PERSPECTIVE

Perspective: Early-Life Nutrition Research Supported by the US National Institutes of Health from 2018 to 2020

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ABSTRACT

The *Dietary Guidelines for Americans, 2020–2025*, included guidelines for pregnancy, lactation, and children from birth to age 24 mo (B-24) to reflect the growing body of evidence about appropriate nutrition during the earliest stages of life. Guidelines were based on a thorough review of the existing scientific evidence by the 2020 Dietary Guidelines Advisory Committee (DGAC). This study's objective was to enumerate early-life (pregnancy, lactation, and B-24) nutrition research needs that are already being addressed by the scientific community and to identify remaining research gaps. The *Scientific Report of the 2020 Dietary Guidelines Advisory Committee* was reviewed, and 138 research gaps relevant to early life were identified. Research gaps were consolidated into 13 topic areas. A total of 1632 nutrition- and early-life–focused research projects funded by the NIH between 2018 and 2020 were manually coded using title, abstract, and public health relevance statement available on NIH RePORTER. Projects were coded as affirmative if they addressed a research gap within 1 of the 13 research gap topic areas. Of coded projects, 235 (14.4%) addressed any early-life nutrition research gap. Between fiscal years 2018 to 2020, total costs of projects addressing any gap represented only 15% of total costs for all projects reviewed. Complementary foods, breastfeeding (never vs. ever), and frequency of eating were research gap areas most frequently coded as being addressed by a funded project. Iron supplementation, seafood consumption, and maternal diet food allergens were research gap areas least frequently coded as being potentially addressed by a funded project. This analysis highlights opportunities for changes in the federal government investment in maternal and child nutrition research to support development of effective, evidence-based dietary guidelines for improvement in early-life nutrition practices and overall public health. *Adv Nutr* 2022;13:1395–1401.

Statement of Significance: The National Institutes of Health (NIH) funded 1632 research projects between 2018 and 2020 focused on early-life nutrition. Of these, less than 15% intended to address any early-life–related dietary research gap identified by the *Scientific Report of the 2020 Dietary Guidelines Advisory Committee*. Results suggest an opportunity for more strategic investment in maternal and child nutrition research by the NIH to support the development of effective evidence-based dietary guidelines for pregnancy, lactation, and infants and toddlers aged birth to 24 mo.

Keywords: dietary guidelines, birth to 24 months, complementary foods, dietary pattern, early-life nutrition, research funding, pregnancy, lactation, breastfeeding, maternal health

Introduction

The *Dietary Guidelines for Americans, 2020–2025* (DGA), for the first time since the 1985 edition included guidelines from birth to age 24 mo (B-24) to reflect the growing body of evidence about appropriate nutrition recommendations during the earliest stages of life (1). The inclusion of guidance for this population, as well as women who are pregnant, was mandated as part of the Agriculture Act of 2014 (section 4204) (2). Guidelines were based on a thorough review of the existing scientific evidence by the 2020 Dietary Guidelines Advisory Committee (DGAC) (3). Additionally, the DGA included recommendations for pregnant and lactating individuals, together with the B-24 recommendations, comprehensively providing dietary guidance aimed at early life.

The DGAC used several approaches to examine the evidence, including data analyses, food pattern modeling, and USDA's Nutrition Evidence Systematic Reviews (NESR)

(3–5). In addition to conducting new systematic reviews in these early-life stages, the DGAC utilized systematic reviews conducted as part of the Pregnancy and Birth to 24 Months Project or "P/B-24 project" to support its evidence base (6). The P/B-24 project was a joint effort between the USDA and Department of Health and Human Services dating back to 2012 and resulted in a series of systematic reviews on select diet and health questions for women who are pregnant and for infants and toddlers from B-24 (6, 7).

