

Food Is Medicine Research Needs

Summary of Public Responses to the
National Institutes of Health Request for
Information

July 8, 2024



Nicholas J. Jury*, Rachel Fisher¹, Erin M cDonald¹, and Katrina Piercy¹

*Corresponding author: Nicholas J. Jury, PhD, Director of Legislative Affairs and Policy, Office of Nutrition Research, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892, Nicholas.Jury@nih.gov

¹Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services, Rockville, MD

Abstract

Reducing the burden of diet-related chronic diseases in the United States (U.S.) will require a broad range of actions, including Food Is Medicine (FIM) approaches that promote optimal health and healing and reduce disease burden by providing nutritious food—in conjunction with human services, education, and policy change—through collaboration at the nexus of healthcare and community. To guide development of effective strategies to advance FIM, more work is needed to understand how to best implement and sustainably integrate FIM activities within health systems and the community to improve nutrition and advance health equity. In 2023 the National Institutes of Health (NIH)—in collaboration with other U.S. Department of Health and Human Services (HHS) agencies, the U.S. Department of Agriculture, and the U.S. Department of Veterans Affairs—released a Request for Information (RFI) to gather information on FIM research opportunities and best practices for implementation. Respondents identified gaps related to intervention and implementation effectiveness, including how to scale and sustain initiatives, as important areas of priority. Additionally, developing common definitions for essential terms, identifying core program

components, and establishing key measurement domains to streamline comparisons across evaluation studies and expanding outcomes beyond clinical endpoints to include quality-of-life, behavioral and mental health, and community resilience were key themes identified in the RFI. As part of a new HHS FIM initiative to unify and advance collective action, HHS is committed to developing tools and resources informed by the RFI responses to foster research advancement and opportunities for greater alignment across sectors implementing FIM.

Introduction

Good nutrition is essential for health across the lifespan. Unfortunately, diet-related chronic diseases, such as type 2 diabetes and heart disease, are the leading cause of death in the United States¹ Food insecurity—which affected 44.2 million people living in food-insecure households in 2022—further exacerbates nutrition challenges and disproportionately impacts underserved communities.²

In 2022, the Biden-Harris Administration set a goal to end hunger and increase healthy eating and physical activity by 2030 so that fewer Americans experience diet-related chronic diseases. The

Administration also released a National Strategy on Hunger, Nutrition, and Health (National Strategy) that outlines actions the federal government will take to achieve this goal.³ Better integration of nutrition and health using Food Is Medicine (FIM) approaches is a key component of the National Strategy.

Following the release of the National Strategy, the United States (U.S.) Department of Health and Human Services (HHS) developed a FIM initiative in response to a congressional directive in fiscal year 2023 to unify and advance collective action. This directive called for the Secretary of HHS, in consultation with other federal agencies, to develop and implement a federal strategy to reduce nutrition-related chronic diseases and food insecurity to improve health and racial equity in the U.S. This includes diet-related research and programmatic efforts that will increase access to FIM programs and benefits. As part of this initiative, HHS is working collaboratively with federal partners and non-governmental organizations and communities to develop resources that can be used to advance FIM approaches across the country.

HHS describes FIM as a broad range of approaches that promote optimal health and healing and reduce disease burden by providing nutritious food—in conjunction with human services, education, and policy change—through collaboration at the nexus of healthcare and community.⁴ Approaches include a variety of food-based interventions to help prevent, manage, and treat diet-related chronic diseases. While FIM is not a new concept, there is increasing interest and efforts by a broader range of enterprises to advance these approaches. To guide development of a diverse approaches, more work is needed to understand how to best implement and sustainably integrate FIM activities within health systems and communities to improve nutrition and advance health equity.

As part of the larger HHS effort to unify and advance collective FIM action, the National Institutes of Health (NIH)—in collaboration with other HHS agencies, the U.S. Department of Agriculture (USDA), and the U.S. Department of Veterans Affairs—released a Request for Information (RFI) to gather information on FIM research opportunities

and best practices for implementation in April, 2023.⁵ The RFI listed 37 specific questions that were organized under five topic areas: (1) Research, (2) Provision of Services and Activities, (3) Community Outreach and Engagement, (4) Education and Training, and (5) Coverage for Services. A total of 141 respondents, representing academic institutions, healthcare organization, non-profit community-based organizations, professional associations, food manufacturers, producers, and growers, and individual constituents, provided comments.

