

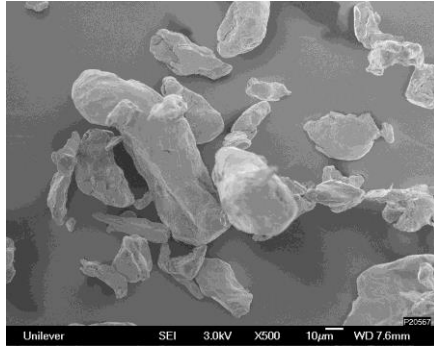
Flour fortification with iron: findings from Kenya



Hans Verhoef
London School of Hygiene and Tropical Medicine, UK/
Wageningen University, The Netherlands

Pauline Andang'o
Maseno University, Kenya

Rationale

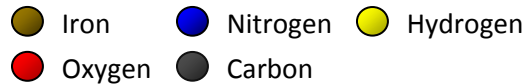
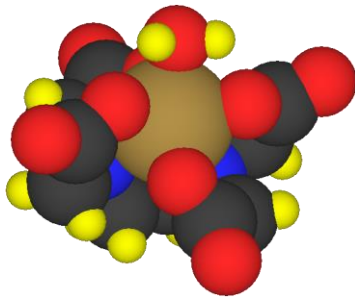


Electrolytic iron:

- Low-cost, stable, does not cause sensory changes
- Absorption and thus efficacy varies widely, depending on particle size, shape, surface:weight ratio
- By far most widely used iron fortificant worldwide

NaFeEDTA:

- Iron is 'jacketed' and thus protected from phytates that hamper iron absorption
- Absorption 2-3 times better than with FeSO_4 if phytate content of food vehicle is high



Objectives

- To assess the effect of consumption of whole maize flour fortified with high and low doses of NaFeEDTA, and with electrolytic iron,* on iron status of children aged 3-8 years
- To assess the influence of initial iron status on the efficacy of iron fortification

* Median particle size: 34 μm (10th–90th percentiles: 14–62 μm)

Interventions

- Vehicle: *uji*, a porridge of maize flour cooked in water, sweetened with sugar
- Target daily intake:
 - Children aged 3–5 years: 0.7 L *uji* containing 100 g flour
 - Children aged 6–8 years: 1.0 L *uji* containing 150 g flour
- Intake of fortificant iron:
 - High-dose NaFeEDTA/electrolytic iron (56 mg iron/kg flour): 7.4 mg/kg body weight
 - Low-dose NaFeEDTA (28 mg iron/kg flour): 3.6 mg/kg body weight

585 children eligible for screening

57 not screened

- 47 refused
- 2 migrated
- 2 without baseline blood sample
- 1 died before screening
- 8 for other reasons

528 screened at baseline

12 excluded

- 7 haemoglobin concentration <70 g/L
- 2 migrated
- 2 non-compliant
- 1 chronic absentee

516 randomly allocated

121 high-dose NaFeEDTA

140 low-dose NaFeEDTA

127 Electrolytic iron

128 Placebo

- 1 migrated
- 1 absent

- 2 withdrawn
- 1 migrated
- 1 admitted to hospital
- 1 absent

- 3 withdrawn
- 1 absent

- 2 withdrawn
- 1 migrated
- 1 admitted to hospital
- 1 absent

121 analysed
0 excluded
119 completed
2 imputed

139 analysed
1 excluded
135 completed
5 imputed

127 analysed
0 excluded
123 completed
4 imputed

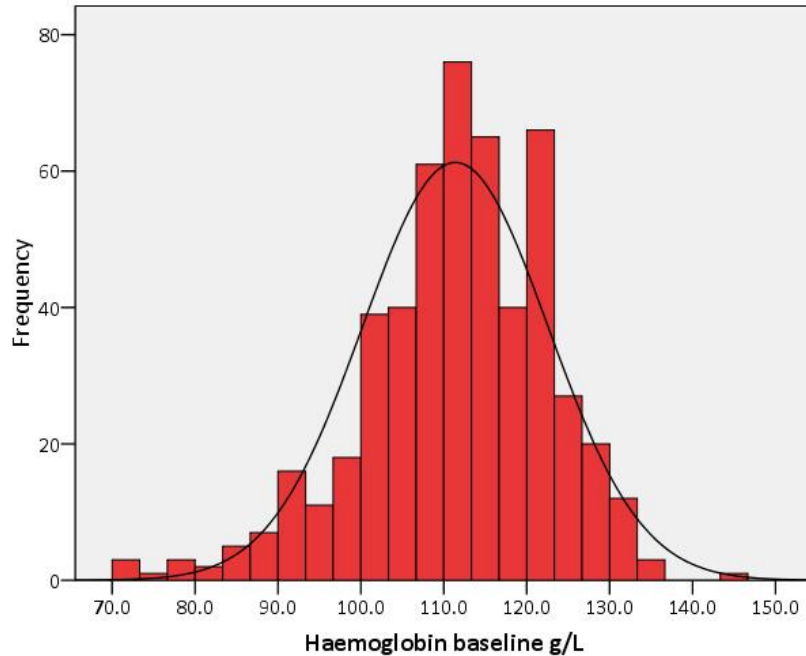
128 analysed
0 excluded
123 completed
0 imputed