The DGA encourages the ideology of "make every bite count" (1). This is especially fitting considering the role of optimal maternal nutrition from preconception through pregnancy and lactation on maternal and child health outcomes (8). The importance of establishing health-promoting dietary patterns in infancy and early childhood is also well known, as early-life nutrition interventions have lasting implications for lifelong health (9, 10). Despite this acknowledgment, the development of evidence-based dietary guidance for early-life nutrition was hindered by lack of evidence. The *Scientific Report of the 2020 Dietary Guidelines Advisory Committee* indicated that additional research could inform evidence-based dietary guidelines in many areas where conclusions were not able to be drawn due to lacking or inconclusive evidence. For example, the DGAC concluded that "there was insufficient evidence to draw a conclusion about the relations between types and amounts of complementary foods and beverages consumed and developmental milestones" (part D, chapter 5) (3).

Advancements in research are needed to provide additional evidence to inform the evidence-based guidelines included within the *Dietary Guidelines for Americans, 2025–2030*. However, it is uncertain if the current funded biomedical research addresses any of the known dietary research gaps. The purpose of this study was to enumerate early-life nutrition (pregnancy, lactation, and infants and toddlers aged B-24) research already being addressed by the largest funder of biomedical research in the world, the NIH, and identify remaining dietary research gaps that should be prioritized in future research efforts.

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Perspective articles allow authors to take a position on a topic of current major importance or controversy in the field of nutrition. As such, these articles could include statements based on author opinions or point of view. Opinions expressed in Perspective articles are those of the author and are not attributable to the funder(s) or the sponsor(s) or the publisher, Editor, or Editorial Board of Advances in Nutrition. Individuals with different positions on the topic of a Perspective are invited to submit their comments in the form of a Perspectives article or in a Letter to the Editor.

Supplemental Tables 1–3 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at https://academic.oup.com/advances/.

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Abbreviations used: B-24, birth through 24 mo; DGA, *Dietary Guidelines for Americans*; DGAC, Dietary Guidelines Advisory Committee; FY, fiscal year; NESR, Nutrition Evidence Systematic Reviews; P/B-24 project, Pregnancy and Birth to 24 Months Project; RCDC, Research, Condition, and Disease Categorization; RCT, randomized controlled trial.

Methods

Identification and grouping of early-life dietary research gaps

The *Scientific Report of the 2020 Dietary Guidelines Advisory Committee* (3) was reviewed, and 138 research gaps relevant to early life were identified. The gaps represented a question that the DGAC determined to have no evidence or insufficient evidence resulting in "Grade Not Assignable." Additionally, chapter 7 on "Future Directions" was also reviewed by the research team. Gaps that addressed topics of surveillance were excluded as NIH funding does not provide a mechanism for this type of research. The research team then condensed research gaps into 13 topic areas (**Supplemental Table 1**) and subtopics as needed. For example, the breastfeeding duration topic area was divided into 4 subtopic areas (allergies, child cardiovascular disease risk, micronutrient status, and child overweight/obesity at $\geq$2 y).

Selection of relevant NIH projects

To investigate the proportion of funded projects with potential to address an early-life research topic gap within the Dietary Guidelines, the NIH IMPACII database was queried using the NIH iSEARCH tool in December 2020 by NIH staff (AJV). To identify projects on gaps identified by the DGAC for both pregnant and lactating individuals, the search criteria required that the applications were awarded by NIH during fiscal years (FYs) 2018–2020 and that the projects were coded by the NIH Research, Condition, and Disease Categorization (RCDC) coding system as *1*) nutrition and pregnancy focused or focused on breastfeeding, lactation, or breast milk, respectively, or *2*) nutrition focused on children aged B-24 (including newborns, infants, and/or toddlers). Projects were not restricted to any specific NIH institute. Both newly funded and continuing awards were considered. For each search, all funding mechanisms, award types, and activity codes were considered eligible for inclusion. After duplicate removal, there was a total of 1632 projects that were eligible for screening (including only subprojects for U and P mechanisms, except for U01s, which were treated like all other awards) (11).

