



A blueprint for fortification planning and programming: Lessons learned from an analytical review of existing fortification frameworks

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Abstract

With multiple food fortification frameworks, countries can find it challenging to determine optimal methods for planning and implementing food fortification programmes to combat vitamin and mineral deficiencies, especially without additional technical support. To address this challenge, this study aimed to review existing frameworks to determine consistencies, differences, strengths, and weaknesses across the frameworks, and based on the review findings, formulate an enhanced and streamlined fortification framework. Nineteen frameworks were ultimately examined following a comprehensive literature review and key informant interviews. Generally, the reviewed frameworks amply describe motives and methods for the determination of fortification need and feasibility, industry engagement/quality assurance and quality control, and impact evaluations/surveillance. However, there was limited inclusion or discussion throughout the reviewed frameworks around harmonization of fortification with existing micronutrient interventions; fortification policy and/or strategy; enforcement, incentives, and penalties to ensure producer compliance with industry standards; and periodic fortification programme review and reassessment. The findings were used to develop a comprehensive Fortification Blueprint that aims to provide structured guidance and a library of tools and resources to fortification programme managers and key stakeholders to ensure optimal and sustainable programme design.

KEYWORDS

food fortification, fortification design, fortification framework, fortification implementation, micronutrients

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1 | INTRODUCTION

As per recently released global estimates, over half (56% or 372 million) of preschool-aged children and about two-thirds (69% or 1.2 billion) of women of reproductive age suffer from vitamin and mineral deficiencies, or deficiencies in essential nutrients such as folic acid, vitamin A, iron and zinc (Stevens et al., 2022). When considering all essential micronutrients, as well as all age and sex groups, these estimates are most likely an underestimation of the true worldwide burden of micronutrient malnutrition. Micronutrient deficiencies contribute to a significant proportion of the morbidity and mortality experienced by individuals, largely women of reproductive age and young children, in low- and middle-income countries (LMICs) (Brown et al., 2021). However, these deficiencies are not restricted to this demographic; vitamin and mineral inadequacies and deficiencies can also affect the general populace in LMICs, as well as those in high-income countries. As a result, in terms of physiological manifestations, it is estimated that undernutrition and micronutrient deficiencies account for 45% of under-five child deaths and ~7.3% of the global burden of disease (Olson et al., 2021).

The consequences of such deficiencies consist of a multitude of adverse outcomes including nutritional anaemia, which reduces cognitive function, and birth defects. When experienced during pregnancy, nutritional anaemia is further associated with increased risks of maternal death, low-birth weight, infant mortality and metabolic disease in adults (Figueiredo et al., 2018; Peña-Rosas et al., 2015). Neural tube defects (i.e., spina bifida, anencephaly and encephalocele) or birth defects that primarily stem from insufficient maternal folate throughout the periconceptual period (i.e., 3–4 weeks before through 3–4 weeks after conception) lead to stillbirths, infant deaths and life-long physical disabilities (Bailey & Hausman, 2018; Blencowe et al., 2018). Deficiencies in other nutrients, for example, calcium, iodine, selenium, vitamin A, B vitamins such as vitamin B12, vitamin D, and zinc, lead to decreased immunity, increased susceptibility to infections, decreased cognitive function and increased mortality (Brown et al., 2009; Imdad et al., 2017; Martineau et al., 2017; Mayo-Wilson et al., 2014; Stevens et al., 2015).

Large-scale food fortification is one means by which to address such nutritional inadequacies and deficiencies. With the addition of essential vitamins and minerals to commonly consumed and industrially processed foods—such as wheat and maize flour, cooking oil, salt and rice—during their processing, fortification is a proven and effective intervention to increase the nutritional quality of food by providing populations with critical nutrients that may be inadequate or absent from the diet (Hoddinott et al., 2013; Horton et al., 2008). Consequently, fortification can decrease the health and economic burden associated with micronutrient deficiencies (Hoddinott et al., 2013; Horton et al., 2008).

Following a national decision to pursue the adoption of a mandatory fortification programme, governments often seek technical support from organizations with expertise—such as non-governmental organizations or United Nations agencies—to aid national ministries and regulatory bodies, food producers, academia

Key messages

- Multiple food fortification frameworks currently exist to guide the design, implementation, scale-up, and monitoring of mandatory large-scale fortification programmes.
- Four design elements cited the least frequently throughout 19 reviewed frameworks included: (1) Fortification Policy and Strategy; (2) Harmonization with Existing Interventions/Policies; (3) Enforcement/Incentives/Penalties; and (4) Reassessment.
- Elements cited the most frequently in the frameworks included (1) Impact Evaluations/Surveillance; (2) Determining Need and Feasibility; and (3) Industry Engagement/Quality Assurance and Quality Control.
- A revised novel approach is proposed based on the research findings to refresh programme thinking and priorities and guide scaling fortification initiatives.

and/or civil society groups throughout the design and implementation process. Once governments establish fortification programmes, and as dietary patterns, nutritional needs, food production infrastructures and capacities, and/or global recommendations change, programme managers should review fortification programmes approximately every 5 years and/or as these contextual factors change, to ensure their continued relevance and potential to generate positive nutritional impacts (World Health Organization [WHO] & Food and Agricultural Organization of the United Nations [FAO], 2006). To aid the initial design of programmes and the review of existing programmes, the availability of a guiding blueprint or framework is beneficial for programme managers to use and reference on a continual basis. Such a framework or blueprint should outline critical programme inputs and processes, specify relevant stakeholders to involve at each step, provide advice on appropriate tools to use to operationalize the guidance and recommend a general programming sequence based on global best practices.

