food after the food has been cooked and has cooled to a temperature acceptable to eat



Mix Sprinkles with an amount of food that the child can consume at a single meal



Mix the food well after you have added the package of Sprinkles

Give no more than one full package per day at any mealtime



Do not share the food to which Sprinkles were added with other household members since the amount of minerals and vitamins in a single package of Sprinkles is just right amount for one child.



The food mixed with Sprinkles should be eaten within 30 minutes because the vitamins and minerals in the Sprinkles will cause the food to gradually darken.





Involving other caregivers in the family in feeding Sprinkles to the child should be encouraged. In addition, it is important to inform caregivers that Sprinkles is not a substitute for feeding nutritious foods to their child and that they should continue to feed their child a variety of good quality, nutritious foods.

Sprinkles can be added to *any* semi-solid complementary foods cooked in the household. No alcohol or porcine products are used in the production of Sprinkles, thus they may be used as part of a traditional Muslim or Jewish diet. Because of the lipid coating of the iron, Sprinkles do not mix well with liquids such as drinks, breast milk and soup (they float to the top of the liquid). Therefore, it is recommended that Sprinkles not be mixed into liquids.

4. Managing side effects of Sprinkles

A crucial point to consider and integrate in the training of health workers is the occurrence of potential side effects when using Sprinkles. Caregivers should be informed about possible side effects and how to manage them. Results of clinical studies show side effects to be minimal. Potential side effects include darkening of the stool, constipation or mild diarrhea. It is important, however to ensure caregivers are aware of these side effects to prevent them from discontinuing the use of Sprinkles should they occur. Parents should be told that these mild side-effects are not serious and should most likely subside in a few days to a few weeks. If the side effects do not subside after a few days to a few weeks, caregivers should use half a package of Sprinkles added to complementary foods at 2 different mealtimes throughout the day. For example, if half a Sprinkles package is added to the complementary food in the morning, the other half should be added at the next mealtime. If the side effects still do not subside, caregivers should be advised to divide a Sprinkles package in 3 and feed it throughout the day with complementary foods at 3 different mealtimes.

Refer to **Appendix B** for Frequently Asked Questions.

Sprinkles use in areas of high malaria transmission

Sprinkles distribution programs in high malaria transmission areas should be integrated with malaria control programs such as the use of insecticide treated bed-nets or the treatment of detected cases of malaria. When implementing a Sprinkles program and wherever feasible, we recommended monitoring safety and adverse effects. Considering the conflicting results to date and the possibility that iron delivery may exacerbate malaria and other infectious diseases, it is crucial to ensure that iron interventions are safe for young children in all regions, especially where malaria is present. From both a biological and practical standpoint and until more data becomes available on the safety of long-term iron delivery to young children, it is recommended to provide Sprinkles for a shorter rather than longer period of time. A short-course regimen (e.g. 60 sachets) would ensure higher compliance and acceptability as compared to a longer-course regimen,



would be provided at a relatively low cost and would most likely reduce the chances of any negative adverse effects on health.

Refer to **Appendix C** for the official position statement by the Sprinkles Global Health Initiative.

Key messages

It is important to give consistent messages on how and when to take Sprinkles and on how to manage the potential side effects. It is also crucial to ensure that caregivers understand what to expect and what not to expect from the use of Sprinkles. Messages must be developed within the context of the community's current beliefs, attitudes and health knowledge.

Channels to convey messages will vary depending on the resources available. For example, messages can be communicated through the print and broadcast media such as radio, television or newspapers or simply by a poster or a brochure. Memory aids may also be developed to help caregivers remember to give Sprinkles to their child. Methods to promote community participation in the Sprinkles intervention are crucial to ensuring adherence to the intervention. For example, mothers who have been educated in the community about anemia and Sprinkles should help educate other caregivers (word of mouth).

Below is an example of a key message for caregivers who will give Sprinkles to their children:

- Vitamin and mineral deficiencies affect the health of your child.
- Sprinkles (which contain vitamins and minerals) can be added to your child's food to improve the quality of the food and to provide the needed vitamins and minerals.
- Sprinkles have been used in thousands of children around the world, and are safe and helpful to your child.

Refer to **Appendix D** to view general guidelines to follow when creating messages.



MONITORING AND EVALUATION

Monitoring and evaluation activities aim to produce credible information about the performance of a program in order to aid in improving the program, as an advocacy tool to funders and to provide justification for continuing the program. Any Sprinkles program should be carefully assessed with monitoring and evaluation in order to improve and adjust program operations, ensure the safety of beneficiaries, address issues preventing program success as they arise and to measure whether overall program objectives are achieved.

