Évaluation de la performance et le potentiel de l'impact des programmes nationaux d'enrichissement des aliments à grande échelle

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Évaluation de la performance et le potentiel de l'impact des programmes nationaux d'enrichissement des aliments à grande échelle

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RÉSUMÉ

Les carences en micronutriments restent prévalentes dans les pays à revenu faible et intermédiaire et touchent de manière disproportionnée les jeunes enfants et les femmes en âge de procréer (FAP). Malgré le fait que l'impact de l'enrichissement des aliments sur le statut en micronutriments de populations ait été démontré de manière incontestable, ce potentiel d'impact est limité dans la pratique en raison de lacunes importantes dans la conception et la mise en œuvre des programmes. Ces lacunes sont en partie liées à une collecte et une utilisation non optimale des données employées pour les prises de décision. L'objectif général de cette thèse était d'évaluer les méthodes d'évaluation de la performance et du potentiel d'impact des programmes d'enrichissement des aliments à grande échelle, et de fournir des conseils sur la prise de décision en se fondant sur des données probantes afin de favoriser la conception et la mise en œuvre efficaces de programmes.

Nous avons quantifié les apports apparents en micronutriments provenant d'aliments enrichis chez les FAP dans le cadre d'enquêtes transversales auprès de ménages infranationales (Nigeria [n=1461], Afrique du Sud [n=419]) et nationales (Tanzanie [n=957], Ouganda [n=719]). De surcroît, nous avons comparé deux méthodes d'évaluation diététique simplifiées (un questionnaire sur l'acquisition et l'achat d'aliments (QAAA) et un questionnaire semi-quantitatif sur la fréquence de consommation alimentaire (SQ-FCA)) avec des rappels de 24 heures pour estimer la consommation d'aliments fortifiables chez 123 enfants (12-18 mois) et leurs mères (18-49 ans) à Mandaluyong City, aux Philippines. Enfin, nous avons appliqué le cadre analytique GRADE (en anglais Grading of Recommendations Assessment, Development, and Evaluation) de preuves à la décision pour les décisions relatives aux systèmes de santé et à la santé publique dans le cadre du programme d'enrichissement nigérian, afin d'explorer son utilité pour la prise de décision dans les programmes d'enrichissement des aliments.

Dans les enquêtes auprès des ménages, nous avons constaté que, malgré un manque de rigueur en termes de mise en œuvre du programme, les aliments enrichis ont largement contribué aux apports en vitamine A et en iode, mais pas en fer, chez les FAP. Ces indicateurs ont permis d'identifier les améliorations nécessaires à apporter au programme afin de minimiser le risque d'apports faibles ou excessifs. Dans l'étude comparative, nous avons constaté que le SQ-FCA, mais pas le QAAA, a permis de récolter des informations utiles sur les habitudes de consommation d'aliments enrichissants pouvant servir à la prise de décisions relatives à la conception et au suivi des programmes d'enrichissement. La méthode QAAA doit être renforcée pour prendre en compte les aliments préparés et minimiser les sous-estimations et les surestimations. Le cadre analytique GRADE de preuves à la décision est un outil pratique pour faciliter et documenter l'utilisation des données qui servent à la prise décisions relatives au lancement, au renforcement, au maintien ou à la poursuite des programmes d'enrichissement. Cet outil pourrait aider les décideurs à renforcer les processus de prise de décision en matière d'enrichissement.

Une bonne conception du programme ainsi qu'un processus continu de collecte et utilisation de données de suivi des performances tout au long du cycle du programme d'enrichissement des aliments, sont essentiels pour s'assurer que le potentiel d'impact est réalisé et que les risques sont atténués. Les résultats de cette recherche fournissent des preuves sur les outils et les méthodes appropriés pour la collecte et l'utilisation de ces données afin d'informer les processus de prise de décision politique nécessaires pour améliorer la conception du programme, sa mise en œuvre et, en fin de compte, son impact sur la santé.

Mot clés : enrichissement des aliments à grande échelle ; aliments enrichis ; évaluation diététique ; apports nutritionnels ; prise de décision

ABSTRACT

Micronutrient deficiencies remain prevalent in low- and middle-income countries and disproportionately affect young children and women of reproductive age (WRA). Although the impact of food fortification on the micronutrient status of populations has been demonstrated beyond a doubt, this impact potential is constrained in practice by critical gaps in program design and implementation. These are partly linked to suboptimal collection and use of data for decision making. The overall aim of this thesis was to evaluate methods for assessing performance and potential for impact of large-scale food fortification programs and provide guidance on evidence-based decision making for effective program design and delivery.

We quantified apparent micronutrient intakes from fortified foods among WRA in subnational (Nigeria [n=1461], South Africa [n=419]) and national (Tanzania [n=957], Uganda [n=719]) cross-sectional, clustered household surveys. Additionally, we compared two simplified dietary assessment methods (i.e., a food acquisition and purchase questionnaire (FAPQ) and a 7-d semi-quantitative food frequency questionnaire [SQ-FFQ]) against 24-h recalls for estimating consumption of fortifiable foods among 123 children (12-18 mo) and their mothers (18-49 y) in Mandaluyong City, Philippines. Finally, we applied the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Evidence to Decision (EtD) framework for health system and public health decisions to the Nigerian fortification program to explore its utility for decision making in food fortification programs.

In the household surveys, we found that, despite inconsistent fidelity of program implementation, fortified foods were major contributors to vitamin A and iodine intakes, but not iron, among WRA. These indicators helped identify program improvements needed to minimize risk of low or excessive intakes. In the comparison study, we found that the SQ-FFQ, but not the FAPQ, generated useful information on fortifiable food consumption patterns that can inform decisions related to fortification program design and monitoring. The FAPQ method needs to be strengthened to capture prepared foods and minimize under- and over-estimation. The GRADE EtD framework is a practical tool to facilitate and document the use of evidence to inform decisions to start, strengthen, sustain, or continue fortification programs. This tool could help policymakers strengthen fortification decision-making processes.

Good program design and continual collection and use of performance monitoring data throughout the fortification program cycle are essential to ensure that impact potential is realized, and risks are mitigated. Findings from this research provide evidence on appropriate tools and methods for collecting and using such data to inform policy decision making processes necessary to improve program design, delivery, and ultimately health impacts.

Key words: large-scale food fortification; fortified foods; dietary assessment; nutrient intakes; decision making

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Abbreviations

AME	Adult male equivalent
EAR	Estimated average requirement
EtD	Evidence to Decision
FAP	Femmes en âge de procréer
FACT	Fortification Assessment Coverage Toolkit
FAPQ	Food acquisition and purchase questionnaire
GAIN	Global Alliance for Improved Nutrition
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
HCES	Household consumption and expenditure surveys
LMIC	Low- and middle-income country
PIP	Program impact pathway
QAAA	Questionnaire sur l'acquisition et l'achat d'aliments
RNI	Recommended nutrient intake
SQ-FCA	Semi-quantitatif sur la fréquence de consommation alimentaire
SQ-FFQ	Semi-quantitative food frequency questionnaire
UL	Tolerable upper intake level
VAS	Vitamin A supplements
WRA	Women of reproductive age

RÉSUMÉ DÉTAILLÉ

Contexte et justification

Les carences en micronutriments restent prévalentes dans les pays à revenu faible et intermédiaire et touchent de manière disproportionnée les jeunes enfants et les femmes en âge de procréer (FAP) (1). Ces groupes de population sont plus exposés au risque de malnutrition en micronutriments étant donné leurs besoins plus élevés en nutriments au cours de ces étapes critiques de la vie pour assurer une croissance et un développement appropriés (2). Les stratégies courantes pour remédier aux carences en micronutriments comprennent la supplémentation en vitamines et minéraux (à court terme), l'enrichissement des aliments (à moyen et long terme) et la diversification alimentaire (objectif ultime à long terme pour la plupart des nutriments, mais pas tous).

L'enrichissement des aliments, défini dans cette thèse comme l'ajout de vitamines et/ou de minéraux essentiels lors de la transformation des aliments de base et des condiments couramment consommés par une population, est une stratégie largement mise en œuvre dont les effets positifs sur le statut en micronutriments et le fonctionnement biologique des populations ont été démontrés (3). En septembre 2021, l'enrichissement des aliments était obligatoire dans 124 pays pour le sel, 85 pays pour la farine de blé, 17 pays pour la farine de maïs, 27 pays pour l'huile comestible, 9 pays pour le sucre et 7 pays pour le riz, et de nombreux autres pays avaient adopté des directives volontaires pour ces produits et d'autres alimentaires (4,5). Malgré ce nombre élevé de pays mettant en œuvre des programmes d'enrichissement dans le monde, des données probantes sur leur performance et de leur potentiel d'impact biologique sont un manque tangible. C'est également le cas concernant l'utilisation systématique et transparente de ces données pour la prise de décision liée à la conception et à la mise en œuvre des programmes. Ce manque de données probantes a suscité le scepticisme de certains quant au potentiel d'impact et la crainte d'effets négatifs liés aux programmes d'enrichissement des aliments (6).

Des méthodes et des outils standardisés, tels que le Fortification Assessment Coverage Toolkit (FACT) (7), ont été mis au point afin de faciliter la collecte et l'analyse de données sur la performance et l'impact potentiel des programmes d'enrichissement. Cependant, une recherche plus approfondie est nécessaire pour renforcer certaines composantes. Par exemple, bien qu'il ait été démontré que l'utilisation d'indicateurs sur la couverture des ménages en aliments fortifiés permettait d'identifier les améliorations à apporter aux programmes (8,9), l'utilisation et l'utilité des indicateurs sur les apports en micronutriments des aliments fortifiés pour estimer la performance et l'impact potentiel des programmes n'ont pas été démontrées. De plus, afin de réduire les ressources techniques et financières nécessaires à la collecte et à l'analyse des données, la méthode FACT utilise des méthodes d'évaluation diététique simplifiées pour estimer les apports alimentaires fortifiables au niveau individuel. Plus précisément, elle utilise un questionnaire d'acquisition et d'achat d'aliments (QAAA) (pour la plupart des aliments) et un questionnaire semi-quantitatif sur la fréquence de consommation alimentaire (SQ-FCA) de 7 jours (pour la farine de blé uniquement dans certains contextes). Alors que les méthodes simplifiées pourraient augmenter la disponibilité des données pour des prises de décision programmatiques, des données probantes quant à leur précision par rapport aux méthodes de référence sont limitées. Parmi les études qui ont utilisé des données sur l'acquisition et l'achat d'aliments pour évaluer la consommation d'aliments de base potentiellement fortifiables par rapport aux méthodes de référence, la consommation de farine de blé a été systématiquement sous-estimée, tandis que la concordance entre les études variait pour les autres aliments (10-12). Aucune étude n'a comparé les SQ-FCA aux méthodes de référence pour évaluer spécifiquement l'apport en aliments fortifiables ; cependant, parmi celles qui ont évalué l'apport en aliments généraux et/ou en groupes d'aliments, la concordance variait et une validation spécifique au contexte est recommandée (13-15).

En outre, si la nécessité d'utiliser les données pour éclairer la conception et la mise en œuvre des programmes de nutrition est bien reconnue (16), sa mise en pratique dans le domaine de l'enrichissement des aliments est souvent limitée en raison de divers facteurs. La disponibilité limitée de données probantes pour éclairer les décisions relatives aux programmes (17) et les processus décisionnels complexes des décideurs (18) font partie du problème. Cependant, une contrainte majeure est l'absence d'un cadre conceptuel qui structure explicitement le cycle de programme d'enrichissement des aliments et identifie les décisions clés à prendre lors des différentes étapes. En conséquence, alors que les programmes d'enrichissement des aliments sont censés servir de moyens d'interventions à moyen ou long terme pour remédier aux carences en micronutriments, ils sont souvent mis en place avec peu ou pas de révision, ni de planification pour des futurs ajustements (19). En outre, les décisions relatives aux programmes d'enrichissement des aliments sont souvent prises et mises en œuvre indépendamment d'autres de lutte contre les carences en micronutriments qui se chevauchent (par exemple, la supplémentation) interventions effectuées par différentes parties prenantes nationales et internationales (20). Finalement, il n'existe pas de directives ou de réglementations pour définir la manière de coordonner efficacement les interventions afin d'assurer l'impact et la sécurité dans le temps (21). Des recherches sont donc nécessaires pour développer des outils pratiques et accessibles aux parties prenantes dans le domaine de l'enrichissement des aliments, qui montrent comment utiliser les données afin de prendre des décisions programmatiques à différents stades du processus et, dans le contexte d'interventions en micronutriments qui se chevauchent, pour assurer un impact et une sécurité continus et durables dans le temps.

Objectifs

L'objectif général de cette thèse était d'évaluer les méthodes d'évaluation de la performance et du potentiel d'impact des programmes nationaux d'enrichissement des aliments à grande échelle, et de fournir des conseils sur la prise de décision en se fondant sur des données probantes afin de favoriser la conception et la mise en œuvre efficaces de programmes.

Les objectifs spécifiques étaient de :

1. quantifier les contributions mesurées et potentielles des aliments fortifiés aux apports en micronutriments dans les régimes alimentaires des FAP et démontrer l'utilisation et l'utilité de ces indicateurs pour évaluer la performance et le potentiel d'impact des programmes d'enrichissement des aliments;
2. comparer deux méthodes d'évaluation diététique simplifiées (c.-à-d. un QAAA et un SQ-FCA de 7 jours) aux rappels de 24 heures pour estimer la consommation d'aliments fortifiables chez les jeunes enfants et les FAP; et
3. démontrer comment un cadre décisionnel pour le système de santé et les décisions de santé publique peut être appliqué pour formuler des recommandations et prendre des décisions dans le cadre des programmes nationaux d'enrichissement des aliments.

Résumé des résultats

Pour répondre à l'objectif 1, en utilisant les données d'enquêtes transversales FACT menées dans quatre pays africains, nous avons quantifié les apports apparents en nutriments provenant d'aliments enrichis chez les FAP et démontré comment utiliser les résultats pour comprendre la performance et l'impact potentiel des programmes. Nous avons constaté qu'en dépit du manque de rigueur lors de la mise en œuvre, les aliments fortifiés contribuaient encore largement aux apports en vitamine A et en iode, mais pas en fer, chez les FAP. Nos résultats ont mis en évidence plusieurs programmes risquant d'entraîner des apports faibles ou excessifs en nutriments en raison d'une conception et/ou d'une mise en œuvre médiocre du programme, et ont permis d'identifier des améliorations potentielles du programme afin de minimiser ces risques. En outre, la méthode FACT employée dans les enquêtes a utilisé des données de consommation alimentaire au niveau des ménages et des hypothèses quant à la distribution intra-ménage de l'aliment (selon la méthode de l'équivalent homme adulte) pour estimer la consommation apparente au niveau individuel d'aliments fortifiables chez les FAP. Ce faisant, nous avons constaté que la méthode de l'équivalent homme adulte présente probablement des erreurs de précision et d'estimation importantes pour certains aliments. Cette situation pourrait être liée à des inexactitudes dans la mesure de produits fabriqués à partir de l'aliment fortifié achetés et/ou consommés hors du domicile, des inexactitudes dans l'utilisation au sein des ménages, ou une distribution inéquitable entre les ménages. Par exemple, dans ces analyses, il est probable que la méthode de l'équivalent homme adulte ait sous-estimé la quantité de farine de blé fortifiable consommée (et les apports en fer qui en découlent) dans la population ougandaise, car d'autres études ont rapporté que le pain et d'autres produits contenant de la farine de blé préparés à partir de farine de blé fortifiable sont largement achetés, alors que les analyses actuelles ont estimé que les quantités consommées étaient négligeables. En outre, il est possible que la quantité d'huile (et les apports en vitamine A qui en découlent) consommée dans certains pays ait été surestimée, car la méthode de l'équivalent homme adulte suppose que la quantité totale disponible dans le ménage est consommée, mais ne tient pas compte de l'huile qui est jetée ou réutilisée lors de la préparation des aliments.

Pour répondre à l'objectif 2 et explorer plus avant les limites de la méthode de l'équivalent homme adulte mentionnées ci-dessus, nous avons utilisé les données d'une étude menée à Mandaluyong City, aux Philippines, qui a évalué l'apport en vitamine A chez des enfants de 12 à 18 mois exposés à des suppléments de vitamine A. Parmi les enfants et leurs mères (18 à 49 ans), nous avons évalué la consommation de farine et d'huile de blé fortifiables ou de farine de blé fortifiable uniquement à l'aide d'un QAAA ou d'un SQ- FCA de 7 jours respectivement, et nous avons comparé les résultats avec les rappels de 24 heures utilisée comme méthode de référence. Pour la farine de blé enrichie, nous avons constaté que les estimations de la SQ- FCA se situaient dans une fourchette de 5 à 22 % par rapport à celles des rappels de 24 heures, tandis que la méthode QAAA sous-estimait systématiquement et significativement la consommation de farine de blé enrichie (plus de 6 fois) par rapport aux rappels de 24 heures. Ce dernier point est en grande partie dû au fait que le QAAA n'a pas mesuré les aliments contenant de la farine de blé achetés et/ou consommés en dehors du foyer. En ce qui concerne les huiles fortifiables, le QAAA a surestimé les apports en huiles fortifiables (de 2 à 2,5 fois) par rapport aux rappels de 24 heures. Cela était probablement dû à des inexactitudes dans l'utilisation du ménage et/ou à une distribution inéquitable des aliments au sein du ménage. Alors que le SQ- FCA a généré des informations utiles sur les habitudes de consommation d'aliments fortifiables qui peuvent éclairer les décisions relatives à la conception et au suivi des programmes d'enrichissement des aliments, la méthode du QAAA doit être renforcée pour prendre en compte les aliments préparés et minimiser la sous-estimation et la surestimation.

Pour répondre à l'objectif 3, nous avons appliqué le cadre analytique GRADE (en anglais Grading of Recommendations Assessment, Development, and Evaluation) de preuves à la décision pour les décisions relatives aux systèmes de santé et à la santé publique, à un exemple concret afin d'illustrer comment il peut être utilisé pour formuler des recommandations et prendre des décisions dans le cadre de programmes nationaux d'enrichissement des aliments. L'exemple spécifique était une recommandation visant à modifier le programme d’enrichissement des aliments à grande échelle au Nigeria afin de réduire le risque d'apports excessifs en vitamine A. L'exemple du Nigéria démontre comment le cadre preuves à la décision peut faciliter l'engagement des parties prenantes et guider les processus décisionnels des programmes d’enrichissement des aliments, renforcer la crédibilité des décisions prises en documentant les données (ou l'absence de données) de manière systématique et transparente, et accroître la prise en compte des résultats par les décideurs grâce à son format accessible. Cet outil pourrait aider les décideurs à renforcer les processus de prise de décision dans les programmes nationaux d’enrichissement des aliments.

Contributions de la recherche aux programmes d’enrichissement des aliments

Contributions méthodologiques

L'élaboration de la méthode FACT en 2013 a permis de combler une lacune dans le domaine des outils normalisés et adaptés à l'évaluation de la couverture des programmes d’enrichissement des aliments (22). Lors de son déploiement dans plus de 16 pays (7), l'utilisation et l'utilité des indicateurs de couverture des ménages pour identifier les lacunes dans la conception et la mise en œuvre des programmes et les domaines à améliorer ont été clairement démontrées (8). Cependant, l'utilisation et l'utilité des indicateurs sur les apports en micronutriments des aliments fortifiés parmi les populations cibles pour estimer la performance du programme et son impact potentiel n'ont pas été démontrées. Par conséquent, une contribution substantielle de cette recherche a été la quantification de ces indicateurs et la démonstration de leur utilisation et de leur utilité pour comprendre la performance et le potentiel d'impact des programmes d’enrichissement des aliments. En outre, nous avons montré que ces indicateurs sont relativement simples et directs à calculer, mais qu'ils génèrent une mine d'informations qui peuvent facilement (et visuellement lorsqu'ils sont présentés sous forme de graphique) identifier les améliorations spécifiques à apporter aux programmes pour augmenter leur potentiel d'impact.

Les méthodes d'évaluation diététique simplifiée, telles que les QAAA et les SQ- FCA, sont plus fréquemment utilisées dans les pays à revenu faible et intermédiaire que les rappels de 24 heures, souvent dans le cadre d'enquêtes nationales (par exemple, les enquêtes sur la consommation et les dépenses des ménages ; en anglais, Household Income and Expenditure Surveys). Ces méthodes, et les enquêtes plus récentes de FACT, ont un grand potentiel pour augmenter la disponibilité des données de consommation d'aliments fortifiables pour la prise de décision dans plusieurs étapes du programme d'enrichissement des aliments. Cependant, peu d'études ont comparé leur précision aux méthodes de rappel de 24 heures pour évaluer les apports en aliments fortifiables. Par conséquent, une contribution importante de la présente recherche a été la comparaison de ces deux méthodes simplifiées avec les rappels de 24 heures pour estimer la farine et l'huile de blé fortifiables dans deux groupes de population (jeunes enfants et FAP) qui sont le plus souvent les cibles des programmes d'enrichissement des aliments. Cette comparaison a permis d'identifier les principales sources d'erreur lors de l'utilisation de ces deux méthodes simplifiées pour estimer la farine et l'huile de blé fortifiables, c'est-à-dire l'erreur systématique pour le QAAA et l'erreur aléatoire pour la SQ-FCA. Ces résultats ont permis d'identifier des orientations importantes pour les futures recherches nécessaires pour mieux comprendre ces sources d'erreur et renforcer la précision de ces méthodes.

Contributions théoriques

Cette recherche a également apporté d'importantes contributions théoriques. Bien que la nécessité d'utiliser des données pour éclairer la conception et la mise en œuvre des programmes de nutrition soit reconnue (16), sa pratique dans le domaine de l'enrichissement des aliments est souvent limitée en raison de nombreux facteurs, y compris (mais sans s'y limiter) le manque de disponibilité de données probantes pour éclairer les décisions relatives aux programmes (17), la complexité des processus décisionnels (18) et le manque de conseils et d'outils pratiques démontrant comment et quand utiliser les données pour la prise de décision. Pour répondre à cette dernière contrainte, cette recherche visait à ajouter une structure au processus de prise de décision dans les programmes d’enrichissement des aliments en développant un cadre conceptuel qui énonce explicitement le cycle du programme d’enrichissement des aliments et identifie les décisions clés à prendre (et les décideurs correspondants) durant les différentes phases en lien avec le chemin d’impact programme d’enrichissement des aliments. À travers cadre conceptuel proposé, les possibilités d'évaluer (ou de réévaluer) les décisions clés du programme sont mises en évidence, ainsi que les questions spécifiques auxquelles il est nécessaire de répondre à chaque étape. En intégrant ce cadre et un système d'examen régulier de ces questions dans un cycle de programme d’enrichissement des aliments, les processus de prise de décision peuvent être renforcés, et un examen continu et une correction de trajectoire basée sur des données peuvent devenir une routine pour s'assurer que le potentiel d'impact est réalisé et que les risques sont atténués.

Implications pour les programmes d’enrichissement des aliments

L'efficacité et l'impact de l’enrichissement des aliments dépendent de la conception et de la mise en œuvre appropriées des programmes. Par conséquent, les parties prenantes des programmes nationaux d’enrichissement des aliments (y compris les décideurs politiques, les transformateurs d'aliments et les partenaires de développement) doivent donner la priorité à l'évaluation systématique des résultats des programmes, y compris la qualité, la consommation et la contribution en micronutriments des aliments fortifiés, par le biais d'efforts de suivi continus. Ce faisant, les programmes d'enrichissement seront en mesure de générer les informations nécessaires pour suivre les progrès, identifier et surmonter les obstacles et, en fin de compte, atteindre leur objectif qui consiste à combler les lacunes en micronutriments et d'améliorer la santé de la population. Cette recherche fournit des preuves sur les méthodes et les outils appropriés pour évaluer ces indicateurs, décrit comment ils sont liés à la performance du programme et à son potentiel d'impact, et démontre comment utiliser les données résultantes pour éclairer les décisions.

Traduire les données en recommandations et en décisions est souvent un défi majeur auquel sont confrontés les programmes de nutrition, y compris l'enrichissement des aliments. Bien que les résultats de la troisième étude fournissent des preuves convaincantes quant à l'utilisation d'un cadre décisionnel pour renforcer et promouvoir des processus décisionnels systématiques et transparents dans les programmes nationaux d'enrichissement des aliments, l'adhésion et la capacité des parties prenantes (généralement les décideurs), qui seraient finalement responsables de la mise en œuvre de ces processus, sont essentielles pour qu'ils soient efficaces et durables dans le temps. Pour aller de l'avant, il est nécessaire d'explorer les obstacles potentiels et les domaines de développement des capacités parmi les parties prenantes en ce qui concerne l'utilisation de tels cadres de prise de décision.

Orientations pour les recherches futures

Les méthodes d'évaluation de la consommation d'aliments fortifiés et les apports subséquents en micronutriments provenant des aliments fortifiés présentées dans les deux premières études, sont de nature transversale et présentent donc des informations décrivant un programme d'enrichissement des aliments à un moment (et un lieu) précis. Bien que ces méthodes soient utiles pour prendre des décisions relatives à la conception des programmes (par exemple, la sélection des aliments à enrichir) et pour comprendre la performance des programmes (par exemple, la qualité par rapport aux normes nationales d'enrichissement) et leur impact potentiel (par exemple, la contribution à la réduction des carences en micronutriments dans le régime alimentaire), comme nous l'avons vu précédemment, elles présentent des limites, notamment en ce qui concernent *les raisons* pour certains programmes ne sont pas (ou sont) mis en œuvre efficacement et n'atteignent ainsi pas (ou atteignent) leur potentiel impact. Par exemple, pourquoi la conformité de l'industrie pour certains aliments est-elle faible (et donc les apports en micronutriments sont faibles) et comment pourrait-on améliorer cette situation ? Pour combler cette lacune, des recherches sur la mise en œuvre, qui visent à comprendre les forces et les faiblesses au sein et entre les différents domaines qui affectent la mise en œuvre (23), devraient être intégrée dans les programmes d'enrichissement des aliments. Ceci afin de comprendre comment aborder les obstacles spécifiques à une mise en œuvre efficace des programmes identifiés dans différents contextes. L'importance et la nécessité de donner la priorité à la recherche sur la mise en œuvre dans le domaine de la nutrition ont été récemment soulignées comme un champ de recherche essentiel pour combler le fossé entre la compréhension des interventions efficaces et la réalisation effective des impacts dans les programmes à grande échelle (23,24). On trouve dans la littérature quelques exemples récents de la façon dont cela peut être fait dans les programmes d'enrichissement des aliments. Par exemple, une évaluation de processus qui visait à comprendre les moteurs de l'adhésion au double enrichissement du sel en Inde (25).

Les résultats sur l'exactitude d'un QAAA ciblé au niveau des ménages et d'un SQ-FCA au niveau individuel pour évaluer la consommation d'aliments fortifiables présentés dans la deuxième étude ont permis d'identifier d'importants domaines de recherche future liés à une meilleure compréhension des sources d'erreur dans l'application de la méthode de l'équivalent homme adulte aux données QAAA. Cependant, étant donné que de nombreux pays à revenu faible ou intermédiaire connaissent actuellement une transition nutritionnelle, y compris un changement majeur vers l'achat de produits alimentaires préparés et transformés (26), l'utilité d'un QAAA au niveau des ménages peut être réduite au fil du temps, à moins qu'il ne puisse être adapté pour répondre à ces changements dans les habitudes d'achat et de consommation. Bien que la méthode SQ- FCA au niveau individuel, qui tient compte des aliments fortifiables à la fois à la maison et à l'extérieur, puisse sembler une solution de rechange simple étant donné son succès dans l'évaluation de la farine de blé fortifiable dans la deuxième étude, des recherches plus approfondies sont nécessaires pour le confirmer. Il serait probablement en effet plus difficile de concevoir une méthode pour d'autres aliments fortifiables (p. ex., l'huile, le sel) en raison de la difficulté d'évaluer les quantités consommées dans les aliments préparés obtenus à l'extérieur du foyer. De plus, il pourrait être plus aisé de modifier un module QAAA au niveau du ménage qui est déjà utilisé dans les enquêtes existantes menées de façon routinière (par exemple, les enquêtes sur la consommation et les dépenses des ménages) que d'essayer d'ajouter un nouveau SQ- FCA au niveau individuel. Les futures recherches devraient explorer la faisabilité et les compromis en termes de coût et d'effort pour mettre en œuvre et intégrer dans différentes enquêtes existantes entre ces deux méthodes simplifiées (et potentiellement d'autres).

Enfin, le cadre analytique GRADE de preuves à la décision pour les décisions relatives au système de santé et à la santé publique utilisé dans la troisième étude n'est qu'une des nombreuses ressources disponibles qui peuvent être utilisées pour aider lors des processus de prise de décision dans le cadre des programmes d’enrichissement des aliments. Il existe d'autres cadres et méthodes d'analyse des politiques, comme la méthode " The Eightfold Path " proposée par Bardach et Patashnik (27). Cette méthode comprend les huit étapes suivantes 1) définir le problème ; 2) rassembler quelques données ; 3) élaborer des alternatives ; 4) sélectionner des critères ; 5) projeter les résultats ; 6) confronter les compromis ; 7) s'arrêter, se concentrer, restreindre, approfondir, décider ; et 8) raconter son histoire. Bien que le cadre analytique GRADE de preuves à la décision ait suivi une approche initiale similaire, il ne s'est concentré que sur les étapes 1 à 4 du "chemin octuple". D'autre recherches sont nécessaires pour déterminer comment renforcer les étapes suivantes du processus de prise de décision, notamment en ce qui concerne les compromis (par exemple, lorsqu'on essaie de coordonner des interventions en micronutriments qui se chevauchent) et la concentration et la prise de décision pour garantir l'accord, l'appropriation et l'adoption de recommandations dans le contexte de l'enrichissement des aliments et d'autres programmes de nutrition.

Conclusions

Il ne fait aucun doute que, lorsqu'elle est bien conçue et mise en œuvre, l'enrichissement des aliments est une stratégie efficace pour lutter contre les carences en micronutriments et que les décisions relatives aux programmes doivent être fondées sur des données probantes. Malgré cela, la mise en pratique de programmes bien conçus et mis en œuvre s'est avérée être un défi majeur limitant l'impact des programmes d'enrichissement des aliments dans le monde entier. Cet ensemble de recherche fournit des données pratiques sur les méthodes et les outils appropriés pour évaluer la performance des programmes et leur potentiel d'impact et démontre comment utiliser les données résultantes pour éclairer les décisions nécessaires à l'amélioration de la conception et de la mise en œuvre des programmes et des résultats sanitaires. L'établissement d'un lien entre les données et la prise de décision est essentiel pour libérer tout le potentiel de l'enrichissement des aliments.

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CHAPTER 1: Introduction

1.1 Background and rationale

Micronutrient deficiencies remain prevalent in low- and middle-income countries (LMICs) and disproportionately affect young children and women of reproductive age (WRA) (1). These population groups are at greater risk of micronutrient malnutrition given their higher nutrient requirements during these critical life stages to ensure proper growth and development (2). Common strategies to address micronutrient deficiencies include supplementation with vitamins and minerals (short-term), food fortification (medium- to long-term), and dietary diversification (ultimate long-term goal for most, but not all, nutrients).

Food fortification, defined in this thesis as the addition of essential vitamins and/or minerals during processing to staple foods and condiments that are commonly consumed in a population, is a widely implemented strategy that is proven to have positive impacts on the micronutrient status and biological outcomes of populations (3). As of September 2021, food fortification is mandated in 124 countries for salt, 85 countries for wheat flour, 17 countries for maize flour, 27 countries for edible oil, 9 countries for sugar, and 7 countries for rice with many additional countries having voluntary guidelines for these and other food vehicles (4,5). Despite this high number of countries implementing fortification programs globally, evidence on their performance and potential for biological impact is scarce, as is the systematic and transparent use of such data for decision making related to program design and implementation. This gap in evidence has led to skepticism among some on the potential for impact and fear of negative effects of food fortification programs (6).

Standardized methods and tools, such as the Fortification Assessment Coverage Toolkit (FACT) (7), were developed to facilitate the collection and analysis of data on performance and potential for impact of fortification programs. However, further research is needed to strengthen some components. For example, although the use of indicators on household coverage of fortified foods have been shown to identify program improvements needed (8,9), the use and utility of indicators on micronutrient contributions from fortified foods to estimate program performance and potential for impact have not been demonstrated. In addition, to reduce the technical and financial resources required for data collection and analysis, the FACT method employs simplified dietary assessment methods for estimating individual-level fortifiable food intake. Specifically, it uses a food acquisition and purchase questionnaire (FAPQ) (for most foods) and a 7-d semi-quantitative food frequency questionnaire (SQ-FFQ) (for wheat flour only in some contexts). While simplified methods could increase the availability of data for programmatic decision making, evidence on their accuracy compared to reference methods is limited. Among studies that used food acquisition and purchase data to assess intake of potentially fortifiable staple foods compared to reference methods, wheat flour intake was consistently underestimated while agreement varied for other foods (10–12). No studies have compared SQ-FFQs against reference methods for assessing intake of fortifiable foods specifically; however, among those that assessed intake of general foods and/or food groups, agreement varied and context specific validation is recommended (13–15).

Furthermore, while the need to use data to inform the design and implementation of nutrition programs is well recognized (16), its practice in food fortification is often constrained due to a variety of factors. Limited availability of evidence to inform program decisions (17) and complex decision-making processes by policymakers (18) are part of the issue. A key constraint, however, is the absence of an explicit framework that structures the fortification program cycle and identifies key decisions to be made at varying stages. As a result, while fortification programs are intended to serve as medium- to long-term interventions to address micronutrient deficiencies, they are often put in place with little to no review or planning for future adjustments (19). Moreover, fortification program decisions are often initiated and implemented independently of other overlapping micronutrient deficiency control interventions (e.g., supplementation) by different national and/or international stakeholders (20) and there is an absence of guidance or regulations to define how to effectively coordinate interventions to ensure impact and safety over time (21). Research is therefore needed to develop practical and accessible tools for fortification stakeholders that demonstrate how to use data to make program decisions at different stages and, in the context of overlapping micronutrient interventions, to ensure continued and sustainable impact and safety over time.

1.2 Aims

The overall aim of this thesis was to evaluate methods for assessing performance and potential for impact of national large-scale food fortification programs and provide guidance on evidence-based decision making for effective program design and delivery.

The specific aims were to:

1. quantify the measured and potential contributions of fortified foods to micronutrient intakes in the diets of WRA and demonstrate the use and utility of these indicators to assess the performance and potential for impact of fortification programs;
2. compare two simplified dietary assessment methods (i.e., a FAPQ and 7-day SQ-FFQ) against 24-hour recalls for estimating consumption of fortifiable foods among young children and WRA; and
3. demonstrate how a decision-making framework for health system and public health decisions can be applied to formulate recommendations and make decisions in national food fortification programs.

1.3 Structure of the thesis

As context, Chapter 2 provides a review of the burden of micronutrient malnutrition and common strategies to address micronutrient deficiencies with a specific focus on food fortification, including an overview of the necessary conditions for programs to be impactful, the methods and tools available for assessing program performance and potential for impact, and the challenges with using data to inform programmatic decision making.

Aim 1 is addressed in Chapter 3: we used data from FACT surveys conducted in Nigeria, South Africa, Tanzania, and Uganda to estimate apparent micronutrient intakes from fortified foods among WRA. We also examined how the results can be used to assess performance and potential for impact. This chapter is published in the Journal of Nutrition.

Aim 2 is addressed in Chapter 4: we used data from a study conducted in Mandaluyong City, Philippines that assessed vitamin A intake among children 12-18 months selected for a study assessing child vitamin A intake and status to estimate fortifiable food consumption among the children and their mothers using two simplified methods (i.e., a FAPQ and a 7-d SQ-FFQ) and 24-h recalls. We compared the results from the two simplified methods against those from the 24-h recalls as the reference method and examined the utility of these methods to generate data for fortification program decision making. The chapter is submitted to the journal Public Health Nutrition.

Aim 3 is addressed in Chapter 5: we applied the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Evidence to Decision (EtD) framework for health system and public health decisions to the Nigerian fortification program to illustrate how evidence-informed assessments and conclusions can be made. The chapter is published in the journal Current Developments in Nutrition.

Finally, Chapter 6 provides a summary of the findings and discussion of the overall conclusions and implications of this body of research.

CHAPTER 2: Literature review

2.1 The burden of micronutrient malnutrition

2.1.1 Micronutrient deficiencies

Micronutrient deficiencies are defined as insufficient intake, absorption, and/or utilization of essential vitamins and minerals. They can lead to serious adverse health and functional outcomes including blindness and increased risk of mortality from infections (vitamin A) (22), reduced linear growth and greater risk of infectious disease as a child and premature birth later in life (zinc) (22), impaired cognitive and/or motor development and productivity (iodine, iron) (23,24), osteopenia, osteoporosis, and bone fractures and greater risk of developing cancers, hypertension, and autoimmune and infectious diseases (vitamin D) (25), anemia and other gastrointestinal and neuropsychiatric effects (B-vitamins) (26), and increased risk of neural tube defects (folate among women of reproductive age (WRA)) (27).

The assessment of micronutrient deficiencies is done through clinical diagnosis, measurement of biomarkers, or analysis of dietary intake data. Clinical indices can be used to diagnose deficiency of some micronutrients (e.g., blindness for vitamin A, goiter for iodine); however, as described above, the outcomes of deficiency for many micronutrients are not always visible and therefore require biomarker or dietary data to characterize. Nutritional biomarkers are most often biochemical or functional indices that can be measured in biological samples (such as blood, plasma, or urine) and indicate exposure, status, function, or effect (28). (For a list of key biomarkers recommended for assessing status of selected micronutrients by expert groups see Brown et al (29)). Biomarkers are considered the most objective and accurate method for assessing micronutrient status as they are not subject to the inherent limitations of self-reported dietary intake questionnaires (30). When biomarker data are not available, dietary intake data are a useful alternative for assessing micronutrient status. Dietary intake data on usual nutrient intakes (collected from methods such as 24-h dietary recalls, food records, or food frequency questionnaires) can be used to estimate prevalence of inadequate micronutrient intakes by comparing total nutrient intakes to the estimated average requirement (EAR) (for most nutrients) or using the probability method (for iron) (31).

