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# FOOD HEALS Food is Medicine **Research Action Plan**

### 3 About the Authors

- 5 Introduction to the New Research Action Plan
- 7 <u>Executive Summary</u>

### 12 <u>Section I: Introduction</u>

### 25 Section II: About the Food is Medicine Initiative

Introduces the goals and target audience of the Research Action Plan and describes how it was developed.

### 29 Section III: Food is Medicine Defined

Establishes the scope of the Research Action Plan and a corresponding definition of "Food is Medicine," identifying three categories of interventions that meet this definition.

### 43 Section IV: Key Considerations for Food is Medicine Research

Discusses key considerations for research that pertains to food and nutrition, the health care system, and the intersection of these complex fields.

### 51 Section V: Foundational Research

Provides a comprehensive overview of the published, peer-reviewed research on health outcomes associated with food insecurity and federally funded food support programs, laying the foundation for the emerging research on Food is Medicine interventions.

### 61 Section VI: Research on Food is Medicine Interventions

Provides an in-depth overview of the published, peer-reviewed research on Food is Medicine interventions, summarizing key findings and identifying critical gaps.

### 97 <u>Section VII: Recommendations</u>

Identifies 18 recommendations for the future of Food is Medicine under the following categories: equity throughout the research continuum, research design, the next phase of exploration, research funding, and broader research to support transformative change.

### 102 <u>Endnotes</u>

113 Acknowledgments

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### **Food is Medicine Advisory Board**

Key informant interviews and meetings with the Food is Medicine Advisors, beginning in June 2020 and continuing throughout 2024, have directly informed this report. Their expertise and generosity of time, insight, and examination shaped this work, and Food & Society at the Aspen Institute as well as the Action Plan authors are extremely grateful for them.

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Our Food is Medicine work has been uniquely gratifying and exciting, because it's like watching time-lapse photography in front of our eyes as the field takes off at warp speed. We started in the fall of 2019, but the accelerating levels of interest in the field—and the levels at which Food is Medicine has attracted interest!—make that time feel like a lot longer.

We haven't stopped asking our first questions: What does Food is Medicine mean? How can it reach and improve the health of the largest number of people? From the start, our focus has been on research. Who has done what peer-reviewed research on which nutrition interventions? What does the research show? What kinds of future research will best build the case for long-term reimbursement?

From the beginning, we've been fortunate to have been guided by leading lights in the field. The truism that "if you want something to get done, ask a busy person" certainly held for us. Like the best researchers and scientists, they are generous. Our advisors are front and center in this report and on our website, aspenfood.org. We're particularly grateful to our convening partners who made the three in-person meetings leading up to this revised Research Action Plan such collaborative and fruitful successes: Ceres Foundation for our Sacramento meeting, Community Servings in Boston, and the Sunflower Foundation in Topeka.

We wouldn't have been in any of those places or here today without the generous support of the Walmart Foundation. Our program officers have been wise and strategic. They challenge us to improve our work and are always around to offer a kind and buoying word—dream supporters, really.



New researchers and practitioners are constantly coming aboard, and we've worked to include the broadest possible range in our advisory group and gatherings. A few of the big national organizations that are planting their flags on a wonderfully broadening map include the Food Is Medicine Coalition, the American Heart Association, Kaiser Permanente, the Rockefeller Foundation, the Bipartisan Policy Center, Feeding America, Tufts University, and a raft of government agencies who were galvanized by the September 2022 White House Conference on Hunger, Nutrition, and Health. The National Institutes of Health, Centers for Disease Control, Department of Health and Human Services, Department of Agriculture, Veterans Administration, Indian Health Services, and others all see a path to better health that passes straight through Food is Medicine. This is a moment of historic opportunity.

We were extremely lucky to have Sarah Downer and Emma Clippinger as our masterminds and beautifully eloquent main authors for our first version, and Kurt Hager for this revised Action Plan. In the weeks and months leading up to the release of the updated plan, we repeatedly read through the report from start to finish. Each time I read it, I was knocked out by how fundamental and clear the writing is. Through both revisions, Alexandra Lewin-Zwerdling has been a conceptual guide, organizer, thinker, cheerleader, and fulcrum. She and my Food & Society colleagues Mary Castillo and Nicole Corea worked constantly and wisely to complete this revision.

The Food is Medicine Research Action Plan doesn't say who should conduct what studies and where, though it celebrates and collects all of the peer-reviewed research to date. It does lay out a framework for how that research should be designed, conducted, and evaluated. That way, in brief, is extremely collaborative and welcomes everyone into the field. Our 18 honed recommendations, along with the updated tables and at-a-glance sections, are the news of this revision. They are the result of intensive, impassioned discussions by the leaders in the field, old and new. They're aspirational, yes. But they're also rooted in the reality of what research is currently funded.

We're proud of the new Action Plan, and hope it will help and motivate you to do new work in an excitingly expanding field! We invite you to join us for the next phase of our work: a Best Practices Guide for community-based organizations looking to enter the Food is Medicine field. Let's help them learn the lessons and take up the challenge of the wonderful groups that have been leading the way. We're excited to keep collaborating--and being inspired by the ever-growing number of people who want to help everyone lead healthier, well-nourished lives!

Junner

Corby Kummer Executive Director, Food & Society at the Aspen Institute



### **Food is Medicine Research Action Plan**

The United States faces an unrelenting chronic disease epidemic, leading to skyrocketing health care costs and devastating effects for individuals, communities, and the nation. These connections were further accentuated during the COVID-19 crisis, during which diet-related illnesses like diabetes and heart disease became leading risk factors for COVID-19 hospitalization and death. To compound these issues, tens of millions of people living in the United States struggle with food insecurity (not having consistent access to food for a healthy and active life), which is the embodiment of social and economic injustice, as well as persistent poverty throughout the country. Unfortunately, Black and Latinx households are more likely to experience food insecurity and have diet-related chronic diseases, a reflection of historical and contemporary systemic racism.

The connection between chronic disease and nutrition is undeniable; nutrition not only plays a role in the onset of disease but also its prevention, management, and treatment. Efforts that involve a health care response to the need for better nutrition fall under the umbrella term "Food is Medicine." An emerging body of research demonstrates the enormous promise of Food is Medicine interventions across a range of health conditions in improving health and quality of life, while also curbing health care costs.

In order to build on these findings and strengthen the case for widespread integration into the health care system, health care providers, academic researchers, insurance providers, and policymakers alike want more purposeful research. *The Food is Medicine Research Action Plan* answers this call with a comprehensive set of recommendations for creating an evidence base that will advance health care integration, build a holistic understanding of effectiveness, and engage communities, providers, and researchers.

### This Action Plan is for:

- Researchers
- Funders
- Program Implementers
- Advocates

### In the Action Plan, Food is Medicine interventions include the following two components:

**1** the provision of food that supports health, such as medically tailored meals or groceries, or food assistance, such as vouchers for produce; and **2** a nexus to the health care system. <u>Section III</u> elaborates on this definition, as well as the existing interventions that it encompasses.

In the wake of the historic 2022 White House Conference on Hunger, Nutrition, and Health and the acceleration of literature since the first iteration of this report, Food & Society at the Aspen Institute has updated this Action Plan. After careful planning and a two-year process, the report now includes the latest research and data as well as a set of streamlined and updated recommendations. The current recommendations reflect an exciting movement in Food is Medicine and were informed by longtime and new participants in the field through convenings held in 2023 and 2024, including in Sacramento, Boston, and Topeka.

Key considerations for Food is Medicine research;

- An overview of the published, peer-reviewed foundational research on the health outcomes associated with food insecurity, as well as the health outcomes associated with key federal food support programs;
- An overview of all peer-reviewed studies on Food is Medicine in the United States and a discussion of the research on Food is Medicine interventions, specifically medically tailored meals, medically tailored groceries, and produce prescriptions, now updated to include all published studies through December 1, 2023; and
- Concrete recommendations for future research, with respect to:
  - Ensuring that research is conceived, designed, executed, implemented, and disseminated using an equity framework;
  - Identifying key considerations for ensuring that research designs are robust and appropriate for yielding the most valuable and actionable information;
  - Funding critical research to advance the field; and
  - Identifying urgent questions that have yet to be explored.

With over 350,000 annual deaths from cardiovascular disease attributable to poor nutrition<sup>1</sup> and US federal spending on health care nearing 20% of GDP,<sup>2</sup> identifying how dietary interventions can meaningfully influence individual and population health is a national priority. This Action Plan is not meant to stand in for, replace, or undermine plans for broader systemic change in our health and food systems. It is instead intended to be complementary to such plans.