To date, various partners and organizations working in fortification have created differing food fortification frameworks to guide programme managers throughout the design, implementation, scale-up, and monitoring of fortification programmes (Bégin et al., 2001; Darnton-Hill, 1998; Dary, 2009; Food Fortification Initiative [FFI], n.d.; García-Casal, 2014; Garrett, 2018; Lalani et al., 2019; Mark et al., 2019; Martorell & de Romaña, 2017; Micronutrient Initiative, 1996; Nutrition International, 2020; Obare et al., 2017; Peña-Rosas et al., 2008; Rowe & Dodson, 2012; Teachout et al., 2021; Tsang, 2021; USAID, 2021; WHO & FAO, 2006; Wirth et al., 2012). With these multiple frameworks, countries can find it challenging to determine optimal methods for implementing and/or sustaining food fortification programmes, particularly following the cessation of external technical support. To this end, the objective of this study was to review existing food fortification frameworks, assess their strengths and weaknesses, and propose a novel approach as a means of

operationalizing the review findings, with ideals derived from current frameworks.

The goal of a single, streamlined fortification framework, drawing on review findings, is multifaceted. The novel approach intends to: (a) provide a comprehensive and actionable design framework for stakeholders (i.e., government, private sector, civil society, development partners, donors and research and academic institutions) supporting fortification programming; (b) better inform stakeholders about key elements for consideration at each stage of the fortification process, including elements needed and the associated tools available for scaling and sustaining effective interventions; (c) harmonize the approach to key programming elements, such as regulatory monitoring and creation of fortification standards; (d) draw renewed attention to key programming elements often absent from fortification programme design; and (e) inform improved fortification policies and practices enabling the design of more efficient and sustainable programmes that retain the ability to generate a robust and meaningful impact on target populations.

Thus, this review aimed to answer the following questions:

- What food fortification frameworks currently exist to guide countries on fortification programming?
- What are the strengths and weaknesses of these frameworks and what unique attributes do they include?
- What are the insights and recommendations related to effective fortification programme design and needs in terms of global/regional/national guidance from key informants with experience in designing, implementing, and monitoring fortification programmes?
- What is the final configuration of a novel food fortification framework that incorporates the strengths and addresses the weaknesses of current fortification frameworks and that includes further input from experienced key informants?

2 | METHODS

2.1 | Literature search and review

To formulate an enhanced food fortification framework, existing frameworks were reviewed to determine consistencies, differences, strengths and weaknesses. Frameworks were obtained via searches in January 2021 from peer-reviewed and grey literature in Agricola/EBSCO, Embase, Global Health, PubMed and Web of Science databases. The search was conducted without restrictions; however, only accessible frameworks were searched, which omitted publications from before 1975. Search words included over 40 terms further outlined in Supporting Information: Table A1.

The review located 2657 records across the five databases (Table 1). Only articles published in English with the word 'fortification' mentioned in the title were considered for the abstract screening phase. The selection criteria consisted of articles with descriptions of fortification design and/or implementation components, a description or form of a fortification framework or a

TABLE 1 Search results by database.

Database	Search results
Agricola/EBSCO	369 records
Embase	538 records
Global Health	646 records
PubMed	454 records
Web of Science	650 records
Total	2657 records

Note: Existing frameworks were obtained via searches in January 2021 from peer-reviewed and grey literature in Agricola/EBSCO, Embase, Global Health, PubMed and Web of Science databases. Search words included over 40 terms further outlined in Supporting Information: Table A1. The review located 2657 records across the five databases.

discussion of programme successes and/or challenges. The first author (RD), in consultation with the second author (LAR), screened the titles and abstracts. Following the title and abstract screening process, RD and LAR conducted full text reviews to identify articles for final eligibility, that is, articles with fortification frameworks, and MC and MA supported the final eligibility process, which resulted in 13 articles for detailed analysis (Figure 1).

2.2 | Key informant engagements/interviews

Following the literature review, individuals and/or organizations identified by the authors as experts in the field were contacted via e-mail to (1) enquire about other published or unpublished frameworks and/or frameworks used as implementation guides by their respective organizations that were not found through the literature review or (2) gain further clarification concerning frameworks that were reviewed, if necessary. Key informants identified in the initial list aided in the identification of other relevant individuals to interview. Fourteen individuals from 12 organizations were ultimately contacted via e-mail; six additional fortification frameworks were obtained from these contacts, bringing the total number of evaluated frameworks obtained from the literature review (13) and from key informants (six) to 19.

2.3 | Matrix compilation

To systematically evaluate each of the 19 frameworks, a matrix was created detailing recurring themes that surfaced in the frameworks obtained from the literature review and key informant interviews. Additional themes, such as policy and strategy, harmonization with existing interventions/policies, and programme reassessment, were added following an analysis of design and implementation best practices and principles (Garrett, 2018; Martorell & de Romaña, 2017; Neufeld et al., 2017; WHO, 2016). These themes resulted in a total of 15 different pre-identified matrix categories (listed in Table 2)