Globally, existing data indicate that micronutrient deficiencies remain prevalent in many low- and middle-income countries (LMICs), particularly in Asia and Africa, and disproportionately affect young children (6-59 months) and women of reproductive age (WRA) (15-49 years), including those who are pregnant and lactating (1). However, the total burden of micronutrient deficiencies is uncertain given the dearth of micronutrient biomarker data available (29). Among children, most micronutrient interventions and research have centered on vitamin A, zinc, iron, and iodine deficiencies (though others, such as B vitamins, may also be present) (1). Therefore, while some data are available for those nutrients, they are not routinely collected in all countries. For WRA, data are even more scarce. Among the few national nutrition surveys available in LMICs, the prevalence of deficiencies in vitamin B12, vitamin D, iodine, and zinc deficiencies have been shown to be frequently high (32). These data gaps can be attributed to limited understanding of the value and utility of micronutrient status data for program planning and management by policymakers, inadequate ability to advocate for, design, and implement micronutrient status surveys, high logistical and financial resources to implement such surveys, and limited technical capacity to interpret and use the resulting information for the design and evaluation of public health programs (29).

2.1.2 Micronutrient risks and toxicities

In addition to the risks associated with insufficient intakes of micronutrients described above, there are also risks associated with excessive micronutrient intakes. Chronic excessive micronutrient intakes can lead to toxicities, which have serious health consequences. These include: liver damage, risk of teratogenicity, and, among children, bulging fontanelle (vitamin A) (33), copper deficiency, impaired immune function, and adversely affect high-density-lipoprotein cholesterol concentrations (zinc) (34), oxidative damage to organs such as the liver, heart, pancreas, and, in early life, the brain (iron) (35), severe hypercalcemia (vitamin D) (36), and masking of vitamin B12 deficiency anemia, which could permit neuropathies associated with vitamin B12 deficiency to progress undetected (folic acid) (37).

While biomarkers of micronutrient excess are available for the assessment of micronutrient excess or toxicity, their reliability for assessing functional or clinical symptoms of toxicity is less established compared to those for assessing micronutrient deficiency (38). As an alternative, dietary intake data are commonly used to estimate the prevalence of excessive micronutrient intakes by comparing the usual nutrient intakes to the tolerable upper intake level (UL) (i.e., the highest intake level at which there is no risk of adverse effects) (39). While estimates of excess intakes based on dietary intake data help to understand the potential risks in a population, they have some limitations as intakes above the UL do not necessarily indicate harm since the UL does not consider bioavailability issues, may only apply to certain forms of the micronutrient, and may have been set based on limited evidence due to ethical restrictions (38) thus making it difficult to interpret the associated risks.

Based on the few population-based surveys available, the prevalence of excessive micronutrient intakes in LMICs appears to be low, with some notable exceptions (e.g., vitamin A in Guatemala, Zambia, and South Africa (40)). However, simulations suggest it is a risk in some contexts where multiple micronutrient deficiency interventions (e.g., food fortification and supplementation) overlap if they are implemented effectively (38). When designing population-based micronutrient interventions, program managers and policymakers must weigh the benefits and costs associated with reducing deficiency while avoiding intakes above the UL for a given micronutrient accounting for intakes from all dietary sources and interventions.

2.2 Strategies to address micronutrient deficiencies

2.2.1 Dietary diversification

Consumption of diverse diets containing adequate amounts of foods naturally rich in vitamins and minerals should, in most cases, provide enough of the essential micronutrients to meet physiological requirements for growth and good health making dietary diversification the ultimate long-term solution to address micronutrient deficiencies. However, there are exceptions during particular life stages, such as pregnancy and early infancy, when even very diverse diets may not be sufficient to provide the higher requirements for certain nutrients such as iron, zinc, and vitamin A (41). While most other population groups in high-income countries are typically able to meet most of their micronutrient needs through the diet, this is not often the case in LMICs where socioeconomic inequalities persist (1) making such diverse diets not easily accessible (i.e., available and affordable) to all people, in particularly vulnerable segments of the population (e.g. poor, rural).

The major benefits of meeting micronutrient needs through food sources are that it has the potential to be preventative, cost-effective, and sustainable, can address multiple micronutrients at the same time, and reduces the risk of toxicity (42). Additionally, the consumption of whole foods may increase the bioavailability of some micronutrients (43) and provide many other bioactive compounds that may play a role in the prevention and treatment of diseases (44). However, there are several challenges to achieving sufficiently diverse diets. First, it requires functional and equitable food systems to ensure the right amounts of nutritious and safe foods to meet population needs are accessible to all population groups (45). Second, individual-level knowledge of optimal dietary practices and certain behaviour changes are required, which are greatly influenced by a variety of factors, including dietary, cultural, social, socioeconomic, and genetic factors (46). Finally, environmental factors, such as climate change, threaten to reduce food quantity, access, and nutritional content over time (47).

2.2.2 Supplementation with vitamins and minerals

Supplementation with vitamins and minerals (commonly consumed in the form of tablets, capsules, drops, or powders) is intended to be a short-term strategy used to prevent micronutrient deficiencies (48). It is recommended for specific population groups at certain life stages when nutrient needs are higher, such as folic acid, iron, and multiple micronutrient supplementation for WRA during pre-conception, pregnancy, and lactation, vitamin K administration at birth, and vitamin A, iron, and multiple micronutrient supplementation for infants and children (6-59 months of age) (49). In LMICs, supplementation is typically provided through routine health services, for example, biannual campaigns for administering high-dose vitamin A supplements to children (50).

The main benefit of supplementation is that, apart from the additional intake of the supplement itself, it does not require any changes to usual dietary patterns. However, there are several challenges that limit the effectiveness and sustainability of micronutrient supplementation. First, the provision of supplements must be feasible and affordable, and education must be provided to ensure the target populations understand and comply with the recommendations on how much and how often to take the supplements (48). Second, many target populations in LMICs do not have access to routine health services (51) and therefore may be missed if distribution is through those services. Additionally, while intended to be a short-term strategy, some supplementation programs (particularly high-dose vitamin A supplementation programs for children in many LMICs) have been in place for several years or even decades with little to no adjustments over time, as few countries have the required data (e.g. micronutrient surveys) to guide program scale-back decisions (52).

2.2.3 Food fortification

Large-scale food fortification (also referred to as industrial or mass fortification) is the addition of essential vitamins and/or minerals during processing to staple foods and condiments that are commonly consumed in a population (53). It is a widely used strategy to increase micronutrient intakes in the diet that is proven to have an impact on improving micronutrient status and biological outcomes (3). Food fortification is intended to be a medium-term solution to filling micronutrient gaps until a sufficiently diverse diet can be achieved. However, for some nutrients that are not generally prevalent in the food supply, such as iodine, it may also be considered a long-term solution. Food fortification began over a century ago with the addition of iodine to salt in Switzerland and Michigan in the United States to address the high prevalence of iodine deficiency disorders in the 1920s (54,55). Over time, fortification was scaled up and expanded to include milk with vitamin D (56), cereals/flours with iron, B vitamins, and other micronutrients (57), sugar with vitamin A in Latin America in the 1970s and later in Africa (58), and other condiments in Central and West Africa and South East Asia (59). As of September 2021, food fortification is mandated in 124 countries for salt, 85 countries for wheat flour, 17 countries for maize flour, 27 countries for edible oil, 9 countries for sugar, and 7 countries for rice with many additional countries having voluntary guidelines for these and other food vehicles (4,5).

Although food fortification in theory is conceptually simple, several conditions must be in place for programs to have an impact (**Figure 2.1**) (60). At the design phase, the intervention should be justified by demonstrated micronutrient needs in the target population. Then, stakeholder buy in is needed to create fortification policy and legislation. Finally, food vehicles that are widely consumed in a fortifiable (i.e., industrially processed) form and have a large degree of industry consolidation/centralization in production should be selected and appropriate fortification levels should be set based on consumption patterns and need in the population. Then, during the implementation phase, well designed and on-going program monitoring and enforcement is essential to ensure the availability of foods that are fortified at mandated levels. Finally, during the evaluation phase, evidence that high-quality fortified foods are consumed in adequate amounts by the target population is required before evaluating impact on biological or functional outcomes. High coverage and consumption are prerequisites for impact of any intervention or program. Without this information, impact evaluations may be unable to plausibly link any impact seen to the program and not to other factors. Furthermore, they may be unable to provide potential explanations if impacts are not observed. In addition, the underlying assumptions related to the program design (i.e., consumption patterns and nutrient intake and need) must be regularly reassessed to ensure impact and safety are sustained over time.

In practice, however, there are many factors observed that limit effective and sustainable implementation of fortification programs. These include poor design (i.e., choice of a food vehicle that is either not widely consumed or not consumed in a fortifiable form), low compliance with fortification standards, culturally unacceptable changes in organoleptic qualities, and inadequate monitoring and enforcement of fortification regulations, all of which are aspects for which data are often limited (17). In addition, there are major evidence gaps in the collection of data on coverage and consumption of fortified foods in populations (and different sub-groups) for most fortification programs (with the exception of salt iodization programs) and its use for decision making related to program design and implementation (19). This gap in evidence has led to skepticism among some on the potential for impact and fear of negative effects of food fortification programs (6).

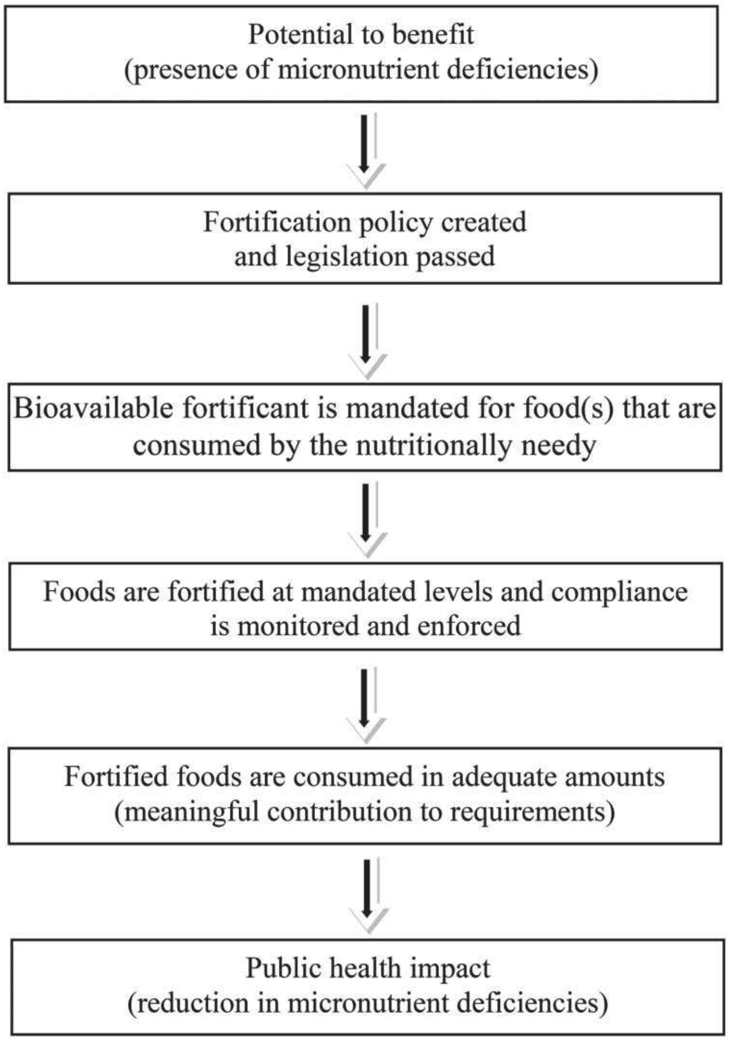

Figure 2.1. Program impact pathway for large-scale food fortification programs (60)

2.3 Methods for assessing performance and potential for impact of food fortification programs

Some methods and tools exist to facilitate the collection and analysis of data on fortification program performance (i.e., the extent to which a program is implemented according to its design, meaning that all foods are fortified according to national standards) and potential for biological impact (i.e., the extent to which a program has the potential to fill micronutrient gaps in the diet and thus reduce micronutrient deficiencies and related biological outcomes). Most notably, the Fortification Assessment Coverage Toolkit (FACT), was developed specifically to fill an identified gap in tools needed for this purpose. The

FACT is a population-based survey methodology that provides standardized methods and indicators to assess quality, coverage, consumption, and micronutrient contributions of fortified foods (7). In addition, guidance manuals exist that define best practice methods for monitoring industry compliance with national standards for salt (61), oil (62), and flours (63). Furthermore, user-friendly tools have been developed to facilitate data collection, analysis, and management of monitoring data. These tools include: FortiMApp, a tailored application and dashboard covering the FACT market data and food sample collection and management through analysis developed by the Global Alliance for Improved Nutrition (GAIN) (personal communication, June 2021), and FortifyMIS, an online platform to facilitate data collection and analysis at production-level of fortification programs (64). While there are no additional tools identified in the public domain specifically designed to assess potential for impact of fortification programs, standard dietary assessment methods, such as 24-h recalls, are recommended to be used during evaluation stages of fortification programs to estimate total micronutrient intakes in the diet (including the contribution coming from fortified foods), which can then be compared to micronutrient requirements using the EAR cut-point method or probability approach to assess the prevalence of inadequate intakes in a population (53).

While the FACT method has made a significant contribution to standardizing and promoting the generation of data on quality, coverage, and consumption of fortified foods, further research is needed to strengthen some of its components. Firstly, although the use of indicators on household coverage of fortified foods have been shown to identify program improvements needed (8,9), the use and utility of indicators on micronutrient contributions from fortified foods to estimate program performance and potential for impact have not been demonstrated. Furthermore, to reduce the technical and financial resources required for data collection and analysis, the FACT method employs simplified dietary assessment methods for estimating individual-level fortifiable food intake. Specifically, it uses a food acquisition and purchase questionnaire (FAPQ) (for most foods) and a 7-d semi-quantitative food frequency questionnaire (SQ-FFQ) (for wheat flour only in some contexts). While these simplified methods could increase availability of data for programmatic decision making, evidence on their accuracy is limited. Among studies that applied the AME method to food acquisition and purchase data to assess intake of potentially fortifiable staple foods compared to 24-h recalls or other reference methods, wheat flour intake was consistently underestimated while agreement varied for other foods (10–12). No studies have compared SQ-FFQs against reference methods for assessing intake of fortifiable foods specifically; however, among those that assessed intake of general foods and/or food groups, agreement varied and context specific validation is recommended (13–15). Finally, the FACT method does not collect data on micronutrient intakes from dietary sources other than fortified foods. As a result, it is not possible to ascertain the extent to which the additional micronutrient intake coming from fortified foods is enough to fill the micronutrient gaps in the diet (i.e., shift intakes from inadequate to adequate) or result in excessive intakes above the UL.

Some work is on-going to address some of these limitations. For example, simplified methods to generate food listing and portion size distribution estimates for use in dietary assessment methods, such as the SQ-FFQ, have been developed and tested in Uganda (65). Additionally, a nutrient-specific SQ-FFQ module that estimates key nutrients of interest from all dietary sources, including fortified and/or biofortified foods, using simplified methods, that can be integrated into FACT or other national surveys has been developed but not yet tested (66). Therefore, further research is needed to address the other limitations listed above.

2.4 Challenges using data to inform decision making in food fortification programs

While the need to use data to inform the design and implementation of nutrition programs is well recognized (16), its practice in food fortification is often constrained due to a variety of factors. Firstly, there is limited availability of evidence on performance and potential for impact from ongoing programs to inform program decisions (17). This is often a result of limited funding, technical capacity, and priority to collect and analyze such data. Secondly, decision-making processes by government ministries (i.e., the primary decision makers in national fortification programs) are not always transparent or well-documented, can be lengthy, and may be influenced by many other external factors (e.g., context, politics, values, and social and economic factors) (18). Thirdly, while fortification programs are intended to serve as medium- long-term interventions to address micronutrient deficiencies (with dietary diversification being the ultimate long-term goal for most, but not all, micronutrients), in reality they are often put in place based on one time decisions with little to no consideration of the program life cycle and thus planning for future adjustments or reviewing continued need does not occur (19). Fourthly, fortification program decision are often initiated and implemented independently of other overlapping micronutrient deficiency control interventions (e.g., supplementation) by different national and/or international stakeholders (20) and there is an absence of guidance or regulations to define how to effectively coordinate interventions to ensure impact and safety over time (21). Finally, while there is clear global guidance on how to design, implement, and evaluate fortification programs (53), there is a dearth of practical and accessible tools for national stakeholders that structure the fortification program cycle, identify key decisions to be made at varying stages, and facilitate the use and documentation of evidence to inform recommendations and decisions.

Some work is on-going to address the limited availability of evidence in fortification programs. Experts have called for greater generation and use of data to inform fortification program decision making as a means to address the unfinished agenda for food fortification in LMICs (67) and actions and investments for nutrition interventions more broadly (16).

While these efforts are important at a global-level, further research is needed to develop practical and accessible tools for national fortification stakeholders that facilitate the use of evidence to inform decisions at different program stages and address the other challenges listed above related to putting evidence-based decision making into practice in food fortification programs.

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CHAPTER 3: Fortified foods are major contributors to apparent intakes of vitamin A and iodine, but not iron, in diets of women of reproductive age in four African countries

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3.1 Abstract

Background: Food fortification is implemented to increase intakes of specific nutrients in the diet, but contributions of fortified foods to nutrient intakes are rarely quantified.

Objective: We quantified iron, vitamin A, and iodine intakes from fortified staple foods and condiments among women of reproductive age (WRA).

Methods: In sub-national (Nigeria, South Africa) and national (Tanzania, Uganda) cross-sectional, clustered, household surveys, we assessed fortifiable food consumption. We estimated daily nutrient intakes from fortified foods among WRA by multiplying the daily apparent fortifiable food consumption (by adult male equivalent method) by a fortification content for the food. Two fortification contents were used: measured, based on median amount quantified from individual food samples collected from households; and potential, based on targeted amount in national fortification standards. Results for both approaches are reported as a percentage of the estimated average requirement (EAR) and recommended nutrient intake (RNI).

Results: Fortified foods made modest contributions to measured iron intakes (0-13% RNI); potential intakes if standards are met were generally higher (0-65% RNI). Fortified foods contributed substantially to measured vitamin A and iodine intakes (20-125% and 88-253% EAR, respectively); potential intakes were higher (53-655% and 115-377% EAR, respectively) and would exceed the tolerable upper intake level among 18-56% of WRA for vitamin A in Nigeria and 1-8% of WRA for iodine in Nigeria, Tanzania, and Uganda.

Conclusions: Fortified foods are major contributors to apparent intakes of vitamin A and iodine, but not iron, among WRA. Contributions to vitamin A and iodine are observed despite fortification standards not consistently being met and if constraints to meeting standards are addressed, there is risk of excessive intakes in some countries. For all programs assessed, nutrient intakes from all dietary sources and fortification standards should be reviewed to inform adjustments where needed to avoid risk of low or excessive intakes.

3.2 Introduction

Food fortification is a cost-effective intervention that aims to increase the content of specific nutrients in a widely consumed food to improve the nutritional quality of the food supply (1,2). Population-based food fortification programs, such as large-scale fortification of staple foods and/or condiments (hereafter referred to as foods), are implemented to address nutrient deficiencies in a population by shifting the distribution of nutrient intakes toward adequacy (3). Globally, mandatory food fortification is legislated in 128 countries for salt, 83 countries for wheat flour, 16 countries for maize flour, and 25 countries for oil (4).

To assess the achievement of food fortification program objectives, we would ideally measure impact on reducing the prevalence and/or severity of nutrient deficiencies or functional outcomes at the population-level. However, this is costly and it may take substantial time for measurable impacts to be realized (5). Assessing coverage, consumption, and quality of fortified foods is a critical prior step to provide vital information on the contribution of fortified foods to nutrient intakes and the extent to which they meet the intended proportion of dietary needs among target populations. This information can be used to understand a program's performance and potential for biological impact and inform specific needs for program improvement related to design or delivery. It is for this purpose that the Fortification Assessment Coverage Toolkit (FACT) method was developed (6,7).

Despite the high number of countries that mandate food fortification programs globally, nutrient intakes from fortified foods among target populations have rarely been quantified. Where such information exists, it is mainly from high-income countries (8–11). In low- and middle-income countries (LMIC), individual-level data that would permit these analyses are limited. Where available, data were collected prior to implementation of the fortification program to estimate potential nutrient contributions of fortified foods thereby informing the design (12–14). Alternatively, household-level data on food purchasing patterns are often routinely collected in LMIC from household consumption and expenditure surveys (also known as household income and expenditure surveys, household budget surveys, etc.). These data have been increasingly used to estimate potential nutrient contributions of fortified foods to inform program design or model potential impacts of existing programs (15–18). However, they are limited in that they do not always distinguish between food that is potentially fortifiable and that which is not (19), and, in the absence of data on current fortification content in the food supply, they cannot assess nutrient contributions of fortified foods in on-going programs.

In this paper, we quantified the measured and potential intakes of iron, vitamin A, and iodine from fortified foods among women of reproductive age (WRA) using data from FACT surveys conducted in Nigeria, South Africa, Tanzania, and Uganda. Additionally, we illustrate the use and utility of these indicators to assess the performance of fortification programs and identify potential program improvement needs.

3.3 Methods

3.3.1 Survey design and setting

In 2015, the Global Alliance for Improved Nutrition (GAIN), Centers for Disease Control and Prevention, and local implementation partners (Oxford Policy Management, University of the Western Cape, Africa Academy for Public Health, and Makerere University) conducted cross-sectional, two-stage, clustered, household surveys in Nigeria, South Africa, Tanzania, and Uganda. Country selection was based on the following criteria: presence of an on-going large-scale food fortification program that GAIN had supported; lack of recent data on coverage and consumption of fortified foods; and level of prior and existing donor investments. The surveys were designed to determine household coverage of fortified foods and their contributions to key nutrient intakes among WRA. Detailed sampling schemes and coverage results are reported elsewhere (20–24). Briefly, the surveys were state or provincially representative in Nigeria (Kano and Lagos states) and South Africa (Eastern Cape and Gauteng provinces) and nationally representative (stratified by urban and rural) in Tanzania and Uganda. In the first stage, primary sampling units were selected by probability proportional to size (South Africa, Tanzania, and Uganda) or simple random sampling (Nigeria). In the second stage, households in these primary sampling units were randomly selected. Sample sizes were calculated based on a 95% confidence interval, 50% prevalence rate, precision of 0.05-0.065, and design effect of 2, and were adjusted according to country specific expected response rates.

3.3.2 Study population

The target study populations included households and WRA (15-49 years of age in Nigeria, Tanzania, and Uganda; 18-49 years of age in South Africa). In each household, the person most knowledgeable about household food preparation and purchasing (≥15 years of age in Nigeria, Tanzania, and Uganda; ≥18 years of age in South Africa) was invited to complete a household questionnaire. Additionally, all WRA in each selected household were invited to complete a women's questionnaire.

3.3.3 Ethical considerations

Ethical approvals were obtained from an academic or national institutional review board in each country and all procedures were followed in accordance with the ethical standards of the responsible institutions. Consent to participate in the survey was obtained from all respondents (verbally in Nigeria and Uganda; in writing in South Africa and Tanzania). Respondents were informed of the nature of the survey, the length of time expected to complete it, and that participation was voluntary and could be withdrawn during any part of the survey.

3.3.4 Data collection

We collected household-level data on coverage and consumption of fortifiable foods (defined as industrially processed and not made at home) along with other demographic and socioeconomic information described elsewhere (20). Additional individual-level data were collected from WRA on dietary diversity and pregnancy and lactation status. We also collected a sample of each fortifiable food assessed from the household if available. All survey questionnaires and modules were taken from FACT templates (7) and adapted to the local context according to the scope of the fortification program (i.e. number and type of foods) and other country specific requirements (e.g. culturally appropriate wording of questions and response options). All survey instruments were translated into the common language(s) spoken in the survey areas and back-translated into English to ensure content validity. Prior to implementation, they were pilot-tested to finalize language, wording, and flow of questions and response options. Trained enumerators collected the data using paper forms (South Africa and Uganda) or mobile devices (Nigeria and Tanzania) in a language well understood by the respondent. Skilled field personnel supervised the data collection and ensured data quality through consistency, range, and allowed value checks during data collection for all surveys and additionally during data entry for paper-based surveys. Up to two attempts were made to survey the selected households.

3.3.5 Laboratory analyses of food samples

Food samples were shipped to reference laboratories in Germany (BioAnalyt (Potsdam) and SGS Institute Fresenius GmBH (Taunusstein)) and analyzed to determine the added nutrient content from fortification in each individual sample. If flour fortification standards mandated the inclusion of both iron and vitamin A, only iron was measured owing to budget constraints and we assumed vitamin A to be present in the same proportion as added iron relative to the national standard amounts. Vitamin A content was measured in all edible oil and sugar samples and in maize flour samples in Nigeria with iCheck Chroma 3 (25,26). Iodine content was measured in all salt samples with iCheck Iodine (27). Iron content was measured in wheat and maize flour samples in Tanzania and Uganda with iCheck Iron (28). Iron content was measured in other flour samples (wheat and maize flours in South Africa and wheat and semolina flours in Nigeria) with atomic emission spectroscopy (DIN EN 15510 mod. ICP/OES method). Since the analysis methods used are unable to distinguish between added and naturally occurring forms of iron, additional unfortified flour samples were collected in each country (1 to 4 for wheat flour; 4 to 8 for maize flour; and 2 for semolina flour) and analyzed as composite samples to determine the mean intrinsic iron content of each flour type by country. The mean intrinsic iron content was then subtracted from the total measured iron in each flour sample to estimate the added iron content from fortification.

3.3.6 Indicator definitions

3.3.6.1 Fortifiable food consumption

The adult male equivalent (AME) method was applied to estimate the daily amount of fortifiable food consumed among WRA in the surveyed households (29). Each member of the household was assigned an age- and sex-specific AME and the AMEs were summed together to calculate a household AME. We estimated the amount of food consumed daily per woman in grams by dividing the woman's AME by the household AME then multiplying that value by the daily amount of fortifiable food consumed by the household (based on the reported quantity purchased and the duration it usually lasts in the household). WRA from households that reported not consuming the fortifiable food were assigned zero for daily amount of fortifiable food consumed. Households with no WRA or those with missing data for reported quantity of fortifiable food purchased and/or the duration it usually lasts in the household were excluded. In households that contained multiple WRA, one was randomly selected, and her consumption was calculated. Because we used household-level food consumption data and AME assumptions of intrahousehold distribution of the food to estimate individual-level consumption of WRA, all estimates refer to “apparent” consumption.

3.3.6.2 Nutrient intakes

We estimated the daily nutrient intakes from fortified foods among WRA by multiplying the daily apparent consumption of fortifiable food per woman by a fortification content. For *measured* intakes, we used the median amount quantified from individual food samples collected from households in each country. For *potential* intakes, we used the targeted amount in the country’s national fortification standard that was in effect at the time of the survey (i.e. the mid-point of the required range). If the standard was set as a minimum required value with no upper limit, we set the target at 50% above the minimum on the basis that industry would have to add at least this amount of overage to consistently achieve the minimum content in all food products.

The resulting daily intakes of each nutrient from all fortified foods were combined and reported as a percentage of the estimated average requirement (EAR) and recommended nutrient intake (RNI) for WRA according to age and pregnancy and lactation status (pregnancy and lactation status were only available for the subset of WRA that completed the women’s questionnaire thus all non-surveyed WRA (i.e. those listed on the household roster but did not complete the women’s questionnaire) were assumed to be non-pregnant and non-lactating). We took RNI values from the World Health Organization and Food and Agriculture Organization to more accurately reflect international populations (30). For iron, bioavailability was assumed to be 12% in all countries (31). We derived EAR values from the RNI values by dividing by published conversion factors for vitamin A and iodine (1). For iron, the EAR should not be calculated for WRA owing to the skewed distribution of requirements by menstruating women (1); therefore, only the percentage of RNI is reported. Additionally, we estimated the prevalence of WRA with nutrient intakes from fortified foods greater than the tolerable upper intake level (UL) based on values taken from the Food and Nutrition Board of the Institute of Medicine (32)).

3.3.7 Data analyses

Data analyses were carried out using SAS version 9.4 (SAS Institute, NC, USA) and Stata version 15.1 (StataCorp LLC, TX, USA), and figures were produced in RStudio version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). Medians with 25th and 75th percentiles and/or means with 95% confidence intervals were calculated for the primary indicators (i.e. measured fortification contents, apparent consumption of fortifiable foods, and apparent nutrient intakes as a percentage of requirements). For consumption indicators, outliers, defined as values greater than three standard deviations from the mean, were considered implausible and set to missing. We applied appropriate weighting factors to account for the complex sampling designs in the Nigeria, Tanzania, and Uganda surveys. Results from the South Africa survey were not weighted owing to low response rates.

3.4 Results

A summary of the survey response rates, women's ages, and food samples collected is shown in **Table 3.1**. Response rates were high in Nigeria (94% in Kano and 92% in Lagos), Tanzania (99%), and Uganda (86%) and low in South Africa (45% in Eastern Cape and 40% in Gauteng). The latter was due predominately to refusal from community leaders or associations and no eligible respondent available at the time of the survey. Among the surveyed households, the majority contained at least one woman of reproductive age (55-92%). Additional information on fortification program activities in each country and characteristics of the survey populations (i.e. household size, respondent age, at risk of poverty, poor women's dietary diversity score, and rural residence) are reported elsewhere (20). The number of food samples collected from households varied across foods and locations. Salt was the most widely available food across all locations (collected from 72-86% of households). Comparatively, wheat and maize flour samples were available in less than 18% and 32% of households, respectively, across all locations (apart from maize flour in South Africa, which was collected from approximately 71% of households).

The measured median amount of vitamin A in wheat flour and oil in Uganda and iodine in salt in South Africa, Tanzania, and Uganda was within the range of the national fortification standards (or above the minimum required where no upper limit was provided) (**Table 3.2**). For all other foods, the measured median amount of nutrient added was below the minimum required in the national standards.

Daily apparent consumption patterns of fortifiable foods among WRA are shown in **Table 3.3**. Fortifiable flour consumption varied greatly by location with the most widely consumed flour being wheat in Kano and Tanzania, maize in Eastern Cape, Gauteng, and Uganda, and semolina in Lagos. The amount of oil consumed daily was similar across Kano, Lagos, and Tanzania but considerably lower in Uganda. Finally, daily salt consumption was approximately twice as high in Kano, Tanzania, and Uganda than in Lagos, Eastern Cape, and Gauteng.

Fortified foods contributed modestly to measured iron intakes (0-13% RNI across all foods and locations); but potential iron intakes if standards are met are higher (14-65% RNI) in most countries (except Uganda, 0%) (**Table 3.4**). For example, in Kano, Nigeria, iron intake from fortified wheat and semolina flours would increase from the measured intake of 13% RNI to a potential intake of 65% RNI if flours are fortified to standard. Fortified foods contributed substantially to vitamin A and iodine intakes (20-125% and 88-253% EAR, respectively, across all foods and locations); potential intakes if standards are met are higher (53-655% and 115-377% EAR, respectively) and would exceed the UL among 18-56% of WRA for vitamin A in Nigeria and 1-8% of WRA for iodine in Nigeria, Tanzania, and Uganda (**Table 3.4)**.

It is also helpful to visualize the contribution of fortified foods to nutrient intakes as a distribution of intakes as this permits a rapid assessment of the current performance of the programs relative to their design (i.e. potential for impact). As such, the measured and potential intakes from fortified foods are also shown as distributions in relation to the EAR, RNI, and UL among WRA for three select examples in **Figure 3.1** (for all country-nutrient combinations, see **Supplemental Figures 1-15**). In **Figure 3.1A**, the measured and potential iodine intakes from fortified salt in Eastern Cape, South Africa are nearly aligned and exceed the EAR and RNI in most of the population without exceeding the UL. In **Figure 3.1B**, the potential iron intake from fortified foods in Gauteng, South Africa is greater than the measured intake; however, in both cases, intakes are below the RNI. In **Figure 3.1C**, the measured and potential vitamin A intakes from fortified foods in Lagos, Nigeria exceed the EAR and RNI in most of the population and additionally exceed the UL; however, the potential intake is greater and would result in 18% of the population with intakes above the UL.

3.5 Discussion

In this analysis, we show that fortified foods are major contributors to apparent vitamin A and iodine intakes in diets of WRA in the programs assessed, while contributions to iron intakes are relatively modest. Our findings additionally suggest that if constraints to achieving the target fortification content as per the national standards are addressed, fortified foods have potential to contribute further to intakes of all nutrients in most countries. However, this increase could result in excessive vitamin A intakes in Nigeria and iodine intakes in Nigeria, Tanzania, and Uganda among some WRA.

Iron fortification programs in all countries are underperforming (contributing 0-13% RNI) due primarily to poor fortification content combined with low consumption of the fortifiable food(s) in some locations. Vitamin A fortification programs are similarly underperforming in all countries (except Uganda) and are primarily constrained by suboptimal fortification content yet are still making substantial contributions to vitamin A intakes across all locations (20-125% EAR). Finally, iodine fortification programs are performing in accordance with their design (i.e. meeting fortification standards) in nearly all locations (with some room for improvement in Nigeria) and, as a result, are making substantial contributions to iodine intakes (88-253% EAR).

The implications of these results vary by nutrient and food in each country program, as follows:

3.5.1 Iron

In most countries with iron fortification programs, the iron content in the fortified foods must be increased to meet standards to produce positive impacts on iron intakes. To achieve this, effective and functioning regulatory monitoring systems are necessary to ensure the food industry is compliant with the fortification standards, which may require increasing technical capacity, accountability and funding, and reducing political barriers (33). Alternatively, in Uganda, the current analyses indicate poor selection of foods for fortification given the low amounts of fortifiable wheat and maize flours consumed at population-level. In this case, even if industry is compliant with the fortification standards, the potential contributions to iron intakes will be negligible as shown. That said, it is likely that the household-level assessment methods used in these analyses underestimated the amount of fortifiable wheat flour consumed in the population as other studies in Uganda reported that bread and other wheat flour-containing products prepared from fortifiable wheat flour are widely purchased (34). However, further research is still needed to confirm the fortification content of the flour in these prepared foods to enable the assessment of their contributions to iron intakes.

3.5.2 Vitamin A

In Nigeria, the results indicate that the vitamin A fortification standards are likely set too high for the current consumption patterns of the five foods mandated for fortification. Currently, this does not pose a major threat to excessive intakes because the food industry is not compliant with the standards. However, if the programs were to improve and become compliant, potential vitamin A intakes would be a major concern as they would result in a large proportion of WRA with intakes above the UL (18% and 56% in Lagos and Kano, respectively) before accounting for other sources of vitamin A in the diet. When fortifying multiple foods with the same nutrient, it is critical to set standards such that the total intake from all fortified foods, as well as other dietary sources and supplements combined, does not consistently exceed the UL in the target population (1). This has been raised as a potential concern in Nigeria and recent efforts have been made to coordinate the array of existing programs, including food fortification and supplementation (35) underscoring the need for effective program monitoring and enforcement systems to tackle this critical issue. Vitamin A intakes above the UL may have adverse effects; therefore, in all countries it is recommended to review the vitamin A intakes results in the context of all vitamin A sources in the diet and adjust fortification standards as needed to ensure safety overtime.

3.5.3 Iodine

Unlike iron and vitamin A, there are few naturally occurring dietary sources of iodine; therefore, it is appropriate in most countries to design a fortification program such that the sole fortification food (i.e. salt) provides 100% of the EAR. In Nigeria, Tanzania, and Uganda, potential iodine intakes if standards are met would result in a small proportion of WRA with intakes above the UL (1-8%). While the risks associated with excessive iodine intakes are not a concern in most people (36), sodium intakes above 2 g per day (equivalent to 5 g of salt) were attributed to 1.65 million deaths from cardiovascular disease globally in 2010 (37). As a result, many countries, including South Africa, are implementing salt reduction strategies that highlight the need to monitor iodine intakes from fortified salt over time and adjust standards as needed to account for changing consumption patterns (38).

3.5.4 Strengths and limitations

The main strengths of this analysis were the use of standardized indicators from the FACT method to assess the apparent consumption and contribution of fortified foods to nutrient intakes, as it allows for comparability across countries over time. The study had several limitations. The survey response rates in both South African provinces were low; therefore, the results may not be reflective of the entire populations. In flour fortification programs where standards mandated the addition of both iron and vitamin A, vitamin A was estimated indirectly using measured added iron as a proxy, which may have overestimated the true vitamin A content as it was not possible to confirm its presence in the premix in those countries and some may have been destroyed during storage. Moreover, further research is needed to confirm the extent to which the estimated vitamin A intakes from fortified oil are likely to reflect true intakes given that it is light-sensitive and predominantly used (and sometimes reused) for cooking rather than being directly consumed, which have been shown to result in significant losses in vitamin A prior to consumption (39). The AME method likely has precision and estimation errors as consumption varies within households and across foods made with them. For example, it may overestimate the amount consumed of foods that are not equally distributed within the household, and it may underestimate the amount consumed of foods that are commonly purchased outside the household and/or in the form of already prepared products as these were not accounted for in the household questionnaire. Finally, the total nutrient intake from dietary sources other than fortified foods was not collected in the surveys owing to the high technical and financial resources required to collect and analyze them (40). As a result, it was not possible to ascertain the extent to which the additional nutrient intake coming from fortified foods is enough to fill the nutrient gaps in the diet (i.e. shift intakes from inadequate to adequate) or result in additional intakes above the UL.

3.5.6 Conclusions

Food fortification programs have potential to reduce nutrient deficiencies by improving nutrient intakes in target populations. Our findings demonstrate the extent of the measured and potential apparent nutrient intakes from fortified foods and highlight several programs at risk of low or excessive nutrient intakes owing to poor program design and/or delivery. In all fortification programs assessed, there is a need to review these results in the context of all nutrient sources in the diet, validate them with biochemical data on nutrient status to confirm problem nutrients, and redesign programs to achieve optimal nutrient intakes where necessary. Moving forward, global research priorities for all fortification programs should include the routine assessment of program outcomes, including quality, consumption, and nutrient contribution of fortified foods, through ongoing monitoring efforts. By filling these research gaps, fortification programs will be able to generate the information needed to track progress, identify and overcome barriers, and ultimately achieve their goal of filling the nutrient gaps and improving health outcomes in the population.