Coding of funded projects

Following the initial identification of projects, 3 research analysts manually coded the output using the title, abstract, and public health relevance statement available on NIH RePORTER (reporter.nih.gov). Projects were coded as "affirmative" if they had the potential to address a dietary research gap within 1 of the 13 topic areas. Of all research projects coded, 10% were randomly selected and reviewed independently by a team of NIH staff members to ensure the accuracy and quality control of coding. Any discordant results were discussed, and consensus results were recorded. Associated metadata (direct, indirect, and total costs; activity code; NIH administrative institute, center, or office code; and FY of funding) were gathered for each

TABLE 1 Total costs of all funded projects focused on nutrition and early life compared with projects addressing an early-life nutrition research gap by fiscal year (2018–2020)

	2018	2019	2020	Total (2018–2020)
Total costs for all nutrition- and early-life–focused projects	$239,744,960	$264,257,957	$290,724,256	$794,727,173
Total costs for projects addressing any early-life nutrition research gap[1]	$41,826,030	$40,023,626	$33,463,284	$115,312,940
Percentage of total costs for projects addressing any early-life nutrition research gap compared with all nutrition- and early-life–focused projects	17%	15%	12%	15%

[1] *P*-trend < 0.001.

project ID. The NIH did not require institutional review board approval as this analysis included only administrative data and no data on human subjects. The present study followed the reporting requirements of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Methods for visualizations

NIH staff used the iSEARCH tool's "Visualize Results" function in September of 2021 to develop a FoamTree visualization created with labeled clusters representing the topics within project titles, abstracts and/or public health relevance.

Statistical analysis

Descriptive summary statistics (frequencies and percentages) were used to describe the data. Test for time trends were completed using logistic regression, with $P < 0.05$ indicating statistical significance. Data were analyzed in RStudio (version 1.2.5042, RStudio Team, 2020; PBC).

Results

Of all 1632 projects focused on nutrition and early life funded by NIH between 2018 and 2020, 235 (14.4%) projects and 15% of the total dollars were allocated to address any identified early-life nutrition–related gap during FYs 2018–2020. Total cost for funded projects addressing an early-life nutrition–related gap across the 3 FYs was $115,312,940 compared to the $794,727,173 administered for all projects focused on nutrition and early life. Total costs of all projects focused on nutrition and early life and projects addressing an early-life nutrition research gap by fiscal year are provided in **Table 1**. While total costs for all projects focused on nutrition and early life increased incrementally year-to-year from 2018 to 2020, the total costs for projects addressing any early-life nutrition gap decreased incrementally over the same time period (*P*-trend < 0.001).

The 235 projects addressing any early-life nutrition–related gap were coded to determine if they could address any of the 328 research gaps across FYs 2018–2020, as single projects addressed multiple research gaps (**Table 2**). Out of the 235 projects, 118 projects on complementary foods and complementary feeding were identified as the topic area with the largest contribution to addressing the research gaps. Research pertaining to complementary foods and complementary feeding encompassed $64,056,656 of total costs for FYs 2018–2020. Other research gap areas addressed frequently by projects were breastfeeding never versus ever (43 projects) and frequency of eating (35 projects). Research gap areas with the fewest number

TABLE 2 Number and total costs of research projects addressing an early-life nutrition research gap by topic and fiscal year (2018–2020)

Early-life nutrition research gap topic areas[1]	Number of projects				Total costs			
	2018	2019	2020	2018–2020	2018	2019	2020	2018–2020
Beverage consumption	2	4	2	8	$634,787	$1,466,332	$1,170,033	$3,271,152
Breastfeeding duration	9	6	14	29	$2,868,226	$3,410,986	$5,111,942	$11,391,154
Breastfeeding intensity, proportion, amount	3	6	9	18	$694,786	$2,213,919	$2,877,793	$5,786,498
Breastfeeding never vs. ever	15	14	14	43	$6,998,279	$6,997,112	$6,008,240	$20,003,631
Complementary foods	52	38	28	118	$26,016,055	$23,446,264	$14,594,337	$64,056,656
Dietary patterns	6	6	7	19	$1,724,235	$1,633,992	$4,355,371	$7,713,598
Folic acid supplementation	2	2	4	8	$769,981	$364,068	$2,136,087	$3,270,136
Frequency of eating	10	6	19	35	$2,659,779	$3,476,484	$7,187,938	$13,324,201
Iron supplementation	1	2	1	4	$56,031	$288,203	$185,564	$529,798
Maternal diet of food allergens	1	2	3	6	$241,666	$764,250	$1,289,071	$2,294,987
Omega-3 fatty acid supplementation	10	7	12	29	$6,317,419	$2,997,353	$6,927,169	$16,241,941
Seafood consumption	1	1	3	5	$1,194,780	$927,100	$2,392,410	$4,514,290
Vitamin D supplementation	2	2	2	6	$1,715,830	$201,324	$294,503	$2,211,657

