

## ASN Response to the NIH Request for Information: Food is Medicine Research Opportunities

Responses to this RFI must be submitted electronically using this form. Fields are available for each question. Text can be directly typed into these fields or “cut and pasted” from another electronic document. **Note, it is not necessary to address each question/item.**

### Information Requested

#### OPTIONAL

This space can be used to provide any optional introductory remarks or information.

The American Society for Nutrition (ASN), a professional nutrition science organization with 8,500 members from more than 100 countries, appreciates the opportunity to respond to the NIH RFI on Food is Medicine Research Opportunities. ASN urges the NIH to support Food is Medicine (FIM) research initiatives with new funding whenever possible, rather than redirecting funds from ongoing basic or applied nutrition research once the NIH takes action to implement this RFI into next steps.

ASN also urges the NIH to develop a consensus definition for the term Food is (as) Medicine and better define the programs, services, and scope of what will be included under the FIM umbrella before supporting research in this area. Because of the lack of an agreed upon definition for FIM, understanding of the phrase differs based on the context in which it is used. For example, the term could refer to maintaining health, treating disease, or both. The FIM definition could refer to the use of nutrition in the treatment or management of disease, the value of healthful dietary patterns in lowering risk for chronic diseases, or research on specific bioactive compounds found in foods. FIM should be interpreted in a way that understands and recognizes that food is not a drug, and its effects must be evaluated accordingly and appropriately. NIH may even want to consider changing the terminology to something such as Food as Health for this reason. Clear goals for FIM research studies should also be determined. FIM research can have a great impact on human health and help treat and prevent chronic disease. Therefore, research questions and goals and future funding should be clearly defined with ongoing monitoring and evaluation.

#### RESEARCH

- What are considered high priority research gaps and opportunities for Food is Medicine?

For current FIM programs, there is generally a paucity of randomized controlled trials (RCTs) that have been conducted, leaving important evidence on the sustainability and effectiveness of these programs with regard to long-term health outcomes lacking. Long term studies may be most important for illustrating the value that diet/nutrition interventions can have, although they are difficult to conduct and should include a dietary pattern focus rather than a reductionist approach. RCTs can infer causal relationships, but it is often difficult to assess chronic disease endpoints with RCTs due to the duration of study required and consequent costs. Shorter duration RCTs complemented by longitudinal cohorts designed to address validated endpoints considered in human trials and cohorts may be needed. This important evidence base is necessary for translation and application of scientific evidence into implementation of successful FIM initiatives and

policy changes. While likely to be effective in the short-term, the long-term implications of many FIM interventions, including any adverse health events, are currently largely unknown. Data is needed to help understand which of the many FIM options are most effective and how best to combine certain FIM options with existing programs, including federal nutrition assistance programs. As states explore and implement Medicaid waivers for FIM projects, well-defined research and evaluation should be planned and incorporated from the outset.

Preventable chronic diseases, including heart disease, cancer, and diabetes, are the leading causes of death and disability in the U.S. and the leading drivers of the nation's \$4.1 trillion in annual health care costs<sup>1</sup>. There is the opportunity to provide FIM food and nutrition interventions before pharmaceutical interventions, potentially saving millions of dollars in health care expenses every year. While many FIM initiatives focus on improving nutrition-related diseases and conditions, we should not ignore dietary interventions and counseling as an effective preventive measure to lower chronic disease risk.

FIM research must continue to include a focus on inclusivity, diversity, equity, and accessibility (IDEA). The inclusion of underrepresented groups/communities in FIM research, both as participants and individuals performing the research, is essential. An important aspect of FIM research should be to ensure that initiatives do not widen disparities, but rather narrow them. 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; ensuring Medicaid and Medicare reimbursements can be accessed; and more. Efforts should continue to focus on increasing the inclusion of underserved populations with health disparities in the field of nutrition and dietetics. Representation and building trust among patients and community is key in creating FIM programs that support underserved populations. IDEA should be part of the framework for FIM programs with the intent to help narrow the gap between underserved populations that are at higher health and nutritional risks. FIM research should also consider working and partnering with groups that have these established relationships to ensure that the needs of underserved communities are prioritized and inclusive of their specific needs.

