

AHA PRESIDENTIAL ADVISORY

Food Is Medicine: A Presidential Advisory From the American Heart Association

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ABSTRACT: Unhealthy diets are a major impediment to achieving a healthier population in the United States. Although there is a relatively clear sense of what constitutes a healthy diet, most of the US population does not eat healthy food at rates consistent with the recommended clinical guidelines. An abundance of barriers, including food and nutrition insecurity, how food is marketed and advertised, access to and affordability of healthy foods, and behavioral challenges such as a focus on immediate versus delayed gratification, stand in the way of healthier dietary patterns for many Americans. Food Is Medicine may be defined as the provision of healthy food resources to prevent, manage, or treat specific clinical conditions in coordination with the health care sector. Although the field has promise, relatively few studies have been conducted with designs that provide strong evidence of associations between Food Is Medicine interventions and health outcomes or health costs. Much work needs to be done to create a stronger body of evidence that convincingly demonstrates the effectiveness and cost-effectiveness of different types of Food Is Medicine interventions. An estimated 90% of the \$4.3 trillion annual cost of health care in the United States is spent on medical care for chronic disease. For many of these diseases, diet is a major risk factor, so even modest improvements in diet could have a significant impact. This presidential advisory offers an overview of the state of the field of Food Is Medicine and a road map for a new research initiative that strategically approaches the outstanding questions in the field while prioritizing a human-centered design approach to achieve high rates of patient engagement and sustained behavior change. This will ideally happen in the context of broader efforts to use a health equity-centered approach to enhance the ways in which our food system and related policies support improvements in health.

Key Words: AHA Scientific Statements ■ chronic disease ■ diet, healthy ■ food ■ food supply ■ health care costs ■ risk factors

Extensive research has demonstrated the link between nutrition and health. Overall, diet quality is low for many in the United States, which is a major driver of chronic disease and health inequities, especially among communities of color and those with low income.^{1–3} Although the elements of a healthy diet are well understood, it has been a significant challenge to get Americans to eat healthy diets. About 90% of Americans eat less than the amount of fruits and vegetables recommended by the 2020 to 2025 Dietary Guidelines for Americans.¹ US diets also typically include less than the recommended amounts of whole grains, beans, legumes, and low-fat or nonfat dairy and more than the recommended amounts of meat, sodium, saturated fats, refined grains, partially hydrogenated fats, and added sugar.^{4–6}

Low diet quality in the United States reflects a multitude of factors, 2 of which are food insecurity and nutrition insecurity. Food insecurity is defined as having insufficient access to enough food needed for a healthy, active life.⁷ Nutrition security is an emerging complementary concept that focuses more on the nutritional composition of available foods. The goal of nutrition security, as described by the US Department of Agriculture, is that “all Americans have consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being.”⁸

There is increasing recognition of the need to use food and nutrition interventions and policy to improve health. One approach is Food Is Medicine (FIM), or what some call Food as Medicine. As we use the term here,

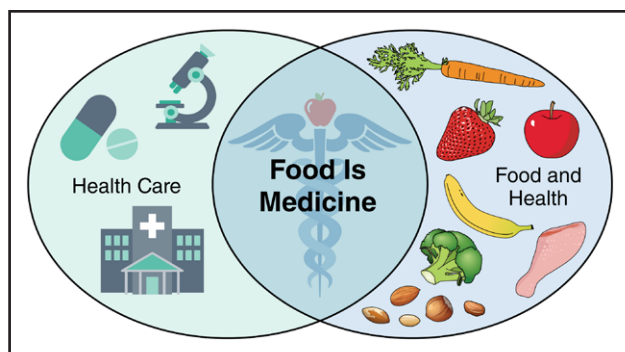


Figure 1. Food Is Medicine sits between the health care sector and food and health.

FIM is the provision of healthy food to prevent, manage, or treat specific clinical conditions in a way that is integrated with the health care sector (Figure 1).

Food plays important roles in communities through social cohesion, community development, and food justice and equity.⁹ Food also plays important roles in identity, reflects cultural heritage and tradition, and serves as a way to express and preserve ethnic, regional, and personal values, beliefs, and preferences.⁹ Furthermore, food plays important roles in society in terms of economic impact and environmental sustainability and through food policies and governance.⁹ These elements represent the broader context in which FIM must be designed and implemented, and they need to be considered for FIM to be accepted and effective in improving population health.

It is important to recognize that FIM is only one of several important ways to improve population health through food and nutrition policy and programs. FIM is complementary to, and does not replace, broader policies on public health nutrition; food marketing, advertising, and labeling regulations; nutrition standards; and other work that is done and should remain outside of health care. In general, more coordination between health care professionals and food and nutrition programs is likely to be beneficial. The possibility of impact is significant: An estimated 90% of the \$4.3 trillion annual cost of health care in the United States is spent on medical care for chronic diseases, and for many of these diseases, diet is a major risk factor.^{10–12} Thus, it is important to evaluate the potential of FIM as a cost-effective approach to improve health among patients with or at risk for diet-related medical conditions.

The literature on FIM and the broader literature on the relationship between diets and health highlight potential impact. The existing FIM evidence, however, is constrained by the limitations of an emerging field, including small sample sizes, nonrandomized comparisons, and broad differences in the intervention intensity, duration, food distribution modalities, and measurement tools tested, as well as differences in the incorporation of complementary intervention approaches such as lifestyle coaching. These factors and the small number of inter-

vention approaches tested in randomized trials preclude definitive conclusions on efficacy or effectiveness.^{14,15}

Both the potential of FIM interventions and the clear limitations of existing research present an important opportunity for coordinated scientific effort to study FIM. This American Heart Association (AHA) presidential advisory provides a rationale for why FIM interventions are important to investigate, gives an overview of FIM research, and describes the foundation for a new FIM initiative to be conducted by the AHA with support from the Rockefeller Foundation and other stakeholders. The initiative aims to establish definitive evidence on effective dose, duration, and intensity of FIM initiatives across diverse health conditions and populations, facilitating coverage decisions by public and private payers. We describe the importance of diet and nutrition to cardiovascular health and other health conditions, highlight unequal access to healthy food and nutrition education, provide a short history of FIM practice and research, review existing and ongoing FIM research, highlight persisting questions and gaps in the field, and suggest potential approaches to close those gaps. This is followed by a high-level description of the planned approach for the AHA FIM initiative, principles of research for the initiative, and efforts to consider concurrent with FIM research, before we conclude with a call to action.

IMPORTANCE OF DIET AND NUTRITION TO CARDIOVASCULAR HEALTH

Evidence from both observational studies and randomized controlled interventions indicates that achieving and maintaining heart-healthy dietary behaviors across the life course is a critical component of promoting cardiovascular health.^{16,17} Heart-healthy dietary patterns have also been linked to reduced risk of obesity, hypertension, dyslipidemia, and the metabolic syndrome.^{16,18} They are consistent with recommendations to prevent and treat type 2 diabetes, to maintain cognitive and kidney function, and to support a healthy gut microbiome.^{16,19}

Heart-healthy dietary guidance was first introduced by the AHA in 1961.²⁰ It has been periodically reviewed and revised as new data emerge, most recently in 2021.¹⁶ Although the diet literature is not always clear or consistent, the existing evidence is compatible with public guidelines. The 10 basic features of heart-healthy dietary patterns are summarized in Table 1 and illustrated in Figure 2. In general, heart-healthy dietary patterns contain primarily fruits and vegetables, foods made with whole grains, liquid plant oils, minimally processed foods, and healthy sources of protein (eg, plants, fish and seafood, low-fat or fat-free dairy products, and, if meat or poultry are desired, lean cuts and unprocessed forms). They also allow adjustment to achieve and maintain a healthy body weight across the life course. Dietary patterns consistent with these basic components tend to be low in

Table 1. Evidence-Based Dietary Guidance to Promote Cardiovascular Health

1. Adjust energy intake and expenditure to achieve and maintain a healthy body weight
2. Eat plenty of fruits and vegetables; choose a wide variety
3. Choose foods made mostly with whole grains rather than refined grains
4. Choose healthy sources of protein
a. Mostly protein from plants (legumes and nuts)
b. Fish and seafood
c. Low-fat or fat-free dairy products instead of full-fat dairy products
d. If meat or poultry are desired, choose lean cuts and avoid processed forms
5. Use liquid plant oils rather than tropical oils (coconut, palm, and palm kernel), animal fats (eg, butter and lard), and partially hydrogenated fats
6. Choose minimally processed foods instead of ultraprocessed foods*
7. Minimize intake of beverages and foods with added sugars
8. Choose and prepare foods with little or no salt
9. If you do not drink alcohol, do not start; if you choose to drink alcohol, limit intake
10. Adhere to this guidance regardless of where food is prepared or consumed

*There is no commonly accepted definition for ultraprocessed foods, and some healthy foods may exist within the ultraprocessed food category.
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salt (sodium), cholesterol, and added sugar; to have a high ratio of unsaturated to saturated fatty acid; and to meet essential nutrient requirements for most individuals. Because they are food based rather than nutrient based, they do not require estimating percentages or grams to ensure compliance with current specific recommendations. Emphasized in the 2021 statement is that heart-healthy dietary patterns are adaptable to personal preferences, ethnic and religious practices, and

life stages and are consistent with low environmental impact.¹⁶
Despite public guidance on the components of a healthy diet, population-level adherence to healthy dietary patterns remains low across the life course in the United States, with analysis of the What We Eat in America data set from the National Health and Nutrition Examination Survey 2017 to 2018 showing a population mean score of 58 (of 100) on the Healthy Eating Index–2015 diet quality measurement tool.²¹ This is especially true among those who experience food insecurity and tends to vary across the life span, highlighting the importance of testing various approaches to changing dietary patterns to improve health.^{1,22}