### **Existing and Forthcoming Research**

The research on Food is Medicine builds on a large and robust body of evidence that links food insecurity to poor health outcomes, both physical and mental. Research repeatedly demonstrates that food insecurity is associated with increased health care use and spending.

Food is Medicine interventions have grown exponentially since the first iteration of the Food is Medicine Research Action Plan. Section VI: Research on Food is Medicine Interventions of this Action Plan provides the most comprehensive analysis to date of research on medically tailored meals, medically tailored groceries, and produce prescriptions through December 1, 2023. Section VI focuses exclusively on published, peer-reviewed research as it is the research most often cited by those making key decisions about Food is Medicine program design, implementation, and funding. Peer-reviewed research is, however, only one part of a larger body of research that includes forthcoming studies, gray literature, and program evaluations.

The rapid acceleration of published literature, ongoing research, and recent multimillion-dollar initiatives from the American Heart Association, Rockefeller Foundation, and National Institutes of Health indicate that the volume and rigor of Food is Medicine research will continue to increase. These studies, which are increasingly using stronger study designs, are beginning to fill important gaps by focusing on health conditions and patient demographics that are underrepresented in the current literature. The greatest challenge is how to propel rigorous, high-impact, translatable research that can rapidly bring necessary changes to the health care and food systems.

### Key takeaways of the updated evidence base:

- Food is Medicine interventions—medically tailored meals, medically tailored groceries, and produce prescriptions—are replicable, scalable, and effective in many circumstances.
- All three interventions are associated with reduced food insecurity, improved dietary intake, and improved participant mental health.
- The literature on medically tailored meals is the most well-developed, with more studies employing rigorous designs. Medically tailored meals have been associated with improvements in health outcomes for HIV/AIDS, type 2 diabetes, heart failure, and chronic liver disease, as well as reduced health care utilization, health care spending, and even mortality among participants with advanced illness, in particular those with heart failure.
- The literature on medically tailored groceries is still emerging, and several health systems launched new medically tailored grocery programs during the COVID-19 pandemic. Programs are sometimes located in health care facilities; or accessible at locations within the community, such as food pantries; or home-delivered. Medically tailored groceries have been associated with improvements in blood pressure and some type 2 diabetes-specific health outcomes. However, results have been mixed across studies.
- The literature on produce prescription is the most voluminous and expansive, representing a wide range of
  program designs. New research has shown positive impacts on clinical markers of cardiometabolic health
  for participants with diabetes, hypertension, and obesity. However, in the produce prescription literature,
  there is a need for stronger study designs, including more randomized trials.



### **Recommendations for the Future of Research**

The proliferation of Food is Medicine interventions and their increasing use within health care has been mostly ahead of the research, driven in large part by nonprofits and advocates who have developed creative programs to meet the nutrition-related needs of people living with chronic illness. However, integrating Food is Medicine interventions into health care is increasingly common, including within federal programs like Medicaid and Medicare. A new wave of interest and investment in exploring the full impact of these interventions offers opportunities to sustainably support and scale access to the most effective interventions.

To inform the next decade of Food is Medicine research, the recommendations in this Action Plan:

- Offer concrete guidance on how to embed equity throughout the Food is Medicine research continuum;
- Identify key considerations to ensure that research designs are robust and appropriate for yielding the most valuable and actionable information;
- Identify the most urgent questions that have yet to be explored; and
- Describe how funders and other stakeholders can support the most valuable research in the field.

Alignment with the core principles that inform these recommendations—equity, attention to research design, potential for translation, purposeful investment of resources, and contextualization of Food is Medicine within broader systems and institutions—should advance a future in which:

- Effective and appropriate Food is Medicine interventions are integrated into the US health care system, providing access to a wide range of proven interventions;
- All Food is Medicine research centers equity throughout the research continuum to ensure that interventions truly empower individuals and communities and are effective across demographic groups; and
- Everyone has the food that will allow them to live a healthy, dignified life.

### **Action Plan Recommendations At A Glance**

### Designing Equity-Centered Food is Medicine Research

- 1 Food is Medicine research should make health equity central to its methods, conduct, and outcomes because diet-related illnesses and their risk factors are major drivers of health disparities.
- 2 Researchers should seek out and include the perspectives of community members who are eligible to receive the intervention in question. At the same time, researchers and funders should seek out a broad variety of perspectives and partnerships with Food is Medicine implementers.
- 3 Research teams should surface and identify their team members' perspectives and potential biases, and fully engage all team members and partners in study design, planning, and decision-making.
- 4 Teams should monitor study recruitment and retention to ensure that the study population fully represents the population being targeted for the intervention. Participants should also be properly compensated for their time.

### Funding Equity-Centered Food is Medicine Research

- 5 Funders and researchers must ensure that there are adequate resources for the time and necessary steps required for true equity-centered research. This includes time for study planning and training to ensure that researchers fully listen to community and practitioner voices and effectively integrate equity principles into the research design framework.
- 6 Congress should provide the National Institutes of Health (NIH) with significant funding dedicated to Food is Medicine research. The NIH should also leverage its own resources to continue its path-breaking work in emphasizing and expanding Food is Medicine research, including by establishing Food is Medicine Centers of Excellence.
- Health care payers should partner with government agencies and one another to enable more cross-disciplinary Food is Medicine research that is ambitious and builds in equity-centered evaluation components from the outset, especially for high-impact opportunities like state Medicaid waiver programs.

### Food is Medicine Study Design

- 8 Eligibility and inclusion criteria for interventions should fully reflect the diversity of the community being studied.
- Qualitative research, which examines the perceptions and experiences of participants, clinicians, and program implementers, should be an essential component of new proposals. Human-centered design also prioritizes these values. Qualitative and human-centered research should include culturally reflective methodologies that support diverse perspectives and attempt to understand the "why" behind quantitative results. At the same time, quantitative analyses should leverage comparison groups, either through randomized trials or quasi-experimental approaches, to compare outcomes among those who participate in Food is Medicine programs and similar patients who do not. These studies will provide the strongest evidence and allow successful models to scale.
- Studies should be designed to test what types of interventions work, at what dose, for what population, and for what duration. For example, researchers can assess the health impacts of providing food interventions plus nutrition education versus providing food interventions alone. The findings will build the case for health plans and payers to adopt, scale, and tailor coverage for highly effective Food is Medicine interventions.

### Food is Medicine Metrics to Advance Clinical and Policy Decision-Making

- Food is Medicine research should measure a broad set of health outcomes so that research metrics will fully capture the effects of interventions on individual and population health. These could include changes in diet, quality of life, clinical outcomes, mental health, engagement with health care, health care utilization, and cost-effectiveness. Assessed outcomes should reflect the needs and desires within a community, including participants and their care team, and not simply reflect the interests of researchers.
- Researchers and experts from the fields of health care, nutrition, public health, and dietetics, as well as Food is Medicine providers and advocacy organizations, should identify a set of meaningful metrics that can be incorporated across Food is Medicine research design and evaluation. Health care practitioners should use standardized metrics and validated tools when possible for specific health conditions. Previously developed toolkits, such as the Nutrition Incentive Hub's Core Metrics Toolkit, may be a helpful starting point for metrics development.

### Food is Medicine Research Outcomes that Will Support a Common Agenda

- Research that focuses on prevention and not solely on managing diet-related disease should be expanded—especially for populations, such as children, that can benefit greatly from a prevention model.
- Researchers should explore, and funding should be available to assess and evaluate, the wider spillover effects of Food is Medicine interventions on improving the health and nutrition security of entire households and not just study participants.
- (L) As part of the effort to build momentum toward integrating Food is Medicine and health care, health care organizations and payers should increasingly highlight data on the cost-effectiveness of Food is Medicine interventions for specific populations.

