Iron Fortified biscuits as a vehicle to improve Iron status of primary school study children of East Delhi: A cluster randomized triple blind controlled trial

Indian Coalition for Control of Iodine Deficiency Disorders, New Delhi

and

Centre for Community Medicine

All India Institute of Medical Sciences, New Delhi
In Collaboration..

- East Delhi Municipal Corporation (EDMC), Delhi
  - Study children, parents, teachers and support staff of EDMC schools
- Indian Coalition for Control of Iodine Deficiency Disorders (ICCIDD), Delhi
- All India Institute of Medical Sciences (AIIMS), New Delhi
  - Centre for Community Medicine (CCM)
  - Department of Psychiatry
  - Department of Hematology
  - Department of Pediatrics
  - Department of Biostatistics
- Health, Education and Awareness League (HEAL) Foundation
- Britannia Nutrition Foundation (BNF)
Why biscuits as a vehicle for Iron fortification?

- Acceptable and palatable
- Available
- Affordable
- Hygienic
- Ready to eat
- Easy to transport, store and distribute
- No side effects
- Existing norm across age groups
AIM

To assess the effectiveness of Iron fortification (using biscuits as a vehicle) on hemoglobin and anemia prevalence in school age children of East Delhi Municipal Corporation schools
• Primary schools of East Delhi Municipal Corporation (EDMC), Delhi
Study design:
- Cluster randomized triple blind controlled trial

Study Duration:
- Nine Months (from 15\textsuperscript{th} August'2013 to 15\textsuperscript{th} May'2014)

Study population:
- study children aged 7-9 years studying in 2\textsuperscript{nd} and 3\textsuperscript{rd} grade of EDMC primary schools, Delhi
**Trial Profile**

**Base line Evaluation**
Socio-demography status of family, 24 hr Dietary intake, Height, Weight and Hemoglobin

620 study children assessed for eligibility

382 children RANDOMIZED

Excluded= 238

Severe anemia: 74
Age (<7 or >9): 159
Chronic absent: 5

Iron Fortified (n=189)

28 (14.8%) lost to follow up

161 included in analysis

Non Fortified n=(193)

28 (14.5%) lost to follow up

165 included in analysis

**Intervention 6 months**
### Time line of study activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Aug,13</th>
<th>Sept,13</th>
<th>Oct,13</th>
<th>Nov, 13</th>
<th>Dec, 13</th>
<th>Jan,14</th>
<th>Feb,14</th>
<th>Mar,14</th>
<th>Apr,14</th>
<th>May,14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study started</td>
<td>15\textsuperscript{th}</td>
<td>Enrollment</td>
<td>28\textsuperscript{th}</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9\textsuperscript{th}</td>
</tr>
</tbody>
</table>

**Study duration:** 185 days

**Intervention days:** 129

* Excluding holidays
### Biscuit Composition
Per serving: 4 biscuits

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortified Biscuit</th>
<th>Non fortified Biscuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrates (g)</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>**Sugars (g)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Proteins (g)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fat (g)</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Energy (Kcal)</td>
<td>70</td>
<td>70</td>
</tr>
</tbody>
</table>

Figures based on calculated values
(Ref: *NIN; **USFDA norm)

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Fortified Biscuit</th>
<th>Non fortified Biscuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron (mg)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Vitamin A (mcg)</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Calcium (mg)</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Vitamin D (mcg)</td>
<td>1.5</td>
<td><strong>Nil</strong></td>
</tr>
<tr>
<td>Riboflavin (mg)</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Vitamin B6 (mg)</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Vitamin B12 (mcg)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Folic acid (mcg)</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>
RESULTS
Baseline characteristics of study children in the study arms
## Mean age of study children

<table>
<thead>
<tr>
<th>Variable</th>
<th>Iron fortified (N=189)</th>
<th>Non fortified (N=193)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Yrs) (Mean ± SD)</td>
<td>7.9 (0.5)</td>
<td>7.9 (0.5)</td>
</tr>
</tbody>
</table>

P=0.7
Prevalence of anemia among study children

Prevalence of anemia (%)

Iron fortified: 50.8%
Non Fortified: 50.3%

P=0.42
Prevalence of Iron Deficiency Anemia among study children

Hb<11.5g/dl

Iron fortified: 27%
Non Fortified: 31.1%

P=0.54
CHANGE IN STUDY VARIABLES
POST INTERVENTION
Change in hemoglobin level post intervention