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3.7 Chapter 3 references

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Table 3.1 Summary of survey response rates, women's ages, and food samples collected[1]

	Nigeria, Kano	Nigeria, Lagos	South Africa, Eastern Cape	South Africa, Gauteng	Tanzania	Uganda
Planned households	951	951	800	920	1050	1101
Surveyed households[2]	896 (94)	871 (92)	361 (45)	372 (40)	1036 (99)	949 (86)
Surveyed households with ≥ 1 woman of reproductive age[3]	783 (87)	678 (78)	198 (55)	221 (59)	957 (92)	719 (76)
Age of selected woman of reproductive age, y	28.1 [15-49]	31.8 [15-49]	30.4 [18-49]	33.1 [18-49]	29.9 [15-49]	30.2 [15-49]
Food samples collected[4]						
Wheat flour	110 (12)	15 (2)	39 (11)	4 (1)	191 (18)	47 (5)
Maize flour	33 (4)	2 (<1)	259 (72)	265 (71)	333 (32)	238 (25)
Semolina flour	23 (3)	233 (27)	–	–	–	–
Edible oil	257 (29)	244 (28)	–	–	725 (70)	278 (29)
Sugar	238 (27)	264 (30)	–	–	–	–
Salt	724 (81)	624 (72)	273 (76)	272 (73)	856 (83)	820 (86)

[1] All values are *n*, *n* (%) or mean [range].

[2] Percentage reported out of total planned households.

[3] Percentage reported out of total surveyed households.

[4] Only foods that were fortifiable (i.e. reported to be industrially processed and not made at home) were collected if available in the household; percentage reported out of total surveyed households.

Table 3.2 Measured and potential fortification contents of iron, vitamin A, and iodine in individual food samples collected from households[1]

	Nigeria[2] (Kano & Lagos)		South Africa[2] (Gauteng & Eastern Cape)		Tanzania		Uganda	
	Measured	Potential	Measured	Potential	Measured	Potential	Measured	Potential
	Median[3] [IQR]	Target[4] (standard)	Median [IQR]	Target (standard)	Median [IQR]	Target (standard)	Median [IQR]	Target (standard)
Iron[5], ppm								
Wheat flour	11.7 (7.7, 33.6)	61.1 (≥ 40.7)	18.7 (0.0, 35.6)	52.5 (≥ 35.0)	20.9 (9.0, 29.6)	40.0 (30.0-50.0)	18.4 (1.1, 31.7)	40.0 (25.0-55.0)
Maize flour	–	–	26.3 (16.6, 34.3)	52.5 (≥ 35.0)	0.0 (0.0, 0.0)	15.0 (5.0-25.0)	0.0 (0.0, 1.2)	15.0 (10.0-20.0)
Semolina flour	23.4 (17.2, 35.3)	61.1 (≥ 40.7)	–	–	–	–	–	–
Vitamin A, ppm								
Wheat flour	2.6[6] (1.7, 7.4)	13.5 (≥ 9.0)	1.0[6] (0.0, 1.8)	2.7 (≥ 1.8)	–	–	1.1[6] (0.1, 2.0)	2.5 (1.0-4.0)
Maize flour	0.0 (0.0, 0.4)	13.5 (≥ 9.0)	1.5[6] (0.9, 2.0)	3.0 (≥ 2.0)	–	–	0.0[6] (0.0, 0.1)	1.0 (0.5-1.5)
Semolina flour	5.2[6] (3.8, 7.8)	13.5 (≥ 9.0)	–	–	–	–	–	–
Edible oil	3.5 (0.0, 30.0)	9.0 (≥ 6.0)	–	–	4.6 (2.7, 12.3)	22.0 (16.0-28.0)	22.4 (11.9, 27.2)	32.5 (20.0-45.0)
Sugar	1.0 (0.0, 2.1)	11.3 (≥ 7.5)	–	–	–	–	–	–
Iodine, ppm								
Salt	28.9 (11.9, 76.2)	45.0 (≥ 30.0)	44.5 (25.9, 54.0)	50.0 (40.0-60.0)	34.0 (8.2, 39.8)	47.5 (25.0-70.0)	36.9 (32.2, 41.3)	55.0 (30.0-80.0)

[1] ppm, parts per million.

[2] Food samples collected from both states or provinces were grouped together for analyses because fortification content is expected to be similar across the country given that food brands are not produced separately for each state/province.

[3] Median added nutrient content of all individual household food samples analyzed.

[4] Target added nutrient content was set at the mid-point of the required range as per the national standard that was in effect at the time the survey was implemented or 50% above the minimum required content if the standard was set with no upper limit.

[5] Measured iron values were adjusted for intrinsic iron by subtracting the estimated mean intrinsic iron content (from analysis of composite samples of non-fortified flours by type from each country) from the total measured iron content.

[6] Estimated using measured added iron as a proxy by assuming added iron and vitamin A were present in ratios that followed the country's fortification standard.

Table 3.3 Daily apparent consumption of fortifiable foods by women of reproductive age based on household assessment with adult male equivalent method[1]

	n[2]	Median [IQR]	Mean (95% CI)
Wheat flour, g/day			
Nigeria (Kano)	770	193 (99.2, 288)	202 (185, 219)
Nigeria (Lagos)	668	0.0 (0.0, 0.0)	19.5 (13.0, 26.0)
South Africa (Eastern Cape)	198	0.0 (0.0, 0.0)	20.8 (13.6, 28.0)
South Africa (Gauteng)	221	0.0 (0.0, 0.0)	1.7 (0.5, 2.9)
Tanzania	909	19.3 (0.0, 162)	90.0 (74.7, 105)
Uganda	716	0.0 (0.0, 0.0)	12.2 (7.1, 17.3)
Maize flour, g/day			
Nigeria (Kano)	780	0.0 (0.0, 0.0)	25.3 (11.1, 39.5)
Nigeria (Lagos)	676	0.0 (0.0, 0.0)	2.0 (0.3, 3.7)
South Africa (Eastern Cape)	193	88.7 (49.7, 133)	101 (91.1, 111)
South Africa (Gauteng)	219	99.1 (69.4, 137)	109 (100, 118)
Tanzania	907	0.0 (0.0, 116)	60.8 (47.5, 74.2)
Uganda	712	0.0 (0.0, 122)	67.4 (49.3, 85.5)
Semolina flour, g/day			
Nigeria (Kano)	781	0.0 (0.0, 0.0)	10.7 (4.6, 16.8)
Nigeria (Lagos)	656	56.2 (23.5, 136)	88.5 (78.9, 98.1)
Edible oil, mL/day			
Nigeria (Kano)	764	25.8 (16.6, 41.4)	29.6 (27.8, 31.4)
Nigeria (Lagos)	669	24.7 (14.0, 36.8)	28.7 (26.3, 31.1)
Tanzania	862	19.6 (10.5, 36.3)	26.3 (23.7, 29.0)
Uganda	688	5.4 (3.1, 9.7)	7.1 (6.1, 8.0)
Sugar, g/day			
Nigeria (Kano)	738	12.2 (7.5, 19.8)	14.4 (13.5, 15.3)
Nigeria (Lagos)	644	6.3 (2.6, 13.1)	8.8 (8.2, 9.5)
Salt, g/day			
Nigeria (Kano)	749	8.4 (4.5, 14.1)	9.9 (8.8, 11.0)
Nigeria (Lagos)	635	3.6 (2.1, 5.5)	4.5 (4.2, 4.9)
South Africa (Eastern Cape)	191	4.2 (2.6, 6.3)	4.8 (4.4, 5.2)
South Africa (Gauteng)	215	2.7 (1.6, 4.3)	3.6 (3.2, 4.0)
Tanzania	869	7.5 (4.6, 11.4)	8.8 (8.1, 9.5)
Uganda	697	8.2 (5.9, 11.9)	9.4 (8.9, 9.8)

[1] Fortifiable is defined as industrially produced and not made at home; CI, confidence interval. Nigeria, Tanzania, and Uganda results were weighted to correct for unequal probability of selection. South Africa results were not weighted owing to low response rates.
[2] *n* excludes observations with missing values for reported quantity of fortifiable food purchased and/or the duration it usually lasts in the household and outliers (values >3 SDs from the mean).

Table 3.4 Apparent iron, vitamin A, and iodine intakes (measured and potential) from fortified foods as a percentage of requirements among women of reproductive age[1]

	N	Nutrient intake as % of EAR Median [IQR]		Nutrient intake as % of RNI Median [IQR]		% of women with nutrient intake >UL	
		Measured[2]	Potential[3]	Measured	Potential	Measured	Potential
Iron							
Nigeria (Kano)[4]	782	–[5]	–[5]	12.9 (6.3, 22.0)	64.8 (31.6, 107)	0.0	1.0
Nigeria (Lagos)[4]	677	–[5]	–[5]	7.0 (2.3, 14.7)	19.1 (6.3, 40.1)	0.0	0.1
South Africa (Eastern Cape)[6]	198	–[5]	–[5]	10.7 (6.6, 17.2)	22.2 (13.2, 36.8)	0.0	0.0
South Africa (Gauteng)[6]	221	–[5]	–[5]	11.0 (7.6, 17.0)	21.9 (15.1, 34.0)	0.0	0.0
Tanzania[6]	931	–[5]	–[5]	0.0 (0.0, 15.2)	13.5 (0.0, 33.8)	0.0	0.0
Uganda[6]	719	–[5]	–[5]	0.0 (0.0, 0.0)	0.0 (0.0, 11.0)	0.0	0.0
Vitamin A							
Nigeria (Kano)[7]	783	125 (73.0, 204)	655 (379, 1072)	89.5 (52.1, 146)	468 (271, 765)	0.1	56.4
Nigeria (Lagos)[7]	678	103 (45.7, 205)	297 (138, 595)	73.3 (32.6, 147)	212 (98.3, 425)	0.1	17.7
South Africa (Eastern Cape)[6]	198	39.3 (23.9, 56.0)	80.2 (49.0, 115)	28.0 (17.1, 40.0)	57.3 (35.0, 82.4)	0.0	0.0
South Africa (Gauteng)[6]	221	37.0 (26.5, 55.8)	74.0 (53.1, 112)	26.4 (19.0, 39.8)	52.8 (37.9, 79.7)	0.0	0.0
Tanzania[8]	862	19.5 (9.8, 38.9)	93.1 (46.7, 186)	13.9 (7.0, 27.8)	66.5 (33.4, 133)	0.0	0.0
Uganda[9]	719	26.8 (12.6, 50.9)	53.2 (25.3, 95.8)	19.2 (9.0, 36.3)	38.0 (18.1, 68.4)	0.0	0.0
Iodine[10]							
Nigeria (Kano)	749	183 (102, 319)	286 (159, 496)	131 (72.9, 228)	204 (114, 355)	0.2	7.7

Nigeria (Lagos)	635	87.8 (51.8, 143)	137 (80.6, 222)	62.8 (37.0, 102)	97.7 (57.6, 158)	0.0	0.8
South Africa (Eastern Cape)	191	169 (103.4, 252)	190 (116, 283)	120 (73.7, 180)	135 (82.8, 202)	0.0	0.0
South Africa (Gauteng)	215	102 (65.1, 180)	115 (73.1, 202)	72.7 (46.4, 128)	81.7 (52.2, 144)	0.0	0.0
Tanzania	869	213 (133, 337)	297 (186, 471)	152 (95.1, 240)	213 (133, 336)	0.1	4.3
Uganda	697	253 (171, 356)	377 (255, 531)	181 (122, 254)	269 (182, 379)	0.7	4.3

[1] RNI values were taken from the WHO and FAO (30) (for iron, bioavailability was assumed to be 12% in all countries); EAR values were derived from RNI values by dividing by published conversion factors (1); UL values were taken from the Food and Nutrition Board of the Institute of Medicine (32). Nigeria, Tanzania, and Uganda results are weighted to correct for unequal probability of selection. South Africa results are not weighted owing to low response rates. AME, adult male equivalent; EAR, estimated average requirement; RNI, recommended nutrient intake; UL, tolerable upper intake level; WRA, women of reproductive age.

[2] Based on daily apparent consumption of the fortifiable (i.e. industrially processed and not made at home) food from the AME method multiplied by the median nutrient content quantified from individual food samples collected from households.

[3] Based on daily apparent consumption of the fortifiable (i.e. industrially processed and not made at home) food from the AME method multiplied by the target nutrient content as per the national standard that was in effect at the time of the survey.

[4] From wheat and semolina flours.

[5] EAR cannot be derived from RNI for women of reproductive age owing to the high variability and skewed distribution of requirements for iron (1).

[6] From wheat and maize flours.

[7] From wheat flour, maize flour, semolina flour, oil, and sugar.

[8] From oil.

[9] From wheat flour, maize flour, and oil.

[10] From salt for all countries.

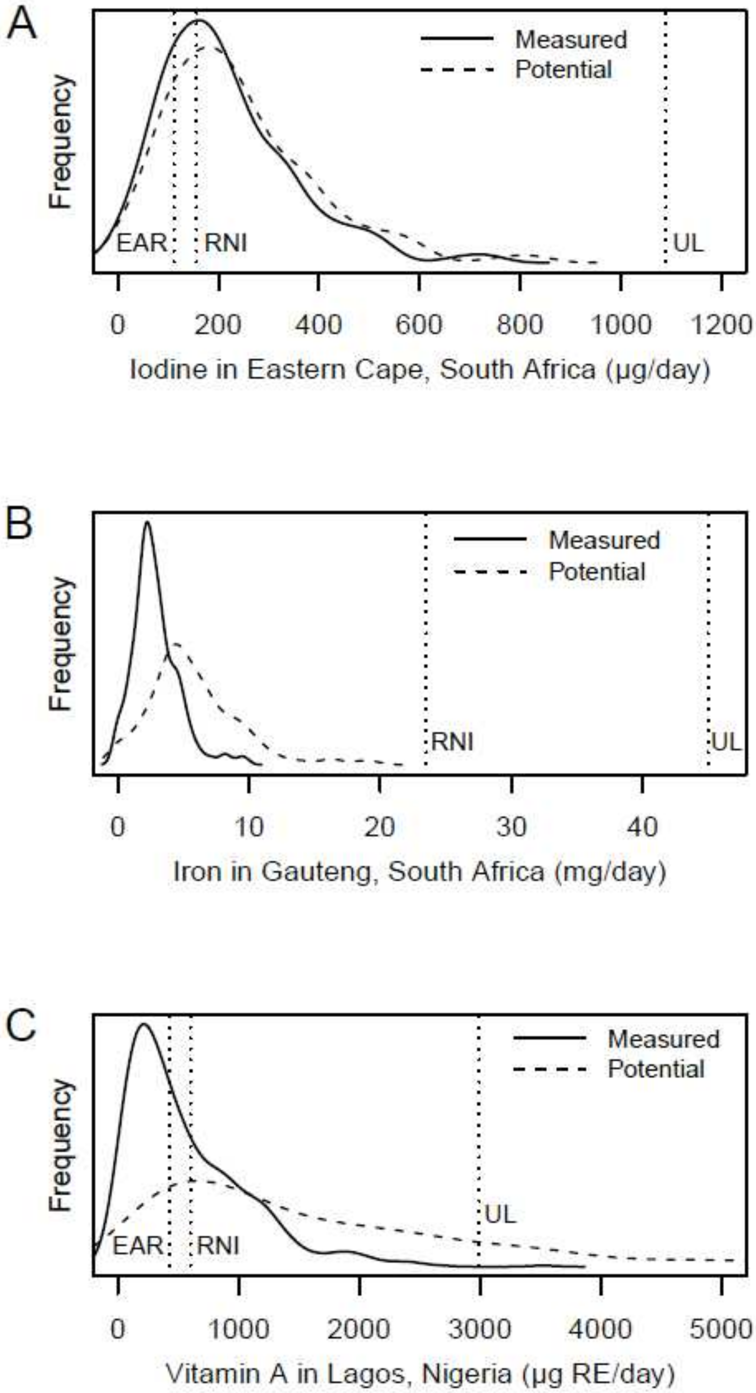

Figure 3.1 Apparent intakes of (A) iodine from fortified salt in Eastern Cape, South Africa; (B) iron from fortified wheat and maize flours in Gauteng, South Africa; and (C) vitamin A from fortified oil, sugar, wheat, maize, and semolina flours in Lagos, Nigeria estimated by multiplying the apparent amount of fortifiable food consumed daily (based on household assessment using the adult male equivalent method) by a fortification content (measured, based on median amount quantified from individual food samples collected from households; potential, based on targeted amount in national fortification standards). RNI values were taken from the WHO and FAO (30) (for iron, bioavailability was assumed to be 12% in all countries); EAR values were derived from RNI values by dividing by published conversion factors (1); UL values were taken from the Food and Nutrition Board of the Institute of Medicine (32). EAR, estimated average requirement; RE, retinol equivalents; RNI, recommended nutrient intakes; UL, tolerable upper intake level.

CHAPTER 4: Comparing two simplified questionnaire-based methods with 24-hour recalls for estimating consumption of fortifiable wheat flour and oil in Mandaluyong City, Philippines

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4.1 Abstract

Objective: Information on fortifiable food consumption is essential to design, monitor, and evaluate fortification programs, yet such data are rarely available from detailed methods such as 24-h recalls (24HRs). Simplified dietary assessment methods may help mitigate this constraint and enable programmatic decisions. We compared two simplified methods (i.e., a household food acquisition and purchase questionnaire (FAPQ) and a 7-d semi-quantitative food frequency questionnaire (SQ-FFQ)) against 24HRs for estimating fortifiable food consumption.

Design: We assessed consumption of fortifiable wheat flour and oil using a FAPQ and, for wheat flour only, a 7-d SQ-FFQ and compared the results against 24HRs.

Setting: Mandaluyong City, Philippines.

Participants: Children 12-18 mo (n=123) and their mothers 18-49 y selected for a study assessing child vitamin A intake and status.

Results: For fortifiable wheat flour, the FAPQ estimated considerably lower mean intakes compared to 24HRs for children and mothers (2.2 vs. 14.1 g/day and 5.1 vs. 42.3 g/day, respectively), while the SQ-FFQ estimated slightly higher mean intakes (15.7 vs. 14.1 g/day and 51.5 vs. 42.3 g/day, respectively). For fortifiable oil, the FAPQ estimated considerably higher mean intakes compared to 24HRs for children and mothers (4.6 vs. 1.8 g/day and 12.5 vs. 6.1 g/day, respectively).

Conclusions: The SQ-FFQ, but not the FAPQ, generated useful information on fortifiable food consumption that can inform fortification program design and monitoring decisions in the absence of more detailed individual-level data. Potential adaptations to improve the FAPQ, such as additional questions on foods prepared away from home and usage patterns, merit further research.

4.2 Introduction

Information on fortifiable (i.e., industrially processed) food consumption is essential to effectively design, monitor, and evaluate large-scale food fortification programs (1). Different dietary assessment methods can be used to collect such data, but they vary in the level at which data are collected (i.e., household or individual), resource requirements, and usefulness for informing fortification program decisions (2). The 24-h dietary recall method is commonly used to collect individual-level data on total food and nutrient intakes (3). Such data are recommended to be collected during program design to inform the selection of foods and fortification levels and during program evaluation to assess impact on nutrient intakes (2). However, these data are rarely available owing to concerns about technical and financial resources required (4). Alternative simplified methods for collecting fortifiable food consumption data that require less effort, time, and cost to implement include targeted food acquisition and purchase questionnaires (FAPQs) and semi-quantitative food frequency questionnaires (SQ-FFQs). Targeted FAPQs collect household-level data on acquisition and purchasing patterns for specific foods, which can be used to estimate individual-level food intakes by applying the adult male equivalent (AME) method (5). Targeted semi-quantitative food frequency questionnaires (SQ-FFQs) collect individual-level data on the frequency of consumption and portion sizes for specific foods over a defined time period (6). Examples of FAPQs include the relevant modules in Household Consumption and Expenditure Surveys (HCES) in low- and middle-income countries (LMICs), which often collect information on commonly fortified staple foods (7). These data have been used to inform the selection of foods for fortification (8,9); however, they do not always distinguish between fortifiable and non-fortifiable forms of these foods (10). Additionally, targeted FAPQs for commonly fortified staple foods and a 7-d SQ-FFQ (for wheat flour only) are included in Fortification Assessment Coverage Toolkit (FACT) surveys (11). These data (along with data on micronutrient content of fortified foods) have been used to monitor fortification program performance and potential for impact on nutrient intakes (12–15).

The use of simplified dietary assessment methods could increase the availability of fortifiable food consumption data for fortification program decision making by facilitating the incorporation of dietary assessment into existing surveys given their lower technical and financial resource requirements and/or enabling the use of secondary data (e.g., from HCES or FACT surveys); however, evidence on the validity of simplified methods for this purpose is limited. Among studies that applied the AME method to HCES data to assess intake of potentially fortifiable staple foods compared to 24-h recalls or other reference methods, wheat flour intake was consistently underestimated while agreement varied for other foods (16–18). Potential explanations for discrepancies between household FAPQ data (analyzed with the AME method) compared to individual-level intake data include inaccuracies in measurement of foods prepared away from home and household utilization, limitations regarding frequency of acquisition versus consumption, and inequitable intrahousehold distribution for the AME method. For SQ-FFQs, selection of appropriate food lists and methods of portion size estimation are likely to influence validity. To our knowledge, no studies have compared SQ-FFQs against reference methods for assessing intake of fortifiable foods specifically; however, among those that assessed intake of general foods and/or food groups, agreement varied, and context specific validation was recommended (19–21).

We used data from a study that assessed vitamin A intake among Filipino children 12-18 months to estimate fortifiable food consumption among the children and their mothers (18 to 49 y) using three dietary assessment methods. These were: two simplified methods (i.e., a FAPQ and a 7-d SQ-FFQ) and a detailed dietary assessment approach, which included multiple 24-h recalls and (among children only) observed weighed food records. In this paper, we compare the results of the two simplified methods against those from the detailed dietary assessment as the reference method and discuss the utility of these methods to generate data for fortification program decision making.

4.3 Methods

4.3.1 Study design and participants

This study was part of a larger study that assessed usual dietary vitamin A intake among Filipino children receiving vitamin A supplementation (VAS) in Mandaluyong City in the National Capital Region of the Philippines. Children were categorized into one of three groups at the time of enrollment: 1) likely high retinol intake (>600 µg RAE/d) and receipt of VAS in the past 30 days; 2) likely high retinol intake (>600 µg RAE/d) and receipt of a VAS in the past 3-6 months; or 3) likely low/adequate retinol intake (200-500 µg RAE/d) and receipt of VAS in the past 3-6 months. Sample size was based on detection of mean retinol intake >600 µg/d in groups 1 and 2 and detection of a difference in total body vitamin A stores between groups 1 and 3. Assuming 80% power, alpha 0.05, and 25% attrition rate, 50 children per group (n=150 total) would be needed. A detailed description of the study design and sample size are reported elsewhere (22).

Mother-child pairs were pre-screened at the time of the national VAS campaigns in March to May 2016 and September to November 2016. Study staff collected information on the child's receipt of VAS in the past 6 months from the master lists of children given VAS as part of the Government of the Philippines vitamin A supplementation program and estimated vitamin A intake using a dietary screening questionnaire. Eligibility criteria included: 1) child 12-18 months of age, 2) mother 18-49 years of age, 3) mother and child living in the selected study communities and planning to stay in the study area for the duration of the study, and 4) the child's receipt of VAS and estimated vitamin A intake were consistent with one of the groups described above. All study procedures were explained to mothers at the time of enrollment and the mother provided written informed consent for herself and the child to participate. The Research Ethics Board of the University of the Philippines-Manila, the Institutional Review Board of the University of California, Davis, and the Institutional Review Board of Newcastle University approved the study protocol, and it is registered on Clinicaltrials.gov (NCT03030339).

4.3.2 Data collection

In this study, we collected data on consumption of fortifiable foods (defined as industrially processed and not made at home) using three methods: a FAPQ, 7-d SQ-FFQ, and a detailed dietary assessment approach, which included multiple 24-h recalls and (among children only) observed weighed food records (**Table 4.1**). Other data, including anthropometric measurements, blood samples, and morbidity information from the child and breast milk samples from the mother, were collected for the main study and are described in detail elsewhere (22).

On day 0 of the study, the mother of the child completed the FAPQ and SQ-FFQ. The FAPQ collected household-level information on acquisition (e.g., gifts, food aid) and purchases of fortifiable wheat flour and oil along with information on the age and sex of all household members. The SQ-FFQ collected individual-level information on consumption of fortifiable wheat flour-containing foods in the last seven days from a list of 25 items for both the child and the mother. For food items consumed, trained interviewers asked the mother to report the frequency of consumption over the past seven days and estimate the usual portion size consumed using a photo album of various portion sizes for each food item. Fortifiable oil consumption was not assessed using the SQ-FFQ method due to the difficulty of assessing amounts consumed in prepared foods obtained outside the household. The questionnaires were developed based on modules from the FACT household questionnaire template (i.e., the household roster and fortification coverage modules for the FAPQ and the individual consumption module for the SQ-FFQ) (23). Questionnaires were adapted to the local context (i.e. response options and language) and, for the SQ-FFQ, a list of commonly-consumed, wheat flour-containing foods and a photo album of portion sizes was prepared by the local field team according to the FACT guidelines (24).

Throughout the 28-d study period, four 24-h recalls were scheduled for the child and two for the mother on nonconsecutive days to capture both weekend and weekday intake. The 24-h recall collected individual-level data on total dietary intake. During each 24-h recall, trained interviewers asked the mother to report all foods and beverages consumed in the past 24 hours for either the child or herself. Interviewers used a multiple pass method and collected recipe information (or best estimation) for all items regardless of source (i.e., prepared at home vs. purchased) (25). For wheat flour and oil, interviewers probed to capture additional details needed to determine whether the food item was fortifiable. In addition, due to the challenges of accurate portion size estimation for young children, one 12-h observed weighed food record (with 12-h recall of the previous night's consumption) was conducted for each child. In cases where 12-h observations could not be conducted (e.g., due to security concerns), an additional 24-h dietary recall was conducted, if feasible. In this analysis, all complete days of data for each child (whether from 24-h recall or 12-h observation plus 12-h recall) were combined to estimate usual intake distributions. For simplicity, we refer to these data as 24-h recalls.

4.3.3 Estimating fortifiable food consumption

The amounts of fortifiable foods consumed daily by the children and their mothers were estimated separately for each of the three dietary assessment methods, as follows.

Food acquisition and purchase questionnaire. We first determined the daily amount of fortifiable food consumed by the household by dividing the reported amount the household obtained on the last occasion by the reported duration that this amount usually lasts in the household. We then applied the adult male equivalent (AME) method put forth by Weisell and Dop (5), which assumes that an individual's consumption of household food is proportional to their energy requirements (26,27). First, we assigned each household member an age- and sex-specific AME and then summed the AMEs together to produce a household AME. We then divided the individual's AME by the household AME and multiplied it by the daily amount of fortifiable food consumed by the household to estimate the amount of fortifiable food consumed by the target individual per day in grams. Individuals from households that reported not consuming a fortifiable form of the food vehicle were assigned zero for the amount of fortifiable food consumed. Because the AME method uses household-level data to estimate individual-level consumption, these estimates are typically referred to as "apparent consumption" but are hereafter referred to as consumption for ease of comparison with the other methods.

7-day semi-quantitative food frequency questionnaire. For the 25 food items in the SQ-FFQ, the grams of food in each of the various portion size options in the photo album were measured during photo album development, and the grams of fortifiable wheat flour in each portion were determined based on food composition tables and nutrition labels for packaged foods. For each food item reported being consumed by the target individual, we multiplied the number of grams of fortifiable wheat flour in the portion size reported by the frequency the item was consumed per week and then divided by seven to estimate the amount consumed daily. We then summed all food items containing wheat flour for the individual per day to obtain a cumulative total of fortifiable wheat flour in grams per day. Any of the food items the individual reported not consuming were assigned zero for the grams consumed for the food item.

24-hour recalls. All food and beverages reportedly consumed by the target individuals in the 24-h recalls were converted into grams based on food composition tables and nutrition labels for packaged foods. The amounts of fortifiable wheat flour and oil in each food item or mixed dish (e.g., the amount of wheat flour in a given quantity of bread or biscuits) were calculated from recipe information. We then summed the resulting grams of fortifiable wheat flour and oil for all food items for each individual on each day to obtain the cumulative total grams of each fortifiable food consumed per person per day. We adjusted the values for within-person variation to estimate usual intake distributions of fortifiable wheat flour and oil by applying the amount-only National Cancer Institute method using the Simulating Intake of Micronutrients for Policy Learning and Engagement (SIMPLE) macro (28).

4.3.4 Data analyses

Data analyses were carried out in Stata version 15.1 (StataCorp LLC, TX, USA) and SAS version 9.4 (SAS Institute Inc., NC, USA). We calculated means, medians, and percentiles of fortifiable food consumption estimates from the three dietary assessment methods. For the FAPQ and SQ-FFQ methods, values >3 SDs from the mean were considered outliers and excluded (i.e., FAPQ: 2 children and 3 mothers for wheat flour, 7 children and 5 mothers for oil; SQ-FFQ: 3 children and 1 mother for wheat flour). Additionally, 24-h recall observations that were missing a corresponding FAPQ or SQ-FFQ observation for comparison were excluded (i.e., when matched to FAPQ: 9 children and 10 mothers for wheat flour, 14 children and 12 mothers for oil; when matched to SQ-FFQ: 10 children and 8 mothers for wheat flour).

We qualitatively compared the distributions of fortifiable food consumed as estimated by the FAPQ and SQ-FFQ methods with those from the 24-h recall reference method. For wheat flour, we also examined and compared the food sources as a percentage of total fortifiable wheat flour consumption to understand potential sources of differences between the SQ-FFQ and 24-h recalls. We did not do formal statistical significance testing to compare the individual-level estimates of consumption from the FAPQ and SQ-FFQ methods with those from the 24-h recalls because the 24-h recall usual intake estimates are intended to be interpreted only at the population-level. Moreover, interpretation of similar data for the purpose of designing and monitoring food fortification programs is typically done at the population-level.

4.4 Results

A total of 123 child-mother pairs were enrolled in the main study. All 123 children and 117 mothers completed the 24-h recalls and 116 child-mother pairs completed the FAPQ and the SQ-FFQ. On average, children were 14.4 mo of age, mothers were 28 y of age, and 50% of children were breastfed at the time of the study. Additional child, maternal, and household characteristics are reported elsewhere (22).

The difference between the amounts consumed as estimated by the FAPQ and SQ-FFQ methods compared to the 24-h recalls varied depending on the method and fortifiable food (**Table 4.2**, **Figure 4.1**, and **Figure 4.2**). For fortifiable wheat flour, the FAPQ mean and median intakes were more than 6 times lower than those from the 24-h recalls for both children and mothers. Conversely, the SQ-FFQ mean intakes were 11-22% higher while median intakes were within 5-7% compared to those from the 24-h recalls. For the SQ-FFQ method, there was greater variation in the distribution of fortifiable wheat flour intake among both children and mothers compared to the distribution estimated using 24-h recalls. For fortifiable oil, the FAPQ mean and median intakes were 2 to 2.5 times greater than those from the 24-h recalls and there was greater variation in the distribution of intake among both children and mothers.

The sources of fortifiable wheat flour (as a percentage of total fortifiable wheat flour consumed from different food groups) estimated by the SQ-FFQ were generally similar but varied for some food groups when compared to those from the 24-h recalls (**Figure 4.3**). Specifically, the SQ-FFQ overestimated the percentage of fortifiable wheat flour from noodles and breads among children and noodles among mothers and underestimated that from crackers and cakes among children and cakes among mothers. Additionally, the SQ-FFQ missed some specific food items that were captured in the 24-h recalls as breads (i.e., pizza), cakes (i.e., pancakes/waffles, sponge cake (*mamon*), steamed cake (*puto*), doughnuts, and pastries), and other foods (i.e., breaded squid/pork/chicken/sardines and spring roll wrappers (*lumpiang*)). The "other" category comprised ≤5% of total fortifiable wheat flour consumed, indicating that the SQ-FFQ captured the major sources of dietary fortifiable wheat flour in this population.

4.5 Discussion

We compared two simplified dietary assessment methods (i.e., a FAPQ and a 7-d SQ-FFQ) against 24-h recalls as the reference method for estimating fortifiable food consumption among young children (12-18 mo) and their mothers (18-49 y) in Mandaluyong City, Philippines. According to the 24-h recalls, mean usual fortifiable wheat flour intake was 14.1 and 42.3 g/d among children and mothers, respectively, and mean usual fortifiable oil intake was 1.8 and 6.1 g/d, respectively. We found that the FAPQ method systematically underestimated fortifiable wheat flour intakes (by more than 6 times) and overestimated fortifiable oil intakes (by 2 to 2.5 times) compared to 24-h recalls while the SQ-FFQ mean estimates for fortifiable wheat flour were 11-22% higher and median estimates were within 5-7% compared to those from 24-h recalls.

For fortifiable wheat flour, the substantial and systematic underestimation of intakes by the FAPQ compared to the 24-h recalls was largely due to the questionnaire excluding measurement of food products made from fortifiable wheat flour that are purchased and/or consumed outside the household. In this study, the FAPQ only captured the quantity of the food item acquired or purchased in its raw form (e.g., as wheat flour obtained by the household). While this works reasonably well in contexts where most foods are prepared in the home, the approach may have limited utility in contexts where prepared food products containing wheat flour are commonly purchased. This was the case in the current study, which took place in an urban setting, where 64% of households reported not using fortifiable wheat flour at home to prepare foods (and thus were assigned zero for amounts consumed), yet the SQ-FFQ and 24-h recall results confirmed that wheat flour is commonly consumed as an ingredient in other foods. The most consumed foods containing fortifiable wheat flour were breads and noodles, which are typically purchased already prepared and are not captured by this specific FAPQ version. Other studies in Cameroon, Uganda, and Bangladesh that applied the AME method to HCES data on acquisition and purchase of potentially fortifiable wheat flour included questions on both raw wheat flour and common wheat flour-containing products (which were combined as wheat flour equivalents), but similarly found that the HCES data underestimated total wheat flour consumed compared to reference methods (i.e., 24-h recalls or observed-weighed food records) among children under 5 y and women of reproductive age (16–18). This suggests there are likely still inaccuracies in measurement with this method, including capturing foods prepared away from home.

On the other hand, the SQ-FFQ method was successful in capturing the main sources of fortifiable wheat flour in the diets of both children and mothers as compared to the 24-h recall reference method. However, the SQ-FFQ had greater variation in the distributions of fortifiable wheat flour intakes compared to the 24-hr recalls. This is likely owing to some missing food items on the food list (as shown in **Figure 3**), the limited portion size options in the SQ-FFQ, and/or challenges recalling portion sizes, which may not have captured the true amounts consumed.

For fortifiable oil, the overestimation of intakes by the FAPQ compared to 24-h recalls is likely due to inaccuracies in measurement of household utilization (e.g., difficulty in capturing amounts directly consumed vs. used for cooking) and/or patterns of intrahousehold food distribution that do not correspond to the assumptions of the AME method. The AME method assumes all fortifiable oil acquired is consumed by the members in the household yet in some contexts oil is discarded or re-used when preparing foods, which would lead to overestimations of intake. Additionally, the AME method assumes that food is distributed within a household in accordance with the individual's proportion of total household energy requirements based on age and sex. However, this is not always the case, particularly with young children who potentially consume less from the family meals given they are often breastfed and/or receive other complementary foods (29). Similar results were observed in studies that applied the AME method to HCES data on acquisition and purchases of fortifiable oil in Cameroon and Bangladesh where mean fortifiable oil intakes among children and women were overestimated compared to reference methods (though median intakes in Cameroon were lower) (17,18) while in Uganda results varied by region (16).

When using different methods to assess fortifiable food intake some variation is expected; however, when considering the utility of these methods for fortification programs the more pertinent question is whether the variation is substantial enough that it would lead to different programmatic decisions. During the program design phase, fortifiable food consumption data are needed to inform the selection of foods for fortification and set fortification levels. In this study, the results from both the SQ-FFQ and 24-h recalls would suggest that fortifiable wheat flour is widely consumed and therefore would likely be an appropriate food for fortification. Conversely, the FAPQ results would incorrectly suggest that wheat flour is not likely an appropriate food for fortification in these population groups given its negligible estimated intakes (i.e., median of 0 g/day among both children and mothers). Despite the slight variation in results, the SQ-FFQ and 24-h recall results would suggest similar fortifications level recommendations if set based on the categories of wheat flour intake defined by the World Health Organization, i.e., both methods resulted in an estimate of <75 g/day flour consumption, which would lead to a recommendation for 92 ppm of added iron as NaFeDTA (30). The mean amount of wheat flour consumption among mothers would have to be 46% higher than the current estimate to reach the next category of intake (i.e., 75-149 g/day flour consumption) and thus a different fortification level recommendation (i.e., 40 ppm iron as NaFeDTA). Furthermore, for oil, the FAPQ and 24-h recalls would both suggest that it is an appropriate food for fortification given it is widely consumed in a fortifiable form. However, the FAPQ method results could potentially lead to lower recommendations for fortification levels compared to 24-h recalls given its substantial overestimation of daily intakes though there are no specific cutoffs recommended for oil for comparison.

At the program implementation phase, fortifiable food consumption data can be used to understand fortification program performance and potential for impact by multiplying intakes by a fortification level (based on actual samples of fortified foods) to estimate additional micronutrient intakes and (if additional data are available on total nutrient intakes from other dietary sources) the extent to which they fill identified gaps in the population. While the range of fortifiable wheat flour intakes varied somewhat between the SQ-FFQ and 24-h recalls, the mean and median additional micronutrient intakes estimates did not differ greatly suggesting random error may contribute to observed differences. As a result, the two methods would yield similar mean and median estimates of additional micronutrient intakes and thus similar conclusions regarding average program performance and potential for impact regardless of the fortification level applied. Conversely, the large and systematic variability between the FAPQ and 24-h recall estimates for both fortifiable wheat flour and oil suggest that true consumption is not likely possible to determine through this method in its current form as additional micronutrient intakes could be greatly over or underestimated. This could result in overly high or low estimates of micronutrient intakes from fortified foods and thus differing expectations about the potential impact of the fortification program. That said, FAPQ data are likely still better than national food supply data (e.g., food balance sheets), which are often used to estimate potential micronutrient intakes in the absence of individual-level data, as those do not account for household food acquisition or purchases or permit assessment of subnational variation in use of fortified foods.