Monitoring is an on-going process and consists of collecting information on specific indicators designed to address all phases of the program from inception to completion. Evaluation is periodic and determines how well a program meets its objectives. There are many terms used to classify monitoring and evaluation activities and definitions may differ somewhat between documents. The terms used by INACG (Stoltzfus and Dreyfuss 1998) to categorize monitoring and evaluation activities, i.e. process evaluation and impact evaluation, will be used in this document and applied to the Sprinkles intervention.

Information can be collected and analyzed in many ways. The chosen evaluation design will depend on the project needs and resources.

The authors of this document acknowledge that monitoring and evaluation is challenging and it may not be possible to measure all of the indicators that are presented below. However, as is the case with any program, the more indicators that can be collected, the more easily a program can be adjusted to improve operations, take remedial measures to solve any problems encountered and measure whether or not the objectives of the program are achieved.

Process evaluation

Process evaluation is used to determine if the program is progressing as planned. It should answer questions such as whether the intended population is participating, whether the program is being implemented as planned, what activities are working well and what can be improved.

Below is a list of measurable indicators that should be used in process evaluation of the Sprinkles intervention. These are called *process indicators*:



Program Management

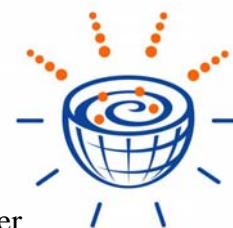
- **Budget dedicated and spent:** this assesses whether all of the personnel and resources are used appropriately and as planned, and if any changes are warranted.
- **KAP (Knowledge, Attitudes and Practices) of health workers and number of training activities undertaken:** this assesses whether health workers are communicating the right messages, educating the caregivers appropriately and being trained as planned, and if any changes are needed.

Inventory/Supply

- **Number of Sprinkles procured:** This ensures that the number of Sprinkles ordered meets program objectives.
- **Number of Sprinkles reaching supply centers:** This ensures that the number of Sprinkles received meets the number ordered.
- **Availability of Sprinkles at distribution points:** this assesses whether enough Sprinkles are delivered to the different distribution points as planned and if any changes are needed.
- **Storage conditions:** this assesses whether Sprinkles are stored adequately, as planned and if any changes are needed.
- **Quality of Sprinkles:** this assesses whether regular quality testing of Sprinkles is conducted as planned and if any changes are warranted.

Program Activities

- **Community education programs in place:** this evaluates whether the community education programs are occurring as planned and if any changes are needed.
- **Distribution system in place:** this evaluates whether the distribution system of Sprinkles is as planned and if any changes are warranted.
- **Number of Sprinkles distributed to the program beneficiaries:** this evaluates whether the necessary amount of Sprinkles is being delivered to the communities as planned and if any changes are needed.



- **Number of Sprinkles reported received by caregivers:** this assesses whether enough Sprinkles is being delivered to caregivers by asking them directly using data collection forms
- **Program coverage:** this assesses the percentage of intended recipients who actually received Sprinkles.

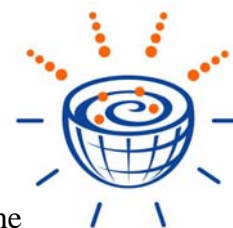
Program Effectiveness

- **Number Sprinkles sachets given to child and amount of Sprinkles consumed by child:** this evaluates *compliance*. It should be done by counting the number of empty sachets and the number of full sachets; by asking if any sachets were thrown out or lost and if yes, how many; by asking if any Sprinkles were used by any other member of the family and if yes, how many; by asking if the full contents of the sachet was usually used; and finally, by asking if the child ate all of the food in the bowl to which Sprinkles were added.
- **KAP of caregivers, community leaders or other agents:** this evaluates whether the intended messages and education materials are being communicated, understood and used properly by caregivers, community leaders or other agents, and if any changes are warranted.
- **Acceptability of the intervention:** this can be measured through focus groups or structure questionnaires. For example, caregivers should be asked about what they think of the different aspects of the Sprinkles intervention, such as the benefits to their children (eg: positive behavior changes), the characteristics (eg: color, size) of the Sprinkles sachet, their ease of use, attractiveness, advantages or disadvantages etc... Refer to **Appendix E** to view sample questions to ask caregivers.

Impact evaluation

Impact evaluation should be used to assess the program's effect on the health status of the target population as stated in the objectives and to improve program operations overtime. Indicators used are sometimes called *impact or outcome indicators*.