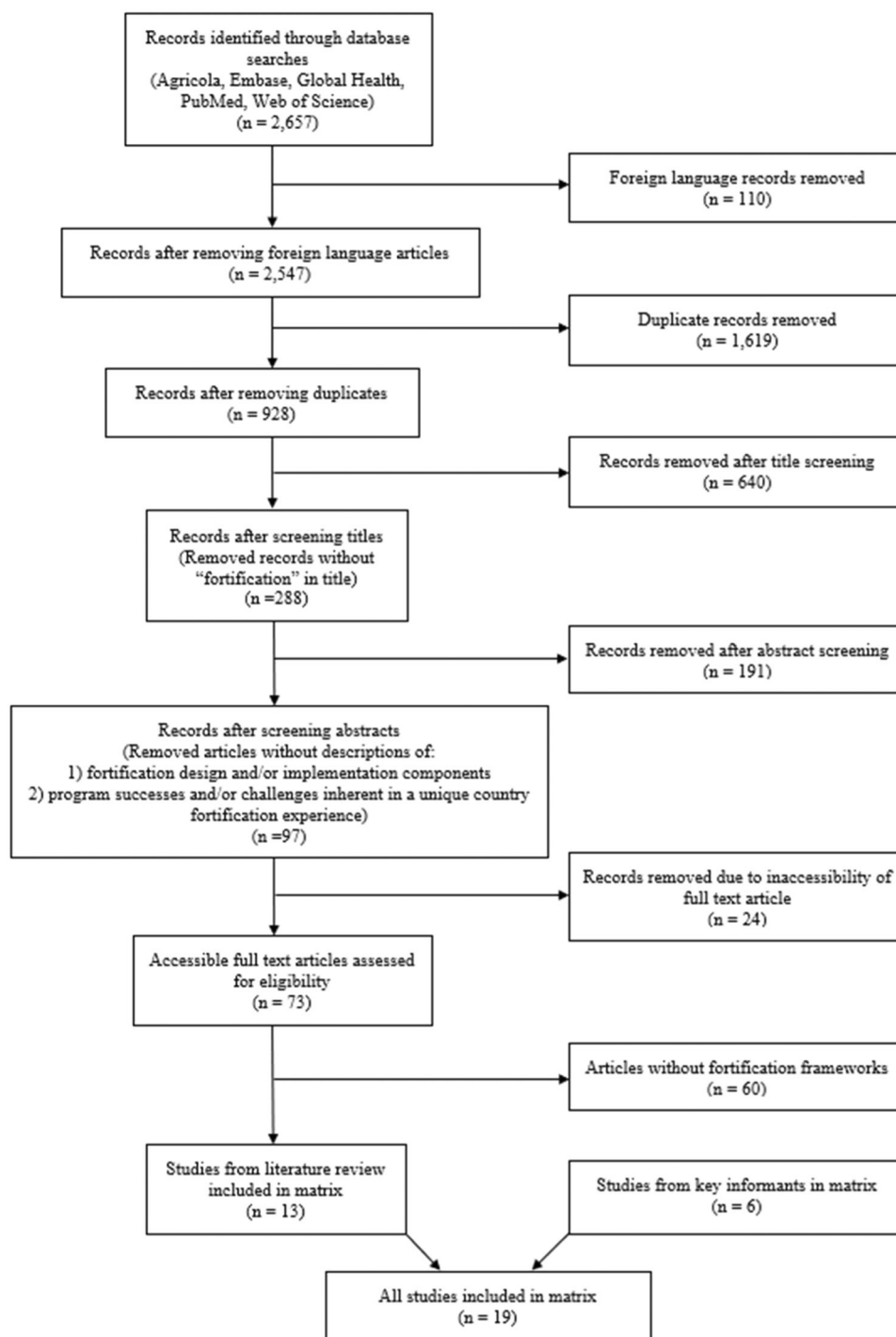


FIGURE 1 Number of records obtained in January 2021 from searching databases for fortification frameworks and resultant studies included in final assessment. The literature review located 2657 records across the five databases. Only articles published in English with the word ‘fortification’ mentioned in the title were considered for the abstract screening phase. The selection criteria consisted of articles with descriptions of fortification design and/or implementation components, a description or form of a fortification framework, or a discussion of programme successes and/or challenges—resulting in 13 articles from the literature review included in the final assessment/matrix.

used to assess each framework. A scoring methodology was then used to rate each category within the assessed frameworks. A range of one to four points, based on the degree of inclusiveness and component specificity (Table 3), was allocated to the 15 different pre-identified matrix categories for each framework. Frameworks

were reviewed, summarized, ranked against these 15 distinct categories derived from the recurring themes and assessed for unique attributes.

The final category, ‘Other unique attributes’ was not scored. Instead, this category captured unique attributes critical to

programme design and implementation based on findings from the literature review and/or key informant interviews but that were not included in the frameworks that were reviewed.

A maximum framework score was 60 points (15 categories × 4 points maximum per category = 60 points). Among matrix categories (e.g., Determining Need and Feasibility, Political Will/Government Engagement, Building Partnership/Alliances and so on), the maximum possible score was 76 points (19 frameworks × 4 points maximum per framework per category = 76 points per category). The two reviewers examined each framework and independently attempted to match

components of the frameworks with categories of the matrix. The reviewers then compared their respective analyses and agreed upon an approach for aligning components of frameworks with matrix categories.

2.4 | Ethics statement

The Institutional Review Board of Emory University exempted this study (IRB00001817) from further review. All key informants

TABLE 2 Matrix categories and definitions.

Matrix category	Definition
Determining Need and Feasibility	Gathering data related to the nutritional need or dietary gap for micronutrients and the feasibility of addressing this need or gap with food fortification
Political Will/Government Engagement	Garnering political commitment to sustain the fortification programme long term
Building Partnerships/Alliances	Involving key stakeholders in the design process and creating national platforms for coordination and planning
Fortification Policy and Strategy	Including fortification as a standalone policy or incorporating fortification in a national strategy, such as a national multisectoral nutrition strategy
Harmonization with Existing Interventions/Policies	Crafting methods to align fortification standards and/or policies with existing nutrition and micronutrient interventions, regional fortification standards, and global fortification recommendations
Standards and legislation	Creating country-specific standards and mandatory fortification legislation
Economic analysis	Determining economic implications of a fortification programme (for government, industry and/or consumers); conducting economic or cost-benefit analyses
Civil society engagement/consumer advocacy	Engaging civil society in design and implementation components; including industry associations; conducting consumer education campaigns
Industry Engagement/Quality Assurance and Quality Control	Involving food producers in planning phases; supporting the implementation of internal monitoring protocols
Premix (sourcing and/or quality)	Premix sourcing, availability, cost, financing and/or quality
Regulatory monitoring	Implementing external monitoring frameworks and protocols (including import monitoring) to ensure apt quality of the fortified food
Enforcement/Incentives/Penalties	Formulating methods to incentivize fortification for the private sector; penalties for noncompliance; effective means of enforcing compliance
Marketing and communications	Industry efforts to communicate the importance of fortified foods to stakeholders; marketing support by and/or for industry
Impact Evaluations/Surveillance	Assessing coverage/reach of the fortified foods among the population via surveillance and/or nutritional impact evaluations
Reassessment	Reviewing the fortification programme every 5 years or as dietary patterns, nutritional needs, food production infrastructures and capacities, and/or global recommendations change to ensure the continued relevance of the programme and potential to generate a positive nutritional impact
Other unique attributes (this category was not part of the scoring methodology used in the matrix; instead, unique attributes mentioned within the assessed frameworks were noted and considered in the design of the Fortification Blueprint)	Additional components not captured under the above matrix categories