There were some limitations to this study. The 24-h recall method was used as the reference method against which the results of the simplified methods were compared; however, it is not a gold standard and has its own sources of error (e.g., recall bias and underreporting) (31). Multiple day weighed food records administered over a sufficiently long time frame would be the most accurate dietary assessment method to use as a reference; however, they are even more resource-intensive than 24-h recalls and are thus rarely conducted, especially in LMICs. Moreover, the study was conducted in an urban setting in the Philippines; therefore, the results may not be applicable to other settings, particularly rural settings where households prepare most of their foods at home and thus the FAPQ may perform better. Finally, we did not assess total nutrient intakes estimates (from both fortifiable foods and other dietary sources) using the simplified methods and compare them against a reference method in this study. Such information would ideally be used to inform fortification program decisions such as setting fortification levels and assessing potential for impact; however, in practice this information is not often available and data on fortifiable food consumption alone are used.

Simplified dietary assessment methods, such as FAPQs and SQ-FFQs, are promising alternatives to more detailed methods for generating data on fortifiable food consumption with reduced effort and cost. While this study and others have shown there are still some important differences in the results, the resulting fortification program decisions may still be similar for some methods and foods (16–18). Potential adaptations to the FAPQ, such as additional questions on acquisition and purchase of food products containing fortifiable wheat flour that are prepared away from home and usage patterns for fortifiable oil, merit further research to mitigate its current limitations. Additionally, further research is needed to better understand the sources of error in the application of the AME method to FAPQ data and whether they are unique to some population sub-groups (such as young children and women or urban and rural populations) or related to the method itself and its assumptions around utilization of foods (particularly for oil), and whether questions on complementary food utilization and/or household distribution may be able to mitigate some of the sources of error. Strengthening simplified dietary assessments methods has potential to increase the generation of fortifiable food consumption data and enable more evidence-based decision making in food fortification programs.

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JCM, RBB, MFDR, MVC, CVDC: conducted the research; VMF, JCM, CDA: analyzed the data; VMF: wrote the paper; VMF, CDA, MNNM, LMN, FTW, GL, MJH, RES: had primary responsibility for data interpretation; VMF and RES: had primary responsibility for final content; all authors: read and approved the final manuscript.

4.7 Chapter 4 references

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Table 4.1 Characteristics of the food acquisition and purchase questionnaire (FAPQ), 7-d semi-quantitative food frequency questionnaire (SQ-FFQ), and 24-h recall (24HR)

Characteristic	**FAPQ**	**SQ-FFQ**	**24HR**
Fortifiable food vehicle assessed[1]	Wheat flour, oil	Wheat flour	Wheat flour, oil
Level of data collection	Household	Individual	Individual
Recall period for data collection	Since the last time the food vehicle was purchased	Previous 7-d	Previous 24-h
Foods included	Fortifiable wheat flour and edible oil	25 commonly consumed food items that contain fortifiable wheat flour	All foods and beverages consumed
Specifies foods consumed (vs. food acquired or purchased for consumption)	No	Yes	Yes
Assesses mixed dishes or products containing the fortifiable food of interest	No	Yes	Yes
Accounts for foods consumed outside the home as well as at home	No	Yes	Yes

[1]Fortifiable was defined as industrially processed and not made at home.

Table 4.2 Amount of fortifiable wheat flour and oil consumed (g/day) by children and their mothers estimated by the food acquisition and purchase questionnaire (FAPQ), 7-d semi-quantitative food frequency questionnaire (SQ-FFQ), and 24-h recall (24HR) methods in Mandaluyong City, Philippines[1]

	Children (12-18 months)				Mothers (18-49 years)			
Method	n[2]	Mean	Median	IQR	n	Mean	Median	IQR
Wheat flour								
FAPQ[3]	114	2.2	0.0	0.0, 3.2	113	5.1	0.0	0.0, 7.6
SQ-FFQ[4]	113	15.7	11.9	5.5, 21.4	115	51.5	40.4	16.7, 80.5
24HR[5]	113	14.1	12.5	8.3,18.1	115	42.3	37.6	25.3, 54.2
Oil								
FAPQ[3]	109	4.6	4.0	2.9, 6.2	111	12.5	10.7	7.5, 16.5
24HR[5]	109	1.8	1.6	1.2, 2.2	111	6.1	5.4	3.7, 7.8

[1] Fortifiable was defined as industrially processed and not made at home.

[2] *n* excludes outliers from FAPQ and SQ-FFQ methods (values >3 SDs from the mean) and 24HR observations without a corresponding FAPQ or SQ-FFQ observation.

[3] Household-level assessment based on reported amount of fortifiable food the household obtained on the last occasion and duration that this amount usually lasts in the household and application of the adult male equivalent method (5).

[4] Individual-level assessment based on reported portion size and frequency of consumption of a list of 25 common food items containing fortifiable wheat flour in the past seven days.

[5] Individual-level assessment based on reported amount of fortifiable food consumed in the past 24 hours; mean 5.0 days of data per child (including one 12-h observed weighed food record plus 12-h recall in 57 children) and 2.0 days of data per mother; values were adjusted for within-person variation to estimate usual intakes by applying the amount-only National Cancer Institute method for estimating usual intake distributions using the Simulating Intake of Micronutrients for Policy Learning and Engagement (SIMPLE) macro (28).

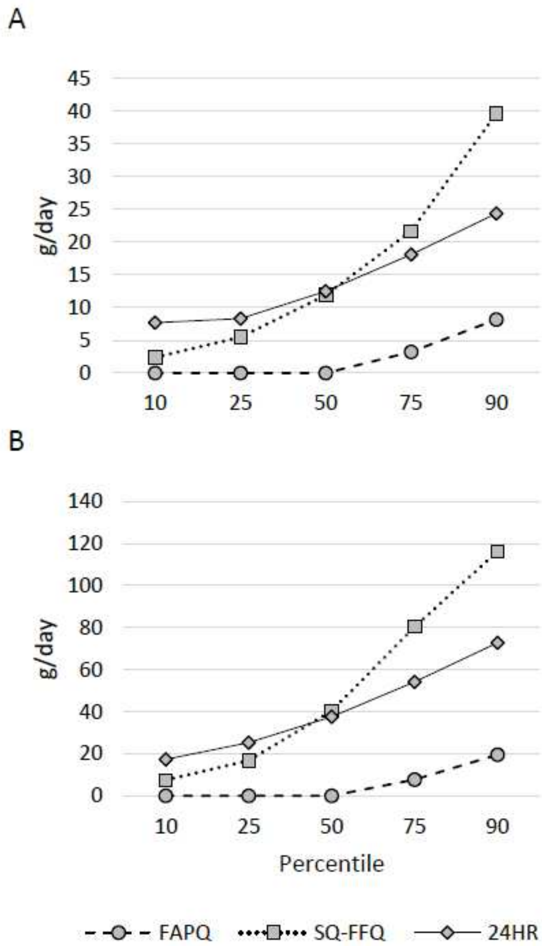

Figure 4.1 Distribution of the amount of fortifiable wheat flour consumed (g/day) among (A) children (12-18 months) (n=114 for FAPQ; n=113 for SQ-FFQ and 24HR) and (B) their mothers (18-49 years) (n=113 for FAPQ; n=115 for SQ-FFQ and 24HR) in Mandaluyong City, Philippines, estimated by FAPQ (household-level assessment based on reported amount of fortifiable food the household obtained on the last occasion and duration that this amount usually lasts in the household and application of the adult male equivalent method), 7-d SQ-FFQ (individual-level assessment based on reported portion size and frequency of consumption of a list of 25 common food items containing fortifiable wheat flour in the past seven days), and 24HR methods (individual-level assessment based on reported amount of fortifiable food consumed in the past 24 hours adjusted for within-person variation; mean 5.0 days of data per child (including one 12-h observed weighed food record plus 12-h recall in 57 children) and 2.0 days of data per mother). FAPQ, food acquisition and purchase questionnaire; SQ-FFQ, semi-quantitative food frequency questionnaire; 24HR, 24-h recall.

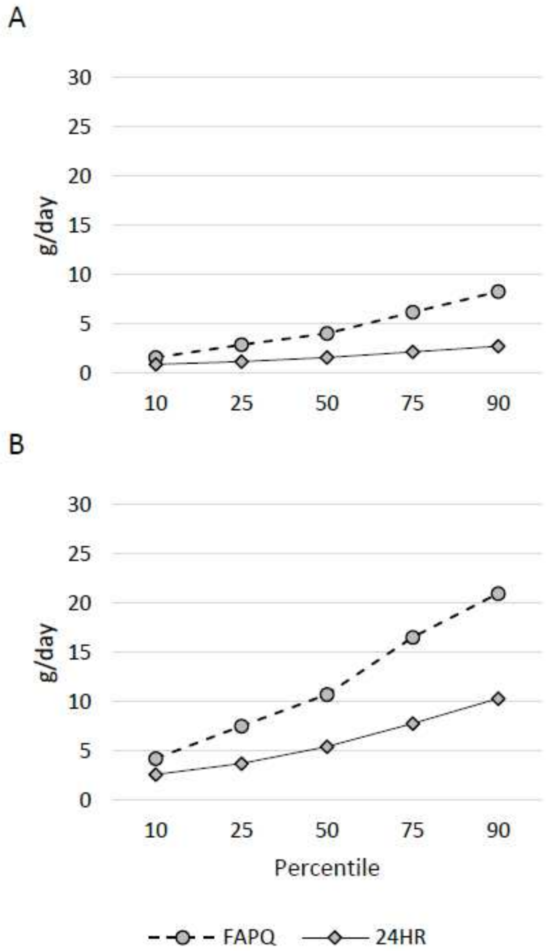

Figure 4.2 Distribution of the amount of fortifiable oil consumed (g/day) among (A) children (12-18 months) (n=109) and (B) their mothers (18-49 years) (n=111) in Mandaluyong City, Philippines, estimated by FAPQ (household-level assessment based on reported amount of fortifiable food the household obtained on the last occasion and duration that this amount usually lasts in the household and application of the adult male equivalent method) and 24HR methods (individual-level assessment based on reported amount of fortifiable food consumed in the past 24 hours adjusted for within-person variation; mean 5.0 days of data per child (including one 12-h observed weighed food record plus 12-h recall in 57 children) and 2.0 days of data per mother). FAPQ, food acquisition and purchase questionnaire; 24HR, 24-h recall.

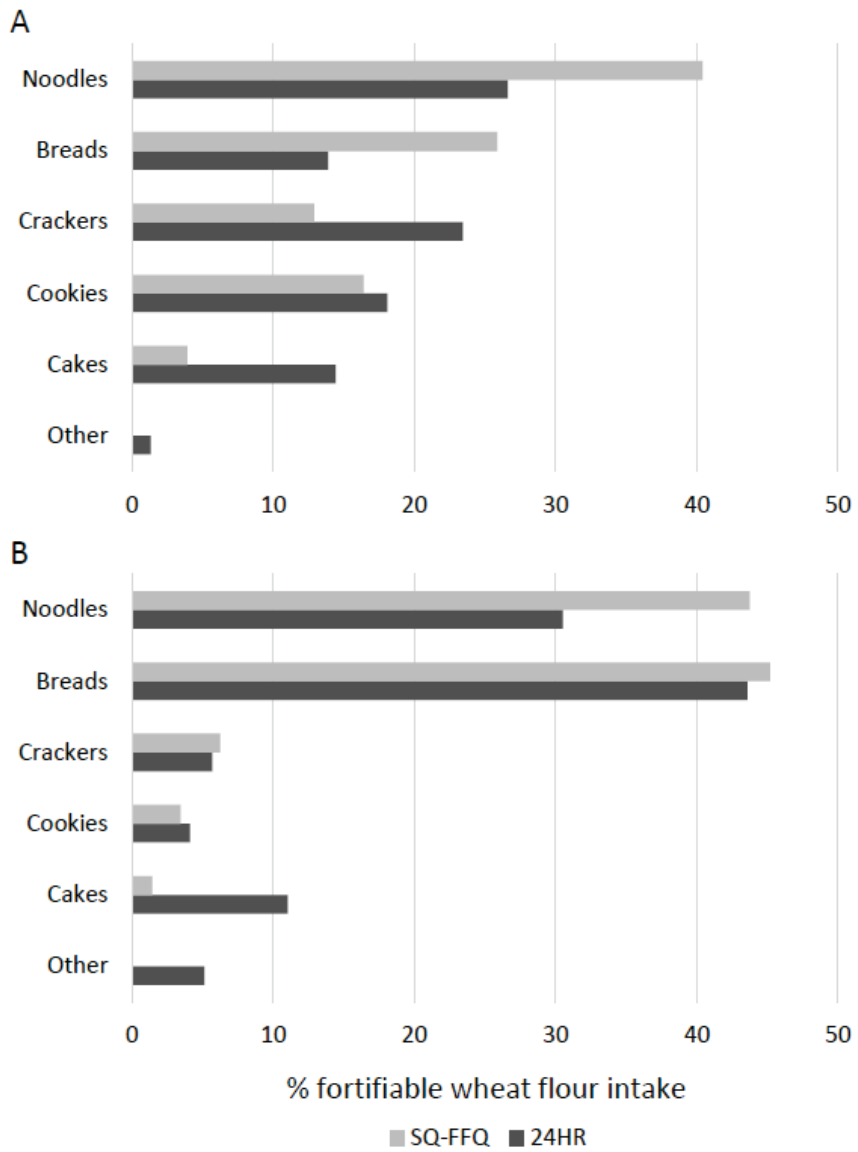

Figure 4.3 Food sources of fortifiable wheat flour among (A) children (12-18 months) (n=113) and (B) their mothers (18-49 years) (n=115) in Mandaluyong City, Philippines, estimated by 7-d SQ-FFQ (individual-level assessment based on reported portion size and frequency of consumption of a list of 25 common food items containing fortifiable wheat flour in the past seven days) and 24HR methods (individual-level assessment based on reported amount of fortifiable food consumed in the past 24 hours; mean 3.9 days of data per child and 2.0 days of data per mother). Values indicate percentage of total fortifiable wheat flour consumed (expressed as g/day) derived from each food group based on unadjusted means. ‘Other’ includes breaded squid/pork/chicken/sardines and spring roll wrappers (*lumpiang*). SQ-FFQ, semi-quantitative food frequency questionnaire; 24HR, 24-h recall.

CHAPTER 5: Decisions to start, strengthen, and sustain food fortification programs: an application of the GRADE Evidence to Decision (EtD) framework in Nigeria

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5.1 Abstract

Background: Although the potential impact of food fortification to improve the micronutrient status of populations has been demonstrated beyond a doubt, it is constrained in practice by critical gaps in program design and implementation. These are partly linked to suboptimal decision making.

Objective: To demonstrate how the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Evidence to Decision (EtD) framework for health system and public health decisions can be applied to formulate recommendations and make decisions in national food fortification programming.

Methods: Following a program impact pathway (PIP), we reviewed the literature to define the key decision types and identify the corresponding decision makers necessary for designing and implementing effective food fortification programs. We then applied the GRADE EtD framework to the Nigerian fortification program to illustrate how evidence-informed assessments and conclusions can be made.

Results: Fortification program decisions were classified into five types: 1) program initiation; 2) program design; 3) program delivery; 4) program impact; and 5) program continuation. Policymakers, food processors, and (in cases dependent on or considering external funding) development partners are the main decision makers in a fortification program, while technical partners play important roles in translating evidence into contextualized recommendations. The availability and certainty of evidence for fortification programs are often low (e.g., quality and coverage data are not routinely collected and there are challenges evaluating impact in such population-based programs using randomized controlled trials) yet decisions must still be made, underscoring the importance of using available evidence. Furthermore, when making program initiation and continuation decisions, coordination with overlapping micronutrient interventions is needed where they coexist.

Conclusions: This framework is a practical tool to strengthen decision-making processes in fortification programs. Using evidence in a systematic and transparent way for decision making can improve fortification program design, delivery, and ultimately health impacts.

5.2 Introduction

Although the potential impact of food fortification to improve the micronutrient status of populations has been demonstrated beyond a doubt (1), there are critical gaps in how programs are designed and implemented. This manifests in what has been termed an unfinished agenda, which can be summarized as follows: first, not all countries that could benefit from fortification have mandatory or voluntary programs in place; and second, where programs are in place, many countries are not reaching their potential for impact due to large gaps in quality (i.e., low coverage of fortified foods generally and even lower coverage of fortified foods that meet national standards), inequity (i.e., fortified foods not available and/or affordable for the poorest segments of the population), and feasibility (i.e., low coverage of industrially processed (i.e., fortifiable) foods (2). Despite these issues, fortified foods have been shown to be major contributors to intakes of key micronutrients, such as vitamin A, iodine, and folic acid, in many countries (3–5) and several program evaluations have demonstrated impact on biological outcomes (e.g., goiter (6), neural tube defects (7), and anemia (8)). In addition to unrealized potential, if the above-mentioned quality gaps are fully addressed, there may be a risk of excessive micronutrient intakes in some settings (3). Such risks and their concomitant effects on individual and population health (9,10) are of particular concern as they may be exacerbated in contexts of cumulative micronutrient intakes from fortified foods plus other dietary sources and/or micronutrient interventions (e.g., supplementation).

These design and implementation challenges can be partly linked to suboptimal decision making. Results from fortification coverage surveys of edible oil, wheat flour, and maize flour in eight countries identified two primary issues related to low coverage (11). First, poor choice of food for fortification (i.e., the food selected was not a staple or was predominately consumed in a non-fortifiable form), which is a program design issue. For example, a high proportion of households consumed maize flour in Tanzania (93%), Uganda (92%), and Nigeria (Kano state) (77%), but only 37%, 42%, and 11%, respectively, consumed it in a fortifiable form. Second, in several countries food processors are failing to fortify owing to poor monitoring and enforcement of fortification mandates and/or lack of incentives for industry to fortify, which is a program delivery issue. This issue cut across all food vehicles assessed.

While part of the problem is the limited availability of evidence to inform program decisions (12), a more pertinent issue is the absence of an explicitly articulated framework that structures the fortification program cycle and identifies key decisions to be made at varying stages. Decision-making frameworks have been used extensively for improving the quality of healthcare (e.g., clinical recommendations, coverage decisions, and decisions about diagnostic tests) (13) and further adapted for use in making health system and public health decisions (14). Such frameworks provide a systematic and transparent process for formulating evidence-informed recommendations and making decisions at critical junctures, with an emphasis on consideration and documentation of all important criteria and the use of the best available evidence.

In this article, we demonstrate how a decision-making framework for health system and public health decisions can be applied to formulate recommendations and make decisions in national large-scale food fortification programs and illustrate the process using a real-world example from Nigeria.

5.3 Methods

5.3.1 Defining decision types and decision makers for food fortification programs

Following the program impact pathway (PIP) for large-scale food fortification as put forth by Martorell et al. (8), we reviewed the literature to define the key decision types and identify the corresponding decision makers necessary for designing and implementing effective large-scale food fortification programs. The PIP illustrates with specificity the underlying program theory (i.e., how a program is envisaged to work). Importantly, it outlines the sequentially dependent program steps and linkages. As such, it can be used to illustrate critical assumptions and necessary processes and inform the decisions that are required at each step to make the program work.

5.3.2 Selection and description of the decision-making framework

We selected the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Evidence to Decision (EtD) framework for health system and public health decisions (14) based on its relevance to large-scale food fortification as a population-based public health program and the global acceptance and use of GRADE EtD frameworks by over 100 organizations worldwide, including the World Health Organization and the Cochrane Collaboration (13). The GRADE EtD framework consists of three main steps: 1) formulating the question; 2) making an informed assessment; and 3) drawing conclusions. In the first step, a general description of the problem and the question details are defined (i.e., problem, option, comparison, main outcomes, setting, perspective from which the decision is being made (population or individual), subgroups, and background). In the second step, data sources are identified, specific criteria are assessed (i.e., priority of the problem, benefits and harms, values, balance of effects, resources required, equity, acceptability, and feasibility), and a judgement for each criterion is made (**Table 5.1**) (14). In the third step, a summary of the judgements for all criteria is made followed by a recommendation. The strength of the recommendation is defined such that a strong recommendation indicates the panel is confident that the benefits outweigh the harms while a conditional recommendation indicates that the panel is less confident and therefore also includes specific guidance on the conditions required for implementing it. Finally, a detailed justification summarizing the most important criteria is provided along with any necessary considerations related to subgroups, implementation, monitoring, evaluation, and research priorities.

5.3.3 Applying the decision-making framework to food fortification program decisions

We applied the GRADE EtD framework to a real-world example, namely a recommendation regarding modifying the design of the large-scale food fortification program in Nigeria to reduce the risk of excessive vitamin A intakes, using the interactive EtD tool template for health system and public health decisions (https://ietd.epistemonikos.org). The completed EtD framework was then reviewed and interpreted by a 'panel' comprised of the authors and a small group of stakeholders from governmental organizations involved in Nigeria's national food fortification program in a virtual workshop, followed by email communications to provide further detail and assessments. This was not a full panel of all relevant stakeholders in Nigeria however as that was beyond the scope of the current work; therefore, judgements and conclusions are our own. The methods deployed in this study primarily involved a narrative review of the literature, coupled with an analysis of data extracted from published articles. As such, they did not meet the definition of research with human subjects and, consequently, were not submitted for ethical review.

5.4 Results

5.4.1 Decision types and decision makers for food fortification programs

The main fortification decisions were classified into the following five decision types mapped to the PIP for large-scale food fortification programs: 1) program initiation; 2) program design; 3) program delivery; 4) program impact; and 5) program continuation (**Figure 5.1**). First is the demonstrated need for food fortification in the population. The prevalence of micronutrient deficiencies suggests the potential to benefit from micronutrient interventions, such as fortification, which informs the decision of whether to explore the initiation of a fortification program as a strategy to address the identified deficiencies. Second, if a program is justified, the magnitude of that need and the consumption patterns of the potentially fortifiable food(s) as well as other micronutrient sources (in the diet and from other interventions) in the population are critical to inform key decisions related to program design, such as the selection of the staple food(s) to fortify and the type and amount of fortificant(s) to add (which are then defined in relevant fortification policies and legislation), to ensure the program is appropriately designed to have the intended impacts in the population. Third, once a program has begun implementation, the quality (i.e., compliance with national fortification standards), coverage, and consumption of fortified foods in the population (and subgroups) inform decisions related to program delivery as they provide evidence to understand how well the program is performing relative to its design and whether the fortified foods are making meaningful contributions to micronutrient intakes. Finally, the change (or lack thereof) in micronutrient deficiencies in the population (and subgroups) informs decisions related to the public health impact of the program and the continued need for the program over time. The latter decision type additionally requires consideration of factors external to the fortification program, such as changes in availability and consumption of other micronutrient-rich foods and coverage of other overlapping micronutrient interventions in the population (and subgroups).

Policymakers (particularly government ministries) and food processors are the main decision makers in a fortification program (**Figure 5.1**). Policymakers are key stakeholders for all five decision types given their responsibility for developing and implementing policies to protect and improve population health, which includes supporting food fortification program in various capacities (**Table 5.2**). Food processors are relevant for program delivery decisions given they are responsible for ensuring the presence of fortificants in the foods selected for fortification in quantities stated in the national fortification standards. Development partners (e.g., bilateral donors, multilateral agencies, and private foundations) are also relevant for program initiation and continuation decisions in contexts dependent on external funding, where such funding is under consideration, and/or where technical assistance is needed. Finally, other technical partners (e.g., non-governmental organizations and the research community) play important roles in translating data and evidence into contextualized recommendations that meet the needs of different decision makers for all decision types.

5.4.2 Application of the GRADE EtD framework to food fortification programs

Formulating the question

In the example framework in **Supplemental File 5.1**, the question was formulated as, *"Should the design of Nigeria's large-scale food fortification program, which aims to reduce vitamin A deficiency, be modified to reduce the risk of excessive vitamin A intakes?"* (i.e., a program design decision). The problem was defined as a goal of reducing vitamin A deficiency in Nigeria through large-scale food fortification without exceeding the tolerable upper intake level (UL) for vitamin A intake in any subgroup of the population. The option considered in the framework was to modify the design of the fortification program by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added based on recent data on population need and consumption patterns. The comparison was to continue implementation of the fortification program as currently mandated (i.e., fortification of oil; sugar; and wheat, semolina, and maize flours with vitamin A as per current national standards (15–19)). The main outcomes considered were vitamin A deficiency prevalence, vitamin A intakes from all dietary sources, and vitamin A intakes from fortified foods alone. The decision setting was a national recommendation for Nigeria from a population-level perspective. Although large-scale food fortification is a population-based program that does not target specific population groups, two subgroups were considered in making the recommendation, i.e., women of reproductive age (15 to 49 years) and children (under five years), as they are the most at risk for micronutrient deficiencies and often the focus of fortification program design, monitoring, and evaluation efforts.

Making an assessment

The following is a summary of the research evidence, additional considerations, and judgements for each criterion assessed.

Priority of the problem

The problem is reducing vitamin A deficiency through large-scale food fortification in Nigeria without exceeding the UL for vitamin A intake in any subgroup of the population. In the most recent national micronutrient survey conducted in Nigeria in 2001, 30% of children under five years had vitamin A deficiency (serum retinol concentration <20 μg/dl) and 13% of mothers and 19% of pregnant women were at risk of vitamin A deficiency (<30 μg/dl), of whom 4% and 9%, respectively, were deficient (<20 μg/dl) (20). To increase vitamin A intakes in the population, several interventions are currently in place, including mandatory fortification of five staple foods with vitamin A, routine public health supplementation among children 6-59 months of age, point-of-use fortification, biofortification, promotion of dietary diversity, voluntary fortification (e.g., infant formula, powdered milk, and cocoa drinks), and ad hoc individual supplement use (21). Unfortunately, there are no more recent national data available on the prevalence of vitamin A deficiency (nor adequacy of intakes) to demonstrate the extent to which the introduction of these programs has led to reduced deficiency prevalence (or increased intakes). At the same time, concerns have been raised in Nigeria regarding the risk of potentially excessive micronutrient intakes because of these multiple overlapping interventions that target the same micronutrient and similar population groups (21). For preformed vitamin A in particular, the effects of chronic excessive intakes can lead to toxicity, which may cause severe adverse effects (e.g., liver damage, teratogenicity) (22). It is therefore crucial to ensure that the total vitamin A intake in the diet coming from all sources does not result in intakes routinely exceeding the UL yet is still enough to shift inadequate intakes to adequate. Based on this, the panel's judgement was that the problem of reducing vitamin A deficiency through large-scale food fortification without exceeding the UL for vitamin A intake in any subgroup of the population is probably a priority.

Benefits and harms, values, and balance of effects

The panel determined that the desirable effects of modifying the design of the fortification program by updating the selection of foods to fortify with vitamin A and/or amounts of vitamin A to be added are moderate, the undesirable effects are trivial, and the overall certainty of effects is very low. There were no studies comparing the option and the comparison; however, there were relevant findings from one cross-sectional subnational study that reported apparent vitamin A intakes from fortified foods alone based on actual consumption patterns (3). In that study, it was estimated that apparent vitamin A intakes would exceed the UL in 18% and 56% of women of reproductive age in Lagos and Kano states, respectively, if all foods were fortified according to national standards. Total vitamin A intakes are expected to be higher when intakes from all sources are considered (21). That said, currently compliance with mandatory fortification standards has been shown to be consistently poor with most foods (apart from salt) being fortified below standards or not at all (11,23,24) and coverage of other vitamin A interventions, such as supplementation and promotion of dietary diversity, is similarly low (e.g., in 2018, vitamin A supplementation reached only 41% of children 6-23 months nationally (25) and, in 2013, only 52% of children 6-23 months reported having consumed vitamin A-rich foods (26)). This likely reduces the present risk of excessive vitamin A intakes in the population; however, if these programs were to improve and be implemented as intended, the risk would increase. There was no evidence on how the population values the main outcomes that were considered. Based on this, the panel's judgement was that there is probably no important uncertainty or variability in how much people value the main outcomes and that the balance of the desirable and undesirable effects probably favors modifying the design of the fortification program by updating the selection of foods to fortify with vitamin A and/or amounts of vitamin A to be added versus continuing to implement it as currently mandated.

Resources required and cost-effectiveness

Costs incurred by food processors related to the fortification process and by government ministries related to monitoring the compliance of fortified foods with national standards must be considered along with costs required to implement other overlapping vitamin A interventions. Cost-effectiveness studies for the Nigeria fortification program specifically have not yet been done and the cumulative costs of all vitamin A ongoing interventions are unknown. However, it is assumed that if modifying the design of the fortification program by updating the selection of foods to fortify with vitamin A in Nigeria leads to fewer foods required to be fortified, then there would likely be some cost savings for both food processors and government ministries. Conversely, if new food vehicles are added, there may be additional costs. Optimizing the set of vitamin A interventions that can be effectively implemented in Nigeria to achieve the greatest impact would likely reduce cost inefficiencies of running multiple programs with low fidelity (compliance). Based on this, the panel's judgement was that, while there may be potential for moderate savings, they do not know the resources required nor the cost-effectiveness of the option versus the comparison.

Equity

There is evidence from two cross-sectional surveys in 4 out of the 36 states of Nigeria (i.e., Kano, Lagos, Ebonyi, and Sokoto) that the coverage of the fortifiable foods currently mandated to be fortified with vitamin A is generally lower in vulnerable households, specifically those that are at risk of poverty (multi-dimensional poverty index ≥ 0.33), have low socioeconomic status (lowest two wealth quintiles), and have low dietary diversity (women's dietary diversity score <5 out of 10 food groups the previous day) (27,28). Similar trends have been shown in other countries and may be due to issues of access, affordability, and/or limited consumption of the respective fortified foods among these at risk groups (11). Comparatively, in Ebonyi and Sokoto, coverage of fortifiable bouillon (which is not currently included in the fortification program) was found to be universal (>98%) with no differences by vulnerable group (28). While updating the selection of foods to fortify with vitamin A based on current consumption patterns would not change existing inequities related to access and affordability, the process would be able to identify which foods currently being fortified and which alternative and/or additional foods have the greatest potential to reach vulnerable populations. Based on this, the panel's judgement was that modifying the design of the fortification program by updating the selection of foods to fortify with vitamin A based on recent data on consumption patterns probably increases equity.

Acceptability

Fortification of staple foods in Nigeria is assumed to be generally accepted by the population as it does not change the characteristics of the food nor require any changes to consumption patterns, but no published studies are available to confirm this. Other key stakeholders, including policymakers, food processors, and development partners, have publicly demonstrated their support for the national fortification program in its current form while recognizing the need for improvements if reductions in micronutrient deficiencies are to be realized (29–31). Therefore, since these stakeholders already accept the current program, it is assumed that they would accept the option of a modified program that would better achieve its goal of reducing vitamin A deficiency while minimizing any risks of excessive intakes and cost inefficiencies, but there is no evidence to confirm this. Based on this, the panel's judgement was that they do not know if updating the selection of foods and/or amounts of vitamin A in Nigeria's fortification program is acceptable to all stakeholders.

Feasibility

Modifying the design of the fortification program by updating the selection of foods to fortify with vitamin A and/or amounts of vitamin A to add would require recent population data on vitamin A intakes and consumption patterns of fortifiable foods. In addition, recent data on vitamin A status would be ideal to serve as a new baseline against which to evaluate program impact in the future. These data are forthcoming as part of the 2021 National Food Consumption and Micronutrient Survey (data are expected to be available in 2022). Technical support and related funding to analyze the new data and propose specific program design changes would also be needed, which may be potential barriers in Nigeria. Once redesigned, fortification standards would need to be updated along with any necessary policy and legislative changes, which would require government buy-in and may be a possible barrier if stakeholders are not accepting of the option or processes are lengthy. Beyond that, the option would be delivered through the existing fortification program structures and thus as likely to succeed as the comparison (i.e., the current program). Based on this, the panel's judgement was that modifying the design of the fortification program to reduce the risk of excessive vitamin A intakes by updating the selection of foods and/or amounts of vitamin A is probably feasible.

Drawing conclusions

Recommendation and justification

The panel made a conditional recommendation for modifying the design of Nigeria's fortification program to reduce the risk of excessive vitamin A intakes by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added based on recent data on population need and consumption patterns (**Box 1**). The justification for this decision was based on the balance between the desirable and undesirable effects and the probable impact on equity. The conditionality of recommending it was based on the need to first fill evidence gaps that were identified in the EtD framework, namely the forthcoming data on nutrient status, nutrient gaps, and food consumption patterns being collected in the 2021 National Food Consumption and Micronutrient Survey (data are expected to be available in 2022), resources required, cost-effectiveness, and acceptability among stakeholders.

5.5 Discussion

In this paper, we prepared the GRADE EtD framework for health system and public health decisions for a real-world example regarding a recommendation for modifying the design of the large-scale food fortification program in Nigeria to reduce the risk of excessive vitamin A intakes. The Nigeria example demonstrated the utility of the EtD framework to help policymakers guide and strengthen fortification program decision-making processes to ensure they are systematic, structured, and transparent. Additionally, it highlighted the flexibility of its use as it does not require significant resources to populate and is still effective even when evidence is lacking given the aim is simply to document the evidence (or lack of) that was used to make judgements.

Using an EtD framework alongside a PIP can help improve decision making in national food fortification programs. Defining and mapping the main fortification program decisions to the PIP explicitly articulates the fortification program cycle and clarifies the end goal to be reached at each stage. This understanding is an important first step in strengthening decision-making processes because while fortification programs are intended to serve as medium- to long-term interventions to address micronutrient deficiencies (with dietary diversification being the ultimate long-term goal) (32), in reality they are often put in place based with little to no review or planning for future adjustments (33). Using an EtD framework as the basis for in-depth review with fortification stakeholders can enhance engagement by organizing a large quantity of information into clear steps for review guided by a set of program relevant questions and criteria. Additionally, it can strengthen the credibility of decisions made by documenting the evidence in a systematic and transparent way and can increase uptake of findings by decision makers given its accessible format (14).

The Nigeria example in this paper illuminates several key findings regarding fortification program decision making that are relevant across countries, as follows.

The availability and certainty of evidence for population-based public health interventions such as fortification, is often low or very low, yet decisions must still be made underscoring the importance of using the best available evidence (34). For decisions related to program initiation, impact, and continuation, the option and comparison in the EtD framework are essentially fortification versus no fortification in the given setting. As such, there would likely be high certainty evidence studies (such as systematic reviews) that demonstrate the efficacy of fortification (though not necessarily in the specific country where the program occurs). Additionally, effectiveness studies that employ variable study designs to evaluate the impact of fortification programs among populations in real-world settings are increasing given the challenges with evaluating population-based programs using traditional designs such as randomized controlled trials (35). On the other hand, for decisions related to program design and delivery, the likelihood of having such high certainty evidence studies (such as randomized controlled trials) that compare different options for a specific national program is very low. In those cases, it may be necessary to rely on lower certainty data sources, such as routine monitoring data for ongoing programs on quality and observational studies on coverage and consumption of fortified foods (while not consistently collected across countries (33), where available, monitoring data can be found in the Global Fortification Data Exchange (36)). This was the case in the Nigeria example that compared two different program design options and relied on evidence from one observational study that assessed only one of the main outcomes in the framework (i.e., vitamin A intakes from fortified foods alone) to examine the desirable and undesirable effects as this was the best available evidence despites its low certainty.

Fortification program decisions do not always occur in a linear process as shown in the PIP. While at the onset of a program decisions are likely to proceed in order (i.e., initiation, design, delivery, and impact), evidence at delivery and impact stages may trigger the need to revisit previous program decisions downstream in the PIP. This was the case in the Nigeria example where evidence from a study examining the potential for program impact triggered the need to consider a program design decision because it estimated a high risk of excessive vitamin A intakes if the program were implemented as currently designed, but with greater fidelity (compliance). Regular assessment of the quality of implementation and initial design assumptions (particularly as they relate to micronutrient needs and consumption patterns of fortifiable foods) are essential as part of a fortification program monitoring throughout the program life cycle (33). While these periodic adjustments have been long recommended in global fortification guidelines (32), in practice few programs have adjusted their fortification standards after being initiated. One notable exception is fortification of sugar with vitamin A in Guatemala where fortification levels were lowered and vitamin A supplementation campaigns were revised to exclude certain child age groups in response to evidence of declining vitamin A deficiency prevalence and vitamin A intakes over time (37).

Fortification decisions related to program initiation, design, and continuation should be made in coordination with those (decisions) that pertain to other complementary micronutrient deficiency control interventions where they coexist. Ideally, decisions on what set of programs should be implemented in a country should be made jointly by all stakeholders involved in micronutrient deficiency control interventions and optimized to maximize impact and cost-effectiveness while ensuring safety over time. However, currently these interventions are often initiated and implemented independently by different national and/or international stakeholders (38) and there is an absence of guidance or regulations to define how to effectively coordinate (9). This was the case in the Nigeria example where multiple vitamin A interventions were being implemented in isolation from one another and their cumulative contribution to vitamin A intakes was unknown. To identify the optimal set of vitamin A deficiency control interventions to achieve a desired level of effective coverage at the lowest cost, an optimization model was used in Cameroon (38). However, this method requires sub-nationally disaggregated data on micronutrient intakes and detailed costing information, along with considerable technical and financial resources to conduct the analyses, which are seldom available in many low- and middle-income countries without external resources. To improve coordination across programs, a national coordination body with strong leadership and a broad vision of nutrition has been suggested to promote balanced, safe, and impactful programs (10). Columbia is one such country that has strived to do this through the development of a separate commission whose purpose it is to strengthen the governance and coordination mechanisms of the different governing entities of their National Food and Nutrition Security Policy, which includes the national micronutrient deficiency prevention and control strategy (39).

There are some limitations to this paper and the use of the GRADE EtD framework for fortification program decision making. First, the example framework was populated by the authors and a small group of stakeholders but did not include a full panel of all relevant stakeholders in Nigeria (including, but not limited to, those involved in fortification as well as other vitamin A micronutrient deficiency control interventions); therefore, the recommendation may not reflect all perspectives. An important next step would be to do a validation workshop with a wider and more diverse range of fortification stakeholders in Nigeria to review and revise the framework and recommendation. Second, the Nigeria example framework completed in this paper was for a design decision, which is only one of the five main decision types relevant to food fortification programs. Future work should explore testing this framework for other fortification decision types at different stages of the PIP as well as in programs carried out in different contexts. Third, there are other factors beyond evidence that influence decision making in national programs (e.g., context, politics, values, and social and economic factors) (40). While this framework can increase the systematic use of evidence or lead to a call for generating missing country-specific data, it does not directly address any other factors. Furthermore, the buy-in and capacity of the stakeholders (particularly policymakers) who would ultimately be responsible for carrying out these processes is essential if they are to be effective and sustainable over time. Moving forward, exploration into potential barriers and areas for capacity development among stakeholders in relation to the use of such decision making frameworks and the uptake of results for decision making in fortification programs and other overlapping micronutrient interventions is needed.