This article is a high-level summary of the perspectives offered in response to the RFI's research-related questions.

What Are Considered High Priority Research Gaps and Opportunities for Food Is Medicine?

This question received the most responses (n=123) out of all questions posed in the RFI. Respondents identified gaps related to intervention and implementation effectiveness, including how to scale and sustain initiatives, as important areas of priority.

Intervention Effectiveness

Defining intervention effectiveness of FIM approaches and obtaining clarity about what measures or outcomes should be considered to evaluate success of FIM interventions from diverse perspectives (e.g., funders, recipients, service providers, and the community) were identified as critical needs. Respondents stressed the importance of assessing the effectiveness of interventions beyond clinical endpoints by including measures that evaluate quality-of-life and behavioral or mental health outcomes. Studying these outcomes could translate into better-tailored programs for specific populations and maximize the return on investment for funders. There is an opportunity for FIM to integrate traditional health impact with climate health metrics, regional economic health/wealth creation, and equity to tell the whole story of force multipliers for health.

Similarly, how to define intervention effectiveness of FIM initiatives as a preventive agent in diet-based diseases, such as type 2 diabetes, was also a priority identified. For example, FIM studies focused on individuals at risk for chronic disease (e.g., individuals experiencing overweight or prediabetes) would advance understanding of whether such interventions can reduce the likelihood of progression toward disease states.

Economic Implications

Limited data to quantify cost-effectiveness or cost neutrality of FIM interventions was identified as an important gap. Respondents stated that more comprehensive economic evaluations (e.g., healthcare cost implications in the short- and long-term) are necessary. These studies should assess the economic impact, return on investment, cost, and cost-effectiveness of different FIM models and interventions. More research is needed to empirically demonstrate that there are sustainable business models for health plans to expand their coverage beyond what is traditionally considered healthcare. Evidence that bolsters the cost saving implications of FIM interventions will encourage wider adoption, investment, and policy change. Commenters proposed comparing the cost-effectiveness of FIM interventions with alternative interventions, evaluating the implementation costs of FIM programs in diverse settings with diverse patient populations, and exploring potential economic benefits for communities.

Implementation

How best to implement FIM programs effectively was another high priority topic. The variation in populations, intervention intensity, duration, and distribution modalities make it difficult to compare the data and results from FIM research across studies. Several responses identified knowledge gaps regarding which programs work best for different populations; disease states (ranging from more common diseases such as cardiovascular disease or type 2 diabetes, to specific genetic diseases); potential variation across geographical regions; how interventions can be adapted to fit different settings; and assessing designs that could

become sustainably integrated into the care continuum.

Respondents highlighted the importance of embedding an equity framework into FIM research efforts. They also emphasized that an important aspect of FIM research should be to ensure that initiatives do not exacerbate disparities. This includes prioritizing equity of the individuals or communities that FIM initiatives reach; accessibility of and how resources are provided to individuals and communities; messaging and communication, including incorporating cultural context into FIM initiatives; education and training; and ensuring Medicaid and Medicare reimbursements can be accessed.

Commenters also stated that research should leverage implementation science to determine the scalability and sustainability of programs and activities, the requirements of individuals or groups participating in programs, and facilitators and barriers to participation and/or adherence. Variability in implementation strategies, program components, and participant characteristics offer an opportunity to understand which strategies and components are most effective in diverse settings and populations. Several comments indicated that the current lack of evidence regarding the feasibility of FIM interventions in underserved and low-income communities severely limits the impacts of this field. To ensure FIM is viable, communities in underserved locations must have the built environment supports necessary to access healthy food and resources. If this infrastructure does not exist, it is likely that FIM cannot be fully utilized by people with the greatest need.

What Is Needed to Address Key Research Gaps?

To address priority research gaps for FIM, commenters suggested developing definitions for essential terms, core program components, and outcomes.