### Coordinating and Strengthening Related Federal Policy Efforts

- Government agencies and researchers should coordinate within and across departments to combine data on health outcomes and health care utilization (i.e., from Medicaid, Medicare, and the Veterans Health Administration) with enrollment and benefits data from the US Department of Agriculture and federal nutrition programs. This will allow researchers to evaluate health outcomes among Food is Medicine participants and within the general population.
- Food is Medicine research should continue to examine the ripple effects of other outcomes that more broadly address social drivers of health, such as reduced social isolation, household economic stability, and improved mental health in addition to Food is Medicine's impacts on local food systems.
- Building on the recommendations from the 2022 White House Conference on Hunger, Nutrition, and Health, the US Department of Health and Human Services should continue to lead and coordinate efforts across federal agencies to explore the impact of Food is Medicine interventions on health outcomes, health care utilization, and cost-effectiveness. HHS should guide federal investments in Food is Medicine research and encourage interagency collaboration. These investments could include cross-sector organizations and agencies working with specific populations like older adults and other vulnerable populations such as pregnant and postpartum women or those with disabilities. New collaborations will accelerate the integration of evidence-based Food is Medicine interventions across government programs and health care providers.

### I: Introduction

Amid a deepening understanding of the fundamental relationship between diet and health, the US health care system is a critical vehicle for addressing individual nutrition to prevent, manage, and potentially reverse chronic diseases. Efforts that involve a health care response to these nutrition needs fall under the umbrella term "**Food is Medicine.**"

The United States has arrived at a critical juncture for Food is Medicine, characterized in equal parts by scientific promise, a public health crisis, and the urgent need to advance equity throughout the food and health care systems.

In this Action Plan, "Food is Medicine interventions" are a spectrum of programs and services that respond to the critical link between nutrition and health. Food is Medicine interventions include:

- The provision of food that supports health, such as medically tailored meals or groceries, or food assistance, such as vouchers for produce; and
- A nexus to the health care system.

The United States faces an unrelenting chronic disease epidemic, leading to skyrocketing health care costs and devastating effects for individuals, communities, and the nation. These connections were further accentuated during the COVID-19 crisis, during which diet-related illnesses like diabetes and heart disease became leading risk factors for COVID-19 hospitalization and racial and ethnic disparities in food insecurity widened. An emerging body of research demonstrates the promise of Food is Medicine interventions across a range of health conditions. But health care providers, academic researchers, insurance providers, and policymakers alike want more purposeful research to build on early findings to facilitate the widespread adoption of effective Food is Medicine interventions.<sup>3</sup>

This Food is Medicine Research Action Plan lays out a comprehensive set of recommendations for creating an evidence base that will advance health care integration, build a holistic understanding of effectiveness, and engage communities, providers, researchers, and others working on Food is Medicine.

**"Health" defined:** In this Action Plan, health is complete physical, mental, and social well-being, which includes adapting to evolving health needs and preventing or optimally managing disease.<sup>4</sup>

Food has a direct relationship to individual and population health. Beyond its role in meeting the body's basic energy requirements, food can protect against many types of chronic disease, aid in disease management, support mental health, and build community and cultural traditions.

While early nutrition research centered on the health impact of particular foods or nutrients, the focus has shifted toward overall dietary patterns that support health. Diets rich in fruits, vegetables, whole grains, legumes, nuts and seeds, and fish are associated with a lower risk of disease; conversely, diets high in refined carbohydrates, added sugars and salt, alcohol, and processed meats are associated with a higher risk of disease.<sup>5</sup> People living with particular primary and comorbid health conditions may also have specific dietary needs that must be met in order to manage their conditions and maximize the effectiveness of medications.

**"Healthy dietary pattern" defined**: In 2015, the US Dietary Guidelines Advisory Committee described a healthy dietary pattern as "higher in vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; ... lower in red and processed meat; and low in sugar-sweetened foods and drinks and refined grains."<sup>6</sup> The 2020–2025 Dietary Guidelines for Americans build on this approach, identifying healthy dietary patterns for different life stages but finding that the "core elements of a healthy dietary pattern are remarkably consistent across the lifespan and across health outcomes."<sup>7</sup>

An estimated 60% of the US adult population suffers from at least one chronic health condition, and those that are diet-related are among the most prevalent: hypertension (27% of all adults), lipid disorders (22% of all adults), and type 2 diabetes (12% of all adults).<sup>8</sup> Diet-related health conditions cost the United States trillions of dollars each year in direct health care spending and lost economic productivity.<sup>9</sup> And these costs are rising.<sup>10</sup>

Diet quality is now the leading risk factor for death in the United States, surpassing tobacco use.<sup>11</sup> Cardiovascular diseases, cancer, and diabetes—all of which count diet as a significant risk factor—account for over half of all adult deaths.<sup>12</sup>

**"Foods that support health" defined:** In this Action Plan, foods that support health are those that allow people to eat according to the dietary patterns that scientific consensus has identified as the most likely to support physical, mental, and social well-being. These foods will evolve as research evolves and should cover a wide range of foods, making room for cultural traditions and individual preferences.

# **1 in 10** meets the US Dietary Guidelines recommendations for fruits and vegetables. **Adults & Communications**

Unfortunately, the diets of most US residents do not align with the healthy dietary pattern identified in nutrition research as most likely to prevent chronic diet-related disease.<sup>13</sup> Only one in 10 adults meet the US Dietary Guidelines recommendations for fruits and vegetables.<sup>14</sup> The majority of young people ages 2 to 19 consume diets that researchers describe as "poor quality," with less than 1% attaining "ideal quality."<sup>15</sup> Technological advances in food processing, the rise of mass marketing and food retail, societal changes that make convenience and shelf-stability key factors in food purchasing, and federal subsidies for staple crops mean that ultraprocessed foods are the most readily available and the least expensive, particularly in marginalized and under-resourced communities.<sup>16</sup> These foods, which are associated with increased caloric intake and weight gain, make up nearly 60% of the US diet and account for 90% of added sugar consumption.<sup>17</sup> Consumption of ultra-processed foods is also associated with increased risk for cardiovascular disease and early death.<sup>18</sup>

In addition to increasing health care costs, diet-related illnesses take a devastating toll on individual quality of life. Those living with these illnesses experience higher rates of physical disability, unemployment, stigma, depression, and anxiety.<sup>19</sup> These stresses are often compounded by onerous—and untenable—out-of-pocket expenses for medical care, also known as "financial toxicity."<sup>20</sup> "Tackling food insecurity is key to boosting our nation's health. Our understanding of science and social determinants that affect nutrition and physical activity has evolved in the past five decades, and it is high time we prioritize nutrition more for the sake of saving lives."

—Xavier Becerra, Secretary of Health and Human Services



### **Table 1: Diet-Related Health Conditions**

The range of diet-related health conditions varies widely, as does the precise role of diet in the prevention, progression, and management of different health conditions. With some health conditions, diet is associated with increased risk; with others, diet may not affect onset but can curb symptoms or even aid in treatment. Strengthening the research that supports this list is an important part of the Food is Medicine movement.

Health condition	Diet as part of primary prevention	Diet aids in treatment/ management
Malnutrition <sup>21</sup>	✓	✓
Diabetes <sup>22</sup> Type 2 diabetes Type 1 diabetes Gestational diabetes Diet-related risk factors (type 2 diabetes): prediabetes (HbA1c of 5.7% to 6.4%), central obesity, high BMI	√ √	✓ ✓ ✓
Cardiovascular conditions, various <sup>23</sup> Atherosclerosis Coronary heart disease (ischemic heart disease, coronary artery disease) Peripheral artery disease Congestive heart failure Stroke Heart attack (myocardial infarction) Hypertension (high blood pressure) Diet-related risk factors: central obesity, high BMI, hyperlipidemia (high cholesterol)	✓ ✓ ✓ ✓ ✓	✓ ✓ ✓ ✓ ✓
Cancer, various types <sup>24</sup>	[varies by type]	[varies by treatment]
<b>Kidney/renal diseases</b> <sup>25</sup> Chronic kidney disease End-stage renal disease/kidney failure	✓ ✓	✓ ✓
<b>Liver diseases</b> <sup>26</sup> Nonalcoholic fatty liver disease (nonalcoholic steatohepatitis) Alcoholic liver disease	√ √	✓
HIV/AIDS <sup>27</sup>		✓
Arthritis <sup>28</sup> Osteoarthritis Rheumatoid arthritis	✓	✓ [emerging]
Mental & neurological health, various conditions <sup>29</sup>	[varies by condition]	[varies by condition]
Pregnancy & early childhood development, various conditions <sup>30</sup>	[varies by condition]	[varies by condition]
COVID-19 <sup>31</sup>		✓

The burden of diet-related disease reflects the country's deepest divisions and inequalities, disproportionately affecting low-income and majority Black, Latinx, and Indigenous communities.<sup>32</sup>