Ideally, the following indicators should be measured at the beginning and end of the intervention in all program beneficiaries. One or two midterm evaluations should also be conducted. Moreover, the changes in indicators should be linked to the degree of Sprinkles usage (coverage and compliance). However, this will rarely be possible due to the vast resources needed to accomplish this. Thus, valuable results can still be found by selecting a sub-sample of the population receiving Sprinkles and by measuring the indicators below. The major challenge however is to prove with absolute confidence that



the observed changes in indicators in the target population are directly related to the program, as other factors may influence results. Nevertheless, if available, information on the change in impact indicators of a representative sample of the target population receiving the Sprinkles intervention is still invaluable for motivating politicians, health administrators and the public to keep supporting the distribution of Sprinkles.

Below is a list of measurable impact indicators.

- **Sub-clinical deficiencies through biochemical assessment:** The feasibility of measuring biochemical indicators will depend on available material and financial resources. Assessment may include hemoglobin (as an indicator of anemia), urinary iodine (as an indicator of iodine deficiency) or serum zinc (as an indicator of zinc deficiency). If it is only possible to measure one indicator, it is recommended to measure hemoglobin concentration by using the portable battery-run Hemocue®. This user-friendly machine efficiently measures hemoglobin in the field from a whole blood capillary sample obtained via a simple finger prick. Proper training on the technique is essential to ensure consistency and to reduce measurement errors (Burger and Pierre-Louis). The cost of materials for measuring hemoglobin in the field (Hemocue cuvette, alcohol swab, needle and bandage) excluding the cost of the Hemocue® machine, is about USD\$ 1.10 per person.
- **Visible clinical signs of micronutrient deficiencies:** These may include xerophthalmia (as indicator of vitamin A deficiency), goiter (as indicator of iodine deficiency) and pallor of the skin and of the conjunctiva (as indicator of iron deficiency). The latter is the least specific.
- **Observed physical changes:** Although subjective and not as specific as visible clinical signs or biochemical assessments of deficiencies, indicators such as observed physical changes, observed increase in appetite and physical activity, a change in sleeping habits, or a change in mood and playfulness may also be used. For example, behavioral changes as reported by caregivers can be evaluated such as the onset of crawling, talking or walking. In addition, there may be physical changes in the child taking Sprinkles such as an observed change in growth rate or improvement in general health conditions. These impact indicators are also valuable to assess the program effect on the health status of children receiving Sprinkles and should be considered by program planners and managers.



WHERE TO ACCESS MORE INFORMATION

Website link: www.sghi.org

This website is useful for groups that are interested in Sprinkles research and programs, and wish to contact the Sprinkles Global Health Initiative. It provides detailed information on Sprinkles publications and on-going and past Sprinkles studies.

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SUGGESTIONS FOR FURTHER READING

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APPENDICES

Appendix A

What Every Family and Community Has a Right to Know about Nutrition and Growth

The essential messages are as follows:

- A young child should grow well and gain weight rapidly. From birth to age two, children should be weighed every month. If a child has not gained weight for about two months, something is wrong.
- Breast milk alone is the only food and drink an infant needs until the age of six months. After six months, the child needs a variety of other foods in addition to breastmilk.
- From the age of six months to two years, children need to be fed five times a day, in addition to sustained breastfeeding.
- Children need vitamin A to resist illness and prevent visual impairments. Vitamin A can be found in many fruits and vegetables, oils, eggs, dairy products, fortified foods, breast milk, or vitamin A supplements.
- Children need iron rich foods to protect their physical and mental abilities. The best sources of iron are liver, lean meats, fish, eggs, and fortified foods or iron supplements.
- Iodised salt is essential to prevent learning disabilities and delayed development in children.
- During an illness, children need to continue to eat regularly. After an illness, children need at least one extra meal every day for at least a week.

Source: Facts for life published jointly by UNICEF, UNESCO, UNFPA, UNDP, UNAIDS, the World Food Programme, and the World Bank.



Appendix B

FREQUENTLY ASKED QUESTIONS (FAQs) ABOUT SPRINKLES

What are the benefits of Sprinkles?

Answer: Along with good child care, health care and nutrition, Sprinkles can help:

- Prevent micronutrient deficiencies including anemia and zinc deficiency;
- Improve the body's immune system;
- Improve a child's appetite;
- Improve a child's energy;
- Improve a child's ability to learn and develop.

For children who are receiving high dose vitamin A capsules twice yearly is there any concern about vitamin A toxicity if they also receive Sprinkles, which also contain vitamin A?