The section below summarizes responses to the following questions: what short-term healthcare, quality-of-life, or patient-centered outcomes can be

most impacted by FIM services and for what populations and what are considered high priority research gaps and opportunities for FIM. Responses demonstrate significant overlap between the two questions indicating that outcomes of greatest impact overlap with the greatest research and knowledge gap areas. Major themes are reported below separately.

Outcomes of Greatest Impact

Outcomes related to equity (n=62), health measured through biometric indicators (n=39), mental and behavioral health (n=35), healthcare utilization and quality (n=24), and food insecurity or food availability (n=19) were of greatest interest to track in future FIM research endeavors. Responses emphasized the need to look at outcomes in underserved and low-income communities that may have higher rates of specific health conditions and limited access to healthy foods and emphasized the importance of prioritizing FIM interventions for individuals that have complex chronic health conditions and are members of marginalized communities.

Outcomes and Specific Populations

There was consensus across comments regarding the need to provide FIM interventions to pregnant women. Respondents further identified the critical nature of appropriate nutrition for the well-being of the pregnant parent and their child, both during pregnancy and after birth. Pregnant women with food insecurity are especially at risk of not meeting their nutritional needs and requirements. The following outcomes were specifically mentioned in relationship to FIM intervention outcomes: prenatal and postnatal (or postpartum), maternal and neonatal, pregnancy, birth outcomes, and fetal development. Other specific population groups with characteristics and/or needs aligned to FIM interventions identified included adults 65 and older, at-risk children, and individuals who are low-income or live in rural and urban settings.

Outcomes and Health State

Respondents provided a range of comments regarding the role of FIM interventions on general and specific health state or disease outcomes. Additional comments called for research evaluating links between nutrition and the relationship with

genomics, transcriptomics, metabolomics, and biometrics such as hemoglobin A_{1c}, body mass index, blood pressure, and markers of nutritional status and stress levels. Specific markers could include mitochondrial damage, micronutrient levels, blood glucose levels, Homeostatic Model Assessment for Insulin Resistance (degree of insulin resistance), and atherosclerosis. There was consensus regarding the need to further study the human microbiome including its composition, the impact of different diets on the microbiome, and its effects on whole-body health.

Healthcare Utilization and Quality

Respondents provided considerations of healthcare utilization and quality of healthcare as related to FIM services.

Reduced and Improved Healthcare Use Related to Measurement of FIM Interventions

Outcomes raised as important to measure in FIM interventions include:

Reduced use:

- Hospital admissions/re-admissions
- Emergency department visits
- Reduced days in hospital (following surgery)
- Nursing home admissions

Increased or improved use:

- Engagement in preventative services (e.g., primary care, mental health, behavioral health, obstetrics, gynecology)
- Adherence to scheduled health appointments
- Compliance with medical recommendations
- Quality of care/healthcare quality

Quality of Life and Behavioral Health

Respondents suggested that prioritizing quality-of-life and self-reported behavioral or mental health outcomes were associated with better-tailored programs for specific populations and maximizing return on investment. Recommended outcomes to track the connection between behavioral health and mental health disorders with FIM initiatives include self-reported depression, stress and anxiety reduction, improved mood, level of socialization, social isolation, and loneliness. Respondents recommended measuring the benefit of interventions

on financial status and associated stress levels. There was a consensus that improved financial status may reduce stress levels, enhancing overall health. Financial stress and debit/credit stability were noted as potential measures.

Quality-of-life measures include:

- Productivity outcomes: decreased loss of work and absence from school, increased productivity and work-life balance, improved rates of school graduation, and improved rates of job placements.
- Perceived self-empowerment outcomes: self-confidence, self-worth, and self-efficacy; ability to connect goals and priorities to lifestyle choices; the power of choice; and self-rated health.
- Perceived quality of life outcomes: physical well-being, energy levels, and satisfaction with life.

Outcomes and Food Security

Respondents stated that underserved and low-income communities often have higher rates of food insecurity and that the health effects of FIM are more pronounced among those with limited access to adequate and/or healthy foods.