Profound disparities by race and ethnicity in food insecurity reflect embodied injustices, and during the COVID-19 pandemic these disparities in food insecurity widened.<sup>33</sup> Addressing the epidemic of diet-related disease requires strengthening every individual's ability to consistently consume foods that support health. Contrary to narratives that emphasize individual behavior and choice, this effort must focus on the structural and systemic forces beyond individual control that overwhelmingly shape food access, diet, and health.<sup>34</sup> In 2022, 12.8% of US households were food insecure for at least some time during the year. But addressing food insecurity alone is not enough—nutrition security is essential for tackling diet-related disease.<sup>35</sup>

**"Structural racism" defined:** At the core of the racial and ethnic disparities that run throughout the food and health care systems is structural racism, which Professor Zinzi D. Bailey and colleagues define as:

Structural racism involves interconnected institutions, whose linkages are historically rooted and culturally reinforced. It refers to the totality of ways in which societies foster racial discrimination, through mutually reinforcing inequitable systems (in housing, education, employment, earnings, benefits, credit, media, health care, criminal justice, and so on) that in turn reinforce discriminatory beliefs, values, and distribution of resources, which together affect the risk of adverse health outcomes.<sup>36</sup>

Centuries of exclusionary policies have denied low-income and majority Black and brown communities access to foods that support health, along with affordable housing, outdoor spaces, quality medical care, stable employment, and well-resourced schools.<sup>37</sup> These interrelated policies continue to reverberate in today's society, resulting in unjust disparities in rates of chronic disease.<sup>38</sup> This reality increases the importance and urgency that Food is Medicine interventions effectively address the wants and needs of individuals and communities who historically have been excluded from equitable treatment at interpersonal, institutional, and systemic levels by majority-white institutions and policymakers.

When compared with other high-income countries, the United States spends nearly twice as much on health care yet has the highest rate of chronic diseases and the lowest life expectancy.<sup>39</sup> Efforts to reform the US health care system in the face of this grim reality have focused on three linked goals, known as the "triple aim": (1) improving the experience of health care among patients, (2) improving the health of populations, and (3) reducing the per capita cost of care.<sup>40</sup> This framework has recently been expanded to the "quadruple aim," with the inclusion of a critical fourth goal: improving the work life of health care providers.<sup>41</sup> The US health care system cannot achieve these aims without addressing diet, but unfortunately, it hasn't traditionally been set up to do so. Early research on Food is Medicine interventions demonstrates the potential for these interventions to have a meaningful impact in all four areas (see Section VI: Research on Food is Medicine Interventions).

Despite the longstanding recognition among the medical community that food and health are fundamentally linked, major public insurance programs have traditionally failed to cover food-based interventions, and the lack of consistent insurance coverage and payment continues to be a barrier for Food is Medicine implementation.<sup>42</sup> Historically, food and nutrition have been the domain of public health, federal assistance programs, and agriculture programs, rather than the health care system.<sup>43</sup>

As noted by the Bipartisan Policy Center: "Despite existing evidence related to the effectiveness of FIM [Food is Medicine] interventions, public and private payers and health care purchasers provide limited coverage. For instance, Medicare fee-for-service does not cover food is medicine interventions, although some Medicare Advantage plans do. Similarly, some state Medicaid plans provide MTM and other FIM interventions through Section 1115 waivers. These arrangements enable Medicaid managed care plans to cover alternative services in place of standard Medicaid benefits, if they are medically appropriate and cost-effective."<sup>44</sup>

Health care entities have only recently begun to formally recognize the disproportionate impact that food insecurity and poor diet have on health outcomes, establishing programs that identify and respond to the need for more or different types of food. However, these programs face numerous challenges. At a foundational level, food has not historically fit neatly into the clinical context; the complexity of daily nutrition is difficult to address in a 15-minute consultation, and many patients with diet-related illnesses don't have insurance coverage for nutritional counseling. Even leaders within the health care system such as physicians have minimal formal nutrition education. Often there is no billing mechanism for food resources. Formal community referral systems face limitations as community-based nutrition programs may not have the resources to provide patients with the food they need. Equipping the health care system to respond appropriately to nutritional needs requires sufficient funding and significant collaboration largely with partners outside of the clinical setting. In addition, these programs face barriers related to data-sharing and confusion around the application of health care fraud and abuse laws, which can create further challenges for operation and administration.45



Ultimately, lack of clarity around when food can be a health care benefit and, if it is not a health care benefit, how it can be utilized to support patients and their families means that formal reforms may be needed to meaningfully integrate Food is Medicine interventions into health care. Because support for health care reforms is driven by research on intervention efficacy, developing a robust body of evidence is critical. The compelling findings of research so far, the proliferation of interventions, and the momentum around Food is Medicine make deep investigation a worthwhile and urgent endeavor.



# Table 2: A Timeline of Select Significant Events in the Evolution of Food is MedicineSince 1929

### The Concept of Food is Medicine is Not New

In the United States, institutional recognition within the medical field of the close link between nutrition and health goes back nearly 100 years. In 1929, the American Medical Association launched its Committee on Foods, which was later broadened to the Council on Foods and Nutrition.<sup>46</sup> In 1941, during World War II, President Franklin Delano Roosevelt convened his first White House conference on the topic of Nutrition for Defense. The conference largely focused on "public health and medical aspects of nutrition" and concluded with a list of key findings, the first being that "great and sometimes startling advances in our knowledge of nutrition in recent years have made it clear that the food an individual eats fundamentally affects his health, strength, stamina, nervous condition, morale, and mental functioning."<sup>47</sup>

- 1929: The American Medical Association launches its Committee on Foods.<sup>48</sup>
- 1941: President Franklin Delano Roosevelt convenes the White House Conference on Nutrition for Defense.<sup>49</sup>
- 1946: Congress passes the National School Lunch Act to "safeguard the health and well-being of the Nation's children and to encourage the domestic consumption of nutritious agricultural commodities and other food."<sup>50</sup>
- 1964: Congress passes the Food Stamp Act, permanently authorizing the Food Stamp Program (renamed the Supplemental Nutrition Assistance Program, or SNAP, in 2008) to support "improved levels of nutrition among low-income households."<sup>51</sup>
- 1966: Congress passes the Child Nutrition Act, which establishes the School Breakfast Program as well as other child nutrition programs, in "recognition of the demonstrated relationship between food and good nutrition and the capacity of children to develop and learn."<sup>52</sup>
- Late 1960s: Dr. H. Jack Geiger and colleagues offer "prescriptions" for food to families with malnourished children out of a community health center in Mound Bayou, Mississippi.<sup>53</sup>
- 1969: President Richard Nixon convenes the White House Conference on Food, Nutrition, and Health.<sup>54</sup> The conference resulted in a report containing around 1,800 recommendations to end hunger and malnutrition in the United States—1,650 of which were implemented within two years of the conference.<sup>55</sup>
- 1971-1972: The 1971 White House Conference on Aging report finds that "one-half to one-third of the health problems of the elderly are related to nutrition" and recommends that nutrition services and counseling be "a required component of all health delivery systems."<sup>56</sup> The following year, Congress passes the Older Americans Act, establishing the Elderly Nutrition Program to provide grants to states for congregate and home-delivered meal programs.<sup>57</sup>
  - **1971–1974:** The Food Stamp Program undergoes significant legislative changes aimed at increasing participation, including the requirement that states expand the program to every political jurisdiction.<sup>58</sup>
  - **1972–1975:** The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) evolves from a pilot to a permanent program, authorized by Congress to "provide supplemental nutritious food as an adjunct to good health care during such critical times of growth and development in order to prevent the occurrence of health problems."<sup>59</sup>