Note: Frameworks were reviewed, summarized, ranked against these 15 distinct categories derived from the recurring themes and assessed for unique attributes.

TABLE 3 Matrix scoring definitions.

Score	Definition
1 point	No mention of component of interest
2 points	Mentioned component of interest
3 points	Mentioned component of interest and specified a reason or provided further explanation concerning the need for the category of interest
4 points	Mentioned component of interest, specified a reason or provided further explanation concerning the need for the category of interest, and provided methods for carrying out the suggested task(s)

Note: A range of 1–4 points, based on the degree of inclusiveness and component specificity, was allocated to the 15 different pre-identified matrix categories for each framework.

provided informed consent to share knowledge of and/or detail their experiences with existing organizational fortification frameworks.

3 | RESULTS

Fortification frameworks were obtained from a wide array of entities including global guidance bodies (e.g., WHO), regional development agencies (e.g., the East, Central, and Southern Africa Health Community), nongovernmental or bilateral partner organizations and independent publications (e.g., publications not affiliated with an organization or agency). A total of 19 frameworks were obtained and included in the matrix, including one from global guidance bodies (WHO & FAO, 2006), one from a regional body (Obare et al., 2017), nine from partner organizations (Dary, 2009; FFI, n.d.; Garrett, 2018; Mark et al., 2019; Micronutrient Initiative, 1996; Nutrition International, 2020; Rowe & Dodson, 2012; Tsang, 2021; USAID, 2021) and eight from individual publications (Bégin et al., 2001; Darnton-Hill, 1998; García-Casal, 2014; Lalani et al., 2019; Martorell & de Romaña, 2017; Pena-Rosas et al., 2008; Teachout et al., 2021; Wirth et al., 2012). The intended audience for all assessed frameworks was global, regional, or national fortification programme managers, planners, or decision-makers from governments, private and civic sectors, and/or technical assistance partners. The total score for each individual framework ranged from 20 to 55 points (data not shown). High or low scores were not differentiated between the type of framework (e.g., partner organization or independent publication).

Among matrix categories, 'Impact Evaluations/Surveillance', 'Determining Need and Feasibility' and 'Industry Engagement/Quality Assurance and Quality Control' generated the highest scores with 57, 50 and 50 points, respectively, implying that these categories were the strongest and mentioned the most frequently across frameworks (Figure 2). 'Enforcement/Incentives/Penalties', 'Fortification Policy and Strategy', 'Harmonization with Existing Interventions' and 'Reassessment based on Changing Patterns/Needs' exhibited the lowest scores with 40, 38, 32 and 28 points, respectively, implying that these categories were included less frequently and, when included, did not contain robust descriptions. The remaining eight categories scored between 41 and 49 points. Supporting Information: Table A2 (see Annex) provides illustrative examples of robust

descriptions, as considered by the authors, found across all evaluated frameworks for each matrix category.

A second approach to scoring included reviewing categories that generated the largest number of frameworks with maximum scores for the assessed category (four points). Categories with multiple frameworks scoring four points implied that these concepts received greater consideration and offered illustrative explanations when included in a framework. Four categories generated the largest number of frameworks with 4-point category scores: 'Impact Evaluations/Surveillance' (with seven 4-point frameworks), 'Political Will/Government Engagement' (with six 4-point frameworks), 'Building Partnerships and Alliances' (with five 4-point frameworks), and 'Marketing Communications' (with five 4-point frameworks). Conversely, no framework received four points for its description of 'Reassessment Based on Changing Patterns/Needs' or 'Fortification Policy/Strategy'. This trend implies that fortification programme reassessment and the inclusion of fortification as a standalone policy or incorporation of fortification in a national strategy, were not considered critical components by multiple fortification framework designers. Figure 2 outlines the results of each scored matrix category and the number of total frameworks with a maximum category score.

Additional concepts and ideas not captured in the scored matrix were also compiled (Darnton-Hill, 1998; Micronutrient Initiative, 1996; Obare et al., 2017; USAID, 2021) and organized into three thematic areas: private sector involvement, business models/financial considerations, and partners and advocacy. These additional components found in the reviewed frameworks have been described in the literature as critical for food fortification programme success (Ebata et al., 2021; Hoogendoorn et al., 2016; Mannar & Hurrell, 2018; Osendarp et al., 2018), with certain countries documenting improved programme impact (Blüthner & Vierck, 2009; Durotoye et al., 2022; Garret et al., 2017; Mannar & Hurrell, 2018; Mora et al., 2000; Sablah et al., 2012; USAID Advancing Nutrition, 2023).