[1] Depending on the scope, a project could address multiple early-life nutrition research gaps and were coded as addressing multiple topic areas. As a result, totals in the table for number of projects may exceed 235 projects and total costs may exceed total costs for grants filling any early-life nutrition gap described elsewhere in the article.

of projects were iron supplementation (4 projects), seafood consumption (5 projects), and maternal diet food allergens (6 projects).

Funded projects addressing a research gap were primarily funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ($n = 93$, 40%), followed by the National Institute of Diabetes and Digestive and Kidney Diseases ($n = 47$, 20%) (**Supplemental Table 2**). Funded projects addressing a research gap were spread among NIH activity codes. Most projects across the 3 FYs were R01 (105, 45%), as R01s are the most frequent award mechanism the NIH uses (**Supplemental Table 3**).

Results from the iSEARCH tool were developed into a FoamTree visualization created with labeled clusters representing the topics within the project titles, abstracts, and/or public health relevance. **Figure 1**A was created from 1632 projects that were eligible for screening and Figure 1B was created from the 235 projects that were coded as having potential to address a research gap within 1 of the 13 early-life nutrition dietary research gap topic areas. Similar topics appeared in both visualizations, including fetal growth, weight gain, breast milk, gestational diabetes, and gut microbiome. Differences among the top 7 areas were also noted within the visualizations. The visualization showing all projects focused on nutrition and early life had the topic themes of "childhood obesity" and "other topics" included within the top 7 most prevalent. Meanwhile, the visualization showing only projects addressing an early-life nutrition research gap has themes of "fatty acids" and "preterm" included within the top 7 most prevalent.

Discussion

The present study details a cross-sectional analysis of the NIH research grant portfolio of early-life nutrition research to determine if recently funded proposals address the major research gaps identified in the *Scientific Report of the 2020 Dietary Guidelines Advisory Committee*. The majority of identified projects (>85%) did not address an early-life nutrition–related gap identified by the DGAC. This analysis demonstrates an opportunity for more nuanced investment in maternal and child nutrition research focused on pregnancy, lactation, and infant and toddler diet during the B-24 life stage. This will directly support the development of effective, evidence-based dietary guidelines to improve nutrition-related public health outcomes. To advance research efforts that directly address the gaps in areas of maternal and child nutrition requires synergistic collaboration between funding agencies, such as the NIH, and extramural investigators to generate research proposals that highlight the aforementioned research gaps.

As the NIH is a multidisciplinary agency that promotes research efforts across various health and medical topic areas, there are a number of worthy research targets and a limited supply of resources. The NIH institutes and centers must determine the appropriate balance of resources among the many activities they fund. As part of the first NIH-wide strategic plan for nutrition research, one of the strategic goals was to define the role of nutrition across the lifespan (12). Pregnancy, infancy, and toddlerhood were identified as developmental periods that have been particularly understudied. This analysis has identified specific topics that have both been identified by the DGAC as important and also remain underfunded. Increasing research funding in these areas would allow for greater advancement towards the strategic goal of understanding the developmental origins of health and disease.

Although female representation has increased in clinical trials (13), there remains a paucity of research directly targeting pregnant and lactating individuals (14). Recruitment of participants may pose challenges as pregnant and lactating individuals may be apprehensive to participate in research opportunities (15). Once individuals are recruited, there are additional challenges for investigators to overcome when conducting research in infants and young children resulting from inconsistent definitions of infant feeding and potential self-reporting biases (16). In combination, these challenges may deter investigators from pursuing research within these vulnerable populations. However, research is pivotal to the advancement of dietary recommendations to support adequate nutritional status prepregnancy (i.e., even before conception for certain nutrients) to reduce the likelihood of nutrition-related deficits in utero, during pregnancy and lactation, and throughout early childhood.

