

## NSNZ Concurrent Oral Session 3: Micronutrient Nutrition

### Efficacy of micronutrient fortification of milk on morbidity in pre-school children and growth – a double blind randomised controlled trial

R Juyal<sup>1</sup>, M Osmamy<sup>1</sup>, RE Black<sup>2</sup>, U Dhingra<sup>2</sup>, A Sarkar<sup>1</sup>, P Dhingra<sup>1</sup>, P Verma<sup>1</sup>, D Marwah<sup>1</sup>, R Saxsena<sup>1</sup>, VP Menon<sup>1</sup>, S Sazawal<sup>1</sup>

<sup>1</sup>Center for Micronutrient Research, Annamalai University India

<sup>2</sup>Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore USA

**Background** - Given the high prevalence of micronutrient deficiencies and infectious diseases in children of developing countries, interventions to reduce infant and pre-school morbidity are a public health priority. With failure of iron supplementation programs for prevention of anaemia, fortification has been suggested as potential strategy for delivery of micronutrients that would reduce interactions and have multiple health benefits.

**Objective** - To evaluate the efficacy of micronutrient fortification of milk in prevention of diarrhoea, acute respiratory infections, iron deficiency and other childhood morbidity, and its impact on growth.

**Design** - The study was undertaken in peri-urban Delhi. Children aged 1-3 years, resident in the area and without any chronic illness or severe malnutrition were invited to participate. After informed consent 633 children were randomly allocated to either receive a milk formulation (MN milk) with a blend of micronutrients ('Nutri-care<sup>TM</sup>') including per 100 g powder: zinc 10 mg, iron 10 mg, vitamin A 350 µg, vitamin E 8.3 mg, vitamin C 50 mg, selenium 7 µg and copper 0.3 mg, or the same milk without the fortification. The milk was provided in sachets of 32 g and children were advised to reconstitute and consume 3 sachets per day for 12 months. A field assistant delivered the milk weekly to the homes. At baseline and end study a blood sample was collected and a detailed haemogram, plasma zinc, ferritin and zinc protoporphyrin were measured. Children were visited twice weekly in the home to record compliance and morbidity. At baseline, six months and one year anthropometric measures were made.

**Outcomes** - Compliance was above 80% with most children consuming at least 2 serves of milk per day. MN milk fed children had significantly lower incidences of diarrhoea (OR 0.78, 95% CI 0.66-0.9; 1 p<0.001), days of diarrhoea (OR 0.80, 95% CI 0.74 -0.84; p<0.001), severe illness (OR 0.85, 95% CL 0.76-0.96, p=0.01), high fever (OR 0.93, 95%CI 0.90-0.98; p=.003), measles (OR 0.12 p=.02) and acute lower respiratory infection (OR 0.72 95% CL 0.60-0.87; p=.01). They also had a significant increase in both height velocity (diff mean: 0.51; 95% CI: 0.27, 0.75, p= 0.00) and weight velocity (diff mean: 0.21; 95% CI: 0.12, 0.31, p= 0.00). There were also greater changes in height for age (HAZ) Z scores (mean diff 0.19 95%CI 0.12-0.26, p<0.001), weight for age (WAZ) Z scores (diff mean 0.24, 95%CI 0.11-0.36; p<0.001), and weight for height (WHZ) Z scores (diff mean 0.16, 95% CI 0.03-0.30; p=0.02) in the MN milk fed group. There was a significant change in mean Hb of 1.26 g (95%CI 1.11-1.60; p<0.001) in the MN milk group. As well as a significant increase in the proportion of non anaemic children with Hb levels above 10 g/L (OR 3.42, 95% CI 2.43-4.83; P<0.001) there was also an 87% decrease (95% CI 44%-99%; p=0.001) in children with severe anaemia, an increase in mean hematocrit 3.34 (95% CI 2.68, 3.99; p= 0.00), MCV, 6.97 (95% CI 5.53, 8.42; p= 0.00), mean RDW -2.49 (95% CI -2.92,-2.05; p= 0.00) and retic count -0.19 (95% CI, -0.27, 0.11; p= 0.00) in the MN milk group.

**Conclusions** – This study is the largest double blind trial showing fortified milk can reduce morbidity from diarrhoea, respiratory infections and other illnesses, as well as improve iron status and growth. Improvements in anaemia and iron status were greater than that documented with therapeutic iron supplementation in most trials.

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