CHALLENGES TO CONSUMING A HEALTHY DIET

Diet quality in the United States falls far short of recommendations for many reasons.
First, elements of the existing food system make acquiring and consuming healthy foods difficult for many people.²³ Over time, the food system has been geared increasingly toward harnessing economies of scale to maximize production and minimize cost of the total quantity of food. In the US industrialized economy, subsidies have facilitated agricultural production geared toward producing cheap cereals and oils used by industry to meet consumer demand for highly processed products with long shelf lives and thus relatively low cost.²³ Many of these products come in the form of snacks and beverages containing high levels of sodium, refined grains, and sugars or large quantities of unhealthy fats. This contrasts with the US dietary guidelines, which emphasize fruits and vegetables, whole grains, varied proteins, and moderate amounts of dairy.¹

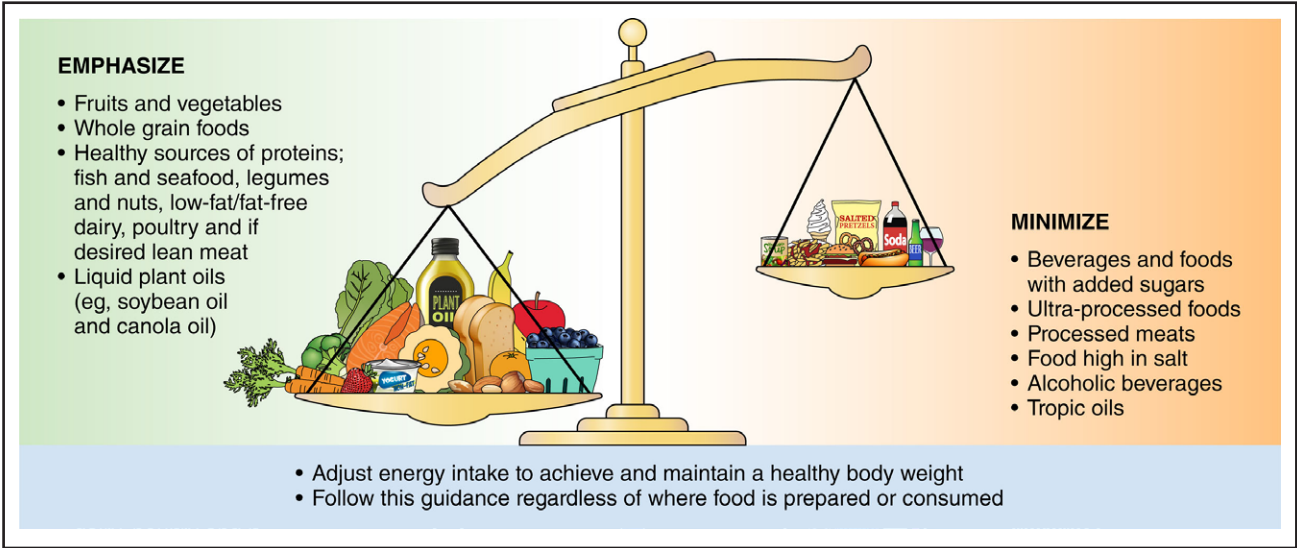


Figure 2. Evidence-based dietary guidance to promote cardiovascular health.
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Another challenge relates to the political economy of food. Prior research has demonstrated that the current food system has large power imbalances that affect food and nutrition policy.²³ Higher health and environmental costs of staple foods are not fully factored into food prices, making foods with these external costs less expensive than their true costs.²⁴ There are, in essence, a set of factors that mean people often have to “swim upstream” in their efforts to be healthy.

Another major challenge is the lack of systemic focus on improving food environments and the food system. In an AHA science advisory, the food system is defined as all of the processes and resources involved in producing, processing, distributing, preparing, and consuming food and is interconnected with food supply chains, farm production practices, food waste, natural resources, health, consumer behavior, food culture, social justice, and policies.²⁵ A healthy food system would promote and maintain nutrient-dense dietary patterns that optimize health.²⁶ Furthermore, a sustainable food system is defined as a food system that meets current population needs without compromising the needs of future generations. However, little systematic attention has been paid to creating a healthy and sustainable food system and research into and development of production of healthy foods. With few exceptions, taxes and financial incentives are not directed toward encouraging purchase of healthy foods, improving the healthfulness of local food environments in which people are enmeshed, or ensuring the health of children and future generations.²⁷ These challenges make consuming a healthy diet harder for many people. Structural racism and factors that contribute to poverty also mean that historically excluded people are overrepresented among those who suffer the consequences of poor-quality diets. Discrimination in the educational system and labor markets and weaknesses in income support policies mean that too many individuals in the United States experience worse social determinants of health, including food insecurity, housing instability, and lack of adequate transportation, all of which present important barriers to consuming a healthy diet.

These challenges help explain the broader context that has contributed to high rates of unhealthy diets in the United States. Although structural interventions to change the broader policy environment are important, FIM interventions focused on the level of the individual can potentially have a significant impact on the health of those who are adversely affected by diet-related conditions.

HISTORY OF FIM PRACTICE

Food has been used as a form of medicine throughout human history. In the era of biomedicine, an early example of a nutrient–disease relationship is the connection between what was later identified as vitamin C and scurvy.²⁸ Beyond such specific relationships, however, there

is a broader relationship among social conditions, poor nutrition, and poor health. For example, Rudolph Virchow identified links among poverty, nutrition, and health while studying a 19th century typhus outbreak.²⁹ In the 1960s, at a community health center in Mound Bayou, MS, Jack Geiger³⁰ and others provided social, educational, and economic services, including, controversially at the time, prescribing food to malnourished individuals. When those prescriptions were challenged by state officials, Geiger responded, “The last time I looked at my textbooks, the most specific therapy for malnutrition was food.”³¹

Contemporary FIM approaches developed along intersecting trajectories—one involving collaborations among health care payers, health care professionals, and community-based organizations (eg, medically tailored meals [MTMs], produce prescriptions) and another involving federal health and nutrition assistance programs (eg, Special Supplemental Nutrition Program for Women, Infants and Children [WIC]).

The community-based strand of FIM had origins in the HIV/AIDS epidemic. Organizations like Community Servings³² in Boston, God's Love We Deliver³³ in New York City, and Project Open Hand³⁴ in San Francisco emerged as philanthropic efforts to provide nutritional and social support for stigmatized individuals living with HIV/AIDS who had insufficient food to meet their nutritional needs. Today, such organizations, many participating in the Food Is Medicine Coalition,³⁵ provide evidence-based food and nutrition support to individuals with chronic illnesses, including cancer, chronic kidney disease, congestive heart failure, and diabetes.

More recently, collaboration between health care and community-based organizations to support FIM initiatives has been encouraged by shifts in health care financing. Moving from fee-for-service reimbursement toward value-based financing arrangements can provide incentives to address health-related social needs that influence health outcomes.^{36,37} This has been furthered by the Affordable Care Act, which required many health care systems to conduct community health needs assessments and pushed for community benefit spending beyond uncompensated care.³⁸ Goals of FIM programs have included improving food security and nutrition, diet quality, cardiometabolic health, and chronic disease management and lowering health care costs by reducing hospital readmissions or emergency department visits.^{39,40} Some health care systems have also sought to use FIM programs to increase trust of and engagement with their patients.

Among federal programs, multiple programs exist to address food insecurity and social justice, including the Supplemental Nutrition Assistance Program, Older Americans Act Nutrition Services Program, and WIC.^{41–43} WIC provides nutritious foods and related services for pregnant individuals and families with young children after certification of nutritional risk by a health care professional.⁴³ Although all these programs offer important

learnings on the challenges and potential benefits of food provision, WIC was a particularly important precursor of FIM programs now being developed and refined in that it requires a referral from a health care professional to enroll. Evidence demonstrating the benefits of WIC in terms of infant mortality, birth weight, diet quality, and childhood anemia clearly shows the effectiveness of the program.^{44–46} Furthermore, its coverage of 6 million⁴⁷ Americans annually also provides proof of concept in terms of creating a sustainable program that provides supplemental nutrition for individuals at elevated nutrition risk. Another federal effort is the Gus Schumacher Nutrition Incentive Program.⁴⁸ One important aspect of the Gus Schumacher Nutrition Incentive Program, intended as a collaboration between health care professionals and community-based organizations, is to provide produce prescriptions to Supplemental Nutrition Assistance Program beneficiaries.⁴⁹ The Gus Schumacher Nutrition Incentive Program also supports FIM implementation through the National Training, Technical Assistance, Evaluation, and Information Centers Program.

Both Medicaid and Medicare also have experience with FIM. Medicaid section 1115 waivers have allowed states, including Massachusetts, California, and North Carolina, flexibility to offer FIM within their Medicaid programs, with the specific benefits ranging widely from state to state.⁵⁰ The CHRONIC (Creating High-Quality Results and Outcomes Necessary to Improve Chronic) Care Act of 2018 also permitted Medicare Advantage plans to offer FIM to beneficiaries.⁵¹ In traditional Medicare, HR 5370, introduced in 2021, would allow piloting of MTM interventions, but this bill has not been passed or reintroduced to the floor at the time of publication.⁵²

CURRENT LANDSCAPE OF FIM RESEARCH

FIM interventions encompass an array of approaches, making it difficult to provide a succinct overview of the evidence.^{53–61} Fundamentally, a key distinction in intervention types lies in how a given intervention provides food resources, typically either as “cashlike” benefits that participants use to select healthy foods from retailers (eg, food vouchers or subsidies) or as “in-kind” benefits that provide foods selected by those delivering the intervention (eg, groceries or prepared meals; Table 2). A second point of variation among interventions is whether and how educational, lifestyle, or skill-building interventions are delivered, along with resource provision.

As summarized in a comprehensive evidence review by the Aspen Institute, most studies to date are pilot projects or are otherwise limited by small sample sizes, short duration, and a wide range of populations, exposures or interventions, and outcomes.⁴⁰ Overall, the existing evidence supports the promise of FIM but indicates that more rigorous scientific investigation aimed at over-

coming current evidence limitations is needed before definitive conclusions about the effectiveness of FIM interventions can be drawn.