Investigator-initiated projects will continue to be the major driver of progress in nutrition research. Investigators conducting research in early-life nutrition can strategically design and report on studies in a manner that allows for them to be included as part of the evidence base for the next iteration of the DGA (17). Conduction of randomized controlled trials (RCTs), non-RCTs, and prospective cohort studies is recommended as these study designs offer the strongest evidence to establish a relationship and are included in NESR systematic reviews (5, 18), although it should be noted that rigorously conducted observational studies can provide evidence that complements RCTs and may answer questions not typically examined in RCTs (19). Researchers proposing to conduct studies in this area should also include diverse populations that reflect the entirety and diversity of the US population with varying gender, race, ethnicity, and socioeconomic background. When examining dietary patterns, foods/food groups, beverages, and/or nutrients, researchers should prioritize the use of valid and reliable assessment methods, as well as standardized definitions when applicable. Researchers should also describe nutrient consumption in as great of detail as possible, including quantities, proportions, and frequencies of consumption, and measure and report confounders, mediating factors, and effect modifiers that have been speculated to impact dietary intake. In some cases, there may be a need for investigators to improve, validate, and/or create new assessment tools that can accurately assess dietary intake during the B-24 period. Last, research must also focus on the implementation of the new early-life nutrition guidelines

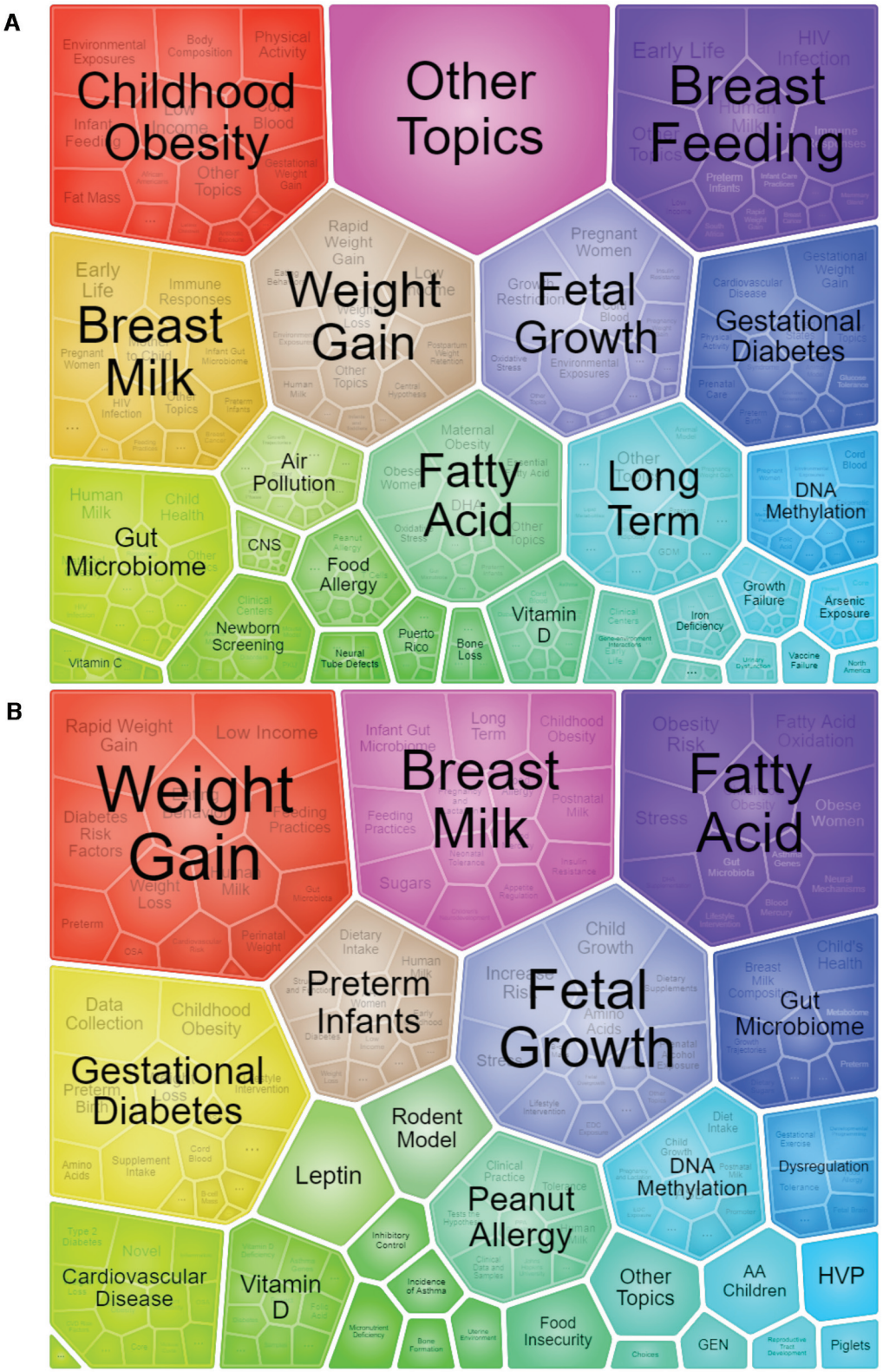

FIGURE 1 FoamTree visualizations created with labeled clusters representing the topics within the project's title, abstract, and/or public health relevance. (A) Created from 1632 projects that were eligible for screening. (B) Created from the 235 projects that were coded as having potential to address a research gap within 1 of the 13 early-life nutrition research gap topic areas.

and adoption of and adherence to the DGA by the public (20).

Limitations

It is important to acknowledge the limitations of this portfolio analysis. Although this analysis examined NIH-funded research, it does not reflect all the early-life nutrition research funded by non-NIH funding entities (e.g., foundations, USDA, CDC). Another limitation is that projects were identified through the RCDC coding system using key terms in which NIH staff are highly confident will encompass