Commenters indicated that further research is needed to understand the impact of food insecurity on health outcomes through various study designs. They also recommended studies of the effectiveness of different interventions intended to address food insecurity. Most respondents were particularly interested in the need to research the intersection of the social determinants of health and food accessibility and availability. Specific measures of associated outcomes were identified and included the purchase of food and vegetables as well as the Hunger Vital Sign Screening⁶ and USDA Food Security screening modules⁷.

Several comments indicated that the current lack of evidence regarding the feasibility of implementing FIM interventions in underserved and low-income communities severely limits the positive impacts of this field.

Participant Engagement and Preferences

Effectiveness of program engagement strategies should be assessed to understand preferences that will improve FIM interventions. Research is needed to better determine trends among different types of participants and their preferences for nutrition education modalities, coaching, and meal delivery services, as well as preferences for different types of food products and meal provision options.

Respondents raised the importance of community engagement and qualitative research to better understand factors that influence member decision-making and nuances in intervention design preferences. This should be complemented by quantitative research to evaluate the effectiveness of different interventions in meeting health needs and impacting health outcomes.

Cultural Food Values and Access

Comments emphasized the inclusion of culturally appropriate foods as central to FIM interventions. The limited research on traditional foods can inhibit the acceptability of FIM interventions, especially for high-risk populations who may also have cultural preferences and values associated with food. Responses acknowledged that nutritious, traditional foods are often replaced in American diets with lower-cost, easily accessible, ultra-processed foods.

Education

Commenters identified the specific need for education in children and young adults related to nutrition and food preparation, such as through teaching kitchens. Measurable outcomes for education include participants' attitude toward food and cooking, measurement of basic cooking skills, and food literacy.

Food Systems

Respondents identified the important role of the food environment on health outcomes and underscored the impact of societal messaging and community practices on food choices and culinary skills. Additional comments indicated that family and household behaviors and intergenerational communication affect food preferences and that

there may be a strong benefit from behavioral interventions to influence food selection. Furthermore, respondents indicated that there is an opportunity for FIM activities and related measures to incorporate consideration of the broader food system. Multiple respondents indicated the importance of measuring prevalence/participation of community farms and small growers, food system values, and operational qualities relevant to the food supply to build the social support for bolstering local economies.

Structural Considerations

Several respondents identified gaps in the research methodologies employed to understand FIM interventions. Many comments highlighted the importance of embedding an equity framework to guide all research efforts as well as the inclusion of factors such as economic empowerment, financial acumen, and mental health. Commenters wanted to see more funding for research that promotes economic security, including research that employs multidisciplinary approaches to understand complex relationships in the context of FIM.

While there is recognition of a robust evidence base, respondents recognize the need to further strengthen the evidence by diversifying experimental designs. The paucity of rigorous experimental designs and the abundance of observational studies hinder the ability to determine causation for various areas of interest and the effectiveness of programs and interventions. Additionally, many studies focus on short-term outcomes, limiting the understanding of the long-term effects of behavior change or FIM programs.

Study Design

Commenters provided a range of suggestions for study design. Commenters noted the need for comparative studies, including but not limited to studies that look at the effectiveness of nutrition interventions and current medical practices or compare different program delivery methods. Several commenters specifically mentioned the need for mixed-method approaches, including qualitative and quantitative studies, and short and long-term studies (i.e., longitudinal studies). Several

commenters also called out the need for randomized controlled trials, which could be used to evaluate different FIM approaches across different needs and populations. Mathematical models and structural equation modeling techniques may also be used to evaluate cost effectiveness.

Data Infrastructure

Comments were clear that investigators and other interested parties seek additional data to inform FIM research. There is also a need for common data elements to be included in datasets and databases. A major theme reflected in the comments was the need for additional data, either through creating new datasets, modifying and increasing the interoperability of current databases, or through expanding access to restricted databases in a responsible manner. The consensus among respondents demonstrates that data infrastructure is an important consideration for FIM future research. Commenters also identified open-source data, comprehensive of diverse participants, as a research imperative. Suggestions for improving FIM researchers' data access included building a data-sharing platform and making existing datasets publicly available, specifically those created by the funding sources that collect and monitor data for FIM services. Metrics collected regularly during routine medical care can be used to conduct modeling of outcomes for FIM services, including patient and cost outcomes. This data collection may be especially beneficial to longitudinal research, meta-analyses, or systematic reviews across different population levels (e.g., population, cohort, and individual level).