The GRADE EtD framework is a practical tool that can be used by stakeholders in national food fortification programs to facilitate and document the use of evidence to inform decisions to start, strengthen, and sustain food fortification programs. Using evidence for decision making in a systematic and transparent way can improve fortification program design, delivery, and ultimately health impacts while reducing risks associated with excess micronutrient intakes.

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5.7 Chapter 5 references

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Table 5.1 Criteria and judgements in the evidence to decision framework for health system and public health recommendations[1]

Criterion		Judgement options						
Priority of the problem	Is the problem a priority?	Don't know	Varies		No	Probably no	Probably yes	Yes
Benefits and harms	How substantial are the desirable anticipated effects?	Don't know	Varies		Trivial	Small	Moderate	Large
	How substantial are the undesirable anticipated effects?	Don't know	Varies		Large	Moderate	Small	Trivial
Certainty of the evidence of effects	What is the overall certainty of the evidence of effects?	No included studies			Very low	Low	Moderate	High
Values	Is there important uncertainty about or variability in how much people value the main outcomes?				Important uncertainty or variability	Possibly important uncertainty or variability	Probably no uncertainty or variability	No important uncertainty or variability
Balance of effects	Does the balance between desirable and undesirable effects favor the option or the comparison?	Don't know	Varies	Favors the comparison	Probably favors the comparison	Does not favor either the option or the comparison	Probably favors the option	Favors the option
Resources required	How large are the resource requirements (costs)?	Don't know	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings
Certainty of evidence of resources required	What is the certainty of the evidence of resource requirements (costs)?	No included studies			Very low	Low	Moderate	High
Cost-effectiveness	Does the cost-effectiveness of the option (the out-of-pocket cost relative to the net benefits) favor the option or the comparison?	Don't know	Varies	Favors the comparison	Probably favors the comparison	Does not favor either the option or the comparison	Probably favors the option	Favors the option

Equity	What would be the impact on health equity?	Don't know	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased
Acceptability	Is the option acceptable to key stakeholders?	Don't know	Varies		No	Probably no	Probably yes	Yes
Feasibility	Is the option feasible to implement?	Don't know	Varies		No	Probably no	Probably yes	Yes

[1] Adapted from Moberg et al. 2018 (14) under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

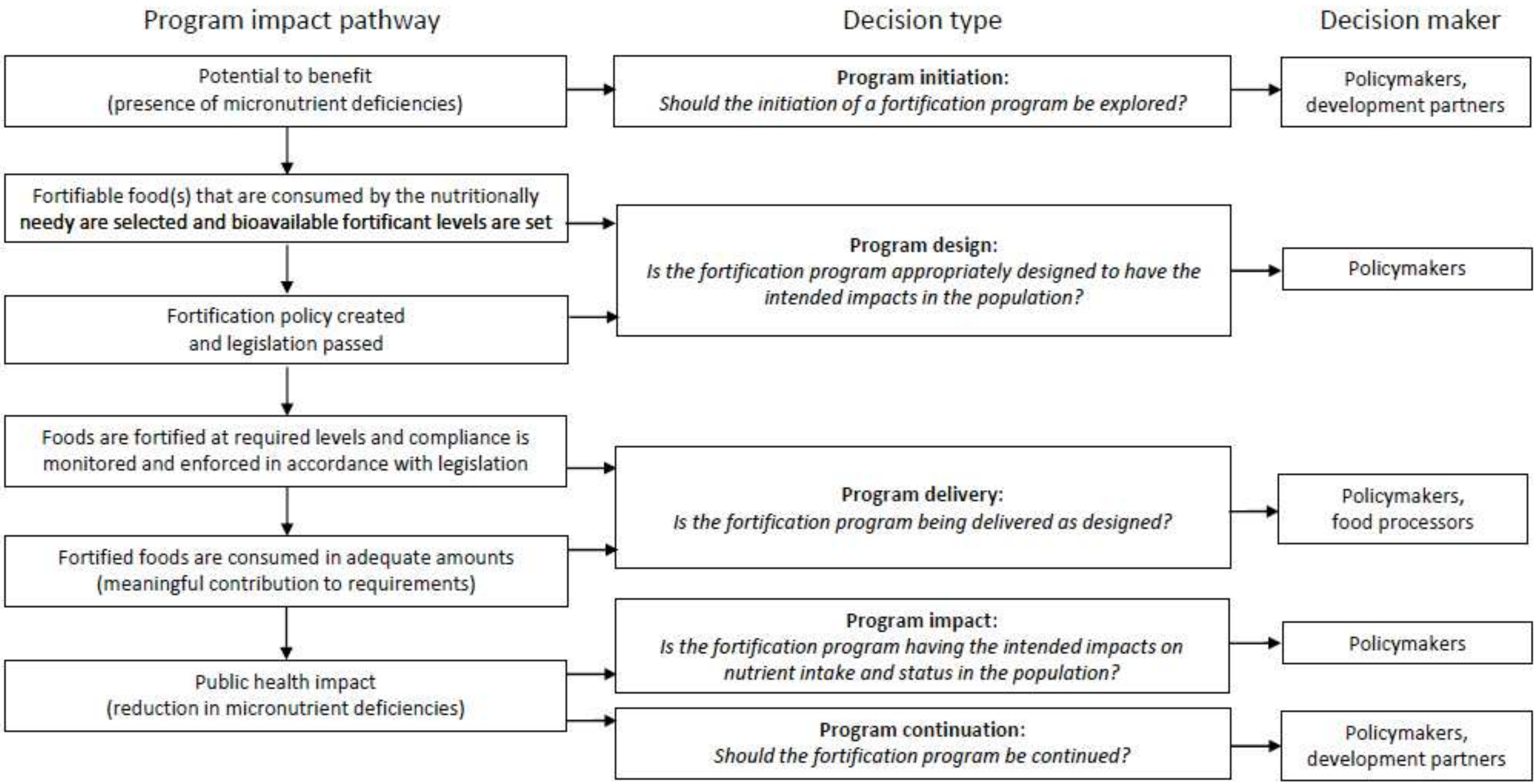

Figure 5.1 Large-scale food fortification program decision types and decision makers mapped to the program impact pathway (adapted from Martorell et al. 2015 (8) under the terms and conditions for articles published under the ASN free access publishing option (http://www.nutrition.org/publications/guidelinesand-policies/license/)).

Table 5.2 Typical policymakers and their decision-making roles in national food fortification programs

Typical policymaker	Role in program
Ministry of Health	Make decisions related to the formulation and implementation of fortification policies and legislation
Ministry of Finance (or Budget and Planning Commission)	Make decisions related to the allocation of funds to support fortification program design, implementation, monitoring, and evaluation
Standards authorities	Make decisions related to the development of fortification standards
Regulatory and food control authorities	Make decisions related to the enforcement of fortification legislation and standards

Box 5.1 Conclusions from the evidence to decision (EtD) framework for a decision about modifying the design of Nigeria's large-scale food fortification program to reduce the risk of excessive vitamin A intakes

RECOMMENDATION: In Nigeria, modifying the design of the national food fortification program to reduce the risk of excessive vitamin A intakes in the population by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added based on recent data on population need and consumption patterns is conditionally recommended *(Conditional recommendation)*.

Remarks:

- The conditionality of this recommendation was based on the need to first fill evidence gaps that were identified in the EtD framework, namely resources required, cost-effectiveness, and acceptability among stakeholders, which should be immediate research priorities.

- The low certainty of the evidence comparing the desirable and undesirable effects should not be a barrier to adopting this recommendation given that high certainty evidence studies (e.g., randomized controlled trials, systematic reviews) examining the option vs. the comparison are not feasible nor necessary to undertake in the context of a national population-based programs for which efficacy of the intervention has already been demonstrated in such studies, as is the case for vitamin A fortification.

- The modifications should be based on the demonstrated vitamin A needs and consumption patterns of fortifiable foods among different subpopulation groups (e.g., children under five years, adolescent boys and girls, women of reproductive age, and adult men) following global guidance on designing fortification programs and using data that are forthcoming from the 2021 National Food Consumption and Micronutrient Survey.

- Implementation of this recommendation should be subject to ongoing monitoring to ensure high quality implementation according to its design, including:
    - compliance monitoring at import, production, and market levels with effective enforcement measures as relevant; and
    - coverage and consumption monitoring at household and individual levels as relevant.

- Monitoring of vitamin A intakes from fortified foods must be coordinated with that from other interventions that similarly aim to increase vitamin A intakes to ensure that the total vitamin A intake in the diet is considered when reviewing risks of excessive intakes.

Supplemental File 5.1 Evidence to decision framework for a decision about modifying the design of Nigeria's large-scale food fortification program to reduce the risk of excessive vitamin A intakes

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Should the design of Nigeria's large-scale food fortification program, which aims to reduce vitamin A deficiency, be modified to reduce the risk of excessive vitamin A intakes? (Health system and public health recommendation)

QUESTION

Question details

Problem: Reducing vitamin A deficiency through large-scale food fortification without exceeding the upper tolerable intake level (UL) for vitamin A intakes in any part of the population

Option: Modify the design of the fortification program by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added based on recent data on population need and consumption patterns

Comparison: Continue implementation of the fortification program as currently mandated (i.e., fortification of oil; sugar; and wheat, maize, and semolina flours with vitamin A as per current national standards)

Main outcomes:
- Vitamin A deficiency prevalence
- Vitamin A intakes from all dietary sources (i.e., fortified foods and other foods, beverages, and supplements)
- Vitamin A intakes from fortified foods alone

Setting: Nigeria

Perspective: Population-level

Background

Large-scale food fortification is proven to be a cost-effective intervention to reduce micronutrient deficiencies and their associated outcomes when programs are appropriately designed and implemented (32). In Nigeria, the prevalence of vitamin A deficiencies is high and persistent (20). Several interventions are currently in place that aim to increase vitamin A intakes in the population, including the mandatory fortification of oil, sugar, and wheat, semolina, and maize flours since 2002 (15-19).

This framework presents the research evidence and other relevant information on modifying Nigeria's large-scale food fortification program by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added to the selected foods based on recent data on population need and consumption patterns to reduce the risk of excessive vitamin A intakes.

Subgroups

Subgroup name: Women of reproductive age (15 to 49 years)
Subgroup name: Children (under 5 years)

ASSESSMENT

Problem

Is the problem a priority?

Judgement

☐ Don't know	☐ Varies	☐ No	☐ Probably No	☒ Probably Yes	☐ Yes

Research evidence

In the most recent national micronutrient survey conducted in Nigeria in 2001, approximately 30% of children under five years had vitamin A deficiency (serum retinol concentration < 20 µg/dl) and 13% of mothers and 19% of pregnant women were at risk of vitamin A deficiency (< 30 µg/dl), of whom 4% and 9%, respectively, were deficient (<20 µg/dl) (20).

To increase vitamin A intakes in the population, several interventions are currently in place. These include mandatory fortification of five staple foods with vitamin A (i.e., oil; sugar; and wheat, semolina, and maize flours) since 2002 as well as public health supplementation, point-of-use fortification, biofortification, promotion of dietary diversity, voluntary fortification (e.g., infant formula, powdered milk, and cocoa drinks), and ad hoc individual supplement use (21).

Unfortunately, there are no more recent national data available on the prevalence of vitamin A deficiency (nor adequacy of intakes) to demonstrate the extent to which the introduction of these programs has led to reduced deficiency prevalence (or increased intakes). At the same time, concerns have been raised in Nigeria regarding the risk of potentially excessive micronutrient intakes because of these multiple overlapping interventions that target the same micronutrient and similar population groups (21). Where there are multiple interventions in place that overlap in target population groups, there is a risk of excessive micronutrient intakes if they are not coordinated and closely monitored (9,10). For preformed vitamin A specifically, the effects of chronic excessive intakes can lead to toxicity, which may cause severe adverse effects among young children and women of reproductive age are (e.g., liver damage and teratogenicity) (22). It is therefore critical to ensure that the total vitamin A intake in the diet coming from all sources does not result in intakes routinely exceeding the UL in any part of the population yet is still enough to shift inadequate intakes to adequate.

Additional considerations

None

Desirable effects

How substantial are the desirable anticipated effects?

Judgement

☐ Don't know	☐ Varies	☐ Trivial	☐ Small	☒ Moderate	☐ Large

Research evidence

There are no included randomized controlled trials, systematic reviews, or meta-analyses comparing the option (updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added to the selected foods based on current population need and consumption patterns) and the comparison (continuing the vitamin A fortification program as is) for the main outcomes (vitamin A deficiency and vitamin A intakes in the diet).

However, there were relevant findings from one observational (cross-sectional) study that reported apparent vitamin A intakes from fortified foods alone based on actual consumption patterns. In that study, it was estimated that apparent vitamin A intakes would exceed the UL in 18% and 56 % of women of reproductive age in Lagos and Kanos states, respectively, if all foods were fortified with accordance with national standards (3). This analysis did not account for vitamin A intakes from other interventions; therefore, the total dietary intake from all sources is likely to be much higher in some population groups given the other vitamin A interventions being implemented (i.e., public health supplementation, point-of-use fortification, biofortification, promotion of dietary diversity, voluntary fortification, and ad hoc individual supplement use) (21).

That said, currently compliance with mandatory fortification standards in Nigeria has been shown to be consistently poor with most foods (apart from salt) being fortified below standards or not at all (11,23,24) and the coverage of other vitamin A interventions, such as supplementation and promotion of dietary diversity, is similarly low, e.g., in 2018, vitamin A supplementation reach was 41% among children 6-59 months nationally (25) and in 2013, only 52% of children 6-23 months reported having consumed vitamin A rich foods (26). This likely reduces the current risk of excessive vitamin A intakes (while increasing the risk of deficiency); however, if these programs were to improve and be implemented as intended, the risk of excessive vitamin A intakes is likely to increase.

Additional considerations

A systematic review and meta-analysis of vitamin A fortification programs in low- and middle-income countries confirms that vitamin A fortification is associated with improved nutritional outcomes, i.e., a significant increase in serum retinol (standard mean difference: 0.31; 95% CI: 0.18, 0.45) among children 12-24 months (4 studies, n=2800, moderate certainty of evidence) and a single study among women of reproductive age showed similar improvements (SMD: 0.45 (95% CI: 0.26, 0.64), n=447 (1).

Undesirable effects

How substantial are the undesirable anticipated effects?

Judgement

☐ Don't know	☐ Varies	☐ Large	☐ Moderate	☐ Small	☒ Trivial

Research evidence

No adverse effects of updating the selection of foods to fortify with vitamin A and/or amounts of vitamin A in the selected foods in the fortification program based on current population need and consumption patterns are anticipated if the redesign is done according to global guidelines on designing food fortification programs (32), assuming the redesigned program is implemented effectively.

Certainty of the evidence

What is the overall certainty of the evidence of effects?

Judgement

☐ No included studies	☒ Very low	☐ Low	☐ Moderate	☐ High

Research evidence

The overall certainty for the option is very low owing to the limited availability of evidence to assess, i.e., only one observational (cross-sectional) subnational study included.

However, this is not surprising given that high certainty evidence studies (e.g., randomized controlled trials, systematic reviews) examining the option vs. the comparison are not feasible nor necessary to undertake in the context of national population-based programs when efficacy of the intervention has already been demonstrated in such studies as is the case for vitamin A fortification (1).

Values

Is there important uncertainty about, or variability in, how much people value the main outcomes?

Judgement

☐ Important uncertainty or variability	☐ Possibly important uncertainty or variability	☒ Probably no important uncertainty or variability	☐ No important uncertainty or variability

Research evidence

There was no evidence on how the population (and specific sub-groups) value the main outcomes that were considered.

Additional considerations

None

Balance of effects

Does the balance between desirable and undesirable effects favor the option or the comparison?

Judgement

☐ Don't know	☐ Varies	☐ Favors the comparison	☐ Probably favors the comparison	☐ Does not favor either the option or the comparison	☒ Probably favors the option	☐ Favors the option

Research evidence

See the four preceding criteria.

Resources required

How large are the resource requirements (costs)?

Judgement

☒ Don't know	☐ Varies	☐ Large costs	☐ Moderate costs	☐ Negligible costs or savings	☐ Moderate savings	☐ Large savings

Research evidence

Costs incurred by food processors related to the fortification process itself (e.g., premix, equipment, training, human resources) and by government ministries related to ongoing monitoring and regulation at industry and market levels (e.g., analytical capacity for testing micronutrients, equipment, training, human resources) must be considered along with costs required to implement other overlapping vitamin A interventions. However, there was no available evidence to estimate costs of implementing the option nor of the current costs for implementing the comparison and the cumulative costs of all vitamin A ongoing interventions are unknown.

While food fortification programs have been proven to be among the most cost-effective interventions for improving nutrition (32), cost-effectiveness studies for the Nigeria fortification program specifically have not yet been done. Additionally, optimizing the set of vitamin A interventions that can be effectively implemented in Nigeria to achieve the greatest impact would likely reduce cost inefficiencies of running multiple programs with low fidelity (compliance).

Additional considerations

It is assumed that if the fortification program were modified to include a reduced number of food vehicles requiring the addition of vitamin A, there would likely be cost savings among both food processors and government ministries as fewer foods would mean some food processors would not need to fortify at all if vitamin A were the only micronutrient required to be added previously (e.g., sugar or oil) and thus monitoring efforts for those foods would no longer be needed.

Furthermore, if the vitamin A program were modified to reduce the amount of vitamin A required in the current five food vehicles or remove vitamin A from the standard for foods that still require other micronutrients to be added (e.g., flours), there may also be some cost savings on the side of the food producer (e.g., reduced premix cost) but other aspects of the fortification process would still be required as would government monitoring efforts.

Conversely, if the program were modified to include additional food vehicles requiring the addition of vitamin A, there would likely be additional costs among both food processors and government ministries for both the fortification process and monitoring efforts.

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

Judgement

☒ No included studies	☐ Very low	☐ Low	☐ Moderate	☐ High

Research evidence

No studies available.

Additional considerations

Costs are likely to vary across food processors and settings within Nigeria.

Cost-effectiveness

Does the cost-effectiveness of the option favor the option or the comparison?

Judgement

☒ Don't know	☐ Varies	☐ Favors the comparison	☐ Probably favors the comparison	☐ Does not favor either the option or the comparison	☐ Probably favors the option	☐ Favors the option

Research evidence

While there may be potential for moderate savings associated with modifying Nigeria's vitamin A fortification program (see section on resources required), there was no evidence to estimate the resource requirements nor the cost-effectiveness evidence of the option versus the comparison.

Additional considerations

None

Equity

What would be the impact on health equity?

Judgement

☐ Don't know	☐ Varies	☐ Reduced	☐ Probably reduced	☐ Probably no impact	☒ Probably increased	☐ Increased

Research evidence

There is evidence from two cross-sectional surveys in 4 states out of the 36 in Nigeria (Kano, Lagos, Ebonyi, and Sokoto) that the coverage of fortifiable foods that are currently required to be fortified with vitamin A in Nigeria (i.e., the comparison) is generally lower in vulnerable households, specifically those that are at risk of poverty (multi-dimensional poverty index ≥0.33), have low socioeconomic status (lowest two wealth quintiles), and have low dietary diversity (women's dietary diversity score <5) (27,28).

Similar trends have been shown in other countries and may be due to issues of access, affordability, and/or limited consumption of the respective fortified foods among these at-risk groups (11).

Comparatively, in Ebonyi and Sokoto, coverage of fortifiable bouillon (which is not currently included in the fortification program) was found to be universal (>98%) with no differences by vulnerable group (28).

While updating the selection of foods to fortify with vitamin A based on current consumption patterns would not change existing inequities related to access and affordability, the process would be able to identify which foods currently being fortified and which alternative and/or additional foods have the greatest potential to reach vulnerable populations.

Additional considerations

None.

Acceptability

Is the option acceptable to key stakeholders?

Judgement

☒ Don't know	☐ Varies	☐ No	☐ Probably No	☐ Probably Yes	☐ Yes

Research evidence

Fortification of staple foods in Nigeria is assumed to be generally accepted by the population as it does not change the characteristics of the food nor require any changes to consumption patterns, but no studies are available to confirm this.

Other key stakeholders, including policymakers, food processors, and development partners, have publicly demonstrated their support for the national fortification program in its current form while recognizing the need for improvements if reductions in micronutrient deficiencies are to be realized. For example, in 2018, industry, government, and development partners made commitments at the Nigeria Food Processing and Nutrition Leadership Forum to achieving fortification goals by 2020 (29). In 2019, the Federal Ministry of Health and partners hosted the first national micronutrient conference where they discussed the urgent need to address micronutrient deficiencies by leveraging strengths to scale up the various interventions in the country, including food fortification, supplementation, and dietary diversification (30). Additionally, in 2016, government officials delivered the Lagos statement on Nigeria Food Fortification statement at the Nigeria Future Fortified Stakeholders' Dialogue that outlined a roadmap of activities for effectively implementing the fortification program (31).

Since these stakeholders are already accepting of the current fortification program, it is assumed that they would accept the option of a modified program that would better achieve its goal of reducing vitamin A deficiency while minimizing any risks of excessive intakes, but there is no evidence to confirm this.

Additional considerations

None.

Feasibility

Is the option feasible to implement?

Judgement

☐ Don't know	☐ Varies	☐ No	☐ Probably No	☒ Probably Yes	☐ Yes

Research evidence

Updating the selection of foods to fortify with vitamin A and/or amounts of vitamin A to add based on current population need and consumption would require recent population data on vitamin A intakes and consumption patterns of fortifiable foods. In addition, recent data on vitamin A status would be ideal to serve as a new baseline for which to evaluate impact against in the future. These data are forthcoming as part of the 2021 National Food Consumption and Micronutrient Survey (data are expected to be available in 2022).

Appropriate technical support and related funding to analyze the new data and propose specific program design changes would also be needed, which may be potential barriers in Nigeria.
Once redesigned, fortification standards would need to be updated along with any necessary legislative changes, which would require government buy-in and may be a possible barrier if stakeholders are not accepting of the option or processes are lengthy.

Finally, once approved, changes to food producer processes (either stop or start fortification or change premix) and regulatory monitoring efforts (potentially stop monitoring some foods altogether or for vitamin A) would be needed but efforts to implement such activities would likely be reduced rather than increased.

Additional considerations

If the option is implemented, once designed and approved by the government, it would be delivered through the existing fortification program structures as the current fortification program and thus as likely to succeed as the comparison (i.e., the current program).

CONCLUSIONS

Summary of judgements

Problem	- Don't know	- Varies		- No	- Probably No	✓ Probably Yes	- Yes
Desirable effects	- Don't know	- Varies		- Trivial	- Small	✓ Moderate	- Large
Undesirable effects	- Don't know	- Varies		- Large	- Moderate	- Small	✓ Trivial
Certainty of the evidence	- No included studies			✓ Very low	- Low	- Moderate	- High
Values				- Important uncertainty or variability	- Possibly important uncertainty or variability	✓ Probably no important uncertainty or variability	No important uncertainty or variability
Balance of effects	- Don't know	- Varies	- Favors the comparison	- Probably favors the comparison	- Does not favor either the option or the comparison	✓ Probably favors the option	- Favors the option
Resources required	✓ Don't know	- Varies	- Large costs	- Moderate costs	- Negligible costs or savings	Moderate savings	- Large savings
Certainty of evidence of required resources	✓ No included studies			- Very low	Low	- Moderate	- High
Cost-effectiveness	✓ Don't know	- Varies	- Favors the comparison	- Probably favors the comparison	- Does not favor either the option or the comparison	Probably favors the option	- Favors the option
Equity	- Don't know	Varies	- Reduced	- Probably reduced	- Probably no impact	✓ Probably increased	- Increased
Acceptability	✓ Don't know	- Varies		- No	- Probably No	Probably Yes	- Yes
Feasibility	- Don't know	- Varies		- No	- Probably No	✓ Probably Yes	Yes

Type of recommendation

Judgement

☐ Strong recommendation against the option	☐ Conditional recommendation against the option	☐ Conditional recommendation for either the option or the comparison	☒ Conditional recommendation for the option	☐ Strong recommendation for the option

Recommendation

Modifying the design of Nigeria's large-scale food fortification program to reduce the risk of excessive vitamin A intakes in the population by updating the selection of foods to be fortified with vitamin A and/or amounts of vitamin A to be added based on data on population need and consumption pattern is conditionally recommended.

Justification

Modifying the design of Nigeria's large-scale food fortification program provides an opportunity to ensure it accounts for all vitamin A sources in the diet (given the high number of vitamin A interventions implemented simultaneously) and follows global guidance principles. Doing so would minimize the risk of excessive vitamin A intakes and probably increase equity.

Detailed justification

☐ Problem	
☐ Desirable effects	
☐ Undesirable effects	
☒ Certainty of the evidence	The certainty of the evidence is very low.
☐ Values	
☒ Balance of effects	Updating the selection of foods to fortify with vitamin A and/or the amounts of vitamin A to be added based on current data on population need and consumption patterns (accounting for all sources of vitamin A in the diet, particularly those from other vitamin A interventions being carried out) would likely reduce the risk of excessive intakes of vitamin A (while increasing adequate intakes).
☐ Resources required	
☐ Certainty of evidence of required resources	
☐ Cost-effectiveness	
☒ Equity	Updating the selection of foods to fortify with vitamin A probably increases equity by identifying which foods have the greatest potential to reach vulnerable populations that may not be being reached with the current fortified foods.
☐ Acceptability	
☐ Feasibility	

Subgroup considerations

The modifications to Nigeria's fortification program design should be based on the demonstrated vitamin A needs and consumption patterns of fortifiable foods among different subpopulation groups (e.g., children under five years, adolescent boys and girls, women of reproductive age, and adult men) following global guidance on designing fortification programs (FAO/WHO guidelines 2006) and using the most recent data once available from the 2021 national food consumption and micronutrient survey in Nigeria.

Implementation considerations

- To have an impact on reducing vitamin A deficiency, there needs to be:
    - adequate compliance with national fortification standards by food processors and effective monitoring and enforcement by government to ensure high quality fortified foods are available to the population; and
    - high population coverage of fortified foods so that they are consumed in adequate amounts to making meaningful contributions to vitamin A requirements.
- Monitoring of vitamin A intakes from fortified foods must be coordinated with that from other interventions that similarly aim to increase vitamin A intakes to ensure that the total vitamin A intake in the diet is considered when reviewing risks of excessive intakes.

The political/social context:

- Political support (national and local level) is essential.
- Implementing the intervention as part of the national nutrition strategy is likely to enhance coverage and sustainability.

Monitoring and evaluation

- Implementation of this recommendation should be subject to ongoing monitoring to ensure high quality implementation according to its design, including:
    - compliance monitoring at import, production, and market levels with effective enforcement measures; and
    - coverage and consumption monitoring at household and individual levels.
- Evaluation of impact on reducing vitamin A deficiency in the population should not be undertaken until sufficient evidence from monitoring data is available to demonstrate that all previous stages in the program impact pathway have been achieved.

Research priorities

- Generate the new data on nutrient status, nutrient gaps, and food consumption patterns required to carry out this recommendation (forthcoming in the national food consumption and micronutrient survey is currently being carried out in Nigeria in 2021).
- Determine the resources required and cost-effectiveness of the option versus the comparison.
- Determine the acceptability of implementing the option among stakeholders.

CHAPTER 6: Conclusions and Implications

6.1 Summary of findings

The overall aim of this thesis was to evaluate methods for assessing performance and potential for impact of national large-scale food fortification programs and provide guidance on evidence-based decision making for effective program design and delivery. This was achieved through three specific aims, which are described in Chapters 3, 4, and 5.

In Chapter 3, using data from cross-sectional Fortification Assessment Coverage Toolkit (FACT) surveys conducted in four African countries, we quantified apparent nutrient intakes from fortified foods among women of reproductive age (WRA) and demonstrated how to use the results to understand the performance and potential for impact of the programs. We found that despite inconsistent fidelity of implementation, fortified foods were still major contributors to vitamin A and iodine intakes, but not iron, among WRA. Our findings highlighted several programs at risk of low or excessive nutrient intakes owing to poor program design and/or delivery and helped identify potential program improvements to minimize these risks. In addition, the FACT method employed in the surveys used household-level food consumption data and assumptions of intrahousehold distribution of the food (as per the adult male equivalent (AME) method) to estimate apparent individual-level consumption of fortifiable foods among WRA. In doing so, we found that the AME method likely has major precision and estimation errors for some foods. Potential reasons for this include inaccuracies in measurement of products made from the fortified food that are purchased and/or consumed away from home, inaccuracies in household utilization, or inequitable household distribution. For instance, in these analyses it is likely that the AME method underestimated the amount of fortifiable wheat flour consumed (and subsequent iron intakes) in the Uganda population as other studies reported that bread and other wheat flour-containing products prepared from fortifiable wheat flour are widely purchased yet the current analyses estimated negligible amounts consumed. Additionally, it may have overestimated the amount of oil (and subsequent vitamin A intakes) consumed in some countries as the AME methods assumes that the total amount available in the household is consumed but does not account for oil that is discarded or re-used when preparing foods.

In Chapter 4 we explored the above-mentioned limitation to the AME method further using data from a study in Mandaluyong City, Philippines that assessed vitamin A intake among children 12-18 months exposed to vitamin A supplements. Among the children and their mothers (18 to 49 years), we assessed consumption of fortifiable wheat flour and oil or wheat flour only using a food acquisition and purchase questionnaire (FAPQ) or 7-d semi-quantitative food frequency questionnaire (SQ-FFQ), respectively, and compared the results against 24HRs as the reference method. For fortifiable wheat flour, we found that the SQ-FFQ estimates were within 5-22% of those from 24-h recalls while the FAPQ method systematically and significantly underestimated fortifiable wheat flour consumption (more than 6 times) compared to the 24-h recalls. The latter was largely due to the FAPQ missing measurement of wheat flour-containing foods purchased and/or consumed outside the household. For fortifiable oil, the FAPQ overestimated fortifiable oil intakes (2 to 2.5 times) compared to 24-h recalls. This was likely due to inaccuracies in household utilization and/or inequitable intrahousehold food distribution. While the SQ-FFQ generated useful information on fortifiable food consumption patterns that can inform decisions related to fortification program design and monitoring, the FAPQ method needs to be strengthened to capture prepared foods and minimize under- and over-estimation.

In Chapter 5 we demonstrated how the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Evidence to Decision (EtD) framework for health system and public health decisions can be used to formulate recommendations and make decisions in national food fortification programs using a real-world example for which we prepared the framework fully. This was a recommendation for modifying the large-scale food fortification program in Nigeria to reduce the risk of excessive vitamin A intakes. The Nigeria example demonstrated how the EtD framework can facilitate stakeholder engagement and guide fortification program decision-making processes, strengthen the credibility of the decisions made by documenting the evidence (or lack of) in a systematic and transparent way, and increase uptake of findings by decision makers given its accessible format. This tool could help policymakers strengthen decision-making processes in national food fortification programs.

6.2 Contributions of the research to food fortification programs

6.2.1 Methodological contributions

The development of the FACT method in 2013 filled an identified gap in standardized, fit-for-purpose tools for assessing fortification program coverage (1). In its rollout across more than 16 countries (2), the use and utility of the cascade of household coverage indicators to identify gaps in program design and implementation and areas for improvement were clearly demonstrated (3). However, the use and utility of the indicators on micronutrient contributions from fortified foods among target populations to estimate program performance and potential for impact had not been demonstrated. Therefore, a substantial contribution made by this research was the quantification of those indicators and demonstration of their use and utility for understanding performance and potential for impact of fortification programs. Additionally, we showed that these indicators are relatively simple and straight forward to calculate yet generate a wealth of information that can easily (and visually when presented graphically) identify specific program improvements needed to increased potential for impact.

Simplified dietary assessment methods, such as FAPQs and SQ-FFQs, are more frequently used in low- and middle-income countries than 24-h recalls, often as part of national surveys (e.g., household consumption and expenditure surveys (HCES)). These methods, and the more recent FACT surveys, have great potential for increasing the availability of fortifiable food consumption data for decision making in several fortification program stages. However, there were few studies comparing their accuracy to 24-h recall methods for assessing fortifiable food intakes. Therefore, a substantial contribution made by the present research was the comparison of those two simplified methods against 24-h recalls for estimating fortifiable wheat flour and oil among two population groups (young children and WRA) that are most often the targets of food fortification programs. This comparison led to the identification of the main sources of error when using these two simplified methods to estimate fortifiable wheat flour and oil, i.e., systematic error for the FAPQ and random error for the SQ-FFQ. These findings identified important directions for future research needed to better understand these sources of error and to strengthen the accuracy of these methods.

6.2.2 Theoretical contributions

This research also made important theoretical contributions. While the need to use data to inform the design and implementation of nutrition programs is well recognized (4), its practice in food fortification is often constrained due to a variety of factors, including (but not limited to) the lack of availability of evidence to inform program decisions (5), complex decision-making processes (6), and a lack of guidance and practical tools demonstrating how and when to use data for decision making. To address the latter constraint, this research aimed to add structure to the process of decision making in fortification programs by developing a framework that explicitly articulates the fortification program cycle and identifies key decisions to be made (and corresponding decision makers) at varying stages aligned to the program impact pathway for fortification. Within the proposed framework, opportunities to evaluate (or re-evaluate) key program decisions are highlighted along with specific questions to be answered at each stage. By integrating this framework and a system of regular review of these questions into a fortification program cycle, decision-making processes can be strengthened, and continual review and evidence-based course correction can become routine to ensure that potential for impact is realized and risks are mitigated.

6.3 Implications for food fortification programs

The effectiveness and impact of food fortification is dependent on programs being appropriately designed and implemented. Therefore, stakeholders in national fortification programs (including policymakers, food processors, and development partners) need to prioritize the routine assessment of program outcomes, including quality, consumption, and micronutrient contribution of fortified foods, through ongoing monitoring efforts. By doing so, fortification programs will be able to generate the information needed to track progress, identify and overcome barriers, and ultimately achieve their goal of filling the micronutrient gaps and improving health outcomes in the population. This research provides evidence on the appropriate methods and tools for assessing such indicators, describes how they relate to program performance and potential for impact, and demonstrates how to use the resulting data to inform decisions.

Translating data into recommendations and decisions is often a major challenge faced in nutrition programs, including food fortification. While the findings from Chapter 5 provide convincing evidence on the use of a decision making framework to strengthen and promote systematic and transparent decision-making processes in national food fortification programs, the buy-in and capacity of the stakeholders (typically policymakers) who would ultimately be responsible for carrying out these processes is essential if they are to be effective and sustainable over time. Moving forward, exploration into potential barriers and areas for capacity development among stakeholders in relation to the use of such decision making frameworks is needed.

6.4 Directions for future research

The methods for assessing fortifiable food consumption and subsequent micronutrient intakes from fortified foods presented in Chapters 3 and Chapter 4 are cross-sectional in nature and thus provide information describing a fortification program at a specific moment in time (and place). While these methods are useful for making decisions related to program design (e.g., selection of foods for fortification) and understanding program performance (e.g., quality compared to national fortification standards) and potential for impact (e.g., contributions to filling identified micronutrient gaps in the diet) as previously discussed, they are limited in understanding *why* some programs are not (or are) being delivered effectively and thus limiting (or reaching) their potential for impact. For example, why is industry compliance for some foods poor (and thus micronutrient contributions are low) and how might it be improved? To fill this gap, implementation research, which aims to understand the strengths and weaknesses within and across the various domains that affect implementation (7), should be integrated into fortification programs to understand how to address the specific barriers to effective program delivery identified in different contexts. The importance of and need to prioritize implementation research in nutrition has been recently highlighted as a critical area of work needed to close the gap between understanding efficacious interventions and actually realizing impacts in large-scale programs (7,8). Some recent examples of how this can be done in food fortification programs exist in the literature, such as a process evaluation that aimed to understand the drivers of double-fortified salt adherence in India (9).

The findings on the accuracy of a targeted household-level FAPQ and individual-level SQ-FFQ for assessing fortifiable food consumption presented in Chapter 4 identified important areas of future research related to better understanding the sources of error in the application of the AME method to FAPQ data. However, as many low- and middle-income countries are currently experiencing a nutrition transition, including a major shift towards purchasing prepared and processed food products (10), the utility of a household-level FAPQ may be reduced over time unless it can be adapted to address these changing purchase and consumption patterns. While the individual-level SQ-FFQ method that captures fortifiable foods both at home and away may seem like a straightforward alternative given its success for assessing fortifiable wheat flour in Chapter 4, further exploration is needed to confirm this as it would likely be more challenging to design for other fortifiable foods (e.g., oil, salt) due to the difficulty of assessing amounts consumed in prepared foods obtained outside the household. Furthermore, it may be more feasible to modify a household-level FAPQ module that is already used in existing surveys that are routinely conducted (e.g., HCES) than to try to add in a new individual-level SQ-FFQ. Future research should explore the feasibility and trade-offs in terms of cost and effort to implement and integrate into different existing surveys between these two (and potentially other) simplified methods.

Finally, the GRADE EtD framework for health system and public health decisions used in Chapter 5 is just one of many available resources that can be used to aid in decision making processes in food fortification programs. Other frameworks and methods of policy analysis exist such as 'The Eightfold Path' method put forth by Bardach and Patashnik (11). This method includes the following eight steps: 1) define the problem; 2) assemble some evidence; 3) construct the alternatives; 4) select the criteria; 5) project the outcomes; 6) confront the trade-offs; 7) stop, focus, narrow, deepen, decide; and 8) tell your story. While the GRADE EtD framework followed a similar initial approach, it focused only on steps 1 to 4 in 'The Eightfold Path'. Future exploration is needed into how to strengthen the subsequent steps in the decision making process, particularly related to confronting trade-offs (e.g., when trying to coordinate with overlapping micronutrient interventions) and focusing and deciding to ensure agreement, ownership, and uptake of recommendations in the context of food fortification and other nutrition programs.

