

Title Registration for a Systematic Review: **Mass Food Fortification Programmes for Improving Nutritional Status in Low- and Middle-Income Countries: A Systematic Review**

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TITLE OF THE REVIEW

Mass Food Fortification Programmes for Improving Nutritional Status in Low- and Middle-Income Countries: A Systematic Review

BACKGROUND

Briefly describe the problem that the interventions under review are aiming to address, the relevance to policy and practice, and the objective(s) of the review.

The State of Food Insecurity estimates that around 870 million people globally have been undernourished (in terms of dietary energy supply) in the period of 2010-2012 (FAO, 2012). The majority of these live in developing countries where the prevalence of undernourishment is around 14.9% (FAO, 2012). The World Health Organization (WHO) estimates that more than 2 billion people are deficient in key vitamins and minerals (WHO, 2000). The groups most vulnerable to micronutrient deficiencies are pregnant women and young children (Black, 2001; Black et al., 2008). According to recent WHO estimates, globally about 190 million preschool children and 19.1 million pregnant women are vitamin A deficient (WHO, 2009), approximately 100 million women of reproductive age suffer from iodine deficiency (Leslie, 1991), and about 1.62 billion people are anaemic (Benoist et al., 2008). Food fortification is one of the strategies that has been used safely and effectively to prevent micronutrient deficiencies and has been practiced in developed countries for well over a century. A recent review has identified fortification as an effective approach, although more rigorous evidence is required especially from low- and middle-income countries (LMIC) (Das et al., 2013). Furthermore, the existing evidence has yet to be coherently analyzed to assess the relevance of findings from programmatic settings or large-scale effectiveness evaluations in community settings. The objectives of this review are to evaluate the effectiveness of mass food fortification efforts – and voluntary food fortification efforts that have been taken to scale – with key micronutrients (iron, folic acid, iodine, vitamin A, calcium, vitamin D or multiple micronutrients) and to describe the various contextual and design factors which contribute towards effective implementation of food fortification programs. While mass fortification is nearly always mandatory and thus inherently at-scale, market-driven, voluntary fortification efforts can also have an important impact in a populations' nutritional status when taken to scale (WHO, 2006). Thus, we are considering both mandatory mass fortification and voluntary fortification that has been taken to scale in this review. This review will be a comprehensive analysis of the existing evidence and suggest a way forward in the context of developing countries.

OBJECTIVES

The objective(s) should be listed as questions which the review will aim to answer.

1. What is the effectiveness of mass fortification efforts – and voluntary efforts that have been taken to scale - with key individuals micronutrients and combinations thereof (iron, folic acid, iodine, vitamin A, calcium, vitamin D or multiple micronutrients) on primary and secondary health outcomes.
2. What are the barriers and facilitators of design and implementation of effective implementation of programmes at-scale?
3. What are the beneficiary views of mass food fortification?

EXISTING REVIEWS

List any existing systematic reviews on the topic, and justify the need for this review if existing reviews exist or are in progress.

- Best, C., Neufingerl, N., Del Rosso, J. M., Transler, C., van den Briel, T., & Osendarp, S. (2011). Can multi-micronutrient food fortification improve the micronutrient status, growth, health, and cognition of schoolchildren? A systematic review. *Nutrition Reviews*, 69(4), 186–204. doi:10.1111/j.1753-4887.2011.00378.x
- Das, J. K., Salam, R. A, Kumar, R., & Bhutta, Z. A. (2013). Micronutrient fortification of food and its impact on woman and child health: a systematic review. *Systematic Reviews*, 2, 67. doi:10.1186/2046-4053-2-67
- Ramakrishnan, U., Goldenberg, T., & Allen, L. H. (2011). Do Multiple Micronutrient Interventions Improve Child Health , Growth , and Development ? 1 – 3, 2066–2075. doi:10.3945/jn.111.146845.2066
- Middleton, P., Crowther, C., Bubner, T., Flenady, V., Bhutta, Z., Trach, T. & Lassi, Z. (2012) Nutritional interventions and programs for reducing mortality and morbidity of pregnant and lactating women and women of reproductive age: a systematic review protocol. *The Campbell Collaboration*.

These existing reviews are limited to specific subsets of populations and are based on controlled trials only. The existing evidence has yet to be coherently analyzed to assess the relevance of findings from programmatic settings or large-scale effectiveness evaluations in community settings. A more comprehensive review is required – one that takes into account both quantitative (effectiveness) and qualitative (analysis of programs/barriers/lessons) measures especially in large scale programmatic settings.

INTERVENTION

Describe the eligible intervention(s) and comparison(s) clearly in plain language. What is given, by whom, to whom, and for how long? What are the comparison conditions (what is usually provided to control/comparison groups who don't receive the intervention)?

- 1) Mass food fortification – the mandatory or voluntary addition of essential micronutrients to widely consumed staple foods and/or condiments during production – for the purpose of improving health outcomes of populations. This

review will focus specifically on the addition of iron, folate, vitamin A, vitamin D, iodine, calcium, and multiple micronutrients (MMN) to staple foods and condiments.