In this section, we highlight some key findings on the current state of FIM research.

Cashlike FIM Interventions

The archetypical cashlike FIM intervention is a healthy food prescription program. Healthy food prescription programs provide subsidies, vouchers, coupons, or other ways to make healthy foods more available and affordable. They are typically conducted as partnerships between health care systems and food retailers, sometimes with a third-party coordinating organization.

As described previously, WIC is perhaps the best studied and most widely scaled food provision intervention in the United States. WIC is a cashlike healthy food prescription program that also provides nutrition education. Several reviews have shown that WIC improves infant mortality, increases birth weight, raises diet quality of beneficiaries, and reduces childhood anemia.^{44–46}

One cashlike FIM intervention is produce prescription programs. These can be seen as a subtype of healthy food prescription programs that specifically subsidize fruits and vegetables. Studies evaluating produce prescriptions suggest that partnerships with farmers markets and farmers involved in community-supported agriculture can successfully make vegetables and fruits more accessible^{53,54,65–67} and that produce prescription programs increase the purchasing of targeted foods and likely increase the consumption of those foods. However, the impact of produce prescription programs on health outcomes is still unclear. One concern is that the magnitude of any changes in consumption may be relatively small in the context of overall dietary intake. For example, studies have found that even when a statistically significant increase in produce consumption is reported, magnitudes are modest (eg, <1 serving of additional vegetables or fruits per day),^{53,65} suggesting that to have a bigger impact these programs need to incorporate other patient engagement or behavioral support initiatives. Another issue is relatively low rates of benefit use. Many studies have found rates of produce voucher redemption <50%.⁶⁸ Outcome assessment has been limited; few produce prescription studies have examined cardiometabolic risk factors, and none of those identified assessed health care cost savings.^{62,69} Although some modeling studies have suggested potentially large benefits from produce prescription programs,⁷⁰ these estimates come with substantial uncertainty given that their underlying assumptions about the degree to which reductions in healthy food prices translate into increased consumption have not been borne out in recent trials.⁷¹ A substantial limitation of the produce prescription approach is the exclusive focus on the consumption of fruits and vegetables. Cashlike FIM interventions may be

Table 2. Overview of FIM Interventions With Examples and Potential Advantages and Disadvantages

Type of FIM intervention	Examples	Potential advantages and disadvantages
Cashlike programs		
Produce prescription	Hager et al ⁶² (2023)	Advantages: • Participant choice relative to in-kind interventions • Potentially lower overhead cost than in-kind interventions • Organization conducting intervention does not need to manage food storage or preparation Disadvantages: • Participant must select and prepare foods • Restricted range of foods relative to healthy food prescription • Healthy foods must be available for purchase
Healthy food prescription	Aiyer et al ⁶⁸ (2019)	Advantages: • Participant choice relative to in-kind interventions • Potentially lower overhead cost than in-kind interventions • Organization conducting intervention does not need to manage food storage or preparation • Greater range of health-promoting foods than produce prescriptions Disadvantages: • Participant must select and prepare foods • Healthy foods must be available
In-kind interventions		
Medically tailored groceries	Seligman et al ⁶³ (2018)	Advantages: • Guarantees availability of healthy food relative to cashlike interventions • Typically lower cost per calorie provided relative to prepared meal interventions • Greater control by those delivering intervention over food provided relative to cashlike interventions Disadvantages: • Less participant choice relative to cashlike interventions • Typically more expensive on a per-calorie basis relative to cashlike interventions • Participant must prepare foods • Organization delivering intervention must source, store, and possibly transport food
Nontailored meals	Thomas et al ⁶⁴ (2016)	Advantages: • Guarantees availability of healthy food relative to cashlike interventions • Typically lower cost per-calorie provided relative to MTM interventions • Greater control by those delivering intervention over food provided relative to cashlike interventions • Predetermined portion size • Does not require shopping and meal preparation work from intervention participant Disadvantages: • Less participant choice relative to cashlike interventions • Organization delivering intervention must source and store food, prepare meals, and transport food • Typically more expensive on a per-calorie basis relative to cashlike interventions or medically tailored groceries • Less matching of provided foods to specific clinical needs relative to MTMs
MTMs	Berkowitz et al ⁶⁰ (2019) Go et al ⁶⁹ (2022)	Advantages: • Guarantees availability of healthy food relative to cashlike interventions • Greater matching of meals to clinical needs relative to other FIM interventions • Predetermined portion size • Does not require shopping and meal preparation work from intervention participant Disadvantages: • Less participant choice relative to other FIM interventions • Organization delivering intervention must source and store food, be able to tailor meals, prepare meals, and transport food • Typically more expensive on a per-calorie basis than other FIM interventions

Potential advantages and disadvantages are theoretical and may or may not be applicable for any particular FIM intervention. FIM indicates Food Is Medicine; and MTM, medically tailored meal.

more impactful if they incentivize not only fruit and vegetable purchasing but also other important components of healthy diets such as whole grains, legumes, and lean proteins.

In-Kind Interventions

In-kind interventions typically provide either unprepared groceries that a beneficiary must prepare or fully prepared meals. Furthermore, in-kind interventions can be either medically tailored (eg, chosen specifically accord-

ing to the comorbidities of the individual served) or nontailored (eg, foods that are generally healthful but not chosen on the basis of any specific clinical condition). Medically tailored groceries (or nontailored groceries) can provide many different food groups (eg, vegetables, fruits, beans, grains, lean proteins, dairy⁷²; Figure 3). Grocery provision may involve food banks,^{63,73,74} food pantries,^{56–58,75,76} or food pharmacies (“farmacies”),^{77,78} often affiliated with a health care or clinical facility.^{56,57,75,79} As with healthy food prescriptions, the impact of both medically tailored groceries and nontailored groceries

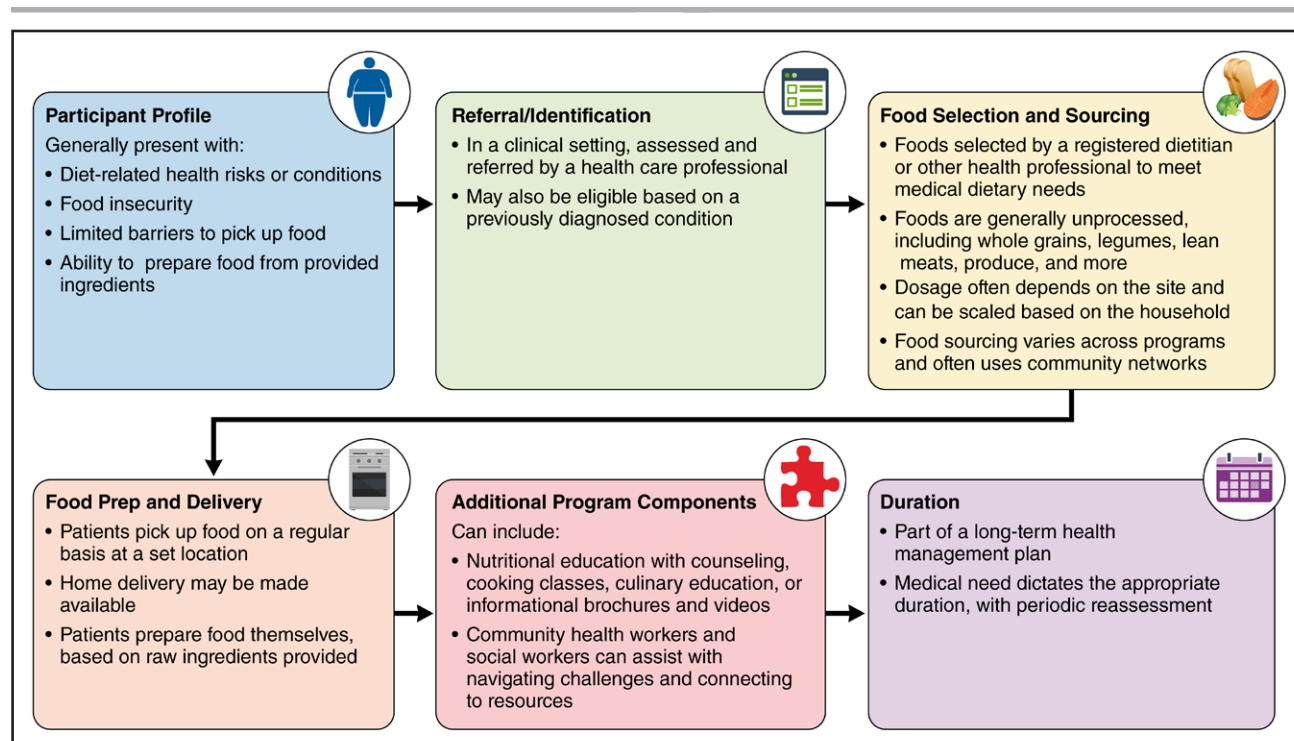


Figure 3. Path to health care system implementation of a medically tailored grocery intervention.

Outlined components may vary according to the individual health care system, partnering organizations, and individual patient.

interventions can be limited by low engagement and incomplete redemption of benefits, with a number of studies finding voucher redemption rates in the range of 35% to 40%.^{57,58,63,73} Some studies have examined clinical outcomes,^{63,74,76–80} but others emphasized operational and implementation factors such as engagement or program participation^{56–58,81} or diet quality or food security.^{73,75,77,82} Among the studies examining clinical measures, the most common outcome was hemoglobin A1c,^{63,74,76,78–80} with a few studies also measuring weight, body mass index, or blood pressure. Only one of the studies identified was a randomized controlled trial⁶³; many had pre-post designs^{58,73,75–78,80,82}; and the others were a mixture of quasi-experimental, pilot, or chart review studies. Only a few of the studies assessing hemoglobin A1c or clinical measures reported statistically significant improvements, and those that did often found this to be true for only a small subset of study participants who were most engaged in the programs or had the most room for improvement.^{63,76,77} The lack of randomized controlled trials and strong study design suggests that findings from a number of these studies should be interpreted with caution. There has also been little investigation into how best to tailor the groceries provided or what the specific “value added” of tailoring is relative to generally healthful but nontailored foods.