- What barriers currently hinder the ability to evaluate the impact of Food is Medicine services on health outcomes, health care utilization, cost of care across the life course, nutrition-based disparities, and recipient experience?

Determining the endpoints to be addressed by FIM initiatives is important before determining how outcomes and impacts can be evaluated and before being able to set metrics for evaluation. Again, clear research questions and goals are necessary to determine how best to evaluate outcomes. Since there is no set standard provision of service for FIM, it is not currently possible to compare and evaluate across different

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<sup>1</sup> <https://www.cdc.gov/chronicdisease/about/costs/index.htm>

sites/areas. A central database of FIM programs in the future could make evaluation more feasible.

A potential barrier might be the fact that dietary interventions may differ in impact compared to drug interventions; consequently, FMI effects on chronic disease outcome or other endpoints must be evaluated accordingly and appropriately, and not based on a drug model. Systematic reviews and meta-analyses often note significant effects due to dietary interventions, but the odds ratios are typically small compared to drug interventions. Linking food to medicine may suggest comparable impacts to pharmaceutical interventions, but more realistic and relevant standards for food-based interventions must be developed. In addition, dietary interventions such as effective dietary patterns may affect multiple metabolic factors to varying degrees and this needs to be considered and accounted for in research designs. Dietary interventions also typically require long-term exposure to have significant impact and often are improved based on additional lifestyle changes.

Another potential barrier to evaluation may be the many touch points within the built environment that impact FIM interventions and recipients, including how and where they shop, transportation to shop and get medical care, food and medical provider access, healthcare coverage and cost, and more. A collective public health approach is needed to ensure all touch points reinforce FIM initiatives and can be evaluated to determine their joint impact on FIM initiatives and resulting health outcomes, including nutrition-based disparities.

- What short-term health care, quality of life or patient-centered outcomes (e.g., quality of care, disease-specific biometric measures, symptom and side effect management during treatment, engagement in preventive services such as primary care, mental health, behavioral health, and obstetrics/gynecology care, prenatal and postpartum outcomes in parent-child dyads, utilization, cost, etc.) can be most impacted by Food is Medicine services and for what populations (e.g., urban, rural, pregnancy, children, underrepresented, underserved populations with health disparities)?

One potential population that may benefit greatly from FIM services includes pregnant individuals with gestational diabetes who are enrolled in Medicaid. These individuals do not currently have medical nutrition therapy as part of their care plan. Increasing medical nutrition therapy access for these individuals, combined with nutrition education and the ability for select or receive more nutritious foods / meals as part of a FIM initiative will better support their health and the baby's health while receiving appropriate medical care and monitoring for gestational diabetes. This type of collaboration can help increase access to care, adequate nutrition and support.

- Are there technologies such as machine learning and AI that can be combined with electronic health records to better utilize healthcare administrative data for use in site-specific or health system Food is Medicine research?

Barriers to accessing electronic health record data should be identified and dealt with before AI/ machine learning can be applied to FIM research to ensure all privacy protections are in place.

- Are there any existing data sets, common data elements, or metrics that could be used for meta-analyses or systematic reviews that seek to assess research on Food is Medicine health and social outcomes?
- What environmental, cultural, social, and mental health aspects influence health, quality of life or patient-centered outcomes of Food is Medicine?
- What are the cost/benefits and/or cost/effectiveness of a Food is Medicine approach relative to other health care strategies to improve long-term health, especially in populations who experience health disparities?

As mentioned above, determining the endpoints to be addressed by FIM initiatives will help to determine cost/benefits and/or cost/effectiveness for various FIM approaches.

- What models exist or can be developed or adapted to test the cost/benefits and/or cost/effectiveness of Food is Medicine strategies for health?
- What type of analysis is needed to assess the relative merits and challenges of differing Food is Medicine strategies? In what context do the various strategies work best?
- What online grocery or online meal delivery systems have propriety data that could be shared to better address Food is Medicine research gaps?