The additional component categorized as 'private sector involvement' included: informing the private sector of national micronutrient deficiencies and its role in providing solutions; addressing the communication gap that often exists between industry leaders and public sector leaders resulting in legislation and standards that may restrict, rather than enable, private sector investment in fortification;

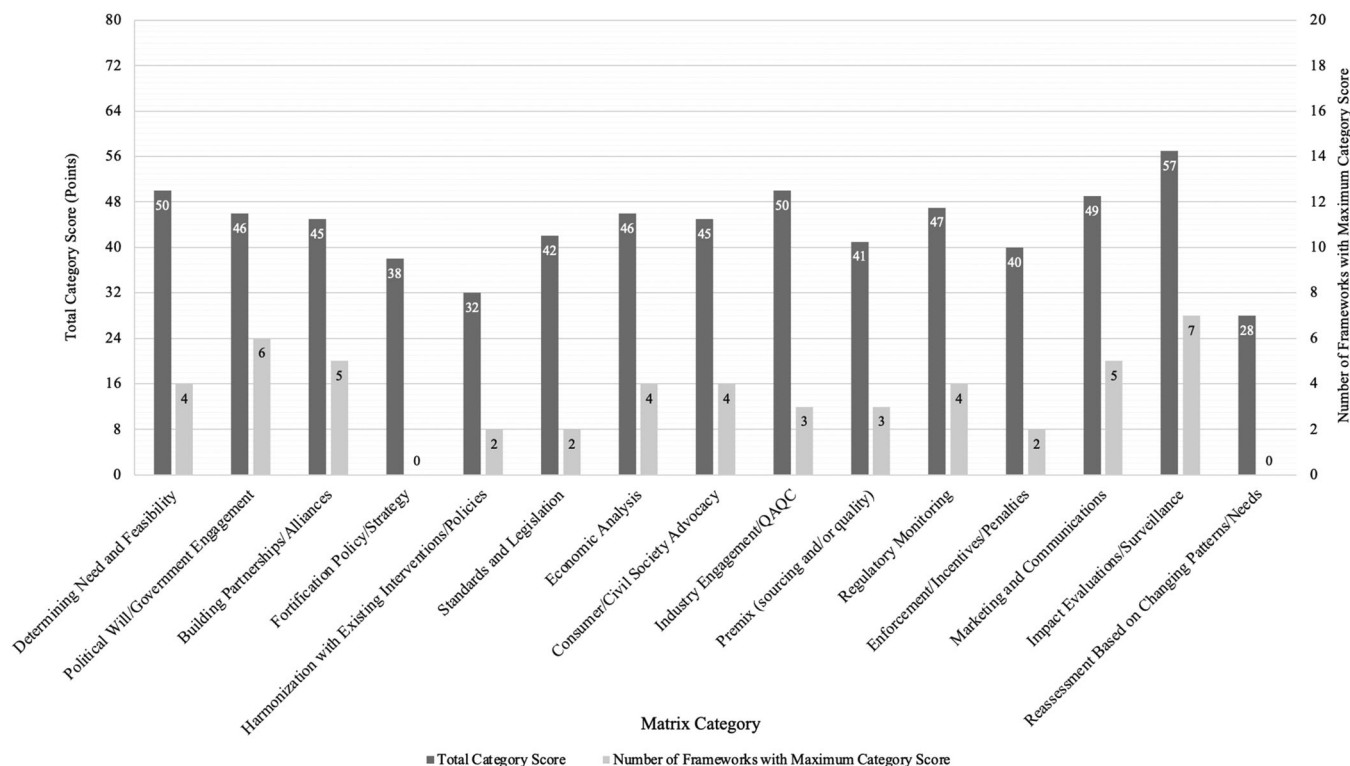


FIGURE 2 Matrix categories by total category score and number of frameworks with a maximum category score. Among matrix categories, 'Impact Evaluations/Surveillance', 'Determining Need and Feasibility' and 'Industry Engagement/Quality Assurance and Quality Control' generated the highest scores with 57, 50 and 50 points, respectively, implying that these categories were the strongest and mentioned the most frequently across frameworks. A second approach to scoring included reviewing categories that generated the largest number of frameworks with maximum scores for the assessed category (four points). Categories with multiple frameworks scoring four points implied that these concepts received greater consideration and offered illustrative explanations when included in a framework. Four categories generated the largest number of frameworks with 4-point category scores: 'Impact Evaluations/Surveillance' (with seven 4-point frameworks), 'Political Will/Government Engagement' (with six 4-point frameworks), 'Building Partnerships and Alliances' (with five 4-point frameworks), and 'Marketing Communications' (with five 4-point frameworks).

and employing a communication plan with unique public and private sector roles.

The additional component classified as 'business models/financial considerations' included: making the business case for fortification to national leaders and private sector food producers; including mitigation strategies to ensure access to finance and foreign exchange does not stymie implementation; offsetting the cost of fortification by improving planning and operational efficiencies and by including food technology and marketing assistance to food producers and processors to maximize the value of by-products (e.g., bran drying); and linking food industry compliance to increased access to finance and financial terms for general operations (including foreign exchange transactions for fortificant and food processing equipment imports).

Lastly, the additional component characterized as 'partners and advocacy' included: providing education and advocacy at the ministerial level regarding the national health and economic impacts of micronutrient deficiencies; involving regional health and monetary bodies from programme inception; involving industry associations and civil society entities from programme initiation; and engaging

development partners to pool resources to support knowledge management processes within countries to allow national governments to generate information for evidence-based planning and advocacy.

In-depth analysis of the literature and identification of critical fortification design and implementation components provided the authors with the basis for constructing a novel framework. Subsequently, the findings from this study were used to inform the creation of a comprehensive Fortification Blueprint that (a) considers the strengths, weaknesses and gaps, and innovative components found across the nineteen assessed frameworks and (b) leverages the decades of research, knowledge, and expertise regarding large-scale mandatory food fortification programme design and implementation. Although certain activities in the Blueprint were frequently mentioned in several evaluated frameworks, additional concepts cited less frequently—but critical to programming—were incorporated into the Blueprint (e.g., the capacitation of academic institutions and national budget allocations).