- 1983: Section 1915(c) of the Social Security Act allows home- and community-based services waivers in the Medicaid program. It is the first vehicle to allow Medicaid dollars to pay for homedelivered meals for certain enrollees (at a minimum, those who would need to be institutionalized if not for the provision of such services).<sup>60</sup>
- 1985: The first medically tailored meal organizations are founded in response to the HIV pandemic. The combination of access to registered dietitian nutritionists and home-delivered meals helped people living with HIV combat wasting and manage medications and side effects.<sup>61</sup>
- 1990: Congress passes the Ryan White CARE Act, establishing the Ryan White HIV/AIDS Program to fund treatment and comprehensive care services, including "nutrition services," for low-income people living with HIV.<sup>62</sup>
- 1994: A group of food and nutrition providers serving people living with HIV holds the first annual conference of the AIDS Nutrition Services Association (ANSA), later renamed the Association of Nutrition Services Agencies, to share best practices and nutrition science.<sup>63</sup>
- Late 1990s-early 2000s: Most medically tailored meal organizations expand their missions to serve people living with all illnesses.<sup>64</sup>
- 2010: Congress passes the Patient Protection and Affordable Care Act (ACA), instituting health care reform across the country and sanctioning many innovative projects that have come to include Food is Medicine interventions.<sup>65</sup>
- 2010-2013: ANSA dissolves and is re-formed as the Food Is Medicine Coalition, a national alliance
  of nonprofits delivering medically tailored meals, nutrition counseling, and education to people
  across the country who are too ill to shop or cook for themselves.<sup>66</sup>
- 2014: The Agricultural Act of 2014 (also known as the Farm Bill) establishes the Food Insecurity Nutrition Incentive Program (FINI) grant program, dedicating \$100 million to support produceincentive programs for SNAP recipients, and permitting a "produce-prescription" design for these incentives.<sup>67</sup>
- 2016: The Centers for Medicare & Medicaid Services (CMS) launch the Accountable Health Communities model, authorized under the ACA, to test whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services will impact health care costs and reduce health care utilization.<sup>68</sup>
- 2016–2018: CMS approves requests from states, such as Massachusetts and North Carolina, to implement Medicaid Demonstration Waivers that allow states to use Medicaid funds to address health-related social needs through a variety of programs, including nutrition interventions.<sup>69</sup>

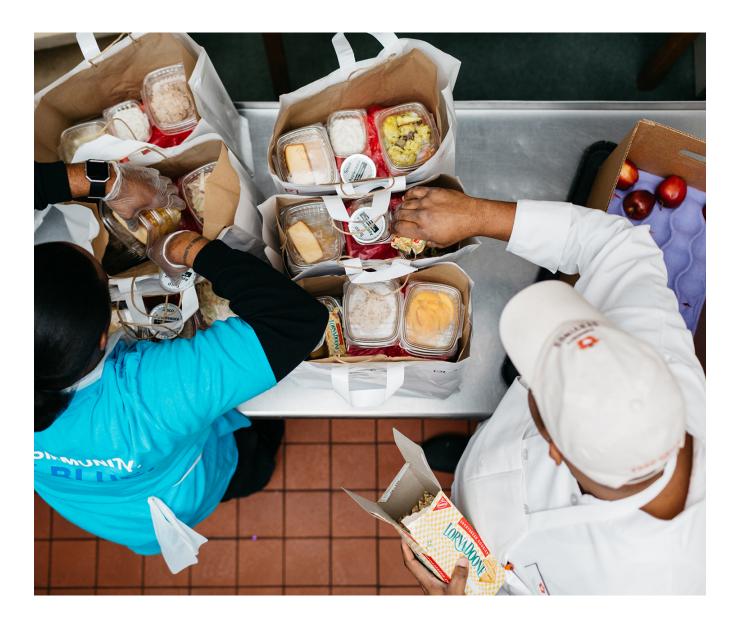
- 2018-2019: CMS broadens the scope of supplemental benefits covered under Medicare Advantage plans so that plans may cover nutrition services for certain groups.<sup>70</sup>
- 2018: The California state legislature appropriates \$6 million for a three-year medically tailored meals pilot for Medi-Cal (the state's Medicaid program) recipients with congestive heart failure.<sup>71</sup>
- 2018: The bipartisan Food is Medicine Working Group forms in the US House of Representatives.<sup>72</sup> 2018: The Agricultural Improvement Act of 2018 (the Farm Bill) renames FINI as the Gus Schumacher Nutrition Incentive Program (GusNIP) and expands funding to \$250 million, with a maximum of 10% set aside to support produce prescription programs over five years (2019–2023).<sup>73</sup>
- 2019: The National Produce Prescription Coalition, comprising produce prescription program operators, researchers, and advocates, forms to "catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness through the healthcare system, and embedding & institutionalizing Produce Prescriptions within the healthcare payment model."<sup>74</sup>
- 2020: North Carolina authorizes \$2.5 million in state funding to expand a pilot produce prescription program across the state.<sup>75</sup>
- 2020: New York includes medically tailored meals on a list of approved services that managed care
  plans can choose to provide to enrolled Medicaid members as covered benefits.<sup>76</sup>
- 2020: The House Appropriations Committee directs the National Institutes of Health (NIH) to research Food is Medicine, explicitly naming medically tailored meals and produce prescriptions.<sup>77</sup>
- 2020: The NIH includes evaluating "how we can improve the use of food as medicine" as one of four strategic goals in its 2020–2030 Strategic Plan for NIH Nutrition Research.<sup>78</sup>
- 2020: The Flexible Services Program launches in Massachusetts' Medicaid as a result of an innovative Section 1115 Medicaid Waiver. This represents the first, large-scale testing of Food is Medicine in a state Medicaid program.
- 2020: Legislation that would require the Massachusetts Medicaid program to mount and evaluate a pilot that connects Medicaid enrollees to a spectrum of food and nutrition interventions is introduced in the state legislature, and reintroduced in 2021.<sup>79</sup>

- 2020: The Medically Tailored Meals Pilot Demonstration Act is introduced in the US House of Representatives, proposing the creation and evaluation of a CMS medically tailored meals pilot program for Medicare enrollees following inpatient hospital admission, but it does not pass. The bill is reintroduced in 2021.<sup>80</sup>
- **2020–2021:** The federal response to the COVID-19 pandemic includes an array of new assistance programs, enhancements, and flexibilities for existing programs and funding opportunities. These include an increase in SNAP's maximum benefit, SNAP emergency allotments, countless flexibilities in SNAP administration, school meal replacement through Pandemic-EBT (electronic benefit transfer) cards, the Farmers to Families Food Box Program, \$75 million in GusNIP COVID Relief and Response grants, extended Medicaid waivers allowing meal delivery, expanded unemployment benefits, stimulus checks, an expanded Child Tax Credit, and more. SNAP benefits also increased by 21% in 2021 after the US Department of Agriculture conducted a review of the Thrifty Food Plan that the SNAP allotment is based on.<sup>81</sup>
- 2020-2021: Congress attempts to appropriate funds for produce prescription pilot programs in both the Veterans Health Administration and Indian Health Service.<sup>82</sup>
- 2021: Virginia establishes a working group to plan for a three-year produce prescription pilot, and requests \$2 million to operate it.<sup>83</sup>
- 2021: California proposes including medically supportive food and nutrition interventions on a list
  of approved services that managed care plans can choose to provide to enrolled Medicaid members
  as covered benefits.<sup>84</sup>
- 2021: The Medical Nutrition Therapy Act of 2021 is introduced in the House of Representatives. It
  would expand Medicare coverage of medical nutrition therapy services.
- 2022: In the 117th Congress (2021–2022), Representatives James McGovern (D-MA) and Michael Burgess (R-TX) propose a House resolution calling on medical schools as well as residency and fellowship programs to strengthen nutrition education for physicians. It passes the House of Representatives in May 2022.
- 2022: US Department of Agriculture (USDA) Secretary Tom Vilsack announces a report detailing the USDA's <u>Actions on Nutrition Security</u> that highlights the department's commitment to advancing nutrition security and the consistent access to safe, nutritious food that supports the optimal health and well-being of all Americans.<sup>85</sup>

- **2022:** The Biden Administration's White House Conference on Hunger, Nutrition, and Health is held, over 50 years after the first conference in 1969. The conference caps a nearly yearlong engagement with stakeholders across the United States and results in the National Strategy on Hunger, Nutrition, and Health. This report features an entire section on how health care can engage issues of nutrition and food insecurity and includes recommendations specific to Food is Medicine, most notably a call to expand access in Medicare and Medicaid to Food is Medicine programs.
- 2022: The Centers for Medicare and Medicaid Services encourage states to submit Section 1115 Medicaid waivers to allow coverage of Food is Medicine programs for Medicaid members. These waivers represent an increasingly popular regulatory pathway to increase payment for Food is Medicine services in Medicaid for select members within participating states, which is not allowed generally under federal law.
- 2023: The Bipartisan Policy Center convenes a Food is Medicine Working Group co-chaired by former Senate Majority Leader Bill Frist, former Agriculture Secretaries Dan Glickman and Ann Veneman, and former US Health and Human Services Secretary Donna Shalala. With the input of external stakeholders, this working group issues a report including 10 recommendations to improve nutrition education and scale evidence-based Food is Medicine interventions.<sup>86</sup>
- 2023: Indian Health Services launches a produce prescription pilot that includes programs in several tribal nations that are tailored in their design to meet the needs and food preferences of tribal communities.
- **2023:** The Veterans Health Administration launches a produce prescription pilot in partnership with the Rockefeller Foundation.
- 2023: The American Heart Association launches a bold and ambitious Food is Medicine Initiative in partnership with the Rockefeller Foundation, promising \$250 million in research funding over 10 years. The funding will prioritize identifying best practices in program design and testing successful Food is Medicine programs in large, randomized controlled trials.
- 2023: NIH demonstrates a growing commitment to Food is Medicine research, which includes a Request for Information on Food is Medicine to guide its research strategy and an announcement of a Food is Medicine Centers of Excellence concept to catalyze such research.
- 2023: By the end of 2023, 10 US states (California, Massachusetts, New Jersey, North Carolina, Oregon, Washington, Delaware, Illinois, New Mexico, and New York) have approved, or have pending requests for Medicaid Section 1115 waivers to cover, Food is Medicine services for select members.