Answer: There is negligible risk of toxicity even if associated with biannual high dose vitamin A supplementation. The dose of vitamin A in Sprinkles is formulated to help the child meet the *daily* vitamin A requirement, assuming additional vitamin A intake from breast milk and complementary food. As such, the use of Sprinkles as a 'home fortificant' complements high dose vitamin A capsule programs. When the WHO initiated the high dose vitamin A capsules, they did not stipulate that the child receiving the capsules should not eat food containing vitamin A. Indeed, they recommended an age-appropriate diet which would contain all micronutrients, including vitamin A.

Can Sprinkles be safely provided to non-anemic infants without producing any toxicity?

Answer: The amount of micronutrients in the Sprinkles sachets (about 1 RNI) is high enough to meet the needs of infants and young children with micronutrient deficiencies but not too high for those who have normal micronutrient status. The safety of Sprinkles has been demonstrated, even in young children without micronutrient deficiencies.

Sprinkles are recommended to be used in young children. Can Sprinkles be used in older children, adolescents, adults and pregnant women?

Answer: Sprinkles can be safely used in any other age groups such as children older than 59 months, adolescents and pregnant women without any risk of toxicity. However, Sprinkles were specifically developed for infants and young children as limited options exist for the treatment and prevention of micronutrient deficiencies in this age group. The reason Sprinkles should not be shared with any other members of the family is because



the young child in the family receiving Sprinkles should be receiving all of the benefits of Sprinkles.

Sprinkles has been put forward as a ‘home fortificant’ that will not change the taste or color of the food into which it is added. However, some parents have noticed a change in the taste and color of the food. Can this be explained?

Answer: In order to mask the strong metallic taste of the iron, the iron in the Sprinkles is coated or encapsulated with a thin coat of a lipid. The melting temperature for the lipid is around 60°C. If Sprinkles are added to food that is hotter than 60°C, the lipid coating around the iron will melt and the food will be exposed to the iron. This will result in undesirable color, taste and odor changes of the food, as iron is highly chemically reactive, dark in color and has a strong metallic taste. To prevent changes in the taste and the color of food to which Sprinkles is added, it is therefore recommended that Sprinkles be added to the food after it is cooled to a temperature below 60°C.

Why does loose stool consistency (loose stools or constipation) and colour change in infants when they start taking Sprinkles?

Answer: Stool consistency does not change in the majority of infants and children receiving Sprinkles. Stool colour, however, changes to a dark or black colour in all infants receiving Sprinkles on a regular basis. Iron itself is dark in colour. When some quantities are left unabsorbed, the iron is excreted in the stool and causes the change in colour. Some very young infants, who have not previously been exposed to any complementary foods containing micronutrients (i.e. who are exclusively breast-fed) may develop loose stools or even mild diarrhea. The diarrhea does not lead to dehydration, but is a valid concern to parents and health care providers. The diarrhea lasts for approximately one week and then will not recur. Parents have reported that diarrhea quickly disappears in these young infants, who are transitioning from breastfeeding to complementary feeding, if 1/3 - 1/2 of a Sprinkles sachet is used.

Loose stools may be caused by a change in bowel flora (microorganisms) associated with the introduction of iron into the diet or possibly the impact of ascorbic acid on bowel peristalsis in infants, who previously had received only very small amounts of ascorbic acid in their diets (in breast milk). Since loose stools have only been observed in infants transitioning from exclusive breastfeeding to complementary feeding, loose stools may possibly be unrelated to Sprinkles, and instead related to the change in stool pattern with the introduction of complementary foods.

Constipation is rarely reported with Sprinkles.



What are the risks of acute iron toxicity from an accidental overdose?

Answer: Symptoms of acute iron toxicity occur between 20 to 60 mg Fe per kg of body weight. A young child would need to consume many Sprinkles sachets (approximately 20) to reach toxicity levels. Single dose packaging, tastelessness of the Sprinkles powder and distribution of a limited supply are deterrents to accidental overdosing.

Can Sprinkles be mixed in breast milk or drinks like milk or juice?

Answer: If Sprinkles are mixed into liquids, the micronutrients will float to the top of liquids and tend to stick to the side of the cup or glass and therefore some will be lost in the process. It is therefore recommended not to add Sprinkles to liquids.



Appendix C

Date: March 27, 2006

Use of Sprinkles in high malaria transmission areas – Considerations for distribution programs

Key Message: Consistent with current WHO recommendations, home-fortification using Sprinkles during early childhood should be combined with malaria control strategies in areas where malaria transmission is high.