The Blueprint intends to refresh programme thinking and priorities and provide renewed guidance concerning programme

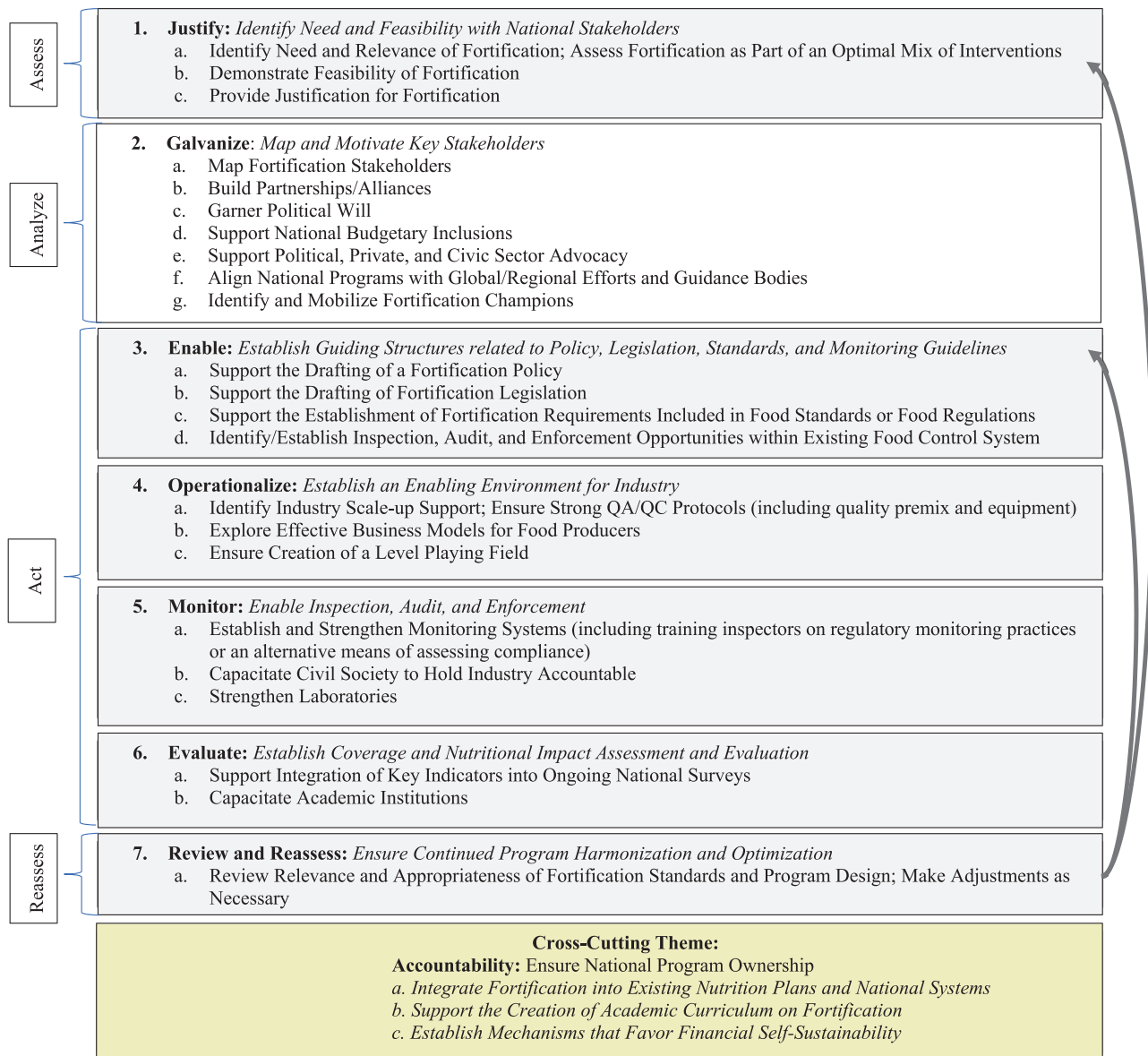


FIGURE 3 High-level summary of Fortification Blueprint. The Blueprint aims to serve as a comprehensive and actionable guide for individuals or entities involved in leading or supporting the design, implementation, monitoring and/or reassessment of large-scale mandatory food fortification programmes. The intended audience for the Blueprint includes all relevant fortification stakeholders, namely, government agencies, supporting organizations, the private sector, civil society groups and academia. The full Blueprint is organized into seven major programming actions with one major cross-cutting theme. Each action or sub-action includes live links for relevant tools and resources available on how to operationalize the action. The arrows flowing from 'Step 7: Review and Reassess' indicate that upon reassessment of a programme, users should either return to 'Step 1' or 'Step 3' and proceed to review these steps and all subsequent steps for relevance.

components required to design, implement, and scale fortification initiatives and achieve sustained nutrition impact goals. Further, the Blueprint intends to help better inform fortification programming policy and harmonize key design components, such as the identification of feasible fortification vehicles, creation of fortification standards that are grounded in public health/dietary inadequacy analyses, and improved regulatory monitoring practices. Thus, the Blueprint aims to serve as a comprehensive guide for individuals or entities involved in leading or supporting the design and implementation of large-scale mandatory food fortification programmes,

including government agencies and other stakeholders, supporting organizations and/or individuals. The audience also includes key stakeholders involved throughout the life cycle of the programme, such as the private sector, civil society groups and academia.

The Blueprint is organized into seven major programming actions, with each action further separated into specific detailed components. A high-level summary of the Blueprint and the full Blueprint resource can be found in Figure 3 and Supporting Information: Figure A1, respectively. Where relevant, the Blueprint provides a compendium of existing tools and/or resources to

complete each action to ensure each step is actionable by the user. As new tools and resources become available and/or the knowledge of the fortification landscape changes, the Blueprint will be updated accordingly.

Following the creation of the Blueprint, 13 key informants from 10 organizations were contacted via email in May 2021 to provide feedback and make suggestions for improvement. Six key informants responded with feedback via email and/or phone during the period of May 2021 to July 2021. Further, a Technical Working Group was formed to review and agree upon the proposed tools and resources provided as actional steps throughout the Blueprint.