Food is Medicine can equip the health care system to respond to nutrition needs while building the evidence base for broader reform.

This Food is Medicine Research Action Plan asserts a cohesive direction for future research that can illuminate who will benefit from what types of nutrition interventions, in what ways, and under what circumstances— while maintaining equity as the guiding force for research prioritization and design. This Action Plan focuses on the health care system as the main vehicle for providing Food is Medicine interventions in the short term. However, the findings from the research proposed in this Action Plan will have important implications for broader structural reforms in the food system and beyond. Inquiry at the intersection of health care and food is a critical pursuit that can push nutrition research in practical, productive, and interdisciplinary directions. By changing and monitoring how Americans typically respond to food insecurity and nutrition needs as they relate to preventative, curative, and ameliorative health care, researchers will uncover important truths that can inform future health, food, labor, agriculture, transportation, and environmental policies.



### **II: About the Food is Medicine Initiative**

In this section, the Food is Medicine Research Action Plan introduces its goals, defines its target audience, and describes its development.

### Mission

The Food is Medicine initiative of Food & Society at the Aspen Institute catalyzes investment in high-impact Food is Medicine research to advance health care integration, build a holistic understanding of effectiveness, and engage new communities, providers, and researchers.

### Vision

### Food & Society works toward a future in which:

- Everyone has the food that will allow them to live a healthy, dignified life according to their specific needs;
- Effective, appropriate Food is Medicine interventions are integrated into the US health care system nationwide; and
- All Food is Medicine research applies an equity framework to ensure that interventions empower individuals and communities and are effective across demographic groups.

### **About the Food is Medicine Research Action Plan**

This Action Plan assesses and builds on Food is Medicine findings to date. The proposed recommendations will allow the health care system to deploy effective nutrition interventions in both the near and longer term, as well as provide a credible basis for redesigning policy and regulatory mechanisms to support that shift.

### This Action Plan includes:

- An overview of the current research on the health impacts of food insecurity, key federal nutrition programs, and Food is Medicine interventions; and
- Concrete recommendations for future research in the field with respect to:
  - Ensuring that research is conceived, designed, executed, implemented, and disseminated using an equity framework;
  - Identifying key considerations to ensure that research designs are robust and appropriate for yielding the most valuable and actionable information;
  - Identifying the most urgent questions that have yet to be explored;
  - Funding the most valuable research in the field; and
  - Understanding the research outside the scope of Food is Medicine that has major implications for nutrition and health, both within and beyond the health care system.

### This Action Plan is written for:

### Researchers

By identifying key evidence gaps, we hope to encourage existing experts in the field and new researchers to explore questions that will move Food is Medicine forward. We also aim to help stakeholders across all sectors increase access to foods that support health. To encourage engagement and alignment with an equity lens, we share methods for centering racial equity in research as well as best practices to ensure that research is a positive and productive experience for participants, and that results are meaningful and translatable.

### Advocates

The Action Plan contains a clear-eyed assessment of Food is Medicine research and specific recommendations on how to build the evidence base. It argues that research can demonstrate the value of Food is Medicine from several perspectives, from impact on health care utilization and cost to individual wellbeing and community resilience.

### Program Implementers

Funders

Comprehensive investigation in the Food is Medicine field requires robust investment from a range of funders, both public and private. The Action Plan identifies opportunities that are particularly suited to certain funders, and to collaborative funding. We encourage funders to review plans to support Food is Medicine research with a focus on equity. Partners and funders ask Food is Medicine programs to demonstrate impact and value. We reflect on research objectives, design, outcomes, and processes to help program implementers use research and evaluation dollars wisely. We also aim to help them invest in research that meaningfully adds to the field while minimizing burdens on program staff and participants.

### **Process**

The first *Food* is *Medicine Research* Action Plan, released in 2022, was the result of a two-year, highly collaborative process that launched just as the COVID-19 pandemic was taking hold. Though the onset of the pandemic altered timelines and plans for in-person meetings, the initiative still actively engaged experts from all sectors, organizations, and institutions working in Food is Medicine. The initiative also responded to the national call for racial justice and an end to systems of racism, exclusion, and oppression.

The report has since been updated to include the latest research data and to streamline the report's recommendations based on new advances and the greatly increased number of organizations, companies, researchers, and advocates bringing new energy and ideas into the Food is Medicine field.

### To inform this Action Plan, the Food is Medicine Initiative:

- Formed an Advisory Board: The Advisory Board includes:
  - Clinical researchers, social scientists, and physicians who study food and health inequities;
  - Representatives from food banks and providers of medically tailored meals, medically tailored groceries, and produce prescriptions;
  - Representatives from relevant federal agencies, including the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention; and
  - Representatives from other key groups, such as health care organizations, health insurers, retail, and philanthropy.
- **Defined "Food is Medicine":** As the term "Food is Medicine" does not have a technical, widely agreed-upon definition, it was important to establish a definition for the purposes of the initiative. The initiative worked closely with the Advisory Board to establish a definition both narrow enough to yield useful recommendations and broad enough to encompass a range of promising interventions.
- Launched the initiative: In June 2020, the leadership team hosted a two-day online meeting to introduce the initiative and explore key topics with some of the field's leading figures. The 55 attendees represented a range of fields and disciplines, including academic research, program evaluation, health care delivery, food and nutrition program delivery, health insurance, policy advocacy, federal policy, and retail. The initial gathering identified areas for further exploration and directly informed the structure and content of this report.
- Gathered data and input: Following the initial launch, the leadership team conducted a series of targeted workshops, listening sessions, and key informant interviews to gather information and go more in-depth. Topics included research methodology, regional challenges, data, COVID-19, payer perspectives, and racial equity in research. Throughout 2023, the initiative partnered with Food is Medicine experts to host meaningful and action-oriented convenings in California, Boston, and Topeka, each focused on national perspectives, local perspectives, and most importantly, lived experiences that played a significant role in updating this year's report.
- Reviewed the literature: The initiative attempted to include all peer-reviewed Food is Medicine studies published in the United States in this report. To that end, we searched the PubMed database for many iterations of key terms associated with Food is Medicine programs and included all the studies that: (1) were conducted in the United States, (2) provided free, healthy food to patients, and (3) had a direct connection with the health care system. To focus our review for this report, we excluded research on federal nutrition programs or research on food insecurity generally that didn't intersect with a health care system. These studies are comprehensively summarized in newly updated research tables (in <u>Section VI: Research on Food is Medicine Interventions</u>) and contain research published until December 2023. These tables are a comprehensive summary of the state of the Food is Medicine field and can serve as a rich resource for policymakers, researchers, and program implementers. Findings from this research review also guided this report's recommendations, in particular helping to identify key gaps in the literature.

### Key Insights that Informed the Food is Medicine Initiative and Action Plan

This Action Plan builds on the knowledge and activities of individuals, organizations, and institutions that have developed and worked in this field for many years. The following key insights gleaned from that work informed the initial outline and creation process:

The existing evidence base demonstrates sufficient promise to warrant further research and implementation of proven interventions.

There is a lack of consensus and coordination about research in the field. This is due, in part, to disparate actors—from researchers and program providers to health care payers and policymakers—operating within a field that is cross-disciplinary by definition.

Food and nutrition interventions are rarely one size fits all. The field needs a nuanced portrait of what works, for whom it works, and why it works to ensure appropriate and effective scale. Large-scale investment in Food is Medicine research will yield results and insights to support effective implementation by program providers and coverage by health care payers.

Non-temporary funding for evidence-based Food is Medicine interventions is best achieved through the public and private health care system. Retrofitting and reforming the health care system to integrate these interventions will require buy-in from the health care sector. It will also necessitate structural reforms to support program coverage and administration, as well as significant philanthropic and government investment in research and program innovation.

Though the impact of Food is Medicine interventions on health care costs can and will be further explored, the key metrics by which Food is Medicine interventions are evaluated must extend beyond cost.

Food is Medicine interventions should further build on and enhance—not replace—the current baseline support for food access across the United States.

In the absence of transformative changes to the social safety net in the United States, and given the economic and health impacts of the COVID-19 pandemic, Food & Society at the Aspen Institute anticipates that rates of food insecurity and chronic diet-related disease will persist in the coming years. Likewise, we anticipate that the country's rampant health disparities, many of which were exacerbated by the recent pandemic, will persist or even rise.

We expect to see a significant impact on health and well-being by better understanding how to leverage nutrition within the current and near-future health care system. A robust body of evidence on Food is Medicine interventions will also have enormous value for informing broader reform efforts in the food and health care systems. However, the full scale of this benefit may not be observable for many years.

Where the health care and food systems intersect is the scope of this Action Plan. While the research shows a measurable clinical impact from increasing access to Food is Medicine interventions, many potential clients, patients, and beneficiaries do not have access to a health care system that includes these types of initiatives. Strategically building the evidence base for health care integration from the outset can help ensure that Food is Medicine interventions do not exacerbate or compound such inequities within the health care system.

### **III. Food is Medicine Defined**

This section lays out the scope of Food is Medicine interventions explored in this Action Plan and describes the main categories of interventions.

The phrase "Food is Medicine" has been used in connection with a broad array of concepts, products, and services. The idea that food is central to health is a tenet of many cultures.<sup>87</sup> The phrase has also been used to market foods and dietary supplements.<sup>88</sup>

Food & Society at the Aspen Institute adopts a more specific definition. The purpose of this Action Plan is to articulate how research can move society toward widespread and equitable access to evidence-based, culturally appropriate, and community-centered nutrition interventions in the context of health care. Accordingly, this report uses "Food is Medicine" to refer to the intersection of food and health care. And "Food is Medicine interventions" refers to the specific activities that increase access to foods that support health in that context.

# In this Action Plan, "Food is Medicine interventions" are a spectrum of programs and services that respond to the critical link between nutrition and health. Food is Medicine

### interventions include:

- The provision of foods that support health, such as medically tailored meals or groceries, or food assistance, such as vouchers for produce; and
- A nexus to the health care system.

### Currently, Food is Medicine interventions are accessed in one of two ways:

- Interventions are actively recommended by a health care provider who has identified the need for the intervention in a clinical setting. In this scenario, a provider screens or assesses a patient and immediately provides a referral or prescription for the intervention.
- Interventions are provided because the individual has been previously screened for, deemed at
  risk for, or diagnosed with a health condition that is related to or affected by diet. Although the
  screening or diagnosis may have taken place in a health care setting, the intervention is provided
  without the active involvement of a health care provider.

For example, someone who is food insecure and diagnosed with type 2 diabetes might access a medically tailored food box at a food bank without their provider's direct involvement or knowledge. In this scenario, identification of the health risk or health-related need that prompts eligibility for the intervention—confirmation of food insecurity and the existence of a diet-related health condition—takes place in a community setting.

The clinical and community access points for Food is Medicine interventions reflect the movement's origins. For example, **medically tailored meals** were initially provided as a community response to a health issue (wasting among people living with HIV), but their provision was divorced from the health care system.<sup>89</sup> As management and treatment of HIV/AIDS evolved and experience demonstrated the critical importance of nutrition, health care providers became more involved.

Today, registered dietitian nutritionists (RDNs) design medically tailored meals for individuals while clinicians assess their needs and eligibility. The Ryan White CARE Act acknowledged the importance of medically tailored nutrition in the management of HIV by providing funding for these services in addition to medical and pharmaceutical interventions.<sup>90</sup> Providers of medically tailored meals quickly recognized that people living with HIV were not the only individuals who needed access to disease-specific nutrition. To date, however, there are not similar federal funding streams for those living with other illnesses.

A 2022 study found that national implementation of medically tailored meals for people with diet-related conditions and activity limitations could prevent approximately 1.6 million yearly hospitalizations<sup>91</sup> and collectively save Medicare, Medicaid, and private payers \$13.6 billion each year.<sup>92</sup>

**Produce prescriptions** also largely originated outside the health care system. Although Dr. Jack Geiger famously prescribed food for his malnourished patients living in the Mississippi Delta in the 1960s, the practice wasn't widespread.<sup>93</sup> In the 1980s and 1990s, a series of federal and state programs began to provide subsidies or vouchers for fruits and vegetables, especially locally grown fruits and vegetables.<sup>94</sup> While these programs often targeted groups with specific nutritional needs and access challenges (such as WIC participants or low-income seniors), they were also created to promote the purchase of local food and were divorced from health care.<sup>95</sup> With increasing recognition of the association between diet and chronic disease, the link between produce subsidies and health care was reemphasized, culminating in the 2018 Farm Bill, which set aside up to 10% of \$250 million in nutrition incentive funding for programs that involve a health care entity and measure success, in part, based on health outcome metrics.<sup>96</sup>

A 2023 study of nearly 4,000 participants from 12 US states found that produce prescription participation was associated with improved food and vegetable intake, food insecurity, and health status of both adults and children. Importantly, among adults with hypertension, diabetes, and obesity, the study also found clinically meaningful reductions in blood pressure, blood glucose levels, and weight. Also that year, a randomized controlled trial of adults with diabetes receiving home-delivered produce found very similar effects on blood glucose levels.<sup>97</sup>

### Interventions Within this Action Plan's Definition and Scope

This Action Plan focuses on three categories of interventions:

- 1 medically tailored meals
- 2 medically tailored groceries
- 3 produce prescriptions

National coalitions of intervention providers have established definitions of two of these categories—medically tailored meals and produce prescriptions—that have recently been adopted by many health care entities and government programs. However, interventions that are evaluated in the peer-reviewed literature and described as medically tailored meals and produce prescriptions do not always align with these definitions.

In describing each intervention category, this Action Plan acknowledges any specific definitions established by national coalitions and the breadth of activities and services that appear in the peer-reviewed literature using the same terminology. Where, as in the case of medically tailored groceries, there is no national coalition that has defined the intervention, this Action Plan describes the breadth of activities and services that appear in the peer-reviewed literature and refers to definitions of similar services adopted by state health care entities.

The goal of describing these interventions is not to limit the scope of Food is Medicine interventions, which are evolving in response to research and the complex realities of the health care and food systems, but to capture where the field is now. As a result, future research can build on and further explore, rather than repeat, the existing literature.

### **Table 3: Overview of Food is Medicine Interventions**

Food is Medicine interventions involve a range of key design and implementation decisions, each with the potential to impact health outcomes. In distinguishing the three intervention categories covered in this report, we largely focus on the preparation level of the food provided (complete meals, a range of perishable and nonperishable grocery items, or produce only) and the amount of food provided (complete or near-complete nutritional needs, partial nutritional needs, or supplemental nutritional needs). This categorization is not intended as a bright-line rule but rather as a helpful schema. Indeed, the line between medically tailored groceries and produce prescriptions is already quite blurry as produce prescriptions are sometimes expanded to offer a greater quantity of food or to cover non-produce items.

	Medically tailored meals	Medically tailored groceries*	Produce prescriptions*
Preparation level and type of food	Ready-to-eat (reheated in an oven or microwave) meals and snacks	A range of perishable and nonperishable grocery items, including produce, that will require further preparation	Produce—fresh, frozen, or canned (no added salt, sugar, or fat)—which, depending on the items, may require further preparation
Amount of food	Complete or near-complete (over 50% of caloric needs met) nutrition	Partial or near-complete nutrition	Supplemental nutrition

\*There is significant overlap between these two categories as some produce prescriptions cover significant amounts of produce (either via voucher or direct provision) or even non-produce, minimally processed items.





**Medically tailored meals defined:** Fully prepared meals designed by an RDN to address an individual's medical diagnosis, symptoms, allergies, and medication side effects.

**Food is Medicine Coalition defined:** "Medically tailored meals are delivered to individuals living with severe illness through a referral from a medical professional or health care plan. Meal plans are tailored to the medical needs of the recipient by a Registered Dietitian Nutritionist (RDN), and are designed to improve health outcomes, lower cost of care, and increase patient satisfaction."<sup>98</sup>

Typically, a physician or other health care provider identifies the need for medically tailored meals and then refers the patient to a medically tailored meal organization and provides information about the patient's diagnoses and other relevant health data. Patients generally have complex and/or terminal illnesses and co-occurring conditions that make it difficult to shop or cook. Medically tailored meal interventions frequently include access to medical nutrition therapy or nutritional counseling from RDNs who are either employed by the meal provider or a health care organization in partnership with the meal provider.

Given the origins of medically tailored meals during the height of the HIV epidemic and the demographic of individuals with very complex health needs who generally receive them today, medically tailored meals are frequently a long-term critical support. Recently, health care insurers and providers have started offering medically tailored meals on a short-term basis as a post-hospitalization outpatient support or to address an acute clinical need, such as very high hemoglobin A1c (HbA1c) levels among people with diabetes.<sup>99</sup> Insurers and providers have also offered medically tailored meals to people experiencing high-risk pregnancies.<sup>100</sup> With these shorter-term uses, the duration of the intervention is set by the insurance plan, funder, or health care organization policy. Where duration isn't set by policy, the ongoing need for medically tailored meals is periodically re-certified by the medical provider.

### **Table 4: Medically Tailored Meals in Practice**

ſ	a member organization of the Food	is Medicine Coalition
	Medically Tailored Meals: In General	Use Case: Medically Tailored Meals for People Living with Diabetes and Renal Failure
Clients/ participants	Medically tailored meal programs typically serve clients living with severe and/or chronic illness with limitations on activities of daily living.	Participants are patients at a dialysis center who have a diagnosis of type 2 diabetes and end-stage renal disease.
	Prevalent diagnoses include congestive heart failure, chronic kidney disease, uncontrolled diabetes, HIV/AIDs, and cancer. Most clients have two or more comorbidities.	
Referral/ dentification	Clients are assessed for the need for medically tailored meals by a health care provider or health insurance plan. Those identified as eligible based on specific program criteria are then referred to the medically tailored meal provider, in many cases a community- based nonprofit organization.	Patients are identified and referred to services in one of two ways: (1) clinicians or staff overseeing the dialysis screen the patients for nutrition needs, or (2) the patient's treating physician, usually an endocrinologist or nephrologist, refers the patient.
ood election ind sourcing	Meal plans are tailored to the medical needs of the client by an RDN, reflecting appropriate dietary therapies based on evidence-based nutritional practice guidelines to address medical diagnoses, symptoms, allergies, and medication side effects.	Following a referral, the medically tailored meals organization conducts an intake with the patient that identifies relevant details about the client's home environment, such as the client's food preparation equipment, and identifies any mobility needs.
	Medically tailored meal providers layer specialty diets, including but not limited to renal, diabetic, heart-healthy, and texture- modified (soft, minced, pureed) diets. Food is Medicine Coalition member organizations follow the Coalition's Medically Tailored Meal Nutrition Standards, which establish specific nutrient requirements for different health conditions.	An RDN then performs an in-depth nutrition assessment to identify nutrition-related problems, determine the level of care, create a treatment plan with the client that includes the planned intervention and frequency of evaluation, assign any necessary dietary restrictions, conduct counseling, and provide verbal and written education following evidence-based nutritional guidelines.
		The RDN selects an appropriate meal plan based on the patient's individual needs. For this patient population, the meal plan would provide an adequate amount of calories and protein, while controlling for the amount of sodium, potassium, phosphorus, fluid, and added sugars.

### Table 4: Medically Tailored Meals in Practice, continued

	Medically Tailored Meals: In General	Use Case: Medically Tailored Meals for People Living with Diabetes and Renal Failure
Food preparation and other program components	For organizations that belong to the Food is Medicine Coalition, nutrition assessment and ongoing opportunities for nutrition counseling and medical nutrition therapy are offered along with the meal program. Organizations must prepare meals from scratch using fresh ingredients, without fillers or preservatives. Medically tailored meal providers must maintain passing grades on food-safety inspections from the local departments of health on a consistent basis. There must be a certified food handler on every food- related shift. Any individuals who work with food must receive food-safety training.	Meals are fully prepared in the organization's commercial-grade kitchen and flash frozen. Patients reheat meals throughout the week according to the instructions; meals can be reheated in a microwave or oven. Meals include a well-balanced entrée, salad, roll, and low-sugar dessert or fruit, as appropriate based on the nutrition assessment. Ongoing nutrition counseling is available to the client throughout. Patients can speak with an RDN on staff at the medically tailored meal organization to discuss how to navigate their meal schedule and medications throughout the day and about foods they are using to supplement their diet for any meals not provided by the program.
Food distribution and/or delivery	Medically tailored meals are available through home delivery or pick-up. Home delivery is an especially important feature for clients with mobility issues. All nutrition services, including assessment and counseling, are delivered either in person or via telehealth.	10-21 meals are delivered once per week to the patient's home in a refrigerated vehicle.
Duration	Medically tailored meals can be utilized for short or long durations. They are frequently part of a long-term health management plan for patients experiencing severe illnesses, like cancer or HIV. Patients with chronic illnesses will generally have an initial assessment and then a reassessment for need and eligibility every six months. Alternatively, medically tailored meals can be episodic, such as during a high-risk pregnancy and the postpartum period, or as part of a patient's recovery process, such as after surgery, during chemotherapy, or after an in-patient hospitalization. Ideally, the duration will match a patient's medical needs and allow for re-dosing as appropriate.	Patients with these diagnoses are usually referred to the program for one year, with an RDN assessment every six months to adjust dietary needs and to determine continued eligibility and need for the program. When meals are provided to a patient as part of a contract with an insurer or hospital, the contract determines the duration and number of meals; it can be shorter or longer than six months and include a varied number of meals per week.



**Medically tailored groceries defined:** Distributions of unprepared or lightly processed foods that recipients are meant to prepare for consumption at home; the contents are sufficient to prepare nutritionally complete meals or provide a significant portion of the ingredients for such meals, including produce, whole grains and legumes, and lean proteins.

Medically tailored groceries range from boxes of store-bought shelf products to a format similar to a meal kit, with ingredients portioned by meal and small allocations of items like spice blends and sauces.<sup>101</sup> Distribution sites include food pantries located on-site in health care settings, community food pantries, and other community organizations. Some programs offer home delivery. Nutrition education and recipes are sometimes made available to recipients, and the food items are approved by an RDN as appropriate for certain medical diets and health conditions, such as a diabetes-appropriate food box. Generally, however, food is not tailored to individual cultural needs, food preferences, or preparation abilities. Recipients are screened for food insecurity or deemed eligible for the intervention due to participation in a means-tested program such as Medicaid or SNAP.

### **Table 5: Medically Tailored Groceries in Practice**

Use Case Provided by Dr. Hilary Seligman of the University of California-San Francisco and Joy Goetz of the Atlanta Community Food Bank		
	Medically Tailored Groceries/Food Boxes: In General	Use Case: Grady Hospital Food as Medicine Prescription Program in partnership with Atlanta Community Food Bank: A Food Pharmacy
Clients/ participants	<ul> <li>Medically tailored groceries or food boxes typically serve clients with diet-related health risks or conditions who are:</li> <li>food insecure or have other documented challenges accessing nutritious foods;</li> <li>able to prepare food for themselves using raw ingredients; and</li> <li>have minimal barriers to picking up food from a community location.</li> </ul>	Participants are patients of primary care physicians within Grady Health System. They have been identified through a clinic visit as having (1) a positive screening for food insecurity, and (2) uncontrolled diabetes (HbA1c over 9), and/or (3) stage 2 hypertension.
Referral/ identification	Identification and referral of patients is done by a health care provider or health insurance plan. Alternatively—and, especially when programs are operated outside of the clinical setting—participants may be eligible because they have previously been diagnosed with a health condition. Sometimes staff at community-based organizations (for example, a food bank) will also provide screenings and assessments on-site.	A health care provider (physician or allied professional) identifies the patient as meeting eligibility criteria and provides the referral.
Food selection and