## **PROVISION OF SERVICES AND ACTIVITIES**

- What strategies are needed for populations with varied functional capabilities (e.g., ability to open a package, chew); housing supports (e.g., access to refrigeration or cooking utensils); or transportation (e.g., ability to access or receive food – delivery to a secure high rise or rural locations)?
- What are best practices and/or lessons learned for providing Food is Medicine services? (e.g., best practices in planning/designing programs; creating awareness and sustaining engagement- directly with intended recipients and indirectly with influencers; fulfillment/delivery; evaluation; and the identification of individuals to be served by these programs, other implementation challenges and how those challenges were overcome, if applicable)?
- What are examples of needed staffing and resources (e.g., information technology, electronic health record coding, IT systems, contractual vehicles, payment mechanisms, vendors/food retailers, CPT codes, etc.) for various types of Food is Medicine interventions across health systems and community-based organizations?

- What are examples of needed staffing (e.g., screening, refer/follow-up, and fulfillment) for various types of Food is Medicine interventions?
- How may Food is Medicine services be combined with other food assistance, nutrition and health education, and health care services (e.g., social services, meals on wheels, Community Health Workers, care transitions case management, etc.) to improve engagement and affect health outcomes?
- How may Food is Medicine services leverage ongoing nutrition education and existing nutrition assistance and access programs (e.g., WIC, SNAP, NSLP, VA Teaching Kitchens, etc.)?
- In what ways can Food is Medicine services be used to address nutrition disparities and unequal access to nutritional foods?

### **COMMUNITY OUTREACH AND ENGAGEMENT**

- What are key strategies for community engagement and outreach, or obtaining local community input from those with lived experience or organizations that provide direct Food is Medicine or related services to persons with hunger and food insecurity, populations who experience health disparities, or other health-related social needs?
- How can health care organizations work effectively with community-based organizations and programs to adequately resource community-responsive approaches for Food is Medicine implementation and research?
- How might Food is Medicine programs integrate a culture is medicine approach that incorporates cultural foods and food practices (e.g., Indigenous gathering, hunting, and agricultural food practices)?
- What issues may arise in a community-living setting, high-rise building, food deserts, rural locations, or other unusual community living settings that may influence Food is Medicine research interventions?
- How may community issues influence interventions or changes within health care settings?
- How can we respectfully include knowledge to enhance Food is Medicine research, services, and activities for American Indian and Alaska Native food and Tribes?
- How do some Food is Medicine research interventions yield spillover benefits for the intervention community, such as supporting local agriculture?
- How may agricultural programs and health care organizations work effectively to center power within communities, and individuals in advancing Food is Medicine as a practice?

## EDUCATION AND TRAINING

- What training is needed for health care providers (e.g., physicians, nurse practitioners, nurses, physician assistants, dentists, pharmacists, registered dietitian nutritionists, doulas, etc.) to successfully use and disseminate Food is Medicine services and information services?

Nutrition education and training is critical for health care providers to successfully provide FIM interventions after FIM definitions, goals, and research has been conducted to support this education and training. FIM research to develop innovative, inclusive teaching and training methods should be prioritized. Adequate nutrition education and training should be provided to every member of the health care team, including awareness of important FIM-related community resources and how to help patients receive access to these resources. Members of the care team should have enough nutrition education to know when it is vital to refer a patient to a registered dietitian nutritionist (RDN) on the care team for targeted, expert nutrition interventions. RDNs should be an essential part of every FIM health care team to provide appropriate dietary counselling and behavior change therapy to accompany FIM interventions aimed at treating patients that include the provision of prescription/medically tailored foods and meals. Increased nutrition education in medical and dental schools is of utmost importance for effective translation, so that health care providers feel competent and comfortable addressing FIM with diverse patient populations. IDEA training to ensure messaging and communications that accompany FIM initiatives with cultural context should be included as well.

- What training is needed for community health workers, federally- and community-funded food and meal program staff (e.g., Older Americans Act Senior Nutrition program staff, 2-1-1, social service intake, referral and benefits counseling staff, food banks, etc.), and nutrition and health education staff to successfully use and disseminate Food is Medicine information or to successfully operate in or advance the Food is Medicine space?