Compliance *

- High-dose NaFeEDTA: 92%
- Low-dose NaFeEDTA: 89%
- Electrolytic iron: 90%
- Unfortified flour: 93%

* Percentage consumed of total amount of flour provided during the intervention

Baseline data

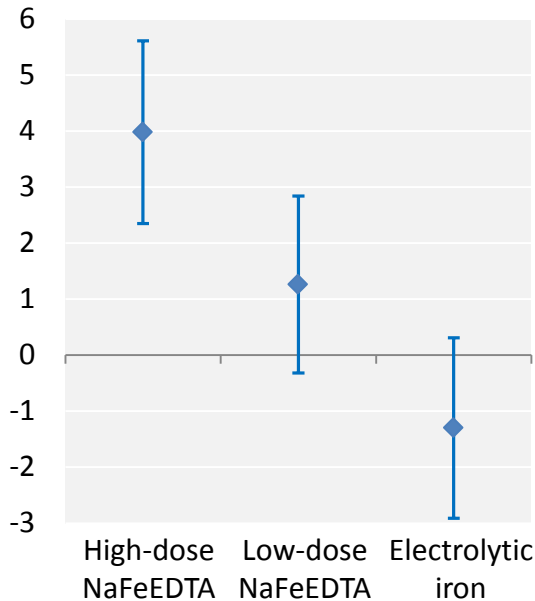


Prevalence:

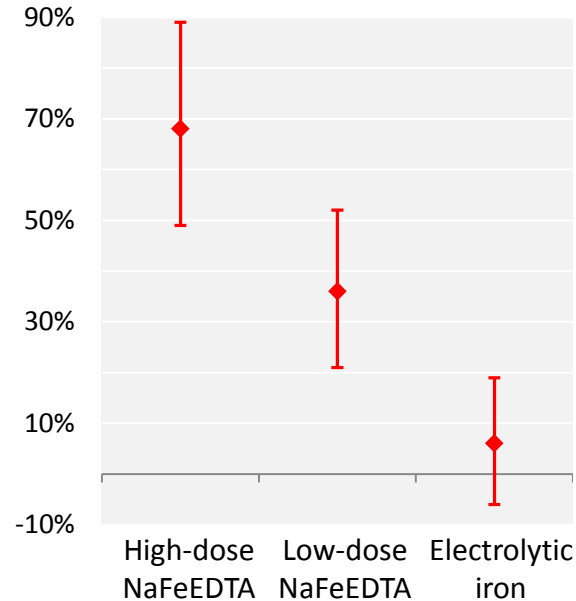
- Anaemia: 56%
- Iron deficiency: 15%
- Iron deficiency anaemia: 11%

