

## **GUIDELINES FOR MICRONUTRIENT INTERVENTION STUDIES**

**The vast majority of such studies targeting human disorders have not followed most of these guidelines and may have resulted in erroneous conclusions. It is suggested that if each of these guidelines are followed, the likelihood of positive results would be increased.**

- Multiple micronutrient administration: Studies usually involve single micronutrient interventions. Such studies are easiest to conduct and result in the most easily analyzed data but their physiological relevance is greatly limited.**
- Optimal micronutrient dosages: Suboptimal amounts of micronutrients are often given, although the targeted condition may require much larger dosages.**
- Adequate treatment duration: Treatment length may be inadequate, especially in studies involving chronic diseases.**
- Correct micronutrient form: If the micronutrient form is incorrect, the intervention is likely to fail, as exemplified by the use of alpha- rather than gamma-tocopherol forms of vitamin E.**
- Micronutrient bioavailability: Micronutrient administration may not coincide with meal ingestion, which is especially important for fat-soluble vitamins and several minerals.**
- Micronutrient potency: Sources of micronutrients vary in potency but this may not be taken into consideration in intervention studies.**

- **Patient compliance:** This is not always assessed, especially not by measurement of micronutrients or their metabolites in body fluids.
- **Patient subgroup evaluation:** Different categories of patients need to be evaluated since they may exhibit positive results despite overall negative results in the targeted disorder.
- **Effective window of administration:** Micronutrient interventions are often begun too late in disease progression.
- **Adequate patient numbers:** Sometimes studies include too few subjects, resulting in inadequate statistical power.
- **Consideration of study source:** Often studies are conducted by those who have ties to the pharmaceutical industry or by those who have a record of antagonism to use of micronutrients.
- **Micronutrient balance:** It is important to use micronutrients appropriately since imbalances can impair utilization or function, especially for fat soluble vitamins and minerals.

**Barry Kandler, PhD, FACN and Jeffrey Moss, DDS, CNS. Nutrition Institute**