Iron supplementation in areas of high malaria transmission

The role of iron in the prevention and treatment of anemia in high malaria transmission areas remains a controversial issue. There are concerns that the administration of iron may exacerbate malaria and other illnesses in otherwise healthy, iron sufficient children. A large-scale randomized, double-blind, placebo-controlled trial conducted in Pemba, Zanzibar was recently published in the Lancet. Researchers found that under certain conditions, supplementation may be associated with adverse effects including increased risk of hospitalization and mortality, primarily due to malaria and other infectious diseases (1). These findings raise concerns about the safety of current WHO guidelines for universal iron and folic acid supplementation. As a result, WHO released a statement suggesting that "...caution should be exercised in settings where the prevalence of malaria and other infectious diseases is high" (2) when providing iron and folic acid supplementation to young children in malaria endemic regions (3). However "...at the present time WHO policy with regard to prevention and treatment of iron deficiency anaemia remains unchanged". Briefly, the statement advises that, "...until the WHO recommendations are revised it is advised that iron and folic acid supplementation be targeted to those who are anaemia and at risk of iron deficiency." In addition, it recommends that these children "...should receive concurrent protection from malaria and other infectious diseases through prevention and effective case management". Furthermore, the WHO advised that "...these conclusions should not be extrapolated to fortification or food-based interventions for delivering iron, where the patterns of iron absorption and metabolism may be substantially different".

Implications for using Sprinkles

Sprinkles is a food-based intervention since the micronutrient powder is added directly to foods (4). From research in West Africa, it has been determined that the iron from Sprinkles is well absorbed from a maize-based food and that infants have the capacity to regulate the amount that is absorbed according to needs (5). The current



INACG/WHO/UNICEF recommendation is to provide daily iron supplementation to all infants 6-24 months where the prevalence of anemia is at least 40% (6). From previous studies to date on the Sprinkles intervention, there is evidence that the administration of 60 Sprinkles sachets is adequate to rapidly improve hemoglobin concentrations and iron stores in a large proportion of young children. After the ingestion of 60 sachets, the hematologic benefits were sustained over a period of at least 6 months. Thus, Sprinkles may not be required for a prolonged period of time thus potentially lowering the risk of adverse effects.

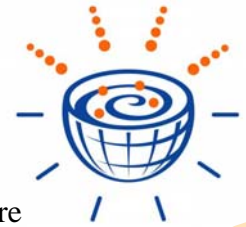
Recommendations

Considering the evidence to date, Sprinkles distribution programs in high malaria transmission areas should be integrated with malaria control programs such as the use of insecticide treated bed-nets or the treatment of detected cases of malaria. When implementing a Sprinkles program and wherever feasible, it is recommended to monitor for safety and adverse effects. Considering the conflicting results to date and the possibility that iron delivery may exacerbate malaria and other infectious diseases, it is crucial to ensure that iron interventions are safe for young children in all regions, especially where malaria is present. From both a biological and practical standpoint and until more data becomes available on the safety of the long-term delivery of iron to young children, we recommend the provision of Sprinkles for a shorter rather than longer period of time. A short-course regimen (e.g. 60 sachets) would ensure higher compliance and acceptability as compared to a longer-course regimen, would be provided at a relatively low cost and would most likely minimize any negative adverse effects on health. Until evidence is available, it would be prudent to withhold giving any iron intervention (including Sprinkles) to a child presenting with fever to minimize the potential that iron could exacerbate the infection. Further research and evaluation of programs should be conducted to develop the most effective strategies for controlling iron deficiency and anemia in regions where malaria transmission is high. The optimal dose, duration and delivery of iron need to be established to ensure that children in these regions gain the benefits of iron during the first years of life without increased risk to malaria or other infectious diseases. The WHO is planning a consultation which will set a research agenda in this area. The Sprinkles Global Health Initiative will continue to seek direction from the WHO on recommendations for iron delivery to children and pursue research to establish the safety of Sprinkles among populations where there is a high prevalence of malaria and infectious diseases.

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Sprinkles Global Health Initiative



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- (3) de Benoist B, Darnton-Hill I, Lynch S, Allen L, Savioli L. Zinc and iron supplementation trials in Nepal and Tanzania. *Lancet* 2006;367:816.
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- (5) Tondeur MC, Schauer CS, Christofides AL, Asante KP, Newton S, Serfass RE, Zlotkin SH. Determination of iron absorption from intrinsically labeled microencapsulated ferrous fumarate (sprinkles) in infants with different iron and hematologic status by using a dual-stable-isotope method. *Am J Clin Nutr* 2004;80(5):1436-44.
- (6) Stoltzfus RJ, Dreyfuss ML. (1998) Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia. INACG/WHO/UNICEF. International Life Sciences Institute, USA.