Although the Blueprint provides the seven major programming actions as a sequence of steps, one following the other, it should be noted that several of the activities could occur simultaneously. The sequencing of the seven actions should be taken as a general guide and should not be interpreted as requiring countries to explicitly follow actions as numbered. For example, although countries will need to establish standards before the private sector begins fortification, a fortification strategy or policy does not necessarily need to be formally prepared before finalization of standards or legislation. Similarly, engaging and/or strengthening civil society or national laboratories can commence in the preliminary stages of fortification implementation and does not need to wait until the formulation of policies or strategies.

4 | DISCUSSION

Multiple food fortification frameworks used by various partners and agencies currently exist to guide programme managers (within governments and/or partner organizations) throughout the design, implementation, scale-up, and monitoring of large-scale mandatory fortification programmes. To optimize the programme design approach and increase the potential for programme impact and sustainability, 19 fortification frameworks were collected from published and unpublished literature and stakeholder interviews. The frameworks were subsequently reviewed and assessed for strengths, weaknesses, and unique attributes. Based on the assessment, a revised novel approach, the Fortification Blueprint, is proposed. To the knowledge of the authors, this study is the only comprehensive review and comparative analysis of global, regional, and/or national fortification frameworks.

According to matrix category scores, most reviewed frameworks included strong descriptions of (1) the necessity to ensure the existence of data related to the nutritional need or dietary gaps for micronutrients, and the feasibility of addressing said need or gap with food fortification ('Determining Need and Feasibility'); (2) the involvement of food producers in the planning phases and support to food producers in the implementation of internal monitoring protocols ('Industry Engagement/Quality Assurance and Quality Control'); and (3) the assessment of coverage and/or reach of the fortified foods among the population via surveillance and/or nutritional impact evaluations ('Impact Evaluations/Surveillance').

Conversely, four design elements cited the least frequently throughout the reviewed frameworks included: (1) the inclusion of fortification as a standalone policy or fortification incorporated in a national strategy initiative ('Fortification Policy and Strategy'); (2) methods to align fortification standards and/or policies with existing nutrition and micronutrient interventions and/or regional or global recommendations ('Harmonization with Existing Interventions/Policies'); (3) the inclusion of industry enforcement, incentives, and penalties ('Enforcement/Incentives/Penalties'); and (4) the reassessment of fortification programmes based on changing dietary patterns, industry structure, or nutritional needs ('Reassessment'). Design elements included the least frequently tended to represent weak areas of general programming across global fortification initiatives (García-Casal, 2014; Luthringer et al., 2015; Neufeld et al., 2017; Osendarp et al., 2018; Solon et al., 2000).

For example, fortification programmes are often designed without due attention to other existing micronutrient interventions in a country. Harmonizing fortification with national nutrition efforts and aligning policies with existing interventions help in the identification and provision of a mix of interventions that ensures populations are receiving adequate amounts of required nutrients (addressing dietary inadequacy while ensuring avoidance of excess amounts of micronutrients) (Neufeld et al., 2017).

In terms of industry enforcement, incentives, and penalties, although over 90% of fortification regulatory agencies in Africa and Asia use penalties to deter noncompliance, 82% of these agencies admit inconsistent use or ineffective enforcement of penalties (Luthringer et al., 2015). Regulatory agencies claim the utilization of penalties is politically risky due to perceived or legitimate resistance from interest groups. The political risk of enforcement results in lenient penalties that do not encourage adequate fortification or are inconsistently applied due to limited resources required to navigate extensive bureaucratic systems (Luthringer et al., 2015). To assuage these concerns, programme managers should facilitate an enabling environment for businesses to operate effectively and efficiently (Solon et al., 2000). Thus, in addition to and/or in place of penalties in such environments, effective incentives and favourable business structures, plans, and environments for food producers to operate should be provided and encouraged.

Finally, re-evaluating or reassessing the design of a national fortification programme after a period of time was least frequently mentioned across reviewed frameworks. This component includes periodically reviewing the data upon which the programme was built to ensure the continual relevance, safety, and potential for impact of the programme (García-Casal, 2014). The review should be based on changes such as in national consumption or dietary patterns, national/subnational micronutrient deficiencies prevalence, structure of the food producing industry, national nutrition needs and/or global fortification recommendations (Neufeld et al., 2017). However, in practice, few national fortification programmes endure a programming review process or document it (Neufeld et al., 2017). Reassessing contextual factors and their subsequent programme design implications is critical.

For instance, following a dietary inadequacy analysis conducted in Senegal after the establishment of the country's large-scale fortification programme, high rates of zinc inadequacy were found nationally among children under the age of five and women of reproductive age, in addition to regional pockets of high vitamin B12 deficiency. However, zinc and vitamin B12 are not currently included as nutrients in the national fortification standards of Senegal (Adams, 2023). Without returning to reassess programme design and implications based on changing contextual factors, this additional programming benefit would not have been determined by country stakeholders.

Additionally, in Guatemala, following a decrease in vitamin A deficiency after introduction of the sugar fortification programme, a potential elevated intake of vitamin A was identified in pregnant and lactating women in urban settings. Since the vitamin A fortification standard in the country was established in the 1960s based on sugar consumption levels during that period, increased levels of sugar consumption and unadjusted fortification standards led to increased levels of vitamin A consumption. As a result, the country modified the sugar fortification level to ensure safe and beneficial levels of vitamin A (Bielderman et al., 2016; Fiedler, 2013; Neufeld et al., 2017; Tanumihardjo et al., 2016). Without the review of the vitamin A level, this improvement to ensure safety would not have been identified.