Effect of flour fortification with iron on iron status indicators

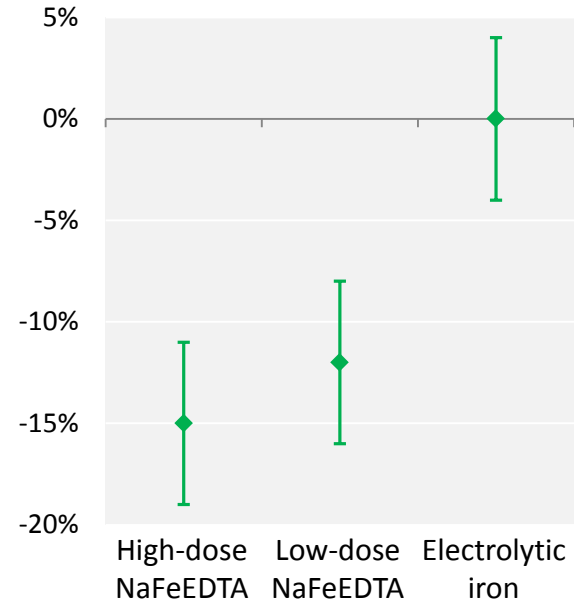
Δ Haemoglobin concentration, g/L



Δ Geometric mean ferritin concentration



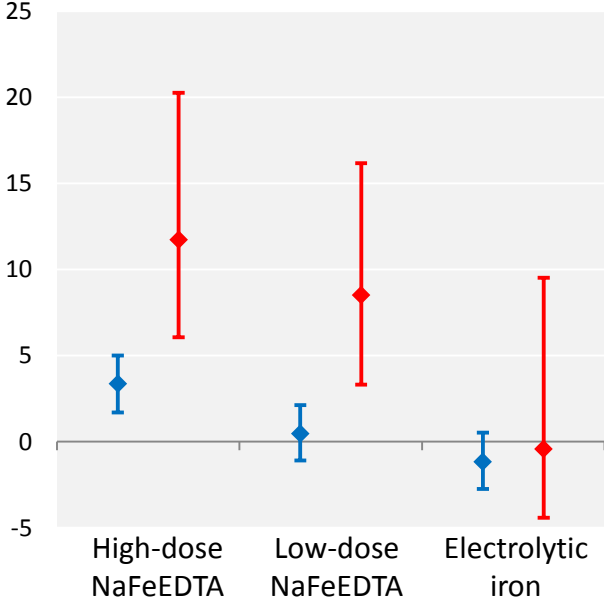
Δ Geometric mean sTfR concentration



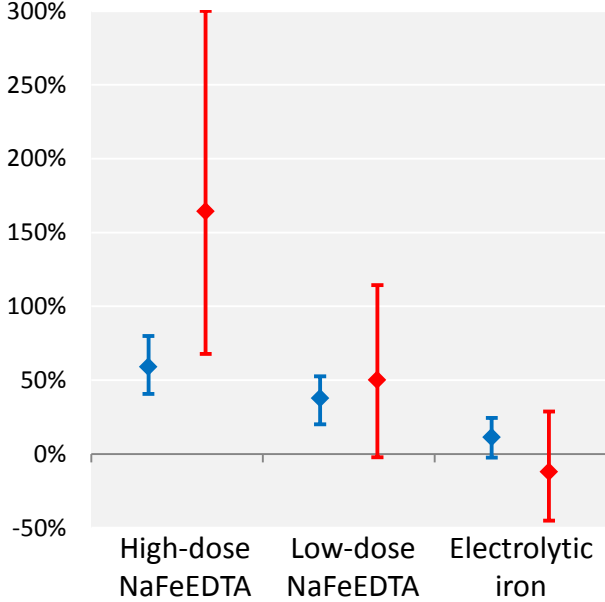
Influence of baseline iron status on response to iron fortification

