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Effectiveness of double-fortified salt with iodine and folic acid (DFS-IoFA) in improving folate levels to reduce the risk of neural tube defects in Ethiopia

THE PROBLEM

Neural tube defects (NTDs) are severe birth defects of the brain and spinal cord that occur when the neural tube fails to close properly during the first 28 days of gestation. These defects vary in severity and are particularly prevalent in Ethiopia (Figure 1).[1,2] A primary cause of NTDs is maternal folate insufficiency in early pregnancy. To prevent NTDs, women capable of becoming pregnant need sufficient folate before conception. Since most pregnancies are unplanned, folate supplementation is recommended for all women of childbearing potential, not just those planning to conceive. Large-scale folic acid fortification programs have successfully reduced NTD prevalence worldwide, with cereal flour being the most common fortification vehicle. However, this approach is not viable in Ethiopia, as only 30% of the population may have access to industrially fortifiable wheat flour.

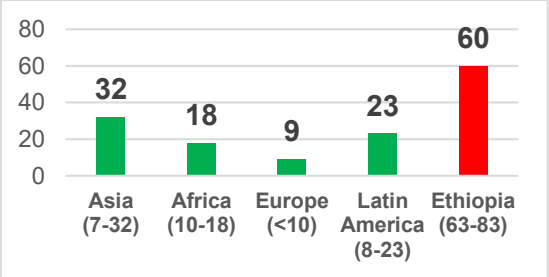

Figure 1: Global and Ethiopian prevalence of NTDs per 10,000 births

The Ethiopian government is considering salt fortification with folic acid as an alternative. However, there is a lack of evidence regarding the acceptability, effectiveness, and safety of this intervention. This study aimed to address this gap by evaluating the biological impact of DFS-IoFA on women's folate status aimed at reducing NTD risk.

METHODOLOGY

To document the biological efficacy of DFS-IoFA, a community-based randomized control trial was carried out in Ethiopia. 360 non-pregnant women of reproductive age (WRA) were randomly assigned to one of three groups, to receive:

1. Iodized salt with ~30 ppm folic acid, providing about 200 µg of folic acid daily (low folic acid group/LFS);
2. Iodized salt with ~90 ppm folic acid, providing about 600 µg of folic acid daily (high folic acid group/HFS); or
3. Iodized salt only (iodized salt/IS or control group).

For 26 weeks, the study salts were delivered to participants' households every two weeks for use by all family members. Blood samples were collected from WRA at the start, midpoint, and end of the study to measure folate, iodine, vitamin B_{12}, other nutrients, inflammation markers, and anaemia. Women's dietary intakes, including discretionary salt consumption, were measured, using in-home, weighed food records. 24hour urine samples were collected to measure sodium and iodine levels.

KEY FINDINGS

Double fortification of salt significantly reduced folate insufficiency

The results of this study indicate that regular consumption of DFS-IoFA significantly improved women's folate status compared with salt fortified just with iodine (Figure 2). Consumption of DFS-IoFA for 6 months markedly reduced the prevalence of folate insufficiency from ~90% to <20%, depending on the level of folic acid fortification. Folate insufficiency nearly disappeared among those who received the higher level of folic acid fortification.

Double-fortified salt was acceptable and safe

Double fortified salt was accepted by all participating women. Salt consumption was similar among participants that consumed salt fortified with iodine only and double fortified

salt with iodine and folic acid. Iodine status was similar between groups. DFS-IoFA did not show adverse effects, including insulin resistance.

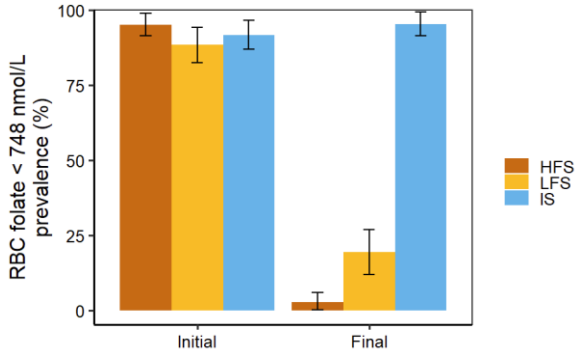

Figure 2: Prevalence of folate insufficiency at baseline and endline, by study arm

HFS: High Folate and iodine supplementation, **LFS:** Low dose folate and iodine supplementation, **IS:** Iodine supplementation

Iodine levels in DFS-IoFA remained as stable as those in salt fortified with iodine alone. DFS-IoFA showed ~94% retention of folic acid throughout the trial.

Both folic acid and iodine were very stable in stored salt over the 10-month period between initial production and final usage (**Table 1**).

Table 1: Salt composition and stability

Fortificant	Study arm	Initial	Final	% Retention
Folic acid	HFS	104±2	96±2	94
	LFS	36±0	36±2	99
	IS	0	0	-
Iodine	HFS	32±1	31±2	96
	LFS	34±1	32±1	95
	IS	32±2	32±1	100

SUMMARY AND IMPLICATIONS OF FINDINGS FOR POLICIES AND PROGRAMS

- Double fortified salt is a safe and effective method to improve women's folate status, which reduces the risk of pregnancies affected by NTDs. This approach is especially useful in populations like Ethiopia with an elevated NTD risk where flour fortification is not a practical option.
- Based on trial results and national salt intake data, our modeling indicates that fortifying iodized salt with 48 ppm could bring down folate insufficiency from the current 60% to ~10% in the population and significantly reduce the risk of NTDs in the country.
- Based on current national salt intake, fortifying iodized salt at 39–48 ppm folic acid is projected to reduce Ethiopia's folate insufficiency rate from 58% to 11–9%, significantly averting NTDs nationwide.

RECOMMENDATION TO NATIONAL STANDARD

- Based on these findings, we recommend the national mandatory fortification of salt with folic acid at a target range of 40 to 50 ppm to effectively reduce folate insufficiency and the risk of NTDs.

References

[1] Ssentongo P, Heilbrunn ES, Ssentongo AE, et al. Birth prevalence of neural tube defects in eastern Africa: a systematic review and meta-analysis. BMC Neurol 2022;22:202.
[2] Gebremariam, Beminet Moges, et al. "Birth prevalence and determinants of neural tube defects among newborns in Ethiopia: A systematic review and meta-analysis." PLoS One 20.1 (2025): e0315122.

Further information:

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