Appendix D

Below are some general guidelines to follow when creating messages with examples from Ghana where appropriate [taken from INACG document: “The role of communication in comprehensive anemia control: a framework for planning and implementing a strategic communication plan” (Hyde et al. 2003)]. The reader is referred to this document for help in designing a strategic communication plan.

1. Messages must be developed within the context of the audience’s current beliefs, attitudes, and emotions. For example, every Ghanaian mother wants to have a strong and healthy child.
2. The message should convey some information or an explanation about why the listener should care. For example, “Your child will be healthy and strong if he or she has enough blood.”
3. The message being sent very likely is competing with many other messages that the audience is receiving. Consequently, the message must be designed to break through that clutter or “noise”.
4. Remaining focused on the behavior change sought is essential when crafting the message. For example, “Giving your child a supplement or complementary food supplement will make him or her strong and healthy.”
5. The message must be sustained over time. Few communication campaigns have succeeded by delivering a single message one time. It is through repetition and hence reinforcement that people begin to internalize the message.
6. The tone of the message must be appropriately matched to the behavioral objective. For example, a humorous tone would not be fitting for a campaign about the importance of using insecticide-treated bed nets to prevent death from malaria.



Appendix E

Below are some of the questions that may be used in a questionnaire, given by trained health workers to caregivers, assessing the acceptability of the Sprinkles intervention (used by BRAC in Bangladesh in 2004):

1. Overall, how do you like using Sprinkles? (Rank answer on a point-scale from 'like extremely' to 'dislike extremely')
2. Which aspect of the Sprinkles intervention do you like?
3. Which aspect of the Sprinkles intervention do you dislike?
4. How do you rank the necessity of Sprinkles for your child's well being? (Rank answer on a point-scale from 'needs extremely' to 'don't need extremely')
5. What main effects do you expect the Sprinkles would have on your child's health?
6. When did you usually mix Sprinkles with your baby's food? (Rank answer on a point-scale with different mealtime throughout the day)
7. What disadvantages did you encounter when using Sprinkles?
8. Was there a change in the smell of the weaning food after mixing in the Sprinkles? (Rank answer on a point-scale from 'no additional smell' to 'strong additional smell')
9. Was there a change in the color of the weaning food after mixing in the Sprinkles? (Rank answer on a point-scale from 'no change' to 'strong change')
10. If the answer is other than 'no change', what type of color change occurred after mixing the Sprinkles to the weaning food?
11. Was there a change in the taste of the weaning food after mixing in the Sprinkles? (Rank answer on a point-scale from 'no change' to 'strong change')
12. As compared to before you used Sprinkles, do you think your child liked or disliked the weaning food after mixing in the Sprinkles? (Rank answer on a point-scale from 'liked more' to 'liked less')
13. Has your child's appetite changed after using Sprinkles? (Rank answer on a point-scale from 'improved' to 'worse than before')
14. Did Sprinkles mix well with the food used? (Rank answer on a point-scale from 'mixed very well' to 'not well at all')
15. What food did you find most appropriate to mix Sprinkles with? (List foods that are culturally appropriate)
16. How did you use Sprinkles for feeding to your child?
17. How many times a week would you prefer to feed Sprinkles to your child? (Rank answer on a point-scale from 'daily' to 'once weekly')
18. What is your suggestion about the total duration of feeding Sprinkles to your child? And why?
19. What do you think about the quantity of Sprinkles contained in a single serving sachet? (Rank answer on a point-scale from 'too much' to 'too less')
20. If Sprinkles were available in your frequently visited stores or with Health Workers at a reasonable price, how likely would you buy it? (Rank answer on a point-scale from 'definitely would buy it' to 'definitely would not buy it')

Sprinkles Global Health Initiative



21. If available in the local stores or with Health Workers, how much money you are willing to pay for one sachet of Sprinkles?
22. What are the tell tale signs of a healthy child?
23. Have you ever heard of anemia or shortage of blood?
24. How can you tell if your child has shortage of blood?
25. How does your child get anemia or shortage of blood?
26. What are some ways to prevent anemia or shortage of blood in your child?
27. Have you ever heard of mineral iron?
28. Do you know which foods contain iron?