Nutrition education and training must be a critical component of all FIM interventions, including food preparation and cooking classes provided by community health workers, federally- and community-funded food and meal program staff, and nutrition and health education staff when items such as food boxes are part of the FIM initiative. Awareness of important FIM-related community resources and how to help recipients access these resources should be part of any training and education for community health workers, federally- and community-funded food and meal program staff, and nutrition and health education staff. IDEA training is important for community health workers, federally- and community-funded food and meal program staff, and nutrition and health education staff to ensure messaging and communications with cultural context accompany FIM initiatives. Community health workers, federally- and community-funded food and meal program staff, and nutrition and health education staff should know when to refer FIM recipients to health care providers, including RDNs, for dietary counseling or other more targeted nutrition interventions.

- What training is needed for Cooperative Extension professionals to successfully advance the Food is Medicine initiatives?

Cooperative Extension professionals should be well versed in nutrition education and training to provide recipes, food preparation and cooking classes, and provide train-the-trainer services that they can pass on to FIM recipients, providers and community members. Cooperative Extension professionals should have awareness of important FIM-related community resources and be able to help recipients access these resources. IDEA training for Cooperative Extension professionals will ensure messaging and communications with cultural context accompanies FIM initiatives. Cooperative Extension professionals should know when to refer FIM recipients to health care providers, including RDNs, for dietary counseling or other more targeted nutrition interventions.

- What training/education is needed at individual, family, and community levels (including K-12, colleges, and universities) to increase knowledge of Food is Medicine throughout the lifecycle for all Americans to reduce diet-related diseases and disparities?

Nutrition education at individual, family, and community levels (including K-12, colleges, and universities) to help consumers understand the linkages between food choices and health will encourage prevention of diet-related chronic diseases and improve health of the American public. ASN's online course, [Nutrition Essentials](#), is an excellent tool for this type of basic nutrition education.

## COVERAGE FOR SERVICES

- How can federal, healthcare, philanthropic, and other funders effectively collaborate to support implementation of these programs (we are interested in strategies for innovative financing arrangements such as value-based payment and braiding together of funding sources as well as better understanding of how services and service components are priced)?
- What dietary interventions or specialized diets are most frequently required by persons who receive Food is Medicine programs, or who might be anticipated to need Food is Medicine programs? How are individual needs accommodated, and which interventions are more or less likely to implement individualized meals, programs, or food items?
- Are there any data sets, common data elements, or metrics that could be interrogated through evidence scans and systematic reviews to help synthesize and disseminate research and increase connections between health plans (payers) that invest in Food is Medicine?
- What types of reimbursement strategies exist and what approaches hold promise for nationwide scaling for Food is Medicine services within health care, state and local governments, and community-based entities?

- What are key milestones, data elements, continuous quality improvement (CQI) processes, or deliverables that could be tracked to measure implementation (acceptability, reach, fidelity, maintenance, cost) to ensure success of Food is Medicine programs?
- What measures or outcomes do you use or should be considered to evaluate the success of Food is Medicine from the perspectives of funders, recipients, service providers, and the community?
- What are the optimal methods to evaluate the success of Food is Medicine programs including measures to determine return on investment (i.e., an ROI calculator)?

#### **ADDITIONAL COMMENTS**

- Are there any additional comments that you would like to share about Food is Medicine services and activities?

One of ASN's ongoing areas of interest related to Food is Medicine is the need for a usable regulatory framework for foods for special dietary uses and medical foods. While foods for special dietary uses, medical foods, and dietary supplements are regulated by the FDA, ASN encourages the NIH to support interagency efforts to clarify the meaning of FIM, and to update related terms, programs, and services and their regulation based on that definition. A well-constructed regulatory framework for reviewing claims that a nutritional product can be used to treat, manage, or mitigate chronic diseases (and not just reduce risk) might also help to encourage research in the FIM space. Research on the efficacy and safety of dietary supplements, medical foods, and foods for special dietary uses should be encouraged as well.