The other major form of in-kind intervention is meal provision, which again can be medically tailored or nontailored. Potential advantages of MTMs are that they can tackle both food insecurity and challenges faced by those

with complex medical conditions who may not have the ability to shop for or prepare meals. MTM programs typically involve the home delivery of registered dietitian- or nutritionist-guided prepared meals based on individual chronic conditions and specific needs. MTMs offer the opportunity for dietary change by not only providing a full range of food groups but also delivering those meals fully prepared, relieving the recipient of the time and labor burdens of preparation (Figure 4). However, this may to some degree limit patient choice, which in turn could lower participation and engagement. Furthermore, providing a wide range of foods and adding the labor necessary to prepare and deliver the meals mean that MTM interventions are typically more costly for a similar quantity of food provided than healthy food prescription programs or grocery provision programs. This makes cost-effectiveness comparisons between intervention types important.

MTM studies have typically had small sample sizes (most were <100),^{60,61,83–86} variable amounts of food provided (single meal per day to all meals and snacks),^{59–61,85–87} and variable duration of intervention (4 weeks–12 months).^{59–61,84,85,87,88} To date, evidence for MTMs suggests improvements in diet quality and quality of life and possibly reductions in certain expensive types of health care (eg, emergency department visits and nursing home admissions).^{60,61,89} As with grocery programs, the value added by medical tailoring of meals compared with provision of healthful but nontailored meals is unclear. There is, moreover, considerable

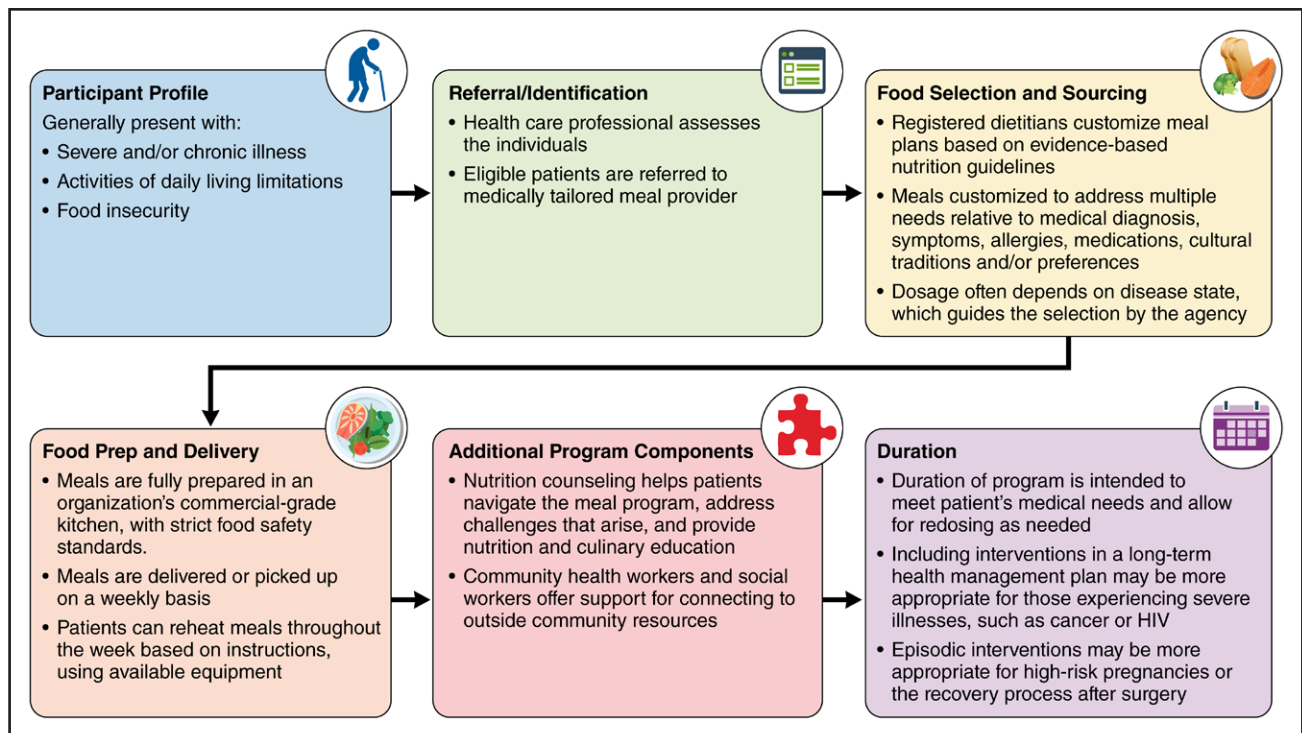


Figure 4. Path to health care system implementation of a medically tailored meal intervention.

Outlined components may vary according to the individual health care system, partnering organizations, and individual patient.

heterogeneity in what constitutes tailoring.^{59–61,90} As with produce prescription interventions, simulation models suggest potentially large benefits of MTM interventions.⁹¹ These modeling studies, however, are substantially limited by the studies completed to date, which in this case included 4 small intervention studies, of which 1 was a randomized trial (with 66 participants).⁹¹ Although matching patients on observable characteristics is sometimes used to provide a comparison group, this does not account for differences between groups in unmeasured factors such as motivation or health habits, leaving the possibility that estimated effectiveness is larger than would have been identified in a randomized comparison.

OUTSTANDING QUESTIONS AND GAPS IN THE FIELD

Given the current state of FIM research, a number of questions remain. Many of these questions can be categorized as relating to the effectiveness of FIM interventions (eg, the ability to affect a particular health outcome), comparative effectiveness (the relative effectiveness of one versus another), heterogeneous treatment effects of FIM interventions (whether the effect of an intervention for one subset of individuals is different from the average effect of the intervention across all individuals), cost-effectiveness of FIM interventions, and implementation questions related to the uptake and use of FIM interventions.

Effectiveness

Effectiveness questions center around the ability of FIM interventions to improve health outcomes in different clinical populations. Outcomes could be related to health care use (eg, emergency department visits or hospital readmissions), clinical events (eg, major adverse cardiovascular events), chronic disease management (eg, hemoglobin A1c or blood pressure), or patient-reported outcomes (eg, health-related quality of life, mental health, well-being).

A key mechanistic question is how to change behavior most effectively, which is the key to achieving clinical effectiveness through these interventions. For interventions to achieve long-term success for individuals, strategies need to be developed that are effective in initiating and sustaining behavior change. Ways to do this could include designing programs that consider patients' lived experiences to guide strategies and ensure that incentives for behavior change are salient, meaning easily understood and visible. Other approaches include non-financial strategies that could be used to make a given incentive amount more effective dollar for dollar such as carefully considering the use of choice architecture by strategically choosing defaults to favor healthy choices and using marketing nudges to make healthy products more likely to be chosen. Choice architecture approaches such as the placement of food in cafeterias has been shown to influence food choice. (People tend to choose the food that is in the prime positions where it is most easily visible and that foot traffic leads naturally

to as opposed to in a more distant corner, and this can be used to increase the likelihood that people will choose healthier options while preserving freedom of choice for those who have strong preferences.⁹³) Interventions may have positive or negative spillover effects on purchasing behavior of other healthy or unhealthy foods and may influence eating behaviors for other members of the household, and funds provided to encourage healthy food consumption may free funds up for other needs such as medications and housing costs.

The outcomes used to assess FIM programs are an important consideration. There may be advantages to collecting a wide range of outcomes, including patient-reported outcomes, health care use and spending data (including deprescription of other medications), clinical events, and the use of biomarkers and anthropometric assessments. Dietary assessment has historically been difficult, but new technologies offer the potential to change that. However, given the difficulty of assessing dietary intake accurately and precisely, measuring biomarkers of dietary change, cardiometabolic biomarkers, or microbiome analyses will help in assessing the impact of interventions. Broad use of common metrics in FIM studies would facilitate comparisons across studies that could support the translation of research to policy. It is important that metrics chosen are validated and informed by input from intervention participants, clinicians, and private and public sector decision makers with an eye to using measures that can inform policymaking, program development, and coverage decisions in the future.

Given both the higher cost and likely benefit of MTM programs, research should focus on identifying ways to improve the health and health care cost trajectories of patients who have predictably high medical costs that are potentially modifiable. Target populations could include frequently hospitalized patients with heart failure or other conditions. Produce or healthy food prescriptions could be applied to a much broader range of populations. Medically tailored groceries likely fall somewhere in between MTM and produce prescriptions on the cost spectrum. Most of the research on produce prescriptions to date has focused on patients with diabetes, likely both because this is a population that has predictably elevated costs that are modifiable through better diet and because hemoglobin A1c provides an intermediate outcome that allows objective assessment of intervention effectiveness. An important strategic question will be the identification of populations with modifiable risk from chronic conditions and the pairing of those patients with intervention approaches that will plausibly be effective and cost-effective in improving their health and health cost trajectories.