◆ Iron replete ◆ Iron deficient

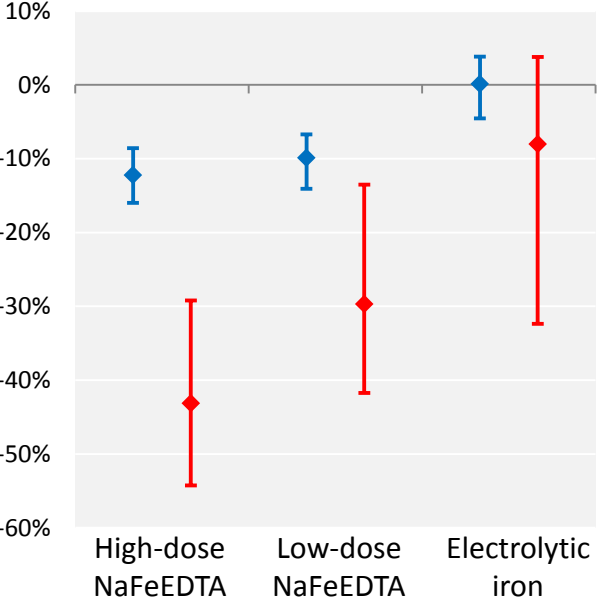
Δ Haemoglobin concentration, g/L



Δ Geometric mean ferritin concentration

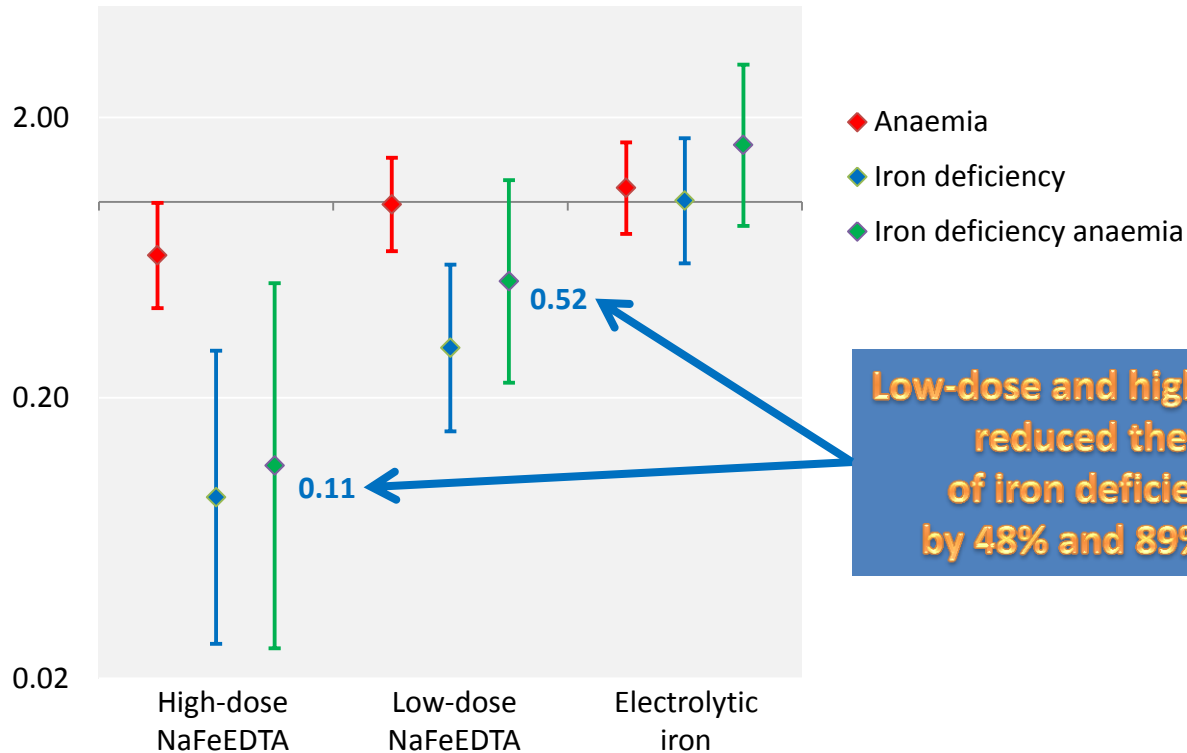


Δ Geometric mean sTfR concentration



Effect of flour fortification with iron on the prevalence of iron status disorders

Prevalence ratio relative to placebo



Low-dose and high-dose NaFeEDTA reduced the prevalence of iron deficiency anaemia by 48% and 89%, respectively

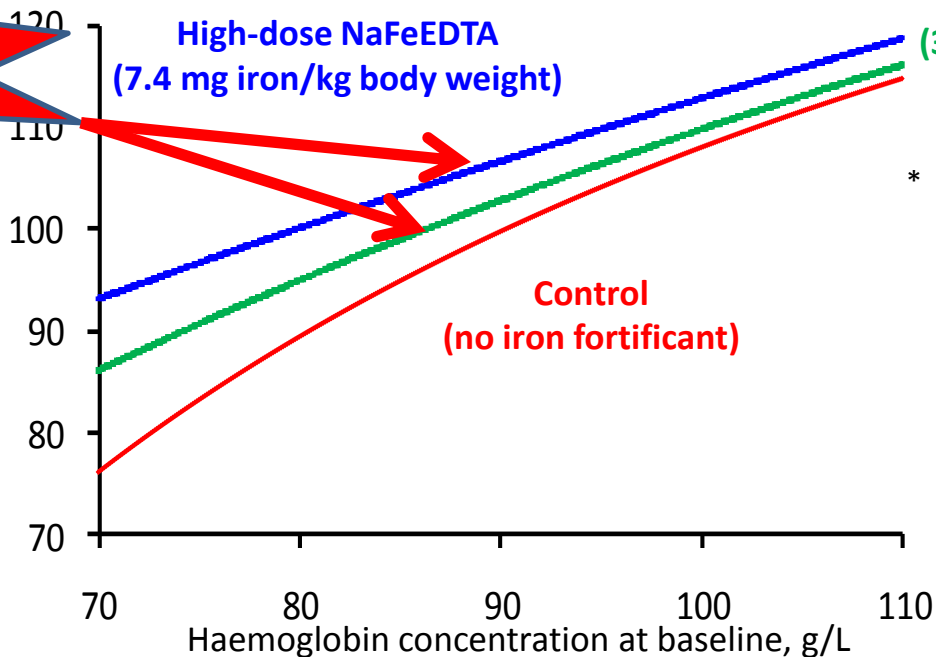
Flour fortification with high-dose NaFeEDTA for 5 months: alleviates but does not resolve severe anaemia

