

**Presented at the Hospital for Sick Children Scientific Retreat, Toronto, November 2004:**

The effectiveness of 'flexible' administration of sprinkles in anemic and non-anemic infants and young children in rural Bangladesh

**Introduction:** The World Health Organization estimates that over 750 million children suffer from iron deficiency and anemia worldwide. 'Sprinkles' were developed at the Sick Kids Hospital as a home-fortification strategy to address the problem of iron deficiency anemia (IDA) by delivering microencapsulated iron and other essential micronutrients to young children in a powder form. Sprinkles are packaged in single-dose sachets and are to be mixed into any weaning food once a day. To scale-up Sprinkles for nation-wide distribution in developing countries, the most effective model of administration needs to be determined. The objective of this study was to compare daily and 'flexible' administration of Sprinkles on changes in hemoglobin, caregiver compliance and acceptability in a community-based rural setting. **Rationale:** Under flexible administration, caregivers were instructed to give a specified number of Sprinkles sachets to their child over a specified number of months, but 'how often' they gave Sprinkles within this period was their own choice provided that no more than one sachet a day was given. Previous studies have suggested that daily administration of Sprinkles may not be necessary to achieve an increase in hemoglobin concentration (Hb). Flexible administration was examined because it may increase compliance and acceptability, since it is less rigid and allows caregivers more autonomy and freedom than daily use. **Methods:** 362 infants aged 6-24 months with Hb concentration  $\geq 70\text{g/L}$  were cluster randomized by their village into one of the following intervention groups: 1) daily use of 60 Sprinkles sachets over two months; 2) flexible use of 60 Sprinkles sachets over three months; or 3) flexible use of 60 Sprinkles sachets over four months. All caregivers were told not to provide more than one sachet per day. Each sachet contained 12.5 mg elemental iron as microencapsulated ferrous fumarate and other micronutrients. Hb was assessed at baseline and end of intervention. Compliance was measured monthly by counting the number of used and unused sachets. Acceptability was assessed using questionnaires and focus group discussions at the end of intervention. **Results:** At baseline, children did not differ significantly in mean Hb concentration or socio/economic status. Between group differences were found in baseline age, weight and height, which were controlled for in determining Hb at the end of intervention. Mean Hb increased significantly from baseline to end of intervention for all groups ( $p < 0.001$ ). Group 3 (4 month intervention) had the highest mean Hb ( $116 \pm 12\text{g/L}$ ) at the end of intervention compared to groups 1 ( $109 \pm 15\text{g/L}$ ) and 2 ( $112 \pm 12\text{g/L}$ ). Groups 1 and 2 did not differ significantly in mean Hb at end of intervention. Mean compliance differed significantly between all groups and was highest in group 3 (98%) compared to groups 1 (88%) and 2 (93%). Questionnaires and focus group discussions revealed that the flexible administration of Sprinkles was highly accepted and preferred by many mothers. Reported benefits of flexible use included more freedom, less pressure and anxiety, and more time to finish using all sachets. **Conclusion:** Findings suggest the flexible use of 60 Sprinkles sachets over four months may be the most effective administration model for large-scale distribution of Sprinkles in rural settings.