The inclusion of national budgetary allocations for fortification programming was not explicitly assessed in the matrix. However, it was noted as an additional concept found in two of the reviewed frameworks (Lalani et al., 2019; USAID, 2021). Its lack of inclusion across the most reviewed frameworks is noteworthy provided that it is a programming component often excluded in the design process but is increasingly critical in practice for programme sustainability (Mannar & Hurrell, 2018). For instance, a lack of budget is identified as a challenge to ensuring fortification compliance, which in turn hinders sustainability (Luthringer et al., 2015). A national budgetary allocation for fortification includes a fortification-specific line item built into national budgets on a recurring basis to demonstrate political ability and willingness to support and prioritize the programme; this component is particularly relevant following cessation of external support. The budget may include line items for recurring monitoring exercises, coordination meetings, consumer advocacy campaigns or other activities.

Other budget or financing mechanisms uncovered in the reviewed frameworks that were not captured in the matrix include providing a whole-of-business approach to supporting food producers. This element includes assistance with business planning, providing access to finance, ensuring operational efficiencies, linking access to finance with compliance with food quality and safety standards, marketing and procuring fortificant and food processing equipment (including foreign exchange transactions for fortificant and food processing equipment imports) (Osendarp et al., 2018; USAID, 2021). Additionally, one framework recommended that development partners should consider pooling resources to support knowledge management processes within

countries to ensure the generation of information to support government in evidence-based planning and advocacy (Obare et al., 2017).

Moreover, the inclusion of national institutional research capacity was noted by only two of the reviewed frameworks. Yet, this component was found to be an element associated with increased sustainability and impact across multiple fortification programmes in Latin America (Martorell & de Romaña, 2017).

The findings from this analysis and the subsequent proposed Fortification Blueprint aim to leverage the existing global momentum around the adoption and maintenance of large-scale mandatory fortification programmes as an effective means of addressing pressing population-wide nutritional deficiencies and dietary inadequacies. For example, at the time of writing global momentum around large-scale fortification can be seen in the current partner alliance which exists between the Bill and Melinda Gates Foundation, UNICEF and the US Agency for International Development. Similarly, the Poshtik Network in India brings together key national and global stakeholders around the design of timely and effective implementation of fortification programming. The Blueprint is proposed at a time when there is a need for increasingly focused support to countries that demonstrate (a) a high potential for impact, based on the burden of specific micronutrient deficiencies, and/or dietary inadequacies (b) a high feasibility for fortification as a strategy to address national micronutrient deficiencies or dietary inadequacies (Kancherla et al., 2021). It is imperative to ensure these countries are provided with clear and concise technical knowledge, guidance, and relevant tools to initiate and maintain programmes. Now more than ever, as the world faces increased rates of nutritional deficiency and increasingly depleted economic situations in the wake of a global pandemic, the design and implementation of nutrition mitigation strategies, such as fortification programmes, should explicitly address the heart of historical programming challenges.

This study includes various strengths and limitations. First, a strength of this study is the comprehensive search criteria used in the literature review, which employed over 41 search terms. The literature review supplemented targeted searching of large guidance bodies that produce fortification programming material, such as WHO and FAO. Second, subject matter experts were contacted to (a) complement the literature review with any missed or unpublished frameworks and (b) provide content-specific feedback on the final proposed Blueprint. This process enabled the Blueprint to reflect the perspectives, experiences and knowledge of a multitude of fortification stakeholders, regional and global experts and in-country programme managers. Third, the study aimed to mitigate concerns regarding subjective framework scoring by utilizing a consistent scoring methodology. The descriptive methodology generated a robust review and assessment, which relied on specificity for future replicability. The main limitations of this study include the use of English language only frameworks and the exclusion of many frameworks published before 1975, as these older frameworks were largely inaccessible.

5 | CONCLUSION

The findings from this study and the proposed Fortification Blueprint intend to provide a call to action (and a means by which to operationalize this call to action) aimed at national and global-level policymakers, programme implementers, and donor agencies around the need to take a renewed look at fortification programme design. Due attention in the programme design process is required to ensure the inclusion of innovative models and overlooked or undervalued programming components that break from status quo operations and aid in swift and feasible programme adoption and maintenance based on the unique contextual needs and realities of the country.

AUTHOR CONTRIBUTIONS

Manpreet Chadha and Mandana Arabi conceptualized the research study and co-designed it with Laura A. Rowe. Laura A. Rowe and Roopa Darwar developed and implemented the search strategy and further data extraction, which was discussed with and reviewed by Manpreet Chadha and Mandana Arabi. Roopa Darwar analysed the data. Laura A. Rowe led the design of the Blueprint with support from Roopa Darwar, Manpreet Chadha, and Mandana Arabi. Roopa Darwar and Laura A. Rowe wrote the paper drafts and Laura A. Rowe and Ana M. S. Rosas wrote the final version. All authors contributed to critically reviewing and revising the paper and approved its final version.

ACKNOWLEDGEMENTS

The authors greatly appreciate the time and input of key consulted experts. The authors would like to specifically thank individuals from USAID, UNICEF and the Bill and Melinda Gates Foundation for their review of the Fortification Blueprint and associated cited resources. This research was undertaken with support from the Government of Canada. Laura A. Rowe conducted part of the analyses while she was an employee of FFI and would like to acknowledge their support and involvement.

CONFLICT OF INTEREST STATEMENT

Co-authors are employed with Emory University, Nutrition International (NI) and, at the time the work was conducted, the Food Fortification Initiative (FFI). Emory University supports evidence generation and dissemination. NI and FFI assist country leaders promote, plan, implement, monitor or evaluate food fortification.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Darwar, R., Rowe, L. A., Chadha, M., Rosas, A. M. S., & Arabi, M. (2023). A blueprint for fortification planning and programming: Lessons learned from an analytical review of existing fortification frameworks. *Maternal & Child Nutrition*, e13571. <https://doi.org/10.1111/mcn.13571>