Comparative Effectiveness

Unanswered comparative effectiveness questions could relate to comparing the ability of ≥ 2 different types of

FIM interventions to improve outcomes in a particular population (eg, healthy food prescriptions versus medically tailored groceries for reduction in hemoglobin A1c) or different versions of an FIM intervention (eg, variation in MTM with regard to method of tailoring; intervention “dose,” duration, frequency, and delivery methods; behavior change strategies; or scaling of the intervention for household size). There are significant questions about the role of households, incremental effectiveness of including coaching or other behavior change strategies, and approaches to tapering the programs toward the end of the intervention period. For instance, how does providing MTM to the entire household instead of solely the identified patient affect behavior and health outcomes for the individual and for other members in the household? Previous work has shown that addressing health conditions in children has an outsized impact on behavior changes for the entire family, suggesting that there may be opportunities to promote increased engagement when the entire household is included in the intervention.^{94–96}

A crucial comparative effectiveness question (which also affects intervention cost and cost-effectiveness) is the optimal duration of intervention. An important area remains understudied: If FIM interventions are time limited, what happens when they end? Developing time-limited interventions with effects that persist after the intervention is over is often an aspiration of behavioral interventions for cost-effectiveness reasons. However, chronic conditions treated with medication tend to be treated lifelong, and it may be an unreasonable double standard to expect a time-limited FIM intervention to have sustained effects. This is less of an issue in the context of clinical situations that are time limited, including pregnancy, patients with cancer receiving chemotherapy, or the posthospital discharge period. FIM interventions could support people through these situations and be terminated as clinical needs change. Social situations that prompt the need for FIM such as changes in personal circumstances, for example, housing or employment, may also be time limited.⁹⁷ In some situations, it may be effective and cost-effective to provide ongoing support, and careful examination of cost-effectiveness in those contexts will be important. Changing habits is difficult, so the effects of time-limited behavioral interventions may wane, making long-term impact more modest than many would hope.⁹⁸

Overall, in programs that are designed to be time limited, it would be useful to understand how they can be tapered as health outcomes improve to empower individuals in sustaining changes in their behavior, increasing self-efficacy, and addressing social needs. Sustained behavior change beyond the intervention is especially challenging with preexisting barriers to healthy food access and other ongoing structural and environmental considerations (deceptive food marketing, high sodium in food supply, mass media industry countermarketing,

relative pricing of healthy/unhealthy foods, income constraints). Ultimately, the question of duration is a cost-effectiveness question: How do FIM interventions of differing durations compare in terms of cost-effectiveness with each other and with other commonly covered (and typically prescribed lifelong) therapies?

Heterogeneous Treatment Effects

Questions about heterogeneous treatment effects relate to identifying the patient population or populations who are best served by specific interventional approaches. As the field looks to measure and understand the clinical effectiveness of FIM initiatives, efforts need to be made to understand how results are affected by participant context and characteristics. Both social context and personal characteristics such as genetic predispositions may modify FIM effects. Approaches to better understand heterogeneous treatment effects can be both quantitative (eg, use of machine learning algorithms to identify unique combinations of participant characteristics that result in treatment effects that differ from the average treatment effect) and qualitative (eg, obtaining perspectives from those who receive and deliver interventions about why an intervention did or did not work for them).

Cost-Effectiveness

Questions about effectiveness, comparative effectiveness, and heterogeneous treatment effects all feed into questions about cost-effectiveness because different intervention approaches and different versions of otherwise similar interventional approaches likely vary in not only their effectiveness but also their cost. A payer perspective would answer whether programs would make financial sense from the standpoint of insurers and could be compared with the cost-effectiveness of currently covered benefits. A broader societal perspective would assess the question of whether such programs should be funded at all, taking into account broader benefits and costs outside the domain of insurers. Time horizons will be a critical question; payer interest will presumably be greatest in interventions that have health and economic benefits that manifest in the short term. Designing studies to be able to capture potential tradeoffs between intervention costs and effectiveness is crucial for making informed decisions about FIM intervention type, specific intervention designs, and matching of intervention types and designs with clinical contexts. A key area in which cost-effectiveness studies may be particularly important relates to the intensity of coaching, educational strategies, or social support provided in FIM interventions. Understanding the incremental effect of different components of FIM interventions will be essential from a cost-effectiveness standpoint.

Implementation

Several important questions are related to improving enrollment and ongoing engagement in programs and to program delivery to maximize their effectiveness. Many behavioral intervention programs do not scale because there is often a “voltage drop” as studies proceed along the National Institutes of Health Stage Model for Behavioral Intervention Development from initial indication of promise (Stage I) to larger-scale efficacy studies in populations who choose to participate (Stages II or III) to effectiveness studies (Stage IV) in all participants to whom a program is offered.^{99–101} This highlights the importance of achieving high enrollment and engagement, incorporating the lived experience of the target population, supporting variability in preferences in program design, and leveraging technology when possible so that an intervention can be less expensive per person as it serves more individuals (economies of scale). We believe a human-centered design approach to innovation will be important, with systematic efforts to incorporate personalized needs, preferences, and insights into program creation. It is notable that in a multicultural and diverse society, personalizing treatment must not just reflect medical conditions or risk factors but also encompass particular food and diet affinities and antipathies.

Innovation approaches suggest that contextual inquiry should be used to help define the problem that the team is trying to solve, with rigor around the development of metrics that need to be identified to determine whether progress is being made before imagining potential solutions and converging on workable testable approaches through rapid-cycle validation.¹⁰² As the field builds on the existing evidence base, continued focus on human-centered design approaches using implementation science frameworks to inform successful implementation, adoption, effectiveness, and dissemination of FIM interventions is needed. There will need to be systematic testing of how to identify patients who may benefit from FIM interventions, how best to increase enrollment in FIM interventions, and how to promote active engagement and retention, as well as identification of early indicators of whether an intervention will work for a given individual versus needing to be changed. All of these are critical to building a strong foundation for personalized programs with high potential effectiveness.

POTENTIAL APPROACHES AND SOLUTIONS TO CLOSE GAPS IN THE FIELD

The previous sections have highlighted major gaps in the field of FIM, with an overarching goal of improving cardiovascular health. This section describes approaches to doing that across several important

sectors that can work together to tackle these challenges. Strategic and purposeful approaches at the individual, community, and population levels are warranted to advance the study of FIM. It will take innovative, patient-centered solutions with public and private sector partnerships to reduce nutrition insecurity and to improve cardiovascular health. Furthermore, potential solutions should be equity focused because individuals with lower socioeconomic status are at disproportionately higher risk of both food insecurity and poor health outcomes.¹⁰³

Initiate Dedicated Studies

We have highlighted different types of FIM approaches, supporting evidence, and limitations to that evidence to date. The research questions discussed previously provide a blueprint for studies to address these limitations. In this section, we highlight a few overarching considerations as these studies are conducted. First, different types of interventions will likely be needed for different individuals based on their underlying health and health care cost trajectories. Understanding both the clinical characteristics and social context that make some FIM interventions more applicable than others will be important for having a set of FIM interventions that can be deployed in a range of scenarios. For example, more expensive MTMs may be helpful for those with high comorbidity and substantial limitations to their ability to prepare food for themselves, whereas healthy food prescriptions may be an effective and less expensive intervention for those for whom financial limitations are the principal barrier to consuming a healthy diet. Research that helps us understand who benefits from which intervention will be central to a rational approach to FIM intervention. Such research should help identify populations with modifiable risk and pair those patients with intervention approaches that will plausibly be effective and cost-effective in improving their health. Efforts to fund research should be coordinated with the National Institutes of Health and its Office of Nutrition Research, the US Department of Agriculture, the Patient-Centered Outcomes Research Institute, philanthropies, commercial partners, and other organizations in support of FIM studies.

A second consideration is the role of nutritional and lifestyle coaching. All FIM interventions provide healthy food resources in some way, but the approach to educational components of the interventions can vary considerably. Overall, nutritionists, coaches, or trained community health workers can provide these intervention components and can engage with community-based organizations in codesigning culturally responsive FIM interventions for diverse populations.¹⁰⁴ It may make sense to base these approaches outside of time-constrained standard clinic-based interactions.⁴⁰

Rigorously Evaluate Ongoing Government Programs and Other Natural Experiments

As described in the previous section on the history of FIM practice, government programs have included some important FIM interventions. In particular, because running randomized trials is costly and is not always possible, rigorous evaluation of ongoing and future government FIM interventions is an important opportunity. Programs such as the Gus Schumacher Nutrition Incentive Program, which provided \$250 million over 5 years (2019–2023) to support produce prescription programs,¹⁰⁵ and state-based Medicaid section 1115 waivers require outcome evaluation.^{106,107} However, state-level waivers are often challenging to evaluate because the implicit comparison groups are typically other states, which may also be making relevant policy changes; because there is often heterogeneity of provided benefits; and because careful measurement of program uptake and engagement is important. Randomizing within state-level Medicaid section 1115 waivers would be a better way to assess program effectiveness. This has rarely been done but would ideally be considered in future Medicaid section 1115 waiver applications as a condition for Centers for Medicare & Medicaid approvals to maximize what can be learned.¹⁰⁸

Occasionally, “natural experiments” present themselves. A study that took advantage of the end of post–World War II rationing of sugar in 1953 in the United Kingdom showed that excessive sugar intake early in life led to higher rates of chronic inflammation, cholesterol, and arthritis.¹⁰⁹ The researchers were able to take advantage of the fact that sugar intake more than doubled shortly after 1953, whereas consumption of other foods and nutrients around that time stayed relatively constant. Looking for situations like this for which there is a plausibly exogenous source of variation in what individuals are exposed to—such as a change in taxes on sugar-sweetened beverages in one municipality compared with another¹¹⁰—that affects dietary habits significantly provides important opportunities to learn with quasi-experimental designs. These study designs are much more likely to reflect causal impacts than epidemiological studies in which it is difficult to determine causal relationships.