Change in hemoglobin (g/dl)

Iron fortified

Non Fortified

Median intervention days: 92

P=0.001
Change in hemoglobin by baseline anemia status in Iron fortified group

- No anemia: Increase in mean hemoglobin level (g/dl) 0.3 (95% CI 0.04 to 0.6)
- Mild anemia: Increase in mean hemoglobin level (g/dl) 1.2 (95% CI 1.7 to 2.7)
- Moderate anemia: Increase in mean hemoglobin level (g/dl) 2.2 (95% CI 1.0 to 1.5)

Hb ≥ 11.5g/dl
Hb 11-11.4 g/dl
Hb 8-10.9 g/dl

P=0.001
Reduction in prevalence of anemia post intervention

- Iron fortified: 41
- Non fortified: 5.5

95% CI 33.4 to 48.6

95% CI 2 to 9

$P=0.001$
Summary

- Iron fortification using biscuits as a vehicle among school study children resulted in decrease in prevalence of anemia (as compared to baseline) by **79 %**

- Effectiveness of biscuits to improve hemoglobin found in this study is consistent with meta analysis results *(1 g/dl; 95% CI; 0.7 to 1.2 Vs. 0.42gdl 95% CI0.28 to 0.56)*

- Plausible analysis confirmed study children with moderate anemia at baseline experienced greater change as compared to mild anemic study children in hemoglobin level.

- Iron fortified biscuits is effective intervention
  - Reduce anemia
  - Increase hemoglobin
Strengths and limitations

- Representative sample of school study children chosen
- High compliance (72%)
- Low drop out rate
- Lack of significant difference in drop out
- Baseline characteristics reasonably comparable
- Non interference with existing mid day meal program or food intake by study children
- Short duration of intervention
What this adds to existing evidence?

School based fortification program is a feasible approach to reduce Iron deficiency anemia among study children
Recommendations

- Biscuits can be used as a potential vehicle for future fortification program to target school study children.

- Larger study exploring the use of biscuits as a vehicle for fortification of other micronutrient should be explored.

- Future fortification program using biscuits as a vehicle should explore the cost effectiveness of this intervention.

- Additional information for dietary practices and acceptability of other fortification vehicle can be explored by future qualitative studies.
Iron fortification using biscuits as a vehicle is an effective strategy to address Iron deficiency anemia among school age study children
### Nutrition Profile of Iron Fortified Tiger Glucose Biscuits used in Britannia, AIIMS-EDMC intervention and Iron Fortified Tiger Choco Cookies for Akshaya Patra Foundation’s (APF) initiative

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>AIIMS-EDMC intervention study</th>
<th>RDA : 7-9 Years (NIN - 2010)</th>
<th>Percent RDA AIIMS-EDMC intervention study</th>
<th>Tiger Choco cookies (APF)</th>
<th>Percent RDA Tiger Choco cookies (APF)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 Biscuits/serving</td>
<td></td>
<td>4 Biscuits/serving</td>
<td>4 Biscuits/serving</td>
<td></td>
</tr>
<tr>
<td>Iron(mg)</td>
<td>20</td>
<td>16</td>
<td>125</td>
<td>8</td>
<td>50</td>
</tr>
<tr>
<td>Folic acid(mcg)</td>
<td>60</td>
<td>120</td>
<td>50</td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>NA</td>
<td>0.8</td>
<td>NA</td>
<td>0.4</td>
<td>50</td>
</tr>
<tr>
<td>Riboflavin(mg)</td>
<td>0.5</td>
<td>1</td>
<td>50</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Vitamin B6(mg)</td>
<td>0.8</td>
<td>1.6</td>
<td>50</td>
<td>0.8</td>
<td>50</td>
</tr>
<tr>
<td>Vitamin B12(mcg)</td>
<td>0.3</td>
<td>0.2-1</td>
<td>30-150</td>
<td>0.5</td>
<td>50-150</td>
</tr>
<tr>
<td>Calcium(mg)</td>
<td>151</td>
<td>600</td>
<td>25</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Vitamin A (mcg)</td>
<td>152</td>
<td>600</td>
<td>25</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Vitamin D (mcg)</td>
<td>1.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Thank you