the projects of interest but acknowledge that there is error involved in qualitative assignment of topics to research projects. Additionally, the analysis did include research contracts (N-activity codes) and NIH intramural research (Z-activity codes) (11). The reporting requirements for these activity codes differ from that of the other activity codes, meaning there is a higher potential to miss N or Z activity codes that addressed research gaps as compared with other activity codes. While this project focused on the NIH-relevant research gaps identified during the DGA Scientific Review process, the DGAC also emphasized a great need for more investment in representative, surveillance data across early life in order to fully support dietary recommendations. The NIH is not the lead agency responsible for public health surveillance, but we do recognize that increased surveillance of nutrition in early life would lead to stronger DGA, aid with prioritization of research topics, and could identify new research topics that have high potential public health impact. Last, the coding relied primarily on the abstracts of the funded grants from only 3 FYs of NIH funding (2018–2020), which may not provide a complete picture of the scope of actual research being conducted. It is also unclear how much actual early-life nutrition research proposed in an application, which when completed, will need to meet the inclusion and exclusion criteria for the questions, in order for it be useful for the development of dietary guideline recommendations for this population.

Conclusions

An extensive body of evidence exists and continues to grow addressing the formative role of nutrition in pregnancy, infancy, and childhood. However, it is critical to further our understanding of these significant relations and fill known research gaps, particularly surrounding nutrition during preconception, pregnancy, lactation, breastfeeding practices (duration, intensity, proportion, and amount), the influence of various dietary components on infant development, and the role of prenatal nutrition in disease outcomes across the lifespan. This analysis highlights multiple opportunities for changes in the federal government investment in maternal and child nutrition research to support the development of effective evidence-based dietary guidelines for the betterment of early-life nutrition practices and overall public health.

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Data Availability

The data that support the findings of this study are available from AJV, upon reasonable request.

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