Leverage Ongoing Developments in Food Retail

The food retail sector has expressed increasing interest in FIM and often uses innovative technology to help improve the diet quality of its customers. For example, one national supermarket chain integrates a color-coded nutrition rating system to facilitate shopping for healthier options (and to suit specific nutritional and diet needs based on medical conditions), using a team of registered dietitians to do so.¹¹¹ In addition, food delivery services may be able to address nutrition-related health equity gaps through patient-centered technology tools.¹¹² Such approaches

could include medically tailored grocery delivery to patient homes after hospital discharge or healthy food subsidies that can be used for online shopping. Although technology-based initiatives have great potential for scalability, there are risks that they could widen gaps in healthy food access for historically excluded people, including Black, Latino, and Indigenous communities, along with individuals with low socioeconomic status.¹¹³ It will be important for such interventions to include strategies to address structural barriers (eg, access to broadband internet) that could make the intervention differentially less effective.¹¹⁴

Build Tools to Scale FIM

An important challenge is to develop the ability to predict what types of programs are likely to be helpful for whom. This is knowledge that will develop only as more trials are conducted with the statistical power to examine subgroups and to determine program effectiveness in subgroups of the population. Over time, this knowledge will become valuable because there will likely be significant heterogeneity in program effectiveness, and better understanding of this heterogeneity will help drive decisions on what types of programs to make available more widely for individuals who differ on specific observable characteristics.

Discussion of scaling FIM seems premature before more reliable data on program efficacy and effectiveness are available. To accelerate that process, researchers can develop toolkits to help standardize measurement of important contextual factors, effect modifiers, and outcomes in FIM interventions to facilitate comparison across studies. This could make possible meta-analyses in which data are pooled across studies, enabling more meaningful examination of subgroups than may be possible in individual relatively underpowered studies. Methods of data synthesis suitable to dietary and lifestyle interventions such as NutriGRADE and Healm may be helpful.^{115,116}

Efforts to facilitate a move toward scaling could also include the development of trial platforms and data platforms that make it easier to conduct high-quality FIM interventions and to analyze data across studies. A broad array of stakeholders are potentially interested in the success of these initiatives, given high rates of diet-related chronic conditions and the ensuing high rates of adverse outcomes and costs. However, all of this can be done only once it is determined what is effective and cost-effective, and accelerating the path in generating that knowledge will make translation of that research into practice more possible.

PLANS AND METHODS FOR THE AHA FIM INITIATIVE

Inspired in part by the White House Conference on Hunger, Nutrition, and Health,¹¹⁷ the AHA and Rockefeller Foundation, with support from other stakeholders, launched

an FIM research initiative in the fall of 2022. A central goal of the initiative is to develop effectiveness and cost-effectiveness evidence to inform public and private payer coverage decisions on specific FIM interventions in appropriate clinical contexts. Pursuing this goal also presents an opportunity to build the research infrastructure necessary to accelerate progress within the FIM field more broadly.

After a phased research progression (Figure 5), the initiative has begun with engaging broader stakeholders to inform our proposed approach. A research planning group convened by the AHA reviewed the literature to identify gaps and will be supporting secondary analyses of existing data and small trials that lay the groundwork for the initiative. The low rates of engagement, adherence, and behavior change identified in much of the literature are driving an initial focus on using rapid-cycle short-term studies to test ways of identifying those gaps before moving to tests of longer-term behavior change and clinical outcomes. These pilot studies will use human-centered design to incorporate the lived experience of patients and practitioners in developing and testing ways of increasing program enrollment and engagement rates across diverse populations (Figure 6). They will also explore questions such as how to “dose” the support provided and increase the salience of the underlying incentives. The next phase of studies will be intermediate-length studies, building on the initial pilots, that focus on increasing short-term and longer-term behavior change. By carefully testing likely components of longer-term interventions, these will help “de-risk” subsequent larger-scale trials.

A key consideration of the initiative is that after initial small-scale pilots, subsequent studies should be sufficiently powered to answer important questions about changes in behavior and improvement in relevant clinical outcomes. Studies that are underpowered to determine, or exclude, clinically meaningful effects preclude coming to definitive conclusions about interventional approaches or contexts to prioritize. Thus, the initiative intends to support larger-scale trials that will be fully powered to test effectiveness and comparative effectiveness in improving clinical outcomes. The initiative will also include qualitative and implementation science studies that help to center the voices of intervention recipients, to understand and address the contextual factors that affect participation in and the results of FIM interventions, to explain heterogeneity in intervention effectiveness, and to inform implementing and adapting FIM interventions in diverse contexts.¹¹⁸ All larger-scale trials will include cost-effectiveness analyses to enable decision makers to compare the value of these new interventions with other already covered services.^{119,120}

FIM interventions involve aspects of both providing resources that overcome financial and other structural barriers to healthy eating and promoting behavior change to help people adopt and sustain healthy dietary

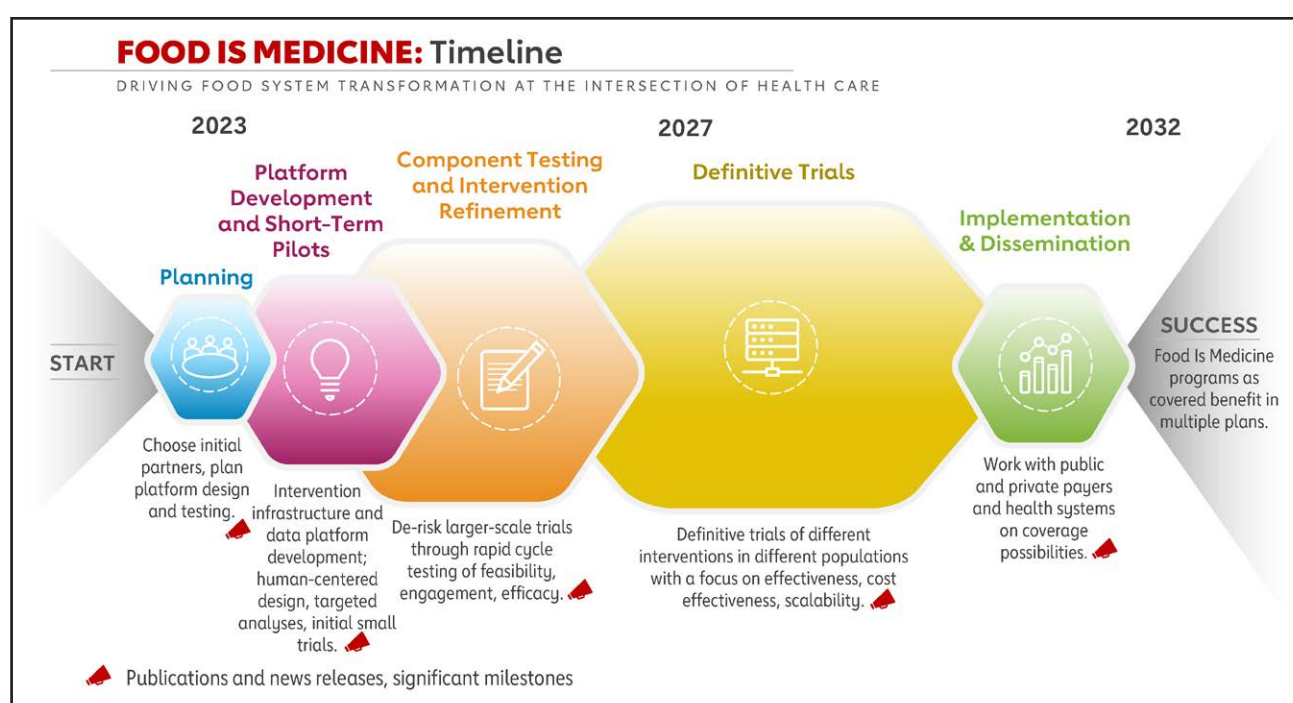


Figure 5. Timeline of American Heart Association Food Is Medicine Research Initiative, launched with support from the Rockefeller Foundation and other stakeholders.

This represents a general overview of the timeline and should be considered a rough guideline to the planned progression.

patterns.¹²¹ An important opportunity for the field is to leverage what is known from behavioral economics and other behavioral sciences to design interventions that will be more likely to be successful in achieving high rates of ongoing engagement and sustained behavior change.¹²² As noted previously, environmental factors, including highly refined efforts by some commercial entities to market and sell unhealthy food,¹²³ make it harder for people to adopt and stick to healthy diets. Many structural factors such as the high degree of availability and affordability and good taste of unhealthy foods mean that many people have to “swim upstream” to improve their health.^{16,124} Previous FIM interventions have at times had limited success in improving diet quality, despite generous incentives, and making those incentives more effective dollar for dollar, combining them with other behavioral strategies, will be an important priority.^{71,55,125,127} We will systematically test various behavior change strategies that recognize the inherent difficulties those with food or nutrition insecurity face and that incorporate human-centered design to create programs that have a better chance of meeting people where they are and achieving successful engagement.^{128–133}

An important contribution of the initiative will be developing common data platforms that facilitate FIM research. The goal is to converge on the use of platforms that help automate behavioral interventions, include the ability to remotely enroll participants, and support ongoing participation in interventions. There is an abundance of data from the many players within this space that are

not publicly accessible; making that data available would be beneficial to inform research efforts. To that end, we will work toward creating a data hub that can integrate and securely store data from health plans, health care systems, food retailers, and delivery services. In addition, to allow standardized measurements that facilitate comparisons across studies, it will be important to consider common data elements and metrics. We will need to make this attractive to all parties to participate through providing insights into questions that relate to their strategic interests with low costs of participation. These platforms will facilitate involvement of multiple sites and protocol standardization, streamline iteration on previous study designs, minimize participant burden, and lower the cost of conducting research.

Lastly, given the scope of the problem that FIM interventions seek to address,¹³⁴ it is important that the interventions tested are scalable. When possible, we will leverage infrastructure that is more scalable than what clinical investigators might typically have available of the local and national partners of the initiative, including grocery chains, online grocery delivery services, community-based organizations, and payment system vendors. Furthermore, we will aim to incorporate self-service customization when we can to strike a balance between the benefits of tailoring each intervention to individual circumstances and the need not to increase the complexity of interventions. Planning for scale, and incorporating technology that can assist with this, will be an important aspect of the initiative.