Ideally, these lines would have been horizontal!!

16.9 g/L

9.9 g/L

Haemoglobin concentration at 5 months, g/L



Low-dose NaFeEDTA
(3.6 mg iron/kg body weight)

* Adjusted for malarial infection, plasma concentration of soluble transferrin receptor concentration, ferritin and C-reactive protein

Interpretation

- Flour intake (and thus fortificant intake) in this trial may have been higher than in real life conditions
- Intake was supervised; compliance was high
- Effectiveness (real-life situation) would probably be less than what was achieved in this efficacy trial

What would have been achieved if interventions would have continued beyond 5 months?

- In people with initial haemoglobin concentration of 70 g/L, consumption of flour for 5 months with high-dose NaFeEDTA results in increase in haemoglobin concentration of 16.9 g/L
- Assuming that efficacy studies carried out over 5 months reach 40% of final impact (Hurrell et al. Food Nutr Bull 2010), such people should end up with mean haemoglobin concentration of 119 g/L
- Thus the prevalence of anaemia in such people would remain $\approx 18\%$ *
- Similarly, for people consuming flour with low-dose NaFeEDTA, the mean end value for Hb is 101 g/L, and the prevalence of anaemia would remain $\approx 82\%$ *

* Assuming $SD_{\text{haemoglobin}} = 10 \text{ g/L}$

Nutritional objective of fortification *

- ‘Mass fortification is designed to improve the bioavailable iron intake of the whole population with the intent of eliminating iron deficiency in the most vulnerable individuals, young children, adolescents and menstruating women.’
- ‘The introduction of a national iron fortification program should decrease the prevalence of iron deficiency in the target at-risk populations to <10% ID and <5% IDA [within 2-3 years].’

* Flour Fortification Initiative. Iron Working Group, document III. Second technical workshop on wheat flour fortification (Atlanta, GA, USA: 31 March – 3 April 2008). Atlanta, GA, USA: The Flour Fortification Initiative, 2008

Recommended levels of iron to add to fortified wheat flour, mg/kg

Type of flour (extraction)	Iron compound	Per capita flour intake		
		<149 g/day	150-300 g/day	>300 g/day
Low	NaFeEDTA	40	20	15
	Sulphate/fumarate	60	30	20
	Electrolytic	NR	60	40
High	NaFeEDTA	40	20	15

* Flour Fortification Initiative. Iron Working Group, document III. Second technical workshop on wheat flour fortification (Atlanta, GA, USA: 31 March – 3 April 2008). Atlanta, GA, USA: The Flour Fortification Initiative, 2008

Conclusions

- Fortification of whole maize flour with NaFeEDTA at intake levels of **3.6** mg iron/kg body weight improve iron status but will certainly not attain nutritional objectives in children aged 3-8 years
- Even fortificant NaFeEDTA intake levels of **7.6** mg iron/kg body weight probably will not attain nutrition objectives
- FFI-recommended fortification levels with NaFeEDTA:
 - Based on an intake of **4.6** mg iron/kg body weight (Viteri et al. 1995)
 - These levels are likely to improve iron status...
 - ... but may not be sufficient to attain nutritional objectives in Africa)
 - Should therefore be considered a minimum

A photograph of a volcanic eruption, showing a bright orange and yellow plume of lava and ash rising from a dark crater. The scene is set against a dark, almost black background. The text "Thank you" is overlaid in the center of the image in a bold, yellow, sans-serif font.

Thank you