There was consensus within the comments regarding the need to establish data infrastructure and sharing across the various repositories and platforms where FIM datasets are stored. Commenters indicated that democratizing access to datasets is integral for supporting the outcome of FIM activities and for gaining support from healthcare professionals and policymakers alike.

Common Metrics and Data Elements

Establishing a set of common metrics and data elements will bolster data analysis by ensuring that datasets adhere to the FAIR principles: findable,

accessible, interoperable, and reusable. Furthermore, establishing common data elements provide a strong foundation for supporting FIM-related activities. Respondents noted that the FIM field is currently fragmented, with a lot of redundancy, and suggested that [the government] strive to rectify these issues.

Research Partnerships

A significant number of comments centered on the importance of including communities in the research process. Several commenters advocated for more community-based participatory research efforts. Others called for studies determining “spill-over” effects of FIM interventions beyond participants to their households, families, and communities. Commenters were particularly interested in partnerships with community-based organizations and elevating the voices of the community in feasibility studies. Commenters indicated that incorporating communities into the research process can improve the scalability and sustainability of FIM interventions.

Next Steps

The robust response to the NIH request for information on dimensions of FIM research illustrates a growing urgency for greater alignment and collective learning to advance FIM research and practice. There is an extensive body of research demonstrating the link between diet and overall health. Yet, for myriad factors, most Americans do not meet the recommendations outlined in the Dietary Guidelines for Americans and are therefore not consuming a dietary pattern aligned with positive health outcomes.⁸ As such, the research gaps identified in response to the RFI are not related to whether healthy foods can prevent or manage chronic diseases, but rather how to include the provision of healthy food more directly in healthcare models to ensure that individuals facing health challenges directly related to a lack nutrition security or diet-related chronic disease have access to the foods that can positively impact their health.

As was identified in the responses, there are key areas of research in the FIM space demanding immediate focus that will support alignment and

collective advancement. These include developing common definitions for essential terms, core program components, and key measurement domains to streamline comparisons across evaluation studies; conducting studies to evaluate comparative-effectiveness and cost-effectiveness across prioritized populations, outcomes, and settings; expanding outcomes beyond clinical endpoints to include quality-of-life, behavioral and mental health, and community resilience; and determining the scalability and sustainability of programs and activities. These gaps also align with those identified in recent analyses conducted the Aspen Institute and the American Heart Association.^{9,10}

As the field of FIM research rapidly accelerates, aligning efforts to mitigate duplication and overlap, foster comparisons, and collectively advance the science will support more reliable conclusions. Through the HHS Food Is Medicine Initiative to unify and advance collective action, we are committed to supporting and fostering research advancement through the creation of priority measurement domains, a map of federal resources, and opportunities for greater alignment across sectors implementing FIM.

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Acknowledgments

The authors would like to acknowledge Christopher Lynch, former Acting Director of the National Institutes of Health (NIH) Office of Nutrition Research (ONR), for his leadership in the conception, development, and collaboration that led to the publication of this interagency request for information (RFI).

The authors are grateful to Christina Deuschle, Zahra Ehtesham Cecelia Garcia, and Kelli Goggans, for their analysis of the responses to this RFI.

The authors would also like to acknowledge the vital contributions of the staff from the following agencies, departments, and offices: Administration for Community Living (ACL); Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); Centers for Medicare & Medicaid Services, (CMS); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Indian Health Service (IHS); NIH: National Center for Complementary and Integrative Health (NCCIH), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute on Aging (NIA), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Mental Health (NIMH), National Institute on Minority Health and Health Disparities (NIMHD), Office of AIDS Research (OAR), Office of Disease Prevention (ODP), Office of Dietary Supplements (ODS), Office of Nutrition Research (ONR), Office of Research on Women's Health (ORWH), Tribal Health Research Office (THRO); United States Department of Health and Human Services (HHS): Office of the Assistant Secretary of Health (OASH), Office of Disease Prevention and Health Promotion (ODPHP); United States Department of Agriculture (USDA); United States Department of Veterans Affairs (VA).