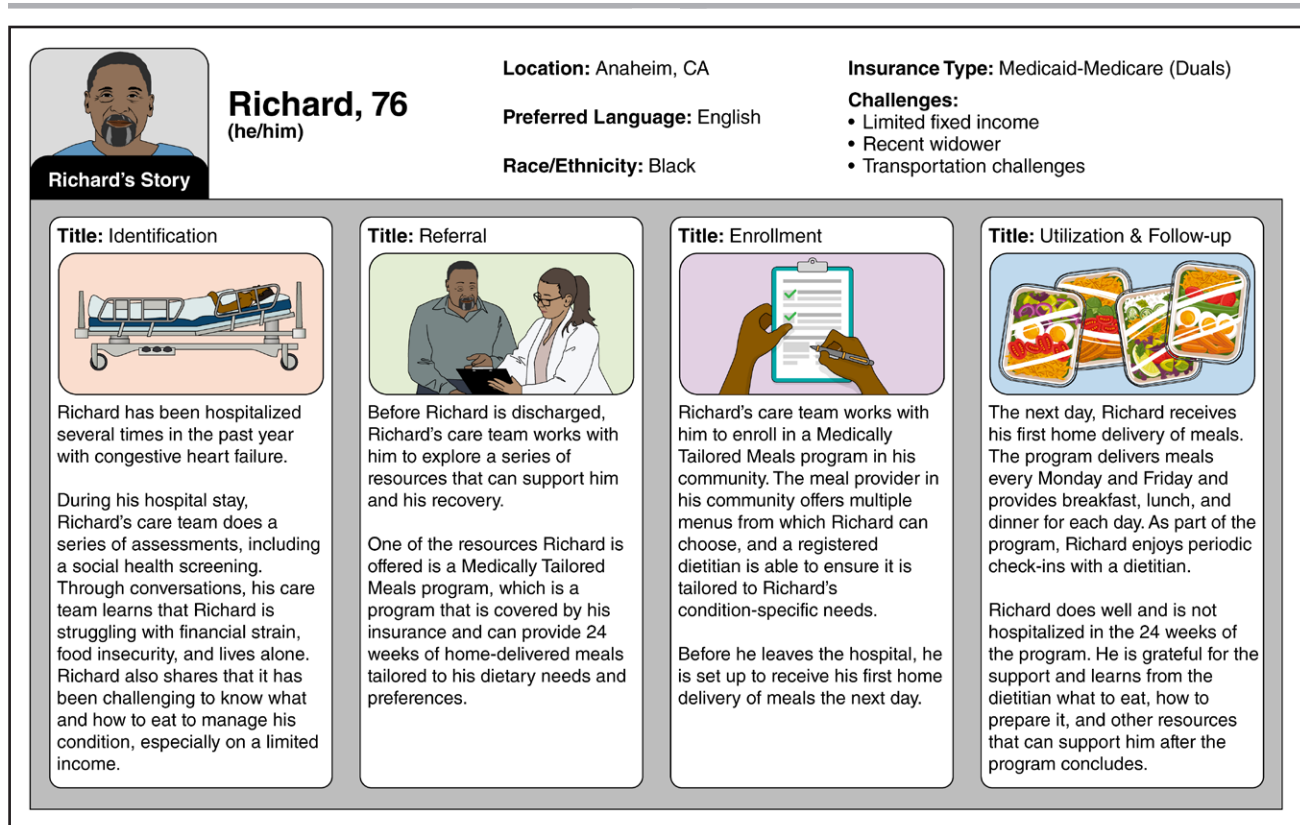


Figure 6. Human-centered design for participant research.

This represents a storyboard to help communicate how a new program or intervention might play out to meet the needs of each individual. This figure was developed in consultation with Kelly Dumke, DrPH, MS, from Kaiser Permanente's National Social Health Practice.

PRINCIPLES OF FIM RESEARCH

FIM activities represent a wide array of interventions in diverse populations, including those who experience food and nutrition insecurity. Because of the complexity inherent to the field, research into the use of food as medicine should follow several principles. Some of these are principles relevant to all biomedical and clinical research, but some are more specific to the study of FIM. The AHA subscribes to these principles for FIM research.

Research Must Meet Standards of Scientific Rigor, Transparency, and Open Science

Scientific rigor must be considered an essential element in all biomedical research, and it represents the strict application of the scientific method to ensure that experimental design, methodology, analysis, interpretation, and dissemination of results are as robust and unbiased as possible. This includes full transparency in reporting experimental details and all planned and measured outcomes, and making data available so that others may replicate findings.¹³⁵

Clinical trials should be listed online in publicly available websites designed for this purpose (eg,

clinicaltrials.gov), with analysis plans prespecified and with results reported there, at appropriate scientific meetings, and in publications. Both positive and negative results should be published within a reasonable time of study completion. Meta-analyses on the utility of FIM interventions are hindered predominantly because of disparate outcomes measures. Adoption of standardized outcome metrics would facilitate cross-study learning.

Research Must Be Conducted Ethically

FIM interventions are potentially intrusive, especially in communities and organizations with a tenuous or fraught relationship with biomedical research. Ethical research practices are critical to robustly overcome historically justified mistrust. Although FIM research has been conducted for decades, the transition to larger-scale clinical trials in this area is relatively new. The 3 principles of the 1979 Belmont Report of respect for individuals, beneficence, and justice are relevant to FIM research.¹³⁶ Studies of food interventions for a medical condition must be carefully crafted to balance the need for ethically obtained, implementable strategies that could potentially improve future health of many similarly situated individuals while serving the immediate needs of these same individuals.

Equity Must Underscore Every Aspect of Research Design and Implementation

Health equity refers to providing equal opportunity for optimal health outcomes for all people independently of age, sex, race, ethnicity, religion, education, immigration status, wealth, or access to resources.¹³⁷ Disparities in acute and chronic illnesses have been recognized for decades in the United States and other countries. Health disparities are driven largely by social determinants of health such as differences in housing, air and water quality, education, neighborhood safety, and other drivers, as well as structural determinants of health, including structural racism and income inequalities. These may result in differential access to high-quality, nutritious foods, with subsequent ramifications for health outcomes. FIM research could enhance health equity in individuals at risk for diet-related health conditions and adverse social determinants of health.

Research Must Conduct Itself With Dignity and Fidelity to the Lived Experience of Patients and Practitioners

Food is a major thread in the interwoven tapestry of culture, history, family, and memory, making alterations in food habits reverberate through individuals, family, and communities. FIM interventions (eg, MTMs) may be delivered to and consumed in the patient's home. FIM practitioners such as those delivering meals, meal kits, produce, or groceries may live in the same communities as patients, grow or produce the food consumed, and develop close, ongoing relationships with communities. Food access is embedded in the social network of a community, including a wide range of local systems and institutions such as schools, markets, and agricultural areas. Research should therefore be designed and implemented with the goal of maximizing the healthy, dignified life of the individual, drawing on the lived experience of those enmeshed in their community. Both quantitative and qualitative research may be valuable in understanding these experiences.

Research Design and Implementation Must Be Inclusive of Cultural Sensitivities

Related to the importance of lived experience, it is essential to recognize that food occupies a central place in people's lives and carries with it specific and essential cultural meaning integral to self-awareness and cultural identification. Unlike pharmaceuticals, which are generally intentionally engineered and regulated to be reliably identical from one instantiation (eg, molecule or pill) to another, food has attributes such as taste, personal meaning (comfort foods), interpersonal meaning (foods shared with family or friends), and cultural meaning (eg,

holiday foods) that may challenge standardization. The goal of FIM research therefore cannot be to identify the one food or combination of foods that leads to health or treats a specific illness; instead, food must be conceived holistically and in the context of its familiarity and cultural meaning. Healthy foods inconsistent with one's culture are unlikely to be consumed and therefore will not contribute to health. Incorporating human-centered design from the patients intended to be served by a given intervention is essential to allow a high standard of dietary quality across an array of culturally tailored approaches that reflect the needs and preferences of a multicultural society.

Research Must Maximize Inclusion of Diverse Populations

To achieve equity, it will be essential to maximize the inclusion of diverse populations, in particular those who have been persistently underrepresented in biomedical research, including women; Black, Hispanic/Latino, American Indian and Pacific Islander, and immigrant communities; gender minorities; differently abled and neurodivergent; and rural populations. FIM research should also seek to be inclusive of the many different aspects of service in the communities that it represents, including patients, family members, and caregivers; FIM practitioners such as food producer, grocers, and delivery services; clinicians and health care professionals; and researchers with different areas of expertise. In addition, to maximize implementation and impact, the research will need to resonate with other stakeholders, including hospital and health system administrators, payers, policy-makers, and others.

Research Should Take Into Account the Life Course of Individuals

Diet-related diseases affect individuals throughout the life course, from within the womb to old age. Periods of life having specific vulnerabilities include the prenatal period (when food exposures lead to developmental programming spanning generations), infancy and childhood (when food habits begin), the onset of puberty and adolescence (when adult eating habits are established), pregnancy, and times of increased physical and mental stress (when metabolic needs accelerate and the effects of unhealthy food and nutrition may be most acute). FIM research should be sensitive to these changes over the life course and consider focusing efforts on shorter-term interventions that may be especially important during time windows when health risks are highest.¹³⁸ Federal programs such as WIC make food available to women and children, for example, and have shown benefits in long-term health outcomes for both the mother and the children.⁴⁴

Research Must Be Funded Intentionally and Strategically

Research should be purposefully funded, with resources directed at the critical questions facing the field. Resources needed to address the questions at hand are substantial, but not unlimited, and should be used in a way that considers the questions for which research is likely to do the most good. Landscape analyses of the different ongoing FIM programs are appropriate to identify gaps in knowledge and opportunities for research and targets for funding. On an ongoing basis, it will be important to have active surveillance of the available evidence to incorporate learnings into new studies. Some replication of findings will be important for the field, and researchers will need to be strategic in determining how much to invest in developing brand new evidence as opposed to purposeful replication. Dialogue with the private sector and public policymakers about evidence gaps will help inform the research and ongoing advocacy efforts in adjacent areas, as well as the design of federal and state benefits programs.