6.5 Conclusions

There is no debate that when well designed and implemented, food fortification works as a strategy to address micronutrient deficiencies and that program decisions should be based on evidence. Despite this, putting well designed and implemented into practice has proved to be a major challenge limiting the impact of food fortification programs worldwide. This body of research provides practical evidence on appropriate methods and tools for assessing program performance and potential for impact and demonstrates how to use the resulting data to inform decisions needed to improve program design, delivery, and health outcomes. Linking data and decision making is key to unlocking the full potential of food fortification.

6.6 Chapter 6 references

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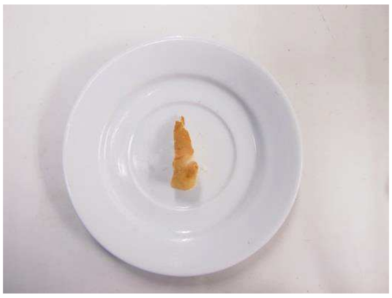
APPENDICES

Appendix 1: Food photo album for SQ-FFQ

BREADS

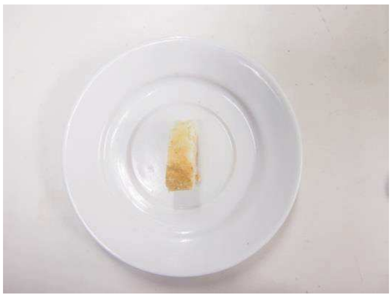
PANDESAL

1



1/16 pandesal

2



1/8 pandesal

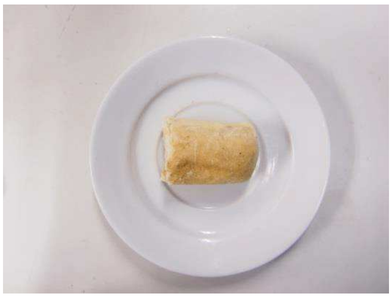
3

1/4pandesal

4

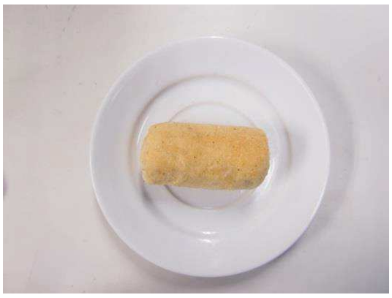
1/2pandesal

5



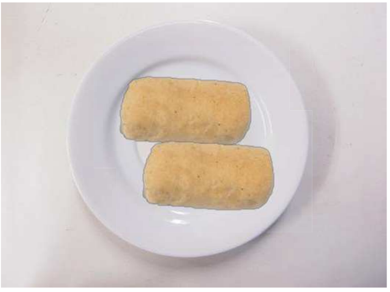
3/4 pandesal

6



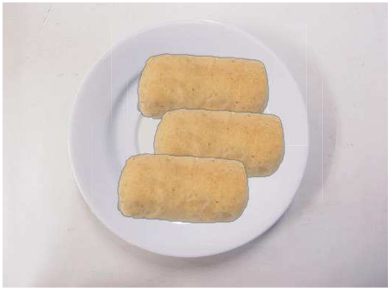
1pc whole

7



2 pcs whole

8



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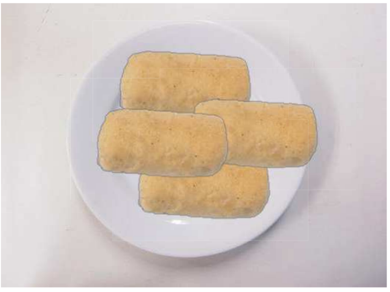
9



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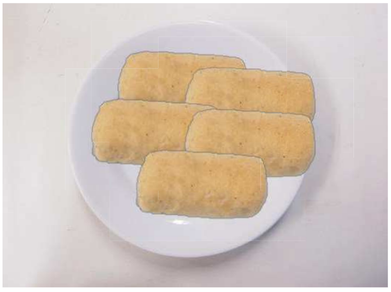
10



5 pcs whole

PUTOK (SMALL)

1

1/8 putok small

2

1/4 putok small

3

1/2 putok small

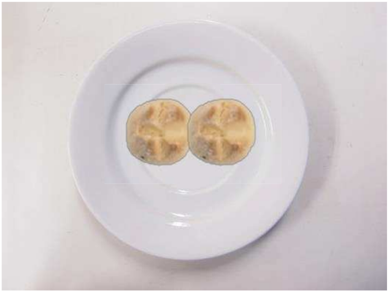
4

3/4 putok small

5

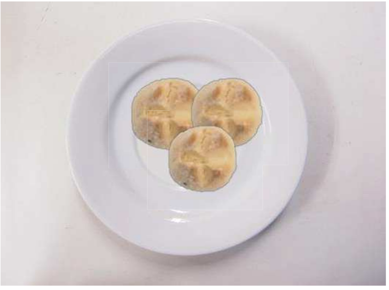
1 whole

6



2 pcs whole

7

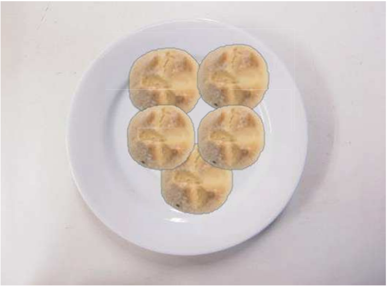


3 pcs whole

8

4 pcs whole

9



5 pcs whole

10

6 pcs whole

MONAY

1

1/8 monay

2

1/4 monay

3

1/2 monay

4

3/4 monay

5

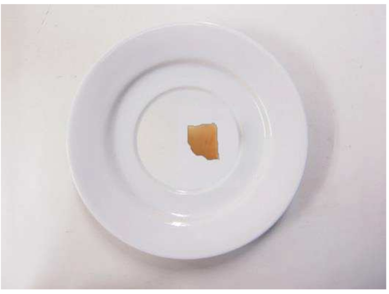
1 whole

6

2 pcs

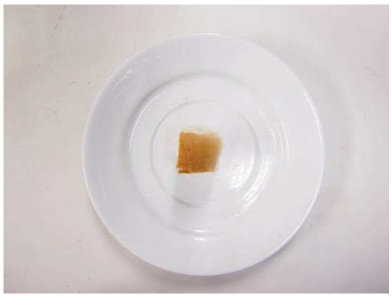
BUN SMALL

1



1/8 bun small

2



1/4 bun small

3

1/2 bun small

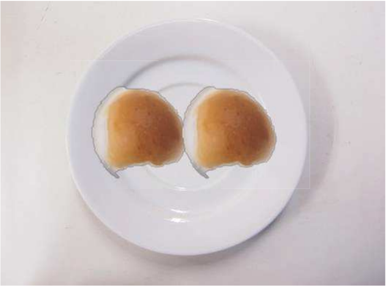
4

3/4 bun small

5

1 bun small

6



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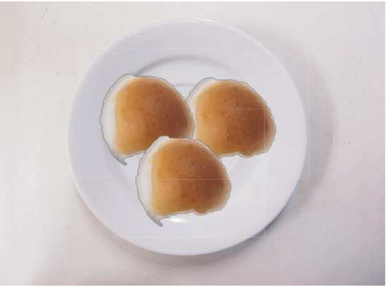
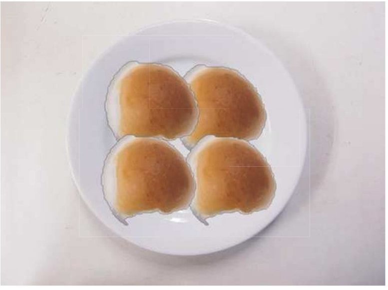


3 pcs

8



4 pcs

BUN BIG

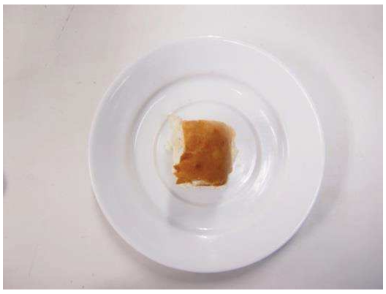
1

1/16 bun big

2

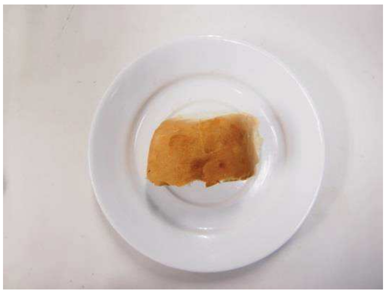
1/8 bun big

3



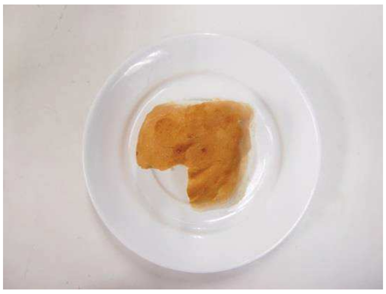
1/4 bun big

4



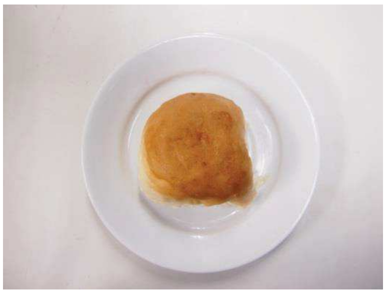
1/2 bun big

5



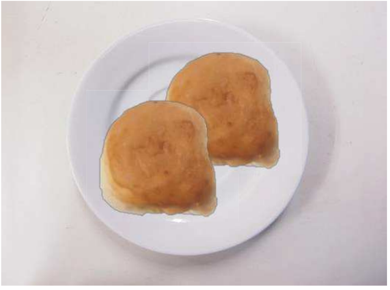
3/4 bun big

6



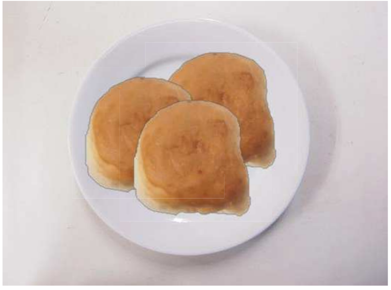
1 whole

7



2 pcs bun, big

8



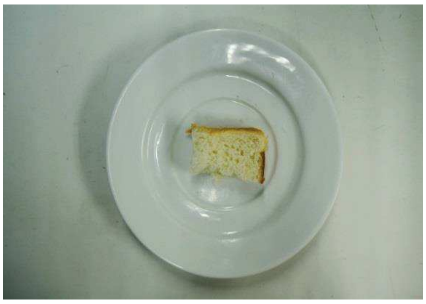
3 pcs

PAN AMERIKANO (BIG)

1

1/16 pan amerikano (big)

2



1/8pan amerikano (big)

3

1/4pan amerikano (big)

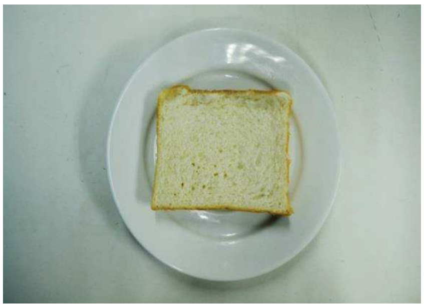
4

1/2 pan amerikano (big)

5

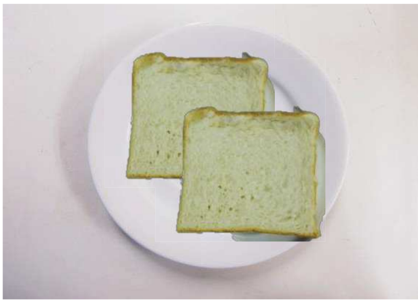
3/4 pan amerikano (big)

6



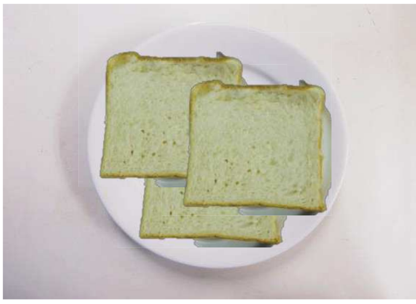
1 slice

7



2 slices

8



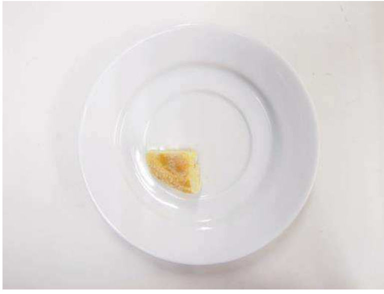
3 slices

ENSAYMADA

1

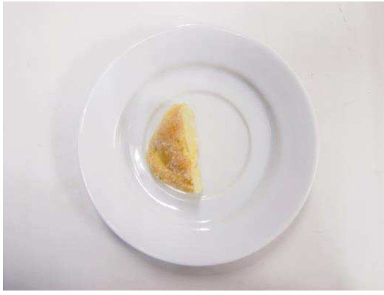
1/8 ensaymada

2



1/4 ensaymada

3



1/2 ensaymada

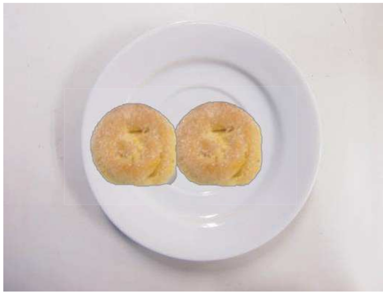
4

3/4 ensaymada

5

1 whole

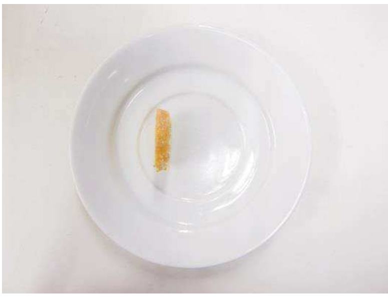
6



2 pcs whole

SPANISH BREAD

1

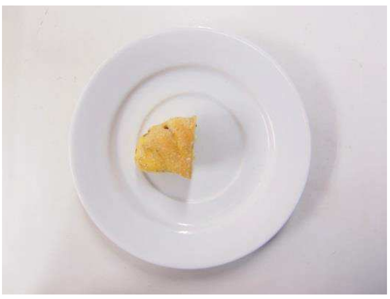


1/8 spanish bread

2

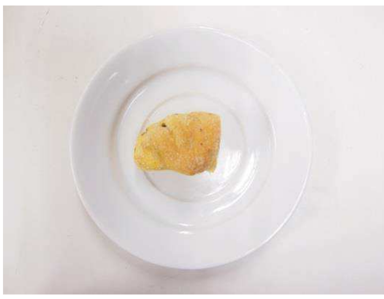
1/4 spanish bread

3



1/2 spanish bread

4

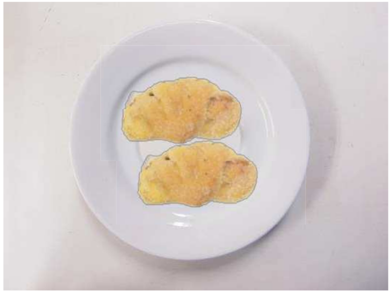


3/4 spanish bread

5

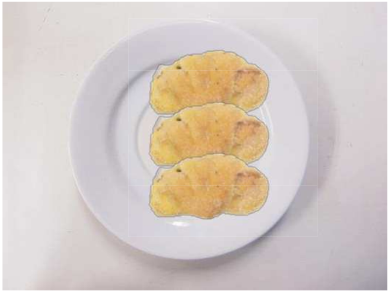
1 whole

6



2 pcs

7



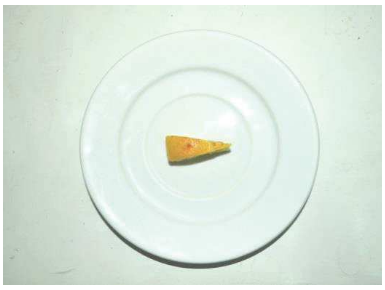
3 pcs

8

4 pcs

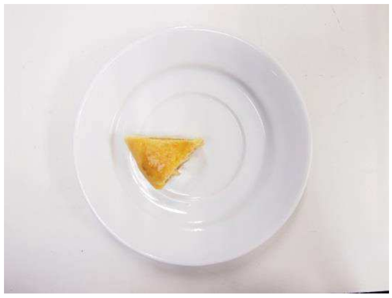
PAN DE COCO

1



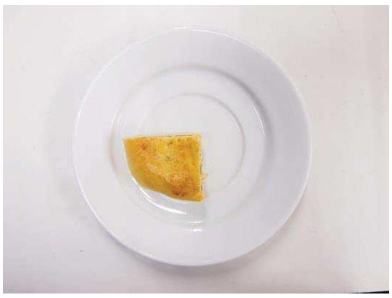
1/16pan de coco

2



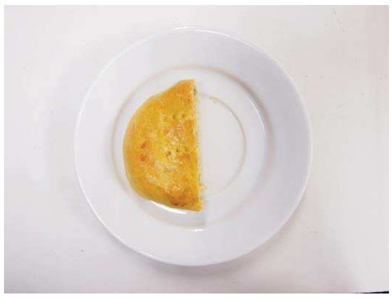
1/8pan de coco

3



1/4pan de coco

4



1/2pan de coco

5

3/4 pan de coco

6

1 whole

7

2 pcs

8

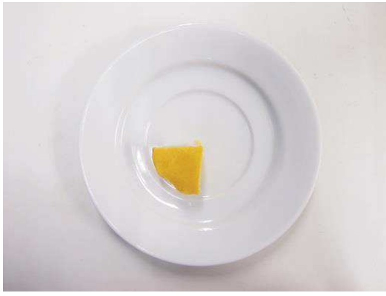
3 pcs

KABAYAN

1

1/8 kabayan

2

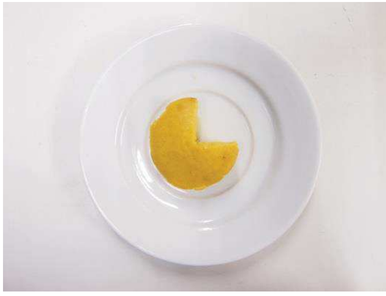


1/4 kabayan

3

1/2 kabayan

4

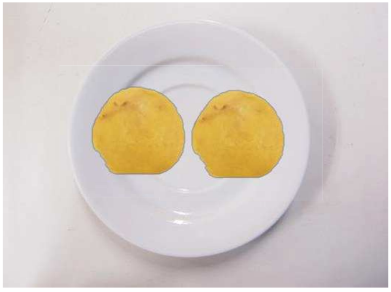


3/4kabayan

5

1 whole

6

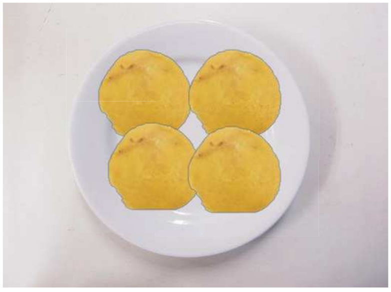


2 pcs

7

3 pcs

8



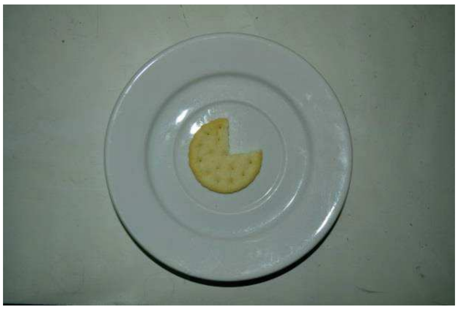
4 pcs

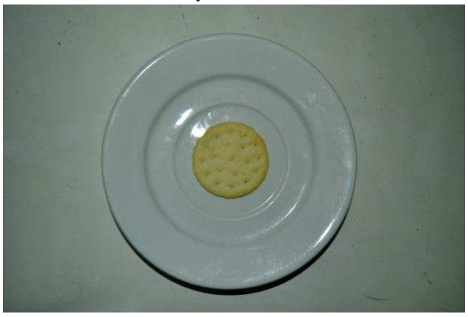
BISCUITS

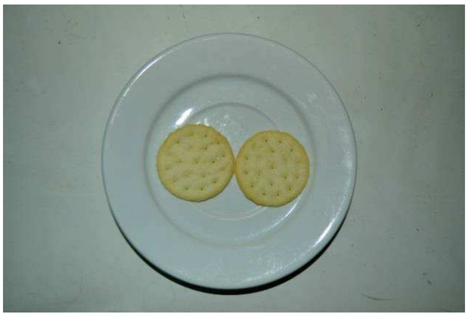
MARIE

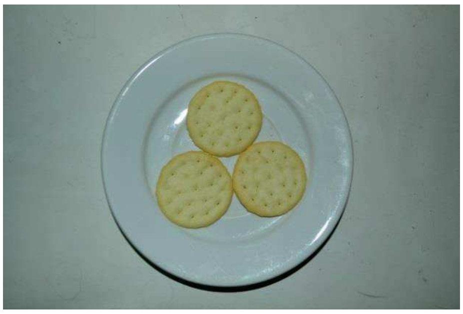
1

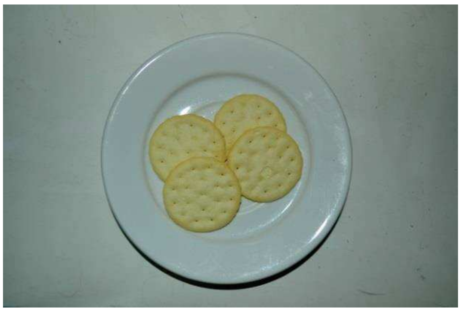
1/2 marie

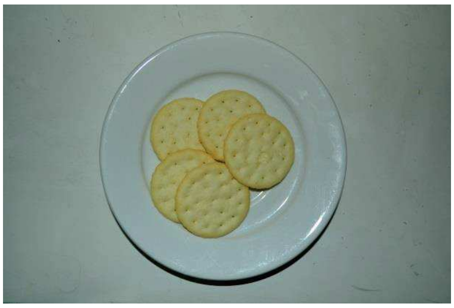
2

3/4marie

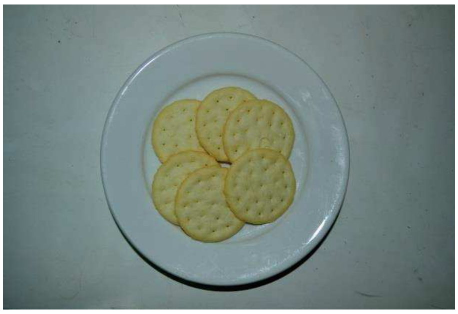
3

1 pc marie

4

2 pcs marie

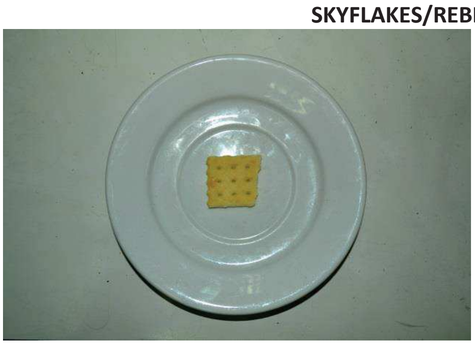
5

3 pcs marie

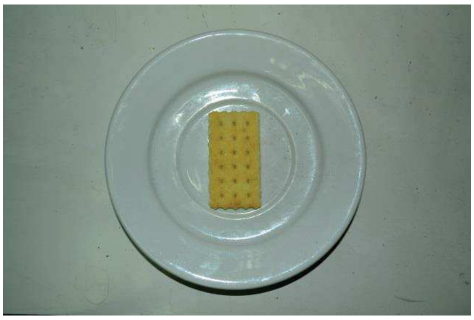
6

4 pcs marie

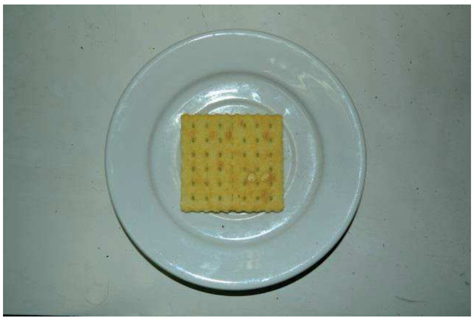
7

5 pcs marie

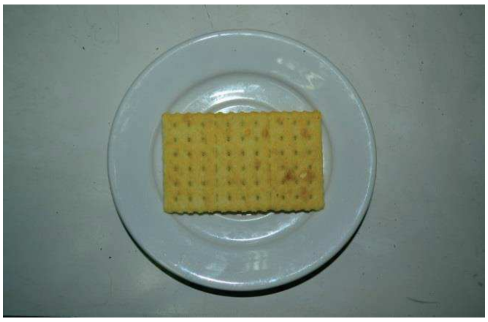
8

6 pcs marie / 1 pack

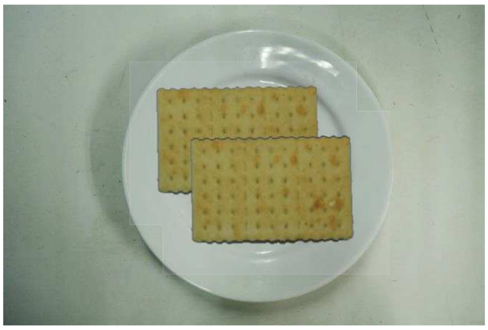
SKYFLAKES/REBISCO/MAGIC FLAKES

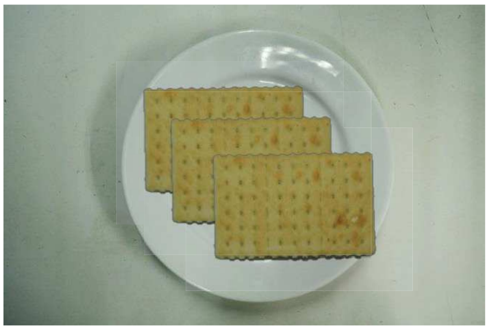
1

1/6 crackers

2

1/3 crackers

3

2/3 crackers

4

1 pc cracker

5

2 pcs crackers

6

3 pcs crackers or 1 pack

FITA / HANSEL PLAIN

1

1/2fita / hansel

2

1 pcfita / hansel

3

2 pcsfita / hansel

4

3 pcs fita / hansel

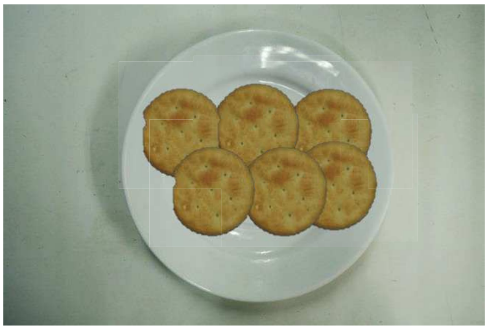
5

4pcs fita / hansel

6

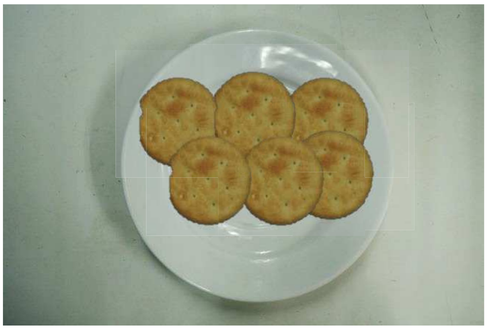
5 pcs fita / hansel

7



6 pcs fita / hansel

8

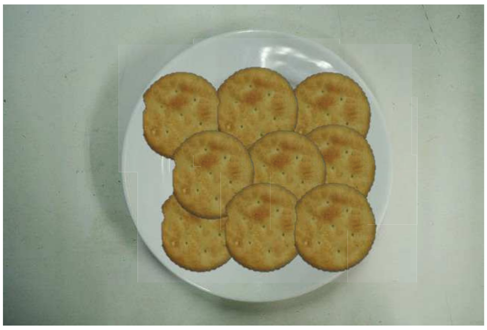


7 pcs fita / hansel

9

8 pcs fita / hansel

10



9 pcs fita / hansel or 1 pack

HANSEL WITH FILLING

1

1/8 hansel

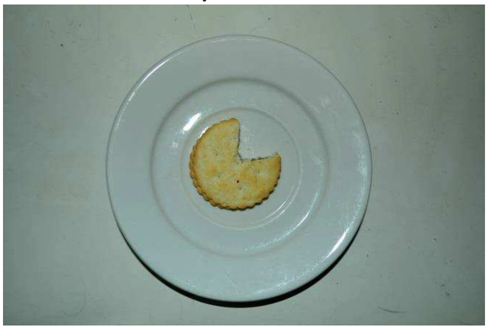
2

1/4 hansel

3

1/2 hansel

4



3/4 hansel

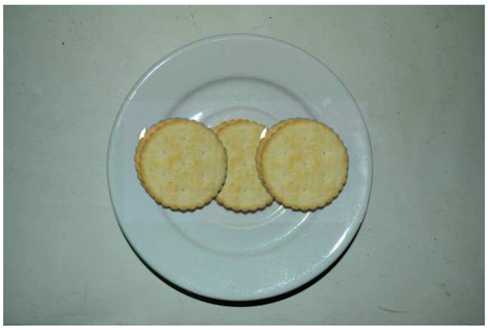
5

1 whole pc

6

2 whole pcs

7



3 pcs

8

4 pcs or 1 pack

FUDGEE BAR

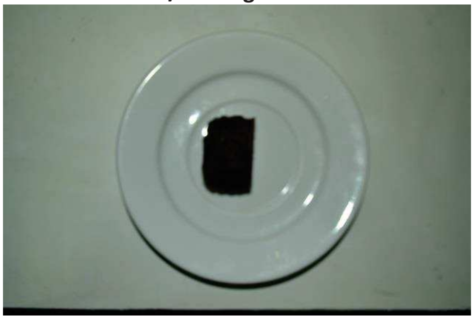
1

1/16 fudgee bar

2

1/8 fudgee bar

3



1/4 fudgee bar

4

1/2 fudgee bar

5

3/4 fudgee bar

6

1 whole

CHEESECAKE LEMON SQUARE

1

1/8 cheesecake

2

1/4 cheesecake

3

1/2 cheesecake

4

3/4 cheesecake

5

1 whole

CREAM-0

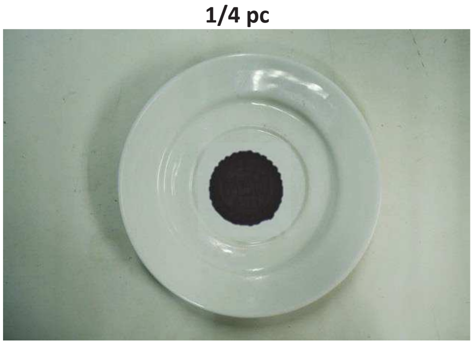
1

1/4 pc

2

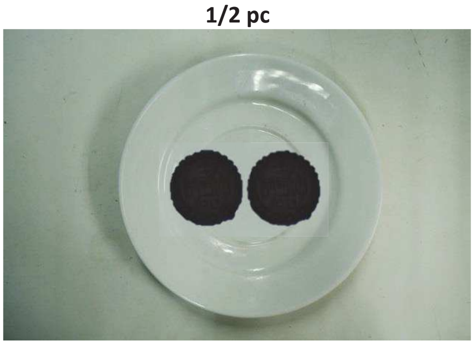
1/2 pc

3



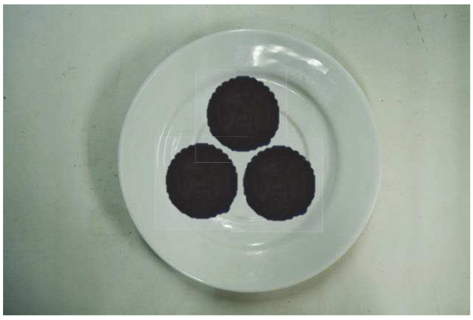
1 pc Cream-O

4



2 pcs Cream-O

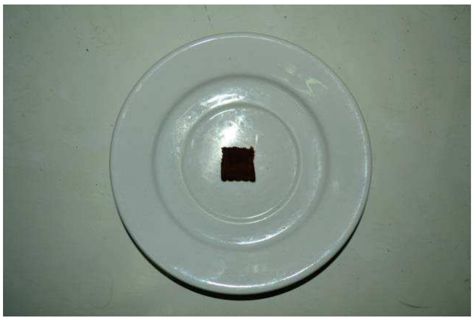
5



3 pcs Cream-O / 1 pack

WHATTATOPS

1



1/16 whattatops

2

1/8 whattatops

3

1/4 whattatops

4

1/2 whattatops

5

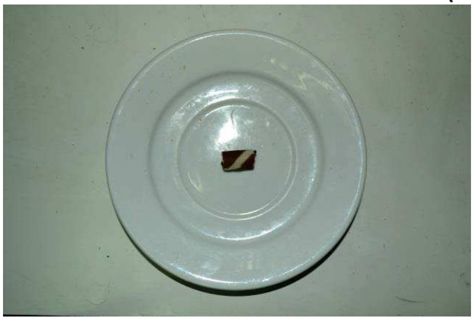
3/4 whattatops

6

1 whole

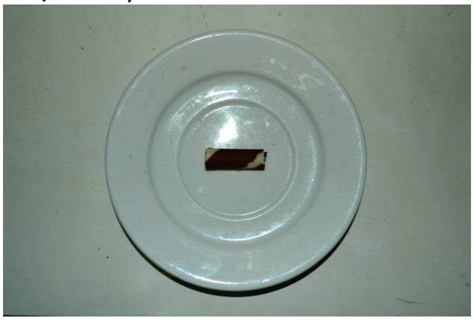
WAFER STICK (NISSIN STICK/ STIK-O)

1



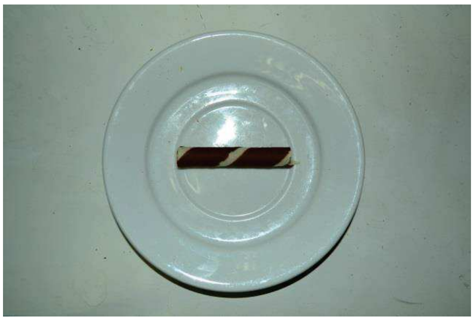
1/8 wafer stick

2



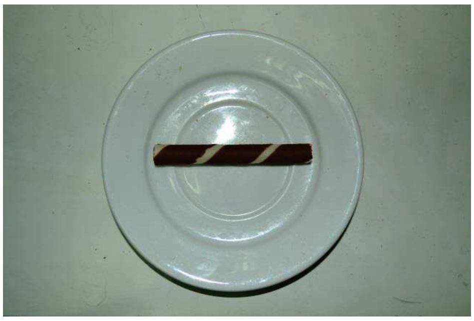
1/4 wafer stick

3



1/2 wafer stick

4



3/4 wafer stick

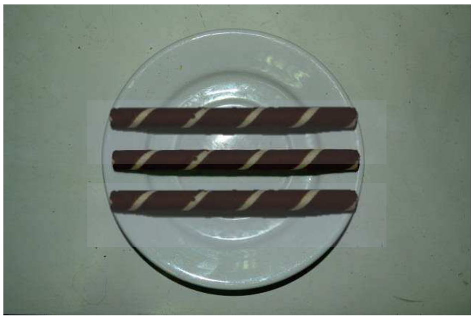
5

1 pcs wafer stick

6

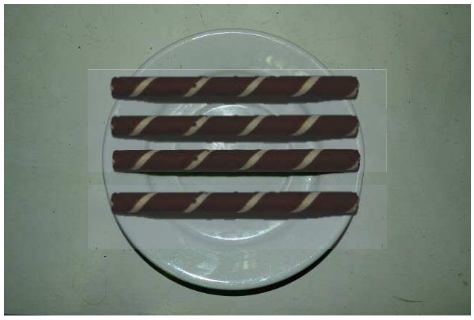
2 pcs wafer sticks

7



3 pcs wafer sticks

8

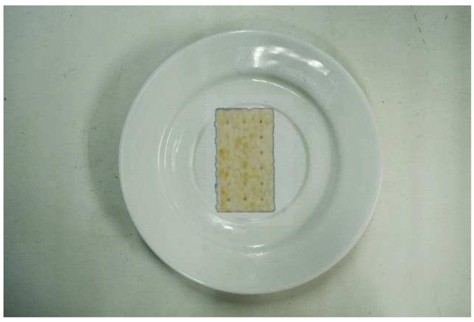


REBISCO WITH FILLING

1

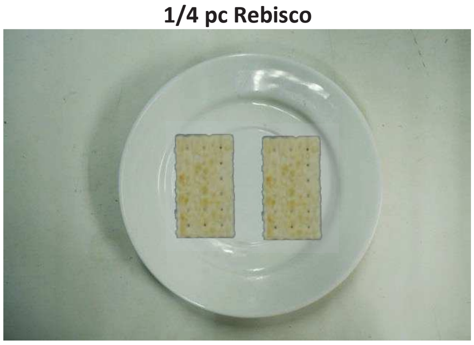
1/4 pc Rebisco

2



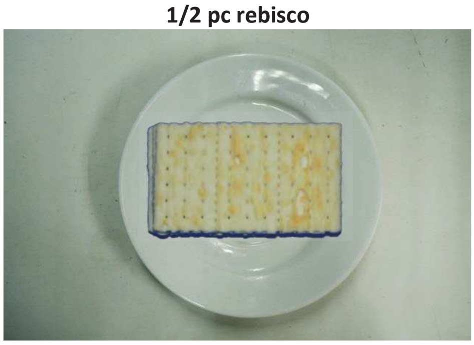
1/2 pc rebisco

3



2 pcs rebisco

4



3 pcs rebisco / 1 pack

NOODLES AND BROTH (Lucky Me/Homi)