- 2) The intervention should not focus on specific subsets of a population (i.e. infants, children at risk for nutritional deficiency, pregnant women). Additionally, there are no restrictions regarding duration of exposure, whom it is provided by, or food vehicle utilized (with the exception of fortified blended foods, fortified complementary foods, and highly processed foods).
- 3) Comparisons may include usual feeding practices (negative control) or alternative nutritional interventions (positive control), such as diet supplementation.

POPULATION

Specify the types of populations to be included and excluded, with thought given to aspects such as demographic factors and settings.

The review will focus on the effects of mass food fortification in low- and middle-income countries only (a brief, summative review of evidence from high-income countries will be provided). Specific demographic factors, such as age and sex, will not be incorporated as exclusion criteria, thus capturing effects of the intervention within and across entire populations at varying levels (sub-national versus national versus international).

OUTCOMES

List the primary and secondary outcomes for the review including all outcomes important to those who will be affected by and those who will make decisions about the intervention(s). Give thought to the inclusion of adverse and unintended effects, resource use, and outcomes along the causal chain.

Outcomes will include both quantitative (effectiveness) as well as qualitative (analysis of programs/barriers/lessons) measures.

Primary health outcomes: changes in the level of micronutrients (iron, folate, vitamin A, iodine) through dietary intake and/or biomarkers of nutrient status

Secondary health outcomes (related to indirect effects): bioavailability, deficiency diseases and related nutrition disorders including, but not limited to, acute malnutrition, stunting, anemia, hypothyroidism and goiter, night blindness and xerophthalmia, adverse pregnancy outcomes, congenital abnormalities, neurological impairment, cognitive dysfunction, morbidity and mortality

Qualitative outcomes: acceptance, including sensory acceptability of beneficiaries, coverage and accessibility of mass food fortification, and contextual factors relating to program implementation and uptake of the intervention among different populations

STUDY DESIGNS

List the types of study designs to be included and excluded (please describe eligible study designs). Where the review aims to include quantitative and qualitative evidence, specify which of the objectives noted above will be addressed using each type of evidence.

Inclusion criteria:

Effectiveness of programs: randomized controlled trials, quasi-randomized trials, interrupted time series studies, cohort studies, case-control studies.

Barriers and facilitators of implementation: any of the study designs listed above, before-after studies, case studies and observational studies of food fortification programs without a comparison.

Beneficiary views: qualitative studies employing any study methods listed above.

We will be including peer-reviewed and non-reviewed reports and articles for each category of our review.

Exclusion criteria:

In vitro research and in vivo animal studies.

Studies on targeted and home food fortification

Studies reporting on populations that are not LMICs

Studies reporting on irrelevant outcomes

Studies reporting on biofortification

Note: meta-analyses will be conducted where appropriate. .

REVIEW AUTHORS

Lead review author: The lead author is the person who develops and co-ordinates the review team, discusses and assigns roles for individual members of the review team, liaises with the editorial base and takes responsibility for the on-going updates* of the review.

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ROLES AND RESPONSIBILITIES

Please give a brief description of content and methodological expertise within the review team. It is recommended to have at least one person on the review team who has content expertise, at least one person who has methodological expertise and at least one person who has statistical expertise. It is also recommended to have one person with information retrieval expertise. Please note that this is the recommended optimal review team composition.

- Content: All
- Systematic review methods: Kerri Wazny, Jai Das
- Statistical analysis: Emily Keats, Aimee Huynh
- Information retrieval: All

POTENTIAL CONFLICTS OF INTEREST

No conflicts of interest.

FUNDING

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PRELIMINARY TIMEFRAME

Note, if the protocol or review are not submitted within 6 months and 18 months of title registration, respectively, the review area is opened up for other authors.

- Date you plan to submit a draft protocol: July, 2014
- Date you plan to submit a draft review: October, 2014

DECLARATION

Authors' responsibilities

By completing this form, you accept responsibility for preparing, maintaining, and updating the review in accordance with Campbell Collaboration policy. The Coordinating Group will provide as much support as possible to assist with the preparation of the review.

A draft protocol must be submitted to the Coordinating Group within one year of title acceptance. If drafts are not submitted before the agreed deadlines, or if we are unable to contact you for an extended period, the Coordinating Group has the right to de-register the title or transfer the title to alternative authors. The Coordinating Group also has the right to de-register or transfer the title if it does not meet the standards of the Coordinating Group and/or the Campbell Collaboration.

You accept responsibility for maintaining the review in light of new evidence, comments and criticisms, and other developments, and updating the review every five years, when substantial new evidence becomes available, or, if requested, transferring responsibility for maintaining the review to others as agreed with the Coordinating Group.

Publication in the Campbell Library

The support of the Coordinating Group in preparing your review is conditional upon your agreement to publish the protocol, finished review and subsequent updates in the Campbell Library. Concurrent publication in other journals is encouraged. However, a Campbell systematic review should be published either before, or at the same time as, its publication in other journals. Authors should not publish Campbell reviews in journals before they are ready for publication in the Campbell Library. Authors should remember to include a

statement mentioning the published Campbell review in any non-Campbell publications of the review.

I understand the commitment required to undertake a Campbell review, and agree to publish in the Campbell Library. Signed on behalf of the authors:

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Date:

References:

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