Research Must Carefully Consider Potential Conflicts of Interest, Relationships With Industry, and Commercialization

FIM research is accelerating rapidly, and new technological developments—including artificial intelligence and machine learning—create opportunities to provide personalization at scale. These innovations should be welcomed into the field, but at the same time, caution is warranted to prevent commercial entities from having too much influence and potentially interfering with high-quality, objective research. These concerns may be particularly relevant in a newly emerging or rapidly expanding field with few regulatory guardrails. Investigators and funders should therefore take extra precautions to ensure the integrity of their research and specifically to ensure that relationships with industry and other conflicts of interests are made public and easily accessible and that the influence of commercial interests is limited in the design, conduct, and interpretation of study data. At the same time, partnering with the food industry and other commercial interests will be imperative given the potential for developing efficient approaches that can be scaled. Thoughtful and careful relations with industry must balance ethical research conduct with translating efficacy to long-term effectiveness.

EFFORTS CONCURRENT WITH FIM RESEARCH

The translation of FIM research into improved health, policy, and acceptance nationally as an approach to im-

proving health and health care will require more than a successful and sustained research effort. Research will need to be combined with several complementary areas of effort, including policy development and implementation, creating support for regulatory or policy changes in systems for payment and quality assurance that will enable FIM-related care, professional and public education, data sharing for care coordination between health care and other agencies delivering FIM programs, and other initiatives.

Policy and Advocacy

A clear goal of the research is developing evidence on feasible and promising intervention strategies that could reduce cardiovascular and chronic disease risk and could be translated into policy and practice. This supports the overarching goal of coverage of FIM interventions shown to be efficacious for those who participate through rigorous scientific investigation, in the same way that pharmaceutical interventions are covered. Development of policy approaches will need to occur before and concurrently with ongoing refinement of the scientific evidence. Investigators seeking to change policy through research findings will need to first determine that research design and measured outcomes are relevant to policy and then assess for potential unintended consequences of policy implementation. Separately, advocacy efforts based on this evidence to encourage related policy changes will be important. Advocacy efforts should continue throughout the research phase to optimize the likelihood of successful implementation at scale after the research is completed and to support broader structural and environmental changes that support healthy eating.

An example of an area in which there are regulatory headwinds that would be good to remove is that, in the United States, food is counted as a nonmedical expense, so at present, FIM interventions may not be included in the numerator of medical loss ratios (the ratio between what an insurer pays out in medical expenses divided by total revenues). This can result in disincentives for payers to offer FIM interventions because insurers are required to have medical loss ratios of at least 80% in the individual and small group markets and 85% in the large group markets, meaning that at least 80% or 85%, respectively, of premium revenues must be spent on what are considered clinical care and quality improvements.¹³⁹

We also want to highlight that the promotion of healthy diets from sustainable food systems is an important area for advocacy to achieve simultaneous improvements in nutrition and health while addressing climate change, biodiversity loss, land and water use, and nutrient pollution.¹⁴⁰ Changing dietary patterns toward diets high in fruits, vegetables, nuts, and whole grains with modest amounts of animal-sourced foods could lead to healthier

diets and more environmentally sustainable food sourcing due to their lower environmental footprint compared with current diets. These changes require appropriate legislation and incentives, as well as the implementation of novel data sets and algorithms that account for the true cost of food, including waste, climate effects, and other negative externalities.²⁴

Quality and Clinical Data Systems

Implementation of FIM at scale will require the creation of payment and quality assurance systems that exist for other aspects of medical care with common data metrics.¹⁴¹ FIM interventions must have adequate financing mechanisms. Consideration should be given to the degree of cost sharing that would accompany these services, particularly because the impact of most FIM interventions will likely be greatest among those with food insecurity. As the evidence for FIM interventions continues to accumulate, efficient implementation in conjunction with health systems and plans will be an increasingly important priority. For instance, FIM practitioners should be appropriately vetted to meet Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards to ensure the protection of patient privacy, and coding standards should be developed to allow health care professionals and community providers to bill for FIM services in consistent ways. FIM practitioners and researchers will need to be involved in these efforts to ensure that they capture the variety of evidence-based interventions. Insurers will need to ensure that these payment approaches and mechanisms for handling them align with their systems of payment for more traditional types of care, with variability based on whether these services are reimbursed as fee for services or as part of risk-adjusted capitated systems. Health care professionals will need to become familiar with screening for nutrition insecurity, counseling patients about FIM options, and entering standardized measures and accompanying data into electronic health records.¹⁴² Similarly, systems for the evaluation of FIM approaches and assessment of their efficacy will be needed. These might include measures of participants' diet quality, food consumption, program satisfaction, and clinical and economic outcomes. As FIM approaches become incorporated into guideline-driven care, performance measures and data quality standards will need to be developed and monitored for their ability to assess appropriate use of these programs. Implementation studies of FIM strategies proven to be of benefit in randomized trials will likely need to be undertaken to identify optimal ways to ensure appropriate uptake.

Professional Education

Few medical schools currently offer a comprehensive nutrition curriculum, and fewer still provide education

in FIM approaches to diet-related disease. There is a growing movement toward culinary medicine, which implies teaching how preparation of healthy food can be used to help manage chronic disease. A scoping review of such programs showed that there is marked heterogeneity in organization and curricula of such programs.¹⁴³ In addition, in the event that FIM interventions affect prescription needs, health professionals should be educated on modifying the use of medications in alignment with FIM interventions. Greater standardization of professional education in nutrition science and its relationship to health and health care use, FIM, and FIM research could lead to a larger and more highly specialized health care professional base, greater rigor in research, and increased likelihood of adoption of FIM in health care.

Public Education

Educating the public about the importance of nutrition and healthy food to health will be a slow and challenging process. Building a movement for health insurance to cover nutritious food will require ongoing efforts over many years, concurrent with the growth of the evidence base. Nonprofit health organizations, associations for physicians and other health care clinicians, public health and prevention specialists, producers of healthy food, and others can coordinate educational programs to maximize impact. Education will likely shape into advocacy by mobilizing people to prioritize health and to raise the issue of diet-related disease and FIM with local, state, and federal candidates for office.

FIM interventions are one component of the multifaceted approach to addressing social determinants of health and unmet social needs. Complementary to this work is the instrumental work of community health workers, social workers, and community-based organizations, whose work is critical for connecting individuals with the resources and social support initiatives that can augment FIM services. Supporting and including their work within FIM interventions potentially could increase the efficacy, longevity, and reach of the programs as they help actualize an equitable, robust public health ecosystem.^{144,145}

CALL TO ACTION

The AHA FIM Initiative, with support from the Rockefeller Foundation, is committed to developing effectiveness and cost-effectiveness evidence to inform public and private payer coverage decisions on specific FIM interventions in appropriate clinical contexts. This will require a concerted, national, cross-sector partnership approach. We propose the specific actions in Table 3.

Table 3. Call to Action

Call To Action
Define and determine the scope of FIM and its role in health care, and strengthen the FIM evidence base across diverse populations to inform our collective understanding of the limitations to the existing evidence and the opportunities for incremental impact.
In partnership with others, lead efforts to increase the rigor of FIM studies so that the field moves away from predominantly conducting pre-post studies in which causal inferences are difficult to draw to one that leads the field of nutrition research by using experimental and quasi-experimental designs that support more robust and reliable conclusions.
Bring behavioral science and human-centered design into FIM trials more systematically to increase engagement and ultimately both efficacy among those who choose to participate and population health effectiveness of interventions.
Make concerted efforts to obtain funding for more rigorous, adequately powered longer-term studies to affect measured clinical outcomes. Conduct comparative effectiveness and cost-effectiveness studies, capturing tradeoffs between intervention costs and effectiveness to inform decisions on which FIM approaches to choose for different populations, outcomes, and settings.
Use rapid-cycle innovation principles to improve program enrollment and engagement and to study design innovations such as adaptive study designs to accelerate learning from research studies.
Embed FIM principles of research, including equity, transparency, rigor, quantitative/qualitative balance, dignity, and incorporating lived experience of patients and practitioners, to ensure that effective FIM interventions have reach, adoption, acceptability, and sustainability within the populations served.
Create common data platforms and standardize data elements and metrics in FIM studies to facilitate comparisons across studies that could support the translation of research into policy.
Catalyze partnerships across communities, food systems, health systems, commercial entities, and funding agencies to empower a patient-driven, health-for-all approach to mitigate food insecurity and to improve diet quality and health outcomes among the most disenfranchised.
Leverage implementation science to examine questions on enrollment, dose, engagement, and adherence inclusive of health system or health plan integration. Identify and develop strategies to examine predictors of implementation success of individuals, and incorporate these into program design.

(Continued)

Table 3. Continued

Call To Action
Expand complementarities of advocacy and policy work through cross-sector, community-engaged, inclusive coalitions at the regional and national levels, as well as governmental partnerships to create dialogue and build trust, collaboration, and collective action.
Standardize professional education nationally to include nutritional science and FIM research to facilitate adoption of FIM best practices in clinical practice by the next generation of health professionals.

FIM indicates Food Is Medicine.

ARTICLE INFORMATION

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

This presidential advisory was approved by the American Heart Association Science Advisory and Coordinating Committee on August 15, 2023, and the American Heart Association Executive Committee on September 7, 2023. A copy of the document is available at <https://professional.heart.org/statements> by using either "Search for Guidelines & Statements" or the "Browse by Topic" area. To purchase additional reprints, call 215-356-2721 or email Meredith.Edelman@wolterskluwer.com

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Disclosures

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(Continued)

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$5000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$5000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

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David L. Katz	Diet ID, Inc.	None	None	None	None	Diet ID, Inc†	None	Diverse (I have long been a proponent of food-as-medicine across a large expanse of professional activities.)*
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This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$5000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$5000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.
†Significant.

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