1

½ tsp noodles + broth

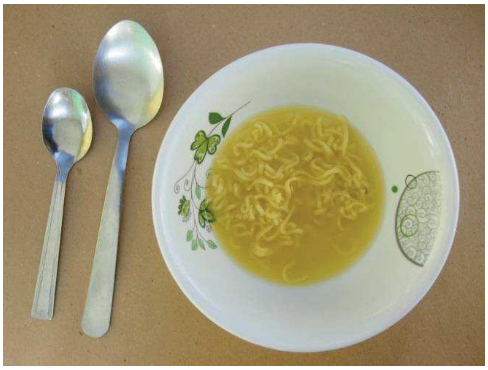
2

1 tsp noodles + broth

3

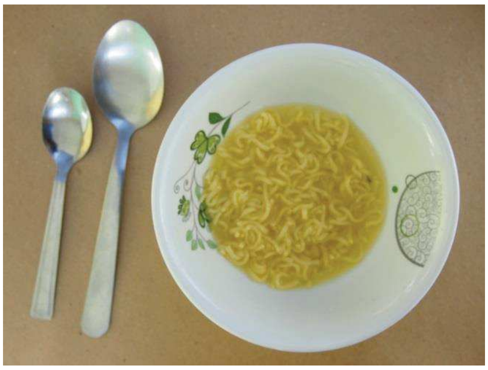
1 TBSP noodles + broth

4



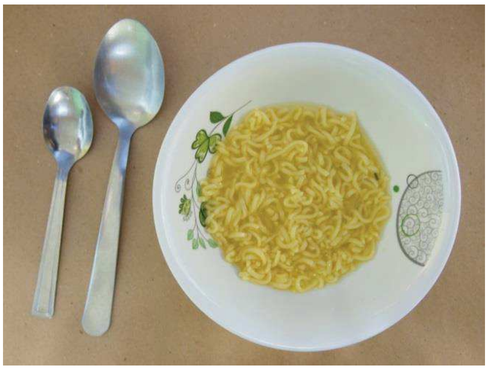
2 TBSP noodles + broth

5



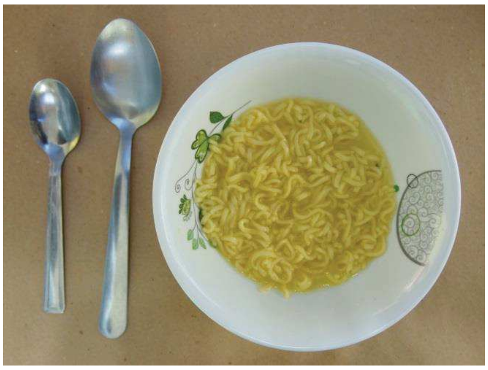
3 TBSP noodles + broth

6



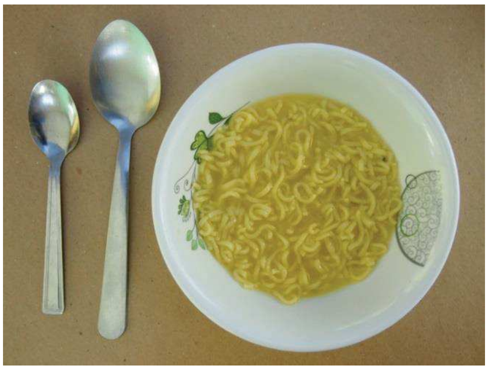
4 TBSP noodles + broth

7



5 TBSP noodles + broth

8



6 TBSP noodles + broth

SOPAS / MACARONI SOUP

1

1/8 cup soup

2

1/4 cup soup

3

1/2 cup soup

4

3/4 cup soup

5

1 cup soup

NOODLES ONLY –in bowl (Pansit Canton)

1

1/2 tspnoodles in a bowl

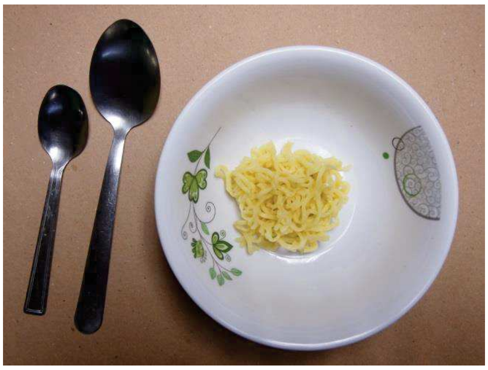
2

1 tsp noodles in a bowl

3

1TBSP noodles in a bowl

4



2 TBSP noodles in a bowl

5

3 TBSP noodles in a bowl

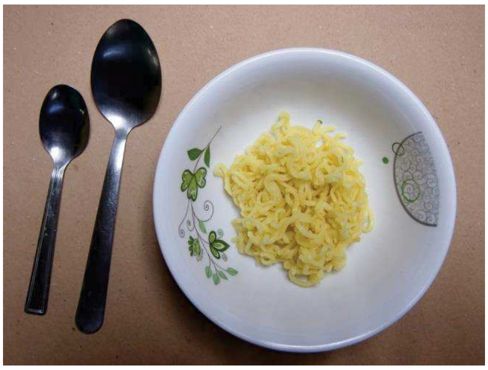
6

4 TBSP noodles in a bowl

7

5 TBSP noodles in a bowl

8



6 TBSP noodles in a bowl

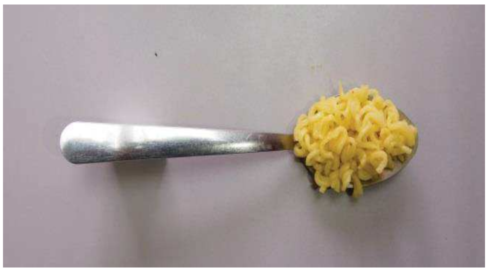
NOODLES ONLY – in spoon (Pansit Canton)

1

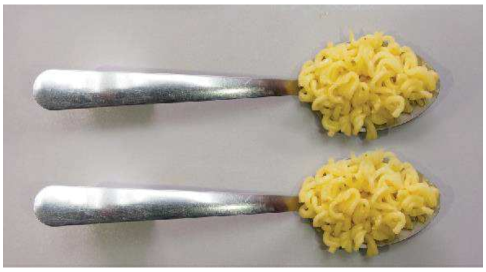
1/2 tsp noodles

2

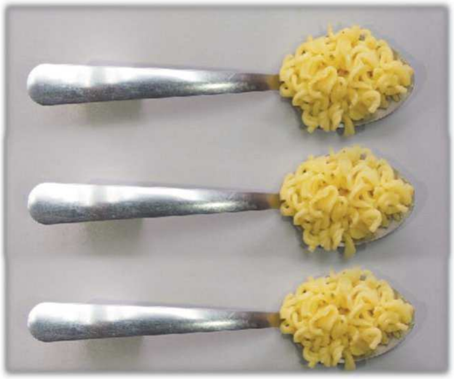
1 tsp noodles

3 

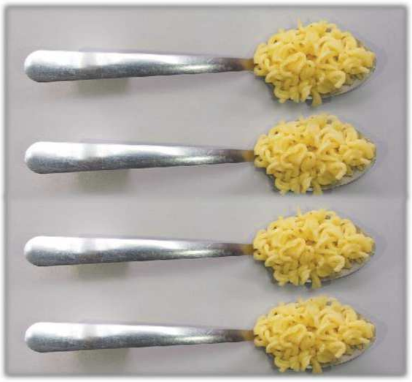
1 TBSP noodles

4 

2 TBSP noodles

13 

3TBSP noodles

14 

4 TBSP noodles

15 

5 TBSP noodles

16 

6 TBSP noodles

PANCIT BIHON

1 

1/8 cup bihon

2 

1/4 cup bihon

3

1/2 cup bihon

4

3/4 cup bihon

5

1 cup bihon

SPAGHETTI

1

1/8 cup spaghetti

2

1/4 cup spaghetti

3

1/2 cup spaghetti

4

3/4 cup spaghetti

5

1 cup spaghetti

Appendix 2: Related paper not included in this thesis - Assessing Coverage of Population-Based and Targeted Fortification Programs with the Use of the Fortification Assessment Coverage Toolkit (FACT): Background, Toolkit Development, and Supplement Overview

Valerie M. Friesen[1], Grant J. Aaron[1], Mark Myatt[2], Lynnette M. Neufeld[1]

[1] Global Alliance for Improved Nutrition (GAIN), Geneva, Switzerland
[2] Brixton Health, Llawryglyn, United Kingdom

Journal of Nutrition 2017;147(Suppl):981S-3S

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Assessing Coverage of Population-Based and Targeted Fortification Programs with the Use of the Fortification Assessment Coverage Toolkit (FACT): Background, Toolkit Development, and Supplement Overview[1–3]

Valerie M Friesen,[4]* Grant J Aaron,[4] Mark Myatt,[5] and Lynnette M Neufeld[4]

[4]Global Alliance for Improved Nutrition, Geneva, Switzerland; and [5]Brixton Health, Llawryglyn, United Kingdom

Abstract

Food fortification is a widely used approach to increase micronutrient intake in the diet. High coverage is essential for achieving impact. Data on coverage is limited in many countries, and tools to assess coverage of fortification programs have not been standardized. In 2013, the Global Alliance for Improved Nutrition developed the Fortification Assessment Coverage Toolkit (FACT) to carry out coverage assessments in both population-based (i.e., staple foods and/or condiments) and targeted (e.g., infant and young child) fortification programs. The toolkit was designed to generate evidence on program coverage and the use of fortified foods to provide timely and programmatically relevant information for decision making. This supplement presents results from FACT surveys that assessed the coverage of population-based and targeted food fortification programs across 14 countries. It then discusses the policy and program implications of the findings for the potential for impact and program improvement. *J Nutr* 2017;147(Suppl):981S–3S.

Keywords: large-scale food fortification, staple foods, infant and young child nutrition, program coverage, toolkit

Introduction

Fortification is a widely used intervention strategy to increase micronutrient intake in the diet. Fortification strategies can be population based or targeted. Population-based fortification strategies are designed to reach the general population through food vehicles that are regularly and frequently consumed by large segments of the population (i.e., staple foods and/or condiments). The implicit assumption is that those at risk of inadequate micronutrient intake will be reached while avoiding toxicity in those with an adequate intake and/or micronutrient status. Targeted fortification strategies are designed to reach a particular population group with the use of specific interventions with products that are fortified at amounts required to meet dietary gaps (e.g., complementary foods for infants and young children, foods designed for pregnant and/or lactating women, emergency rations, or point-of-use fortification such as micronutrient powders in which nutrients are added immediately before consumption).

Fortification, whether population based or targeted, is conceptually simple. Several conditions must be in place, however, for programs to be impactful. Much of this has been outlined in global recommendations (1) and good practice guidance (2). Briefly, considering a typical program cycle at the design phase, the intervention should be justified by demonstrated micronutrient needs in the target population and an assessment of vehicle suitability. At the implementation phase, the intervention should be well designed, and ongoing program monitoring is essential to identify and implement timely course correction, improve the quality of implementation, and measure progress against program goals. At the evaluation phase,

[1] Published in a supplement to *The Journal of Nutrition*. In 2013, the Global Alliance for Improved Nutrition (GAIN), through support from the Bill & Melinda Gates Foundation (BMGF), developed and operationalized a fortification assessment coverage toolkit (FACT) for carrying out coverage assessments in both population-based (e.g., staple food) and targeted (e.g., infant and young child) fortification programs. The Supplement Coordinators for the supplement publication were Grant J Aaron, Valerie M Friesen, and Lynnette M Neufeld (GAIN; Geneva, Switzerland). Supplement Coordinator disclosures: there are no relationships to disclose. The article contents are the responsibility of the authors and do not necessarily represent the official views of institutions or sponsors involved. Publication costs for this supplement were defrayed in part by the payment of page charges. This publication must therefore be hereby marked "advertisement" in accordance with 18 USC section 1734 solely to indicate this fact. The opinions expressed in this publication are those of the authors and are not attributable to the sponsors or the publisher, Editor, or Editorial Board of *The Journal of Nutrition*.
[2] This research was funded by the Bill & Melinda Gates Foundation.
[3] Author disclosures: VM Friesen, GJ Aaron, M Myatt, and LM Neufeld, no conflicts of interest.
*To whom correspondence should be addressed. E-mail: vfriesen@gainhealth.org.

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the impact on biological or functional outcomes should be considered only if data collected during the implementation phase suggest high enough coverage and utilization for such an impact to be plausible. Despite the importance of these conditions, gaps in the design, implementation, and evaluation of fortification programs are common (3), and information on coverage and utilization is rarely available (4, 5). In particular, many fortification programs have forgone household-level coverage assessments (4). Reasons for this include the lack of standardized, fit-for-purpose tools to facilitate the collection of quality and timely information on coverage and utilization at the population level and to provide a potential for comparisons across multiple settings.

Tools and Methods to Inform Fortification Program Design and Assess Program Performance

Some tools are available to guide fortification programmers, but their utility to assess program coverage is limited. For population-based staple food fortification approaches, the Fortification Rapid Assessment Tool was developed in the late 1990s to simplify the collection of information required to select appropriate food vehicles and set fortification levels (6) with the use of modified 24-h recall and FFQ methods. Several countries, particularly in Africa, have used Fortification Rapid Assessment Tool surveys to plan for national fortification programs (7). This method was adapted and used for assessing program coverage in at least one country (8). For some food vehicles, including salt, oil, and wheat flour, detailed monitoring manuals have been developed to encourage standardized and appropriate regulatory monitoring practices (9–11). Regulatory monitoring focuses on the compliance of industry with fortification standards and laws, and, as such, does not include specifics related to coverage and utilization assessment. The Fortification Monitoring and Surveillance tool was designed to track trends in the effectiveness of flour fortification programs over time, relying mainly on data generated from routine program monitoring, as well as tracking of hemoglobin concentration from surveillance systems (12). Tools to assist program managers working with targeted fortification interventions are more limited. For home fortification interventions, the CDC and the Home Fortification Technical Advisory Group recently developed a monitoring manual that provides technical guidance on how to develop and implement monitoring systems to track home fortification programs (13). Similar to the tools described for population-based fortification programs, little information is provided related to methodologies for assessment of coverage and utilization.

The Global Alliance for Improved Nutrition (GAIN) has supported a large portfolio of population-based and targeted fortification interventions since being founded in 2002 (14). In an effort to prioritize and standardize coverage assessments, GAIN developed a Fortification Assessment Coverage Toolkit (FACT) to carry out coverage assessments in both population-based (i.e., staple foods and/or condiments) and targeted (e.g., infant and young child) fortification programs. The toolkit was designed to facilitate coverage and utilization assessments of programs, thereby filling in important gaps in the availability of standardized and program-oriented tools for fortification stakeholders. The ultimate goal of this body of work is to set a precedent for prioritizing coverage assessments of fortification programs that provide timely and relevant information for decision making related to program improvement.

The FACT methods focus on 3 key areas: *1*) identifying and classifying at-risk population subgroups with the use of diverse measures of vulnerability that are associated with poor nutrition and health outcomes in low-resource settings (e.g., poverty, rural residence, poor dietary diversity, and poor infant and young child feeding practices); *2*) assessing coverage and utilization of fortified food vehicles (e.g., staple foods in large-scale fortification programs or fortified foods targeted to specific population groups); and *3*) assessing the quality of fortified foods to determine the adequacy of fortification levels at the local market and/or the household level independently of routine monitoring activities. All survey modules (i.e., question and indicator sets) were taken or adapted from validated instruments where available (15–17). The initial draft of the FACT toolkit detailing design elements and research approach was prepared in May 2013 as part of a grant deliverable to the Bill & Melinda Gates Foundation. The toolkit was reviewed by independent subject-matter experts commissioned by the Bill & Melinda Gates Foundation and then further refined based on feedback.

Timeliness of results often poses a challenge to program managers to use research for decision making (18). Considerations were therefore made to ensure that the toolkit could be implemented, analyzed, and reported rapidly while maintaining rigor and low cost. A pilot survey was conducted in 3 districts in eastern Ghana in July 2013, taking advantage of an already planned coverage assessment of a targeted fortification program for infants and children (15). The instrument was finalized during a 3-d technical workshop in September 2013.

Overview of Supplement

The purpose of this supplement is to bring together information generated from FACT surveys to date. The articles in this supplement demonstrate the applications across different countries and contexts, and provide insights into how this information has been and can be used to improve program decision making. Individual surveys were designed and implemented in partnership with reputed in-country and international technical partners. In all cases, the results were shared in-country with government, industry, and other partners, and have been used to identify and address implementation challenges. Detailed country-specific papers have been published elsewhere (15, 16, 19–22) or are in preparation.

The first paper in the supplement, *Coverage of Large-Scale Food Fortification of Edible Oil, Wheat Flour, and Maize Flour Varies Greatly by Vehicle and Country but Is Consistently Lower among the Most Vulnerable: Results from Coverage Surveys in 8 countries*, presents population-based food fortification program coverage results from 8 FACT surveys conducted from 2013–2015 (17). Results focus on household coverage of edible oil and wheat and maize flours. Data are from Bangladesh, Côte d'Ivoire (Abidjan), India (Rajasthan), Nigeria (Kano and Lagos), Senegal, South Africa (Gauteng and Eastern Cape), Tanzania, and Uganda. The article presents implications in these countries to improve program decision making and summarizes lessons learned and potential areas for further development of the FACT in its application to population-based food fortification programs.

The second paper, *Coverage of Nutrition Interventions Intended for Infants and Young Children Varies Greatly Across Programs: Results from Coverage Surveys in 5 Countries,* presents results on individual coverage of targeted fortification programs from 11 surveys conducted across 5 countries from 2013 to 2015 (23). Results focus on coverage of fortified complementary foods and food supplements as part of fortification interventions for infants and young children. Data are from Bangladesh, Côte d'Ivoire, Ghana, India (Telangana), and Vietnam. The article reviews the implications of the specific programs' findings and for further application of the FACT to fortification programs targeted at infants and young children.

The third paper, *Household Coverage with Adequately Iodized Salt Varies Greatly between Countries and by Residence Type and Socioeconomic Status within Countries: Results from 10 National Coverage Surveys,* presents program coverage results from 10 countries with mandatory universal salt iodization programs (24). Results focus on household coverage of iodized and adequately iodized salt by country, including an investigation of the relation between coverage and socioeconomic status and residence type (i.e., urban compared with rural). These surveys were implemented in 8 of the Universal Salt Iodization GAIN-UNICEF Partnership Project countries (Bangladesh, Ethiopia, Ghana, India, Indonesia, Niger, the Philippines, and Senegal), in addition to 2 national FACT surveys in Tanzania and Uganda.

In the fourth and final paper, *Coverage and Utilization in Food Fortification Programs: Critical and Neglected Areas of Evaluation*, the authors highlight key messages from the preceding papers and discuss in-depth the policy and program implications of the body of work (25). The paper also provides reflections on the strengths and potential areas for improvement of the FACT and its potential application in a more comprehensive system to track coverage and utilization of nutrition interventions.

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Appendix 3: Related paper not included in this thesis - Coverage of Large-Scale Food Fortification of Edible Oil, Wheat Flour, and Maize Flour Varies Greatly by Vehicle and Country but Is Consistently Lower among the Most Vulnerable: Results from Coverage Surveys in 8 Countries

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The Journal of Nutrition
Supplement—Assessing Coverage of Population-Based and Targeted Fortification Programs: Results and Implications for Program Improvement and Measuring Potential for Impact

Coverage of Large-Scale Food Fortification of Edible Oil, Wheat Flour, and Maize Flour Varies Greatly by Vehicle and Country but Is Consistently Lower among the Most Vulnerable: Results from Coverage Surveys in 8 Countries[1–3]

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Abstract

Background: Large-scale food fortification (LSFF) of commonly consumed food vehicles is widely implemented in low- and middle-income countries. Many programs have monitoring information gaps and most countries fail to assess program coverage.

Objective: The aim of this work was to present LSFF coverage survey findings (overall and in vulnerable populations) from 18 programs (7 wheat flour, 4 maize flour, and 7 edible oil programs) conducted in 8 countries between 2013 and 2015.

Methods: A Fortification Assessment Coverage Toolkit (FACT) was developed to standardize the assessments. Three indicators were used to assess the relations between coverage and vulnerability: *1*) poverty, *2*) poor dietary diversity, and *3*) rural residence. Three measures of coverage were assessed: *1*) consumption of the vehicle, *2*) consumption of a fortifiable vehicle, and *3*) consumption of a fortified vehicle. Individual program performance was assessed based on the following: *1*) achieving overall coverage ≥50%, 2) achieving coverage of ≥75% in ≥1 vulnerable group, and *3*) achieving equity in coverage for ≥1 vulnerable group.

Results: Coverage varied widely by food vehicle and country. Only 2 of the 18 LSFF programs assessed met all 3 program performance criteria. The 2 main program bottlenecks were a poor choice of vehicle and failure to fortify a fortifiable vehicle (i.e., absence of fortification).

Conclusions: The results highlight the importance of sound program design and routine monitoring and evaluation. There is strong evidence of the impact and cost-effectiveness of LSFF; however, impact can only be achieved when the necessary activities and processes during program design and implementation are followed. The FACT approach fills an important gap in the availability of standardized tools. The LSFF programs assessed here need to be re-evaluated to determine whether to further invest in the programs, whether other vehicles are appropriate, and whether other approaches are needed. *J Nutr* 2017;147(Suppl):984S–94S.

Keywords: large-scale food fortification, wheat flour, maize flour, edible oil, program coverage

Introduction

Large-scale food fortification (LSFF)[6], the focus of the current article, relies on commonly consumed food vehicles (i.e., staple foods) to deliver micronutrients to as much of the general population as possible while also trying to include a large proportion of members of vulnerable population groups who would stand to benefit most from additional micronutrients (1). This approach to delivering micronutrients has a long history of success to address inadequate dietary intake of essential nutrients in higher-resource countries (2–5), and is increasingly used in low- and middle-income countries to address a range of micronutrient deficiencies (1, 6, 7). LSFF programs generally fall into 2 categories: *1*) mandatory, whereby all producers of branded and packaged fortifiable foods should fortify the selected vehicles according to national legislation standards; and 2) voluntary, whereby producers may choose to fortify of their own accord, usually according to a national voluntary fortification standard. The former should achieve higher coverage levels at the population level, assuming legislation standards are followed (i.e., producers are compliant).

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Despite being widely practiced, many LSFF programs in lower-resource settings have not been able to demonstrate impact (8). This is due to failures to generate, access, or apply data during program design (i.e., for the selection of appropriate vehicles and fortificants) and implementation (i.e., routine program monitoring and evaluation activities for continuous program enhancements). Tools to assist fortification program managers throughout the program cycle are essential to ensure that programs are designed and implemented appropriately.

The WHO has published a general guidance document on fortification practices (1) and an updated consensus statement on recommended fortification levels (9). To facilitate the collection and analysis of the data required to select appropriate food vehicles and fortification levels, the main tool that is available is the Fortification Rapid Assessment Tool (FRAT), which was developed in the late 1990s (10). FRAT surveys have been successfully implemented in several countries before starting programs, particularly in Africa (11). One limitation of the FRAT approach is that although the method emphasizes assessing women and children, it fails to explicitly assess vulnerability, relying instead on overall consumption patterns of these population groups to select appropriate vehicles (10, 11). Programs that have not carried out intake assessments have generally relied on more indirect assessments, such as estimating per capita consumption based on vehicle production estimates to select vehicles for fortification or using data from household expenditure and consumption surveys. There are limitations with such methods, as described elsewhere (12, 13). During the program implementation phase, there are fewer standardized tools available to facilitate program monitoring. One tool that is available is the Fortification Monitoring and Surveillance tool, which was designed to help track the effectiveness of a flour fortification program over time (14). The Fortification Monitoring and Surveillance tool relies largely on available monitoring and surveillance data, and provides little guidance on how such data should be collected. Detailed monitoring manuals have been developed to encourage standardized regulatory and commercial monitoring practices for some vehicles, notably salt, edible oil, and wheat flour (15–17). Regulatory and commercial monitoring practices vary widely by program and context, and are generally dependent on whether enforcement is carried out by government stakeholders. There is far less guidance available to facilitate household-level monitoring practices, and, unsurprisingly, many programs in low- and middle-income countries with ongoing LSFF programs have failed to assess program coverage of the fortifiable or fortified vehicle (6). Without such information, program managers have a very limited understanding of the degree to which an LSFF program can address or is addressing need, and whether, e.g., alternative vehicles or interventions are required.

In 2013, the Global Alliance for Improved Nutrition developed and operationalized the Fortification Assessment Coverage Toolkit (FACT) to support coverage assessments in both population-based (e.g., LSFF) and targeted (e.g., infant and young child feeding) fortification programs (18). The toolkit was designed to assess program coverage and utilization, as well as to facilitate the program feedback loop by identifying bottlenecks and barriers to coverage that could and should be addressed during implementation. The aim of this article was to review and summarize coverage findings from FACT surveys conducted in 8 countries between 2013 and 2015. A total of 18 fortification programs were assessed (7 wheat flour, 4 maize flour, and 7 edible oil programs). The overall aim of this work was to assess the coverage of these programs (i.e., what program implementation has achieved), as well as to determine whether vulnerable or at-risk population groups benefited from the respective programs.

Methods

Fortification program characteristics. The fortification program activities in countries in which FACT surveys were implemented are shown in **Table 1**. Wheat flour programs were implemented in 7 countries (Côte d'Ivoire, India, Nigeria, Senegal, South Africa, Tanzania, and Uganda). Maize flour programs were implemented in 4 countries (Nigeria, South Africa, Tanzania, and Uganda). Edible oil programs were implemented in 7 countries (Bangladesh, Côte d'Ivoire, India, Nigeria, Senegal, Tanzania, and Uganda). At the time of the surveys, fortification of wheat flour was voluntary in one country (India). Oil fortification was voluntary in 2 countries (Bangladesh and India). For all other food vehicles in each respective country, mandatory legislation to fortify the food vehicles was in place at the time the surveys were conducted.

Survey instruments. In all surveys, the instruments collected data on household- and individual-level variables. In 5 surveys (Bangladesh, Nigeria, South Africa, Tanzania, and Uganda) households and women of reproductive age were assessed. For these surveys, data were collected on demographics; socioeconomic status; education levels within the household; housing conditions; recent infant and child mortality; water, sanitation, and hygiene practices; food security; women's dietary diversity; and coverage and consumption of fortified food vehicles. For 3 surveys (Côte d'Ivoire, India, and Senegal) households and caregivers with children in the first 2 y of life were assessed. These surveys collected the same data as above, as well as data on child health, infant and young child feeding practices, and maternal and child anthropometric measurements. All survey modules (i.e., question and indicator sets) were taken or adapted from validated guidelines where available (19, 20).

Ethical clearance and survey administration procedures. Ethical clearance to conduct the coverage surveys was obtained in each setting from a national or academic institutional review board. Consent to participate was obtained from the primary survey respondent on the basis that participation in the survey was voluntary. Oral consent was obtained in 5 countries (Côte d'Ivoire, India, Nigeria, Senegal, and Uganda), and written consent was obtained in 3 countries (Bangladesh, South Africa, and Tanzania). At least 2 attempts were made to conduct the survey at each selected household.

[1] Published in a supplement to *The Journal of Nutrition*. In 2013, the Global Alliance for Improved Nutrition (GAIN), through support from the Bill & Melinda Gates Foundation (BMGF), developed and operationalized a fortification assessment coverage toolkit (FACT) for carrying out coverage assessments in both population-based (e.g., staple food) and targeted (e.g., infant and young child) fortification programs. The Supplement Coordinators for the supplement publication were Grant J Aaron, Valerie M Friesen, and Lynnette M Neufeld (GAIN; Geneva, Switzerland). Supplement Coordinator disclosures: there are no relationships to disclose. The article contents are the responsibility of the authors and do not necessarily represent the official views of institutions or sponsors involved. Publication costs for this supplement were defrayed in part by the payment of page charges. This publication must therefore be hereby marked "advertisement" in accordance with 18 USC section 1734 solely to indicate this fact. The opinions expressed in this publication are those of the authors and are not attributable to the sponsors or the publisher, Editor, or Editorial Board of *The Journal of Nutrition*.
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[6] Abbreviations used: CR, coverage ratio; FACT, Fortification Assessment Coverage Toolkit; FRAT, Fortification Rapid Assessment Tool; LSFF, large-scale food fortification; MN, met need; PSU, primary sampling unit; RC, raw coverage; WDDS, women's dietary diversity score.

TABLE 1 Summary of edible oil, maize flour, and wheat flour fortification program activities in countries in which coverage surveys were implemented[1]

Variable	Bangladesh	Côte d'Ivoire (Abidjan)	India (Rajasthan)	Nigeria	Senegal	South Africa	Tanzania[2]	Uganda
Edible oil								
Start date[3]	2013	2007	2012	2000	2009	NA	2010	2003
Legislation[4]	Mandatory	Mandatory	Voluntary	Mandatory	Mandatory	NA	Mandatory	Mandatory
Micronutrient,[5] ppm								
Vitamin A	15–30	8	7.5	6	20	—	16–28	20–45
Vitamin D_2	—	—	0.05	—	—	—	—	—
Vitamin E	—	—	—	—	—	—	65–190	—
Maize flour								
Start date[3]	NA	NA	NA	2000	NA	2003	2011	2003
Legislation[4]	NA	NA	NA	Mandatory	NA	Mandatory	Mandatory[6]	Mandatory[7]
Micronutrient,[5] ppm								
Folic acid	—	—	—	1.5	—	2.0	0.5–2.5	0.5–1.5
Iron	—	—	—	—	—	35[8]	5–25[9]	10–20[9]
Vitamin A	—	—	—	9	—	1.1	0.2–1.0	0.5–1.5
Thiamin	—	—	—	—	—	2.2	1.5.6.0	3; 2
Riboflavin	—	—	—	—	—	1.7	1.5–6.0	30; 20
Niacin	—	—	—	—	—	25	15–30	2
Pyridoxine	—	—	—	—	—	3.1	2.0–7.5	—
Vitamin B-12	—	—	—	—	—	—	0.002–0.010	0.003
Zinc	—	—	—	20	—	15	20–40	20–50
Wheat flour								
Start date[3]	NA	2007	2012	2000	2009	2003	2010	2003
Legislation[4]	NA	Mandatory	Voluntary	Mandatory	Mandatory	Mandatory[10]	Mandatory[6]	Mandatory[11]
Micronutrient,[5] ppm								
Folic acid	—	2.6	1.3	1.5	2.25–2.75	1.26; 1.43	1–5	1–5; 1–4
Iron	—	60[12]	30[13]	40.7[8]	45[12]	30.08; 35.00[8]	30–50[9]	25–55[12]
Vitamin A	—	—	—	9	—	1.6; 1.8	0.5–3.0	1–4
Thiamin	—	2.8	—	6.2	—	1.7; 1.9	5–15	6; 4
Riboflavin	—	2.8	—	3.7	—	1.6; 1.8	2.5–9.0	3; 2
Niacin	—	36.2	—	49.5	—	20.8; 23.7	40–75	60; 40
Pyridoxine	—	3.1	—	—	—	2.3; 2.6	3–10	3
Vitamin B-12	—	0.02	0.01	—	—	—	0.005–0.025	0.007
Zinc	—	55	—	20	—	15.0; 13.2	30–50	40–60; 30–50

[1] NA, not applicable; ppm, parts per million.
[2] Mainland Tanzania only. Zanzibar is not included in the current legislation.
[3] Year in which fortification standards were initially set but not necessarily when mandatory legislation was passed.
[4] Status of national legislation at the time the survey was implemented.
[5] Value is the required minimum level or range of added micronutrient at retail as per the national standard that was in effect at the time the survey was implemented.
[6] Vitamin A, thiamin, riboflavin, niacin, and pyridoxine are optional.
[7] Different standards exist for whole (high-extraction) and degermed (low-extraction) maize flour. When required levels are different, values are shown as whole or degermed.
[8] Electrolytic iron.
[9] NaFeDTA, sodium iron ethylenediaminetetraacetic acid.
[10] Different standards exist for brown and white wheat flour. Required levels are shown separately as brown or white.
[11] Different standards exist for whole (high-extraction) and white (low-extraction) wheat flour. When required levels are different, values are shown separately as whole or white.
[12] Ferrous fumarate.
[13] $FeSo_4$.

In all surveys, data were collected by trained interviewers under the supervision of experienced field supervisors. All interviewers and field supervisors were trained before the surveys and were supervised by dedicated technical personnel during implementation. The survey instruments were pilot-tested in each setting to ensure that the language and wording of questions were clear, and that question-skip logic and response options were appropriate to the setting. In 5 countries (Côte d'Ivoire, India, Senegal, South Africa, and Uganda) data were collected with the use of paper forms. In these surveys, data quality was ensured by interactive checking (for consistency, range, and legal values) during data entry, as well as batch checking (double-entry and validation, as well as a batch application of consistency, range, and legal value checks). In 3 countries (Bangladesh, Nigeria, and Tanzania) data were collected with the use of mobile devices by using interactive checking to ensure data quality. A description of the sampling schemes used in each coverage survey is shown in **Table 2**. All surveys were designed to be representative of the population in the areas in which the surveys took place. Nationally representative surveys were conducted in 4 countries (Bangladesh, Senegal, Tanzania, and Uganda). Statewide or provincially representative surveys were conducted in 3 countries (India, Nigeria, and South Africa). A citywide representative survey was conducted in one country (Côte d'Ivoire). Results for these surveys are presented by individual state or province surveyed when ≥1 state or province was assessed (Nigeria and South Africa).

Indicators of risk. In this article, we used 3 indicators of risk to assess the relations between coverage and vulnerability. The risk indicators were poverty, poor women's dietary diversity, and rural residence. These indicators were selected on the basis that they were associated with poor micronutrient status and highlighted the more marginalized subgroups within the population (21, 22). Poverty was defined by multidimensional poverty index (23). A household was classified as being in poverty if the multidimensional poverty index score was greater than or equal to one-third. Women's dietary diversity was defined by the women's dietary diversity score (WDDS) (24, 25). A household was classified as having a poor WDDS if the female primary survey respondent had a WDDS below the median WDDS for the survey population. Surveys conducted in Bangladesh, Côte d'Ivoire, India, and Senegal defined the WDDS based on a set of 9 food groups (24). In mid-2014, dietary diversity guidelines were updated, and a new indicator for minimum dietary diversity for women of reproductive age was defined based on a set of 10 food groups (25). Surveys conducted in Nigeria, South Africa, Tanzania, and Uganda defined the WDDS with the use of the updated set of 10 food groups from the minimum dietary diversity for women of reproductive age indicator. Rural residence was determined by reference to the data used to draw the survey sample in each setting.

Indicators of coverage. Three measures of coverage were assessed while following the Tanahashi coverage framework (**Figure 1**) to determine the principal program bottleneck (26). This framework relies

TABLE 2 Summary of sampling schemes used in coverage surveys[1]

Country	Data collection period	Survey population	Sampling areas	Sampling scheme	Target household sample size, *n*
Bangladesh	January–April 2015	Households and women of reproductive age (15–49 y)	National: 3 strata (urban, rural, hard-to-reach rural areas)	First-stage sampling selected 42 PSUs/stratum by PPS Second-stage sampling selected 12 households/PSU by random selection	1512
Côte d'Ivoire (Abidjan)	September 2014	Caregivers with children aged 0–23 mo	Abidjan: all 10 communes	First-stage sampling selected 9 PSUs by random selection Second-stage sampling selected 13 households/PSU by random selection	1170
India (Rajasthan)	December 2013–February 2014	Caregivers with children aged 0–24 mo	Statewide spatial sample	First-stage sampling selected 252 PSUs by spatial sampling Second-stage sampling selected 18 households/PSU by systematic selection in ``ribbon´´ villages, EPI3[2] in ``clustered´´ villages, and random selection in urban blocks	4536
Nigeria	May–June 2015	Households and women of reproductive age (15–49 y)	2 states: Kano and Lagos	First-stage sampling selected 30 PSUs/state by simple random sampling Second-stage selected 31 households/PSU by random selection	1860
Senegal	October–December 2013	Women of reproductive age (15–49 y) and their children aged 0–24 mo	National: 4 strata (urban Dakar, urban medium-size towns, and 2 rural zones) following the 2011 national micronutrient survey	First-stage sampling selected 20 PSUs/stratum by PPS Second-stage sampling selected 20 households/PSU by random selection Rural strata were oversampled	1946
South Africa	May–June 2015	Households and women of reproductive age (18–49 y)	2 provinces: Gauteng and Eastern Cape	First-stage sampling selected 40 PSUs/province by PPS Second-stage sampling selected 23 households/PSU in Gauteng province and 20 households/PSU in Eastern Cape province by random selection	1720
Tanzania	September–October 2015	Households and women of reproductive age (15–49 y)	National: urban and rural strata	First-stage sampling selected 29 PSUs/urban stratum and 41 PSUs/rural stratum by PPS sampling Second-stage sampling selected 15 households/PSU by random selection	1050
Uganda	September 2015	Households and women of reproductive age (15–49 y)	National: urban and rural strata	First-stage sampling selected 35 PSUs/stratum by PPS sampling Second-stage sampling selected 15 (originally) or 16 (increased because of concerns about response rates in early PSUs) households/PSU by random selection	1101

[1] EPI, Expanded Program on Immunization; PPS, probability proportional to size; PSU, primary sampling unit.
[2] EPI3 is an adaptation of the within-PSU sampling method used in EPI coverage surveys. The base EPI method selects neighboring households. The EPI3 adaptation increases the distance between sampled households by selecting every third household. The purpose of this adaptation is to reduce the loss of variance associated with the use of cluster samples and proximity sampling.

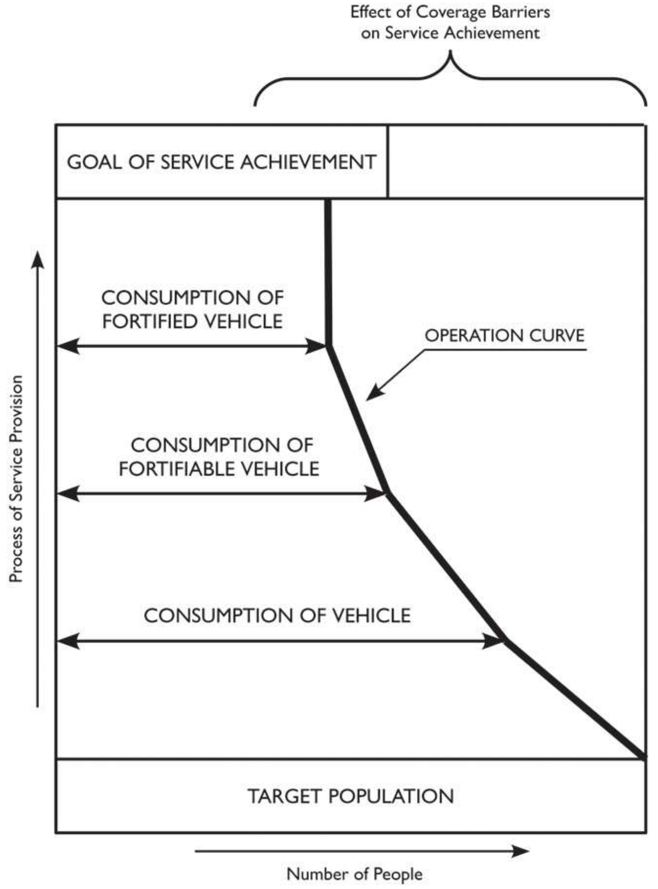

FIGURE 1 Three measures of coverage were assessed while following the Tanahashi coverage framework (26).

on the identification of sequential stages through which coverage is achieved. Each stage relates to an important condition on the pathway to the provision of a service. A coverage measure is defined and measured for each stage. This is usually the proportion of the population for whom the condition is met. The key stages identified for achieving program aims (i.e., high coverage of adequately fortified food) in this article are the following: *1*) consumption of the vehicle—the household consumes the vehicle; *2*) consumption of the fortifiable vehicle—the food vehicle used by the household is processed industrially and hence is well suited to large-scale fortification; and *3*) consumption of the fortified vehicle—the vehicle used by the household is fortified. Each stage depends on all of the preceding stages being true. All stages must be true for a member of the population to be effectively covered.

If, e.g., a coverage assessment finds that 90% consume the vehicle, 20% consume the vehicle in a fortifiable form, and 18% consume the fortified vehicle, then the key program bottleneck is that the vehicle is consumed in a nonfortifiable form. For an LSFF program of wheat flour, then, this might mean that production of wheat flour is dominated by small-scale milling and that wheat flour is not a good choice of vehicle.

Three summary statistics were calculated for each measure of coverage: *1*) raw coverage (RC)—the proportion of all households that were covered (this is a measure of overall program coverage); *2*) met need (MN)—the proportion of households defined as vulnerable that were covered (this is a measure of how well the program addresses vulnerability); and *3*) coverage ratio (CR)—the ratio of the coverage in vulnerable households to the coverage in households considered to be not vulnerable.

The CR ranged between 0 and positive infinity. CR values <1 indicated that coverage favored nonvulnerable population groups. CR values >1 indicated that coverage favored vulnerable population groups. A CR of 1 indicated equitable coverage between vulnerable and nonvulnerable population groups. Further details on the RC, MN, and CR statistics are published elsewhere (19, 20).

None of the fortification programs assessed had predefined or a priori criteria for program coverage or coverage in vulnerable groups (i.e., none of the programs had a clear statement of their coverage goals). Performance for each respective program was assessed with the use of an aggregate summary of the RC, MN, and CR measures. This approach was selected to standardize analyses for crossprogram comparison and on the basis that the criteria meet reasonable program goals for an LSFF program. The criteria used in these analyses were the following: *1*) the point estimate of RC (i.e., total population coverage) should be ≥50% [this criterion indicates the minimum level of total population coverage to which an LSFF should aspire (1, 10)]; *2*) the point estimate of the MN measure should be ≥75% for ≥1 of the 3 indicators of risk that were assessed [this criterion states that an LSFF program should aspire to meet the needs of vulnerable populations (1)]; and *3*) the estimates of all CRs are not significantly <1 [this criterion states that an LSFF program should not exclude vulnerable populations (1)].

The standards associated with the criteria for the RC, MN, and CR measures can be modified or reasonable alternative criteria could be formulated. Results for the RC, MN, and CR measures are therefore presented to enable the reader to apply modified or alternative criteria. The criteria were applied for each vehicle to the highest Tanahashi coverage stage for which results were available (Figure 1). The principal program bottleneck is reported.

Determination of fortification status. Fortification status for all food vehicles assessed in each country setting was determined by brand identification (i.e., by identifying the branded name of the vehicle) and by quantitative laboratory analyses (i.e., by analyzing food specimens to determine fortification levels). For quantitative analyses, food specimens were collected at the household or market level, depending on what was logistically feasible in each country setting. Specimens were shipped to reference laboratories for quantitative analyses. Households were classified as consuming a fortified or nonfortified vehicle based on the laboratory results. In cases in which a brand could not be determined in a household or a specimen was not collected, the household was classified as nonfortified in the analyses.

Data analyses. Survey data were analyzed with the use of the R language for data-analysis and graphics (version 3.2.2), the R-AnalyticFlow scientific workflow system (version 3.0.1), and SAS (version 9.4). Summary statistics were calculated with the use of bootstrap estimation techniques that consisted of a set of within-primary sampling unit (PSU) survey samples that were sampled with replacement and with a probability proportion to PSU population size with the use of a roulette wheel (also known as stochastic sampling with replacement) algorithm (27). For each bootstrap replicate, a total of m PSUs were sampled with replacement (where m is the number of PSUs in the survey sample). Observations within selected PSUs were also sampled with replacement with the same within-PSU sample size that was achieved in the survey. A total of $r = 400$ bootstrap replicates were used. The resulting estimate consists of the 2.5th (lower 95% CI), 50th (point estimate), and 97.5th (upper 95% CI) percentiles of the distribution of the statistic across all replicates.

Results

Characteristics of survey samples. Characteristics of the survey populations and survey response rates (defined as the proportion of the target sample size achieved) are shown in **Table 3**. Survey response rates were >85% in all countries except South Africa, which may have had selection biases because of the poor response rates in both surveyed provinces (i.e., 45.1% in Eastern Cape and 40.4% in Gauteng). The main reasons for nonresponse in these surveys were refusal from community leaders or associations, inability to access gated communities, and no one being present at home at the time of the survey.

Program coverage. RC for each measure of coverage for wheat flour, maize flour, and edible oil at the household level are

TABLE 3 Characteristics of the survey populations[1]

Country	Achieved sample size,[2] *n*	Response rate, %	Household size,[2] *n*	Respondent age, y	At risk of poverty,[3] %	Poor WDDS,[4] %	Rural,[5] %
Bangladesh	1512	100.0	4.9 (4.7, 5.2)	32.7 [15–49]	44.0 (37.5, 50.6)	NA (not used)	74.8 (68.1, 80.5)
Côte d'Ivoire (Abidjan)	1113	95.1	6.1 (5.8, 6.4)	29.0 [15–49]	21.0 (16.6, 26.3)	34.3 (31.5, 37.1)	NA (urban sample)
India (Rajasthan)	4627	102.0	6.7 (6.5, 6.8)	25.1 [16–48]	30.3 (26.9, 33.8)	23.5 (21.1, 25.6)	47.3 (45.8, 48.7)
Nigeria (Kano)	896	94.2	7.4 (7.2, 7.7)	28.3 [15–49]	68.3 (65.3, 71.4)	27.9 (24.7, 31.1)	70.4 (67.4, 73.4)
Nigeria (Lagos)	871	91.6	4.1 (4.0, 4.3)	32.0 [15–49]	8.8 (7.0, 10.7)	45.3 (41.5, 49.1)	11.9 (9.8, 14.1)
Senegal	1910	98.2	12.9 (6.2, 19.6)	28.0 [15–49]	59.9 (53.8, 66.1)	41.5 (36.1, 46.4)	66.9 (57.7, 75.2)
South Africa (Eastern Cape)	361	45.1	4.9 (4.6, 5.2)	30.0 [18–49]	33.5 (24.5, 43.6)	53.1 (46.0, 60.1)	48.4 (30.7, 66.1)
South Africa (Gauteng)	372	40.4	3.7 (3.5, 3.9)	32.7 [18–49]	19.2 (12.9, 26.9)	55.2 (48.6, 61.8)	4.0 (0.0, 14.5)
Tanzania	1036	98.7	4.4 (2.8, 6.2)	28.7 [15–49]	45.0 (37.0, 53.1)	28.4 (24.2, 32.7)	58.5 (55.4, 61.5)
Uganda	949	86.2	5.6 (5.3, 5.9)	30.1 [15–49]	63.4 (57.3, 69.6)	43.7 (38.0, 49.4)	53.6 (50.4, 56.9)

[1] Values are means (95% CIs) or means [ranges]. NA, not applicable; WDDS, women's dietary diversity score.
[2] Sample size within primary sampling units sometimes exceeded quota because of *1*) exhaustive sampling in urban blocks, and *2*) extra households that were occasionally sampled from linear segments in villages.
[3] Defined as multidimensional poverty index ≥0.33.
[4] Defined as WDDS below median value.
[5] Defined as rural place of residence.

shown in **Table 4**. For wheat flour, only Senegal achieved RC ≥50% for consumption of the fortified vehicle (51.2%). For maize flour, only South Africa achieved RC ≥50% for consumption of the fortified vehicle (Gauteng 77.4%; Eastern Cape 86.8%). For edible oil, 3 countries (Côte d'Ivoire, Tanzania, and Uganda) achieved RC ≥50% for consumption of the fortified vehicle. For Bangladesh, RC ≥50% was achieved for consumption of fortifiable oil (88.4%), which was the highest coverage stage for which results were available for this survey. The percentage MN by risk factor (i.e., poverty, poor WDDS, and rural residence) and country for wheat flour, maize flour, and edible oil are shown in **Table 5**. Only 2 countries (Côte d'Ivoire for edible oil and South Africa for maize flour) achieved a percentage MN measure ≥75% for ≥1 risk group.

TABLE 4 Raw coverage of wheat flour, maize flour, and edible oil at the household level by country[1]

Country	Uses vehicle	Vehicle is fortifiable[2]	Vehicle is fortified[3]
Wheat flour			
Côte d'Ivoire (Abidjan)	54.7 (50.1, 59.6)	10.2 (7.5, 13.1)	NA[4]
India (Rajasthan)	83.2 (79.5, 86.5)	7.1 (5.6, 9.1)	6.3 (4.8, 7.9)
Nigeria (Kano)	83.9 (81.5, 86.3)	83.8 (81.4, 86.2)	22.7 (20.0, 25.5)
Nigeria (Lagos)	14.2 (11.8, 16.5)	13.8 (11.5, 16.1)	5.4 (3.8, 6.9)
Senegal	81.8 (76.2, 86.6)	81.5 (75.5, 86.4)	51.2 (44.7, 57.2)
South Africa (Eastern Cape)	25.2 (16.3, 34.1)	25.2 (16.3, 34.1)	16.3 (10.0, 23.7)
South Africa (Gauteng)	4.3 (1.8, 7.6)	4.3 (1.8, 7.6)	0.8 (0.0, 2.3)
Tanzania	51.5 (44.5, 58.5)	50.5 (43.3, 57.7)	33.1 (27.5, 38.7)
Uganda	11.2 (7.7, 14.7)	10.6 (7.6, 13.6)	8.5 (5.7, 11.4)
Maize flour			
Nigeria (Kano)	77.1 (74.4, 79.9)	11.0 (9.0, 13.1)	1.7 (0.9, 2.6)
Nigeria (Lagos)	12.2 (10.0, 14.4)	2.9 (1.8, 4.0)	0.2 (0.0, 0.5)
South Africa (Eastern Cape)	98.7 (96.5, 100.0)	98.7 (96.5, 100.0)	86.8 (80.0, 92.4)
South Africa (Gauteng)	95.6 (90.4, 98.6)	95.4 (90.3, 98.4)	77.4 (69.8, 94.9)
Tanzania	93.0 (89.7, 96.4)	36.6 (29.2, 44.0)	2.5 (1.3, 3.7)
Uganda	91.8 (87.7, 96.0)	42.4 (32.7, 52.1)	6.5 (3.3, 9.7)
Edible oil			
Bangladesh	All	88.4 (84.5, 92.3)	NA[4]
Côte d'Ivoire (Abidjan)	98.5 (97.5, 99.3)	98.0 (97.0, 99.0)	98.0 (97.0, 99.0)
India (Rajasthan)	All	89.4 (87.0, 91.8)	24.3 (21.1, 27.9)
Nigeria (Kano)	98.4 (97.6, 99.2)	35.9 (32.7, 39.1	7.6 (5.9, 9.4)
Nigeria (Lagos)	98.6 (97.8, 99.3)	22.7 (19.9, 25.5)	7.2 (5.5, 8.9)
Senegal	97.8 (96.3, 99.1)	95.0 (92.9, 96.8)	34.1 (29.1, 40.7)
Tanzania	96.2 (93.2, 99.2)	92.6 (89.0, 96.3)	53.6 (46.4, 60.8)
Uganda	89.9 (85.9, 94.0)	89.0 (84.7, 93.2)	54.4 (48.3, 60.4)

[1] Values are % (95% CI). NA, not applicable.
[2] The food vehicle used by the household is processed industrially.
[3] The food vehicle used by the household is confirmed to be fortified by brand identification and quantitative laboratory analyses.
[4] Food specimens were not collected. No fortification levels are available.

TABLE 5 Percentage met need by risk factor and country for wheat flour, maize flour, and edible oil coverage[1]

Country	Uses vehicle			Vehicle is fortifiable[2]			Vehicle is fortified[3]		
	Poverty[4]	Poor WDDS[5]	Rural[6]	Poverty	Poor WDDS	Rural	Poverty	Poor WDDS	Rural
Wheat flour									
Côte d'Ivoire (Abidjan)	55.4 (43.3, 65.0)	52.7 (46.1, 61.3)	NA (urban sample)	4.0 (1.0, 8.4)	6.4 (3.2, 10.0)	NA (urban sample)	NA[7]	NA[7]	NA (urban sample)
India (Rajasthan)	66.4 (59.5, 73.0)	77.4 (71.7, 83.3)	76.5 (71.3, 81.0)	5.0 (3.0, 7.5)	7.1 (4.9, 10.1)	3.0 (1.8, 4.9)	4.7 (3.0, 7.2)	5.5 (3.4, 8.2)	2.6 (1.4, 4.4)
Nigeria (Kano)	81.6 (78.3, 84.2)	84.6 (79.3, 88.9)	82.4 (79.1, 85.1)	81.4 (78.1, 84.1)	84.6 (79.3, 88.9)	82.3 (79.0, 85.0)	17.1 (14.2, 19.9)	14.5 (10.0, 19.7)	18.2 (15.0, 21.2)
Nigeria (Lagos)	10.8 (4.7, 18.1)	12.6 (8.3, 16.7)	12.1 (5.9, 19.2)	10.8 (4.7, 18.1)	12.3 (8.1, 16.1)	12.1 (5.9, 19.2)	1.6 (1.2, 5.4)	5.4 (2.9, 8.7)	5.7 (1.2, 10.5)
Senegal	78.0 (70.6, 84.1)	79.8 (72.1, 86.9)	77.7 (70.4, 83.5)	77.6 (69.5, 83.6)	79.3 (72.2, 86.5)	77.2 (68.5, 83.8)	48.0 (40.4, 55.9)	46.3 (37.9, 55.1)	49.3 (40.6, 57.3)
South Africa (Eastern Cape)	15.3 (7.0, 25.4)	15.1 (6.8, 24.7)	22.3 (11.2, 37.1)	15.1 (7.7, 24.6)	15.0 (6.3, 26.7)	22.0 (11.0, 37.4)	9.1 (3.3, 15.9)	8.1 (3.0, 16.1)	15.0 (5.1, 27.0)
South Africa (Gauteng)	15.2 (7.0, 24.7)	14.6 (7.2, 25.6)	23.7 (11.8, 38.6)	14.9 (6.1, 24.1)	15.2 (6.9, 25.1)	22.7 (12.4, 39.3)	9.2 (3.7, 15.2)	7.7 (2.8, 15.7)	15.4 (5.6, 28.2)
Tanzania	36.5 (31.7, 41.5)	45.2 (38.2, 53.1)	41.4 (37.5, 45.4)	35.4 (30.9, 40.2)	45.2 (38.2, 53.1)	40.1 (36.4, 44.4)	21.7 (17.8, 25.7)	25.9 (20.1, 31.7)	25.1 (21.6, 28.7)
Uganda	7.2 (4.8, 9.4)	10.8 (7.0, 14.7)	8.2 (6.1, 10.6)	6.2 (4.0, 8.5)	10.1 (6.6, 14.3)	7.5 (5.1, 9.9)	4.5 (2.6, 6.5)	7.9 (4.6, 11.4)	6.4 (4.2, 8.5)
Maize flour									
Nigeria (Kano)	76.4 (73.0, 79.7)	79.4 (73.7, 85.3)	75.3 (72.1, 78.2)	9.7 (7.2, 12.5)	12.5 (8.1, 17.6)	7.7 (5.6, 9.8)	1.6 (0.7, 2.7)	0.9 (0.4, 2.4)	1.0 (0.3, 1.8)
Nigeria (Lagos)	32.6 (22.6, 42.9)	11.6 (8.0, 16.2)	47.8 (39.4, 58.5)	5.9 (1.6, 11.5)	1.8 (0.4, 3.9)	4.4 (1.5, 8.6)	0	0	0
South Africa (Eastern Cape)	All	98.4 (92.7, 100.0)	All	All	98.2 (93.9, 100.0)	All	83.6 (74.6, 90.7)	84.4 (74.2, 92.7)	84.4 (74.8, 92.3)
South Africa (Gauteng)	All	98.4 (93.1, 100.0)	All	All	98.3 (93.0, 100.0)	All	83.7 (76.2, 90.0)	84.3 (75.8, 92.3)	84.4 (73.4, 92.5)
Tanzania	89.3 (85.9, 92.3)	92.8 (89.1, 95.8)	92.0 (89.6, 93.9)	23.7 (20.0, 28.0)	42.2 (36.0, 49.0)	20.6 (17.5, 24.2)	2.7 (1.3, 4.4)	3.2 (1.4, 5.8)	1.5 (0.6, 2.7)
Uganda	89.6 (86.8, 92.7)	86.7 (81.6, 91.6)	91.2 (88.7, 93.4)	35.3 (31.3, 40.0)	38.9 (32.6, 45.9)	36.4 (32.5, 40.4)	5.9 (4.0, 8.4)	5.7 (2.9, 9.1)	6.1 (4.2, 8.3)
Edible oil									
Bangladesh	82.1 (75.0, 87.5)	NA (not used)	85.3 (79.9, 89.5)	83.8 (76.0, 89.4)	NA (not used)	86.4 (80.5, 90.8)	NA[7]	NA[7]	NA[7]
Côte d'Ivoire (Abidjan)	98.2 (94.9, 100.0)	98.3 (96.7, 99.8)	NA (urban sample)	97.7 (94.4, 100.0)	98.3 (96.0, 99.7)	NA (urban sample)	97.7 (94.6, 100.0)	98.2 (96.1, 99.7)	NA (urban sample)
India (Rajasthan)	All	All	All	95.0 (92.8, 96.7)	90.7 (87.5, 93.7)	86.3 (82.9, 89.7)	19.7 (14.6, 25.4)	22.9 (16.6, 29.3)	20.5 (16.3, 25.2)
Nigeria (Kano)	98.1 (96.8, 99.0)	99.6 (98.8, 100.0)	98.5 (97.3, 99.3)	35.1 (31.0, 38.7)	39.5 (32.8, 46.9)	31.5 (27.9, 35.2)	8.3 (6.1, 10.5)	8.5 (5.1, 12.7)	7.1 (5.3, 9.2)
Nigeria (Lagos)	All	All	All	17.7 (9.9, 27.7)	26.7 (21.0, 32.0)	14.6 (8.4, 21.6)	4.8 (1.2, 9.7)	8.3 (5.1, 12.0)	4.1 (0.9, 8.2)
Senegal	97.3 (94.8, 98.8)	97.5 (95.3, 99.4)	97.2 (95.3, 99.1)	93.3 (90.1, 96.1)	94.0 (90.4, 96.9)	93.0 (90.3, 95.7)	21.5 (16.9, 26.2)	30.5 (24.4, 37.8)	23.5 (18.2, 29.9)
Tanzania	93.3 (90.2, 95.6)	94.9 (90.9, 97.6)	95.1 (93.2, 96.8)	89.4 (85.0, 92.3)	91.4 (87.1, 95.3)	90.4 (87.6, 92.7)	54.6 (50.0, 60.3)	50.6 (43.5, 56.8)	51.4 (42.7, 55.5)
Uganda	88. (85.2, 91.2)	89.4 (84.7, 93.4)	89.4 (86.5, 92.2)	86.8 (83.4, 90.1)	87.8 (82.8, 92.0)	88.3 (85.5, 91.1)	48.5 (43.4, 52.9)	52.2 (45.0, 59.2)	51.3 (46.5, 55.9)

[1] Values are % (95% CI). Met need = the proportion of households defined as vulnerable that were covered. NA, not applicable; WDDS, women's dietary diversity score.
[2] The food vehicle used by the household is processed industrially.
[3] The food vehicle used by the household is confirmed to be fortified by brand identification and quantitative laboratory analyses.
[4] Defined as multidimensional poverty index ≥0.33.
[5] Defined as WDDS below median value.
[6] Defined as rural place of residence.
[7] Food specimens were not collected. No fortification levels are available.

One country (Senegal for wheat flour) achieved an MN measure ≥40% for ≥1 risk group. All other programs demonstrated considerably lower coverage among vulnerable population groups. CRs by risk group (i.e., poverty, poor WDDS, and rural residence) and country for wheat flour, maize flour, and edible oil are shown in **Table 6**. The trends were consistent with the results from the MN analyses. Overall program performance and program bottlenecks based on the aggregate summary of the RC, MN, and CR statistics are summarized in **Table 7**. Only 2 programs (Côte d'Ivoire for edible oil and South Africa for maize flour) met all 3 criteria. For each program, the principal bottleneck is reported for the highest level of coverage measured.

Discussion

The FACT project fills an important void in the availability of simple, cost-effective tools that fortification programs can use to assess and diagnose program coverage. Results from the analyses highlight the importance of adequate program design and appropriate monitoring activities to ensure program success.

Only 2 of the 18 LSFF programs assessed met all program performance criteria used in the current analyses. This finding is consistent even if lower thresholds are considered for the program performance assessments. For programs with low RC, the results also indicate that coverage was not concentrated in vulnerable population groups (i.e., the MN measure was low). The main reasons for programs failing to meet the criteria were a poor choice of vehicle (i.e., the chosen vehicle was either not a staple or the bulk of the vehicle consumed was not fortifiable) and failure to fortify a fortifiable vehicle. These 2 reasons alone account for the principal bottlenecks in the 16 programs that did not meet the 3 performance criteria used in the analyses. Poor selection of a food vehicle is a failure of program planning and design. Because LSFF is not intended to change population dietary patterns, there is nothing that can be done during program implementation to increase program coverage in such instances. Failure to fortify a fortifiable vehicle may be a problem of program design (e.g., inability to include all large-scale producers in the program or absence of sufficient consolidation and centralization of production, processing, and distribution) or a problem of compliance or enforcement of fortification. Failing to cover vulnerable population groups may be a problem of access, affordability, or the fact that these at-risk groups do not consume the respective fortified food vehicles. Further assessments of these programs are required to determine whether the existing programs need strengthening, whether

TABLE 6 Coverage ratio by risk factor and country for wheat flour, maize flour, and edible oil coverage[1]

	Uses vehicle			Vehicle is fortifiable[2]			Vehicle is fortified[3]		
Country	Poverty[4]	Poor WDDS[5]	Rural[6]	Poverty	Poor WDDS	Rural	Poverty	Poor WDDS	Rural
Wheat flour									
Côte d'Ivoire (Abidjan)	1.0 (0.8, 1.2)	0.9 (0.8, 1.1)	NA (urban sample)	0.3 (0.1, 0.7)	0.5 (0.3, 0.9)	NA (urban sample)	NA[7]	NA[7]	NA (urban sample)
India (Rajasthan)	0.7 (0.7, 0.8)	0.9 (0.8, 1.0)	0.8 (0.7, 0.9)	0.6 (0.3, 0.9)	1.0 (0.7, 1.4)	0.2 (0.1, 0.3)	0.7 (0.4, 1.0)	0.8 (0.5, 1.2)	0.2 (0.1, 0.3)
Nigeria (Kano)	0.6 (0.4, 0.8)	0.9 (0.9, 1.0)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	0.8 (0.5, 1.1)	0.7 (0.5, 1.0)	1.0 (0.9, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.1)
Nigeria (Lagos)	0.6 (0.4, 0.8)	0.9 (0.9, 1.0)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	0.8 (0.5, 1.1)	0.7 (0.5, 1.0)	1.0 (0.9, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.1)
Senegal	0.9 (0.8, 1.0)	1.0 (0.9, 1.0)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	1.0 (0.9, 1.1)	0.8 (0.7, 0.9)	0.9 (0.7, 1.0)	0.9 (0.7, 1.0)	0.9 (0.7, 1.1)
South Africa (Eastern Cape)	1.1 (0.6, 1.8)	1.6 (0.7, 3.3)	1.9 (0.8, 4.1)	1.1 (0.6, 1.8)	1.6 (0.7, 3.1)	1.9 (0.8, 4.3)	1.1 (0.4, 2.5)	1.6 (0.5, 4.6)	2.4 (0.8, 6.8)
South Africa (Gauteng)	1.0 (0.5, 1.8)	1.6 (0.8, 3.3)	2.0 (0.9, 4.3)	1.0 (0.5, 1.8)	1.6 (0.8, 3.3)	2.0 (0.9, 4.1)	1.1 (0.4, 2.4)	1.5 (0.5, 4.2)	2.5 (0.8, 7.2)
Tanzania	0.6 (0.5, 0.7)	0.8 (0.7, 0.9)	0.5 (0.4, 0.6)	0.6 (0.5, 0.7)	0.8 (0.7, 0.9)	0.5 (0.4, 0.6)	0.7 (0.7, 0.8)	0.8 (0.7, 0.9)	0.7 (0.6, 0.8)
Uganda	0.9 (0.8, 0.9)	1.0 (0.9, 1.0)	0.8 (0.8, 0.9)	0.9 (0.8, 0.9)	1.0 (0.9, 1.0)	0.8 (0.7, 0.8)	0.9 (0.8, 0.9)	1.0 (0.9, 1.0)	0.9 (0.8, 0.9)
Maize flour									
Nigeria (Kano)	1.3 (1.1, 1.6)	1.0 (0.9, 1.1)	1.8 (1.5, 2.2)	1.0 (1.0, 1.1)	1.0 (1.0, 1.0)	1.0 (1.0, 1.1)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)
Nigeria (Lagos)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	1.8 (1.5, 2.2)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (1.0, 1.1)	0	0	1.0 (1.0, 1.0)
South Africa (Eastern Cape)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.0)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (0.9, 1.1)	1.0 (0.9, 1.2)	1.0 (0.9, 1.2)
South Africa (Gauteng)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)	1.0 (0.9, 1.1)	1.0 (0.9, 1.2)	1.0 (0.9, 1.2)
Tanzania	0.4 (0.2, 0.6)	0.9 (0.5, 1.7)	0.6 (0.3, 0.9)	0.7 (0.6, 0.8)	1.1 (1.0, 1.3)	0.4 (0.3, 0.5)	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	1.0 (0.9, 1.0)
Uganda	0.4 (0.2, 0.8)	0.4 (0.2, 0.7)	0.5 (0.3, 0.8)	0.7 (0.6, 0.8)	0.9 (0.8, 1.0)	0.4 (0.4, 0.5)	1.0 (1.0, 1.0)	1.0 (0.9, 1.0)	1.0 (0.9, 1.0)
Edible oil									
Bangladesh	0.4 (0.3, 0.7)	NA	0.4 (0.2, 0.8)	0.5 (0.3, 0.8)	NA	0.4 (0.2, 0.9)	NA[7]	NA[7]	NA[7]
Côte d'Ivoire (Abidjan)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	NA (urban sample)	1.0 (0.9, 1.1)	1.0 (0.9, 11)	NA (urban sample)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	NA (urban sample)
India (Rajasthan)	All	All	All	1.1 (1.0, 1.2)	1.0 (0.9, 1.1)	0.9 (0.8, 1.0)	0.8 (0.6, 1.0)	0.9 (0.7, 1.2)	0.6 (0.5, 0.8)
Nigeria (Kano)	All	0.6 (0.2, 1.9)	1.1 (0.3, 3.5)	0.9 (0.8, 1.1)	1.1 (1.0, 1.2)	0.9 (0.8, 1.0)	1.0 (0.9, 1.0)	1.0 (1.0, 1.1)	0.9 (0.9, 1.0)
Nigeria (Lagos)	All	0.6 (0.2, 1.9)	1.1 (0.3, 3.5)	0.9 (0.8, 1.1)	1.1 (1.0, 1.2)	0.9 (0.8, 1.0)	1.0 (0.9, 1.0)	1.0 (1.0, 1.1)	0.9 (0.9, 1.0)
Senegal	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	1.1 (0.9, 1.1)	1.0 (0.9, 1.1)	1.0 (0.9, 1.1)	0.9 (0.8, 1.0)	0.4 (0.3, 0.5)	0.8 (0.7, 1.0)	0.4 (0.3, 0.6)
Tanzania	0.2 (0.1, 0.4)	0.5 (0.2, 1.2)	0.3 (0.1, 0.6)	0.4 (0.3, 0.7)	0.7 (0.4, 1.4)	0.3 (0.1, 0.5)	1.0 (0.9, 1.2)	0.9 (0.8, 1.1)	0.9 (0.7, 1.0)
Uganda	0.6 (0.4, 1.0)	0.7 (0.4, 1.2)	0.7 (0.4, 1.0)	0.5 (0.3, 0.9)	0.7 (0.4, 1.1)	0.6 (0.4, 1.0)	0.7 (0.6, 0.8)	0.8 (0.7, 1.0)	0.6 (0.5, 0.7)

[1] Values are % (95% CI). Coverage ratio = the ratio of the coverage in vulnerable households to the coverage in households considered to be not vulnerable. NA, not applicable; WDDS, women's dietary diversity score.
[2] The food vehicle used by the household is processed industrially.
[3] The food vehicle used by the household is confirmed to be fortified by brand identification and quantitative laboratory analyses.
[4] Defined as multidimensional poverty index ≥0.33.
[5] Defined as women's dietary diversity score below median value.
[6] Defined as rural place of residence.
[7] Food specimens were not collected. No fortification levels are available.

TABLE 7 Overall program performance and program bottlenecks for all surveyed wheat flour, maize flour, and edible oil fortification programs

Country	Region	Program	Criteria[1] Raw coverage ≥50%	Met need,[2] ≥75%	Coverage ratios,[3] ≥1	Main program bottleneck (lowest coverage level)[4]
Bangladesh	Nationwide	Edible oil	●	●	○	Favors nonvulnerable groups
Côte d'Ivoire	Abidjan	Wheat flour	○	○	○	Bulk of vehicle is not fortifiable
		Edible oil	●	●	●	All criteria met
India	Rajasthan	Wheat flour	○	○	○	Bulk of vehicle is not fortifiable
		Edible oil	○	○	○	Bulk of vehicle is not fortified
Nigeria	Kano	Wheat flour	○	○	●	Bulk of vehicle is not fortified
		Maize flour	○	○	●	Bulk of vehicle is not fortifiable
		Edible oil	○	○	●	Bulk of vehicle is not fortifiable
Nigeria	Lagos	Wheat flour	○	○	●	Vehicle is not a staple
		Maize flour	○	○	●	Vehicle is not a staple
		Edible oil	○	○	●	Bulk of vehicle is not fortifiable
Senegal	Nationwide	Wheat flour	●	○	●	Favors nonvulnerable groups
		Edible oil	○	○	○	Bulk of vehicle is not fortified
South Africa	Eastern Cape	Wheat flour	○	○	●	Vehicle is not a staple
		Maize flour	●	●	●	All criteria met
South Africa	Gauteng	Wheat flour	○	○	●	Vehicle is not a staple
		Maize flour	●	●	●	All criteria met
Tanzania	Nationwide	Wheat flour	○	○	○	Bulk of vehicle is not fortified
		Maize flour	○	○	●	Bulk of vehicle is not fortifiable
		Edible oil	●	○	●	Favors nonvulnerable groups
Uganda	Nationwide	Wheat flour	○	○	●	Vehicle is not a staple
		Maize flour	○	○	●	Bulk of vehicle is not fortifiable
		Edible oil	●	○	○	Favors nonvulnerable groups

[1] Solid dot indicates that criterion was met; based on consumption of the fortified vehicle for all with the exception of Bangladesh (oil) and Côte d'Ivoire (wheat flour), where consumption of the fortifiable vehicle was used because it was the highest level of coverage available.
[2] Met need (i.e., the proportion of households defined as vulnerable that were covered) for ≥1 risk-group assessed (i.e., poverty, poor women's dietary diversity score, or rural) is ≥75%.
[3] Coverage ratio (i.e., the ratio of the coverage in vulnerable households to the coverage in households considered to be not vulnerable) for ≥1 risk-group assessed (i.e., poverty, poor women's dietary diversity score, or rural) is ≥1.
[4] "Fortifiable" refers to a food vehicle that is processed industrially; "fortified" refers to a food vehicle that is confirmed to be fortified by brand identification and quantitative laboratory analyses.

other food vehicles should be considered, and whether other interventions to deliver micronutrients are required.

The edible oil program in Côte d'Ivoire met the 3 program performance criteria used in the current analyses. For cost and logistical reasons, the assessment was only conducted in the capital city of Abidjan; therefore, conclusions about the rest of the country cannot be drawn from the current work. Further coverage assessments in rural and other urban areas outside of Abidjan would be needed to fully assess equity of fortification coverage in this country. South Africa's maize flour fortification program met the program performance criteria used in these analyses in the 2 regions surveyed. These regions were selected for surveying because they are the 2 provinces with the highest population density and represent the most diverse areas of the country (28). Even though there may have been selection biases because of the poor response rates from these surveys, it is still likely that this program is performing well. South Africa has one of the most advanced economies in sub-Saharan Africa, and it is possible that the level of industrial consolidation, compliance, and government enforcement is more favorable than that in other countries in the region.

Planning of effective LSFF programs needs to be informed by detailed investigations of patterns of production, distribution, and consumption, and requires the selection of vehicles with the potential for high coverage in the population. Without this due diligence, programs rely largely on chance to achieve impact. The capital-intensive startup phase of these programs means that this is a gamble made with high stakes, as we have reported in other contexts (20). The main program bottlenecks responsible for many of the programs failing to meet the criteria used here for a good LSFF program could and should have been identified before the program started. For example, FRAT surveys conducted before these programs started would have revealed whether they were unlikely to achieve high overall coverage and therefore population level impact. Implementation of LSFF programs requires considerable and ongoing monitoring and evaluation. Effective monitoring and evaluation, particularly regulatory monitoring of the fortification process, is likely to have been lacking in some of the programs in which failure to fortify was the main program bottleneck.

Results from these analyses also highlight the importance of having multiple strategies to address micronutrient needs in the population. LSFF programs by design are not intended to be a panacea for micronutrient malnutrition in the population, and complementary strategies are needed to address specific population groups whose needs may be higher or who for various reasons may not access these fortified staples (1). Many countries do have comprehensive nutrition strategies that include targeted interventions (i.e., supplementation, home fortification, and complementary foods, among others); others include free or subsidized fortified products as part of social protection programs as a means to overcome barriers of access for the poor. For any intervention modality, sound program design, careful implementation, and routine monitoring to identify and correct implementation bottlenecks in a timely fashion are essential.

The principal strengths of the FACT project include the following: *1*) the development of a standardized toolkit to assess program coverage; *2*) a peer-review process that reviewed and refined the research approach; *3*) the use of standardized and validated indicators to assess vulnerability; and *4*) the use of program coverage assessments that were conducted in the overall population and in vulnerable subpopulation groups. As for limitations, household coverage estimates do not capture foods purchased and consumed outside of the households, such as snacks and restaurant meals. This may result in underestimating the potential coverage of fortification interventions in the population. This article reports on estimates that are common to and available from all surveys. Although not presented in this article, most of the surveys also assessed individual-level consumption of foods made with the use of the respective vehicles, which generated information on individual-level coverage and consumption (29). A second limitation is that staple foods fall into the category of fast-moving consumer goods. Repackaging of food vehicles into unbranded packaging was common across all countries. This issue likely resulted in an underestimation of coverage of fortified foods. A third limitation is that the risk factors used in these analyses do not capture all potential vulnerable populations. Definitively, biochemical and full dietary assessments may be preferred, but such assessments are expensive and logistically complex for programs to undertake in routine monitoring and evaluation assessments. One approach that could be considered would be similar to what Cameroon did before starting its fortification program. A biochemical assessment was conducted alongside a FRAT survey before starting the program (30). Such an approach lends itself to confirming which risk factors are associated with biochemical deficiencies. These risk factors could then be assessed subsequently in routine program monitoring, and evaluation activities could be conducted during the program implementation period.

Several observations have been consistent across surveys. The issue of repacking food vehicles at the market level needs to be addressed in future work. This will require linking market- and household-level monitoring activities to better understand fortification practices. Market-level assessments were conducted in some of the countries (Bangladesh, Côte d'Ivoire, and Senegal). Further development of the FACT methods should systematically include or be linked to market-level assessments. Assessing fortification status is challenging to conduct in the field. Quantitative analyses were used to determine the fortification levels of food vehicles, but are costly and time-consuming, and fortificants and micronutrients are subject to degradation over time because of storage conditions and length of time from collection to analysis. Having field-friendly tools to determine the presence of fortificants for all major food vehicles (similar to the rapid test kit that exists for testing iodine in salt and the qualitative iron spot test for determining the presence of iron in flour) need to be developed. Mobile photometers are available that can measure multiple micronutrients in flour (31) and oil matrices quantitatively (32, 33), but the approach still needs refinement to accelerate and improve accurate measurement in field settings.

Conclusions

The FACT project successfully developed and operationalized a program-ready tool for carrying out fortification coverage assessments of LSFF programs. The results identified 2 major areas that programs need to focus on: *1*) the selection of appropriate food vehicles before programs are started, and *2*) routine monitoring of the fortification process to ensure that fortification occurs at the desired level. Where vehicles were chosen that have little potential for population impact, the use of funding to support such programs should be reconsidered. The second issue can and should be improved during the course of the program.

LSFF has been demonstrated to be a highly cost-effective intervention strategy to address micronutrient needs in the population (overall and in vulnerable groups); however, this can only be achieved when the necessary activities and processes during program design and implementation are followed. A number of the programs that were assessed have high potential for impact based on the consumption of fortifiable vehicles, a potential that can only be achieved with substantially improved compliance with fortification (26). For other programs in which nonstaple food vehicles are fortified or coverage of a fortifiable food vehicle is low, governments and industry may wish to reconsider the value of continued investment. The FACT method, if linked with routine monitoring of programs (particularly monitoring of the adequate fortification of the food vehicle), could facilitate the generation of the information required to ensure that such program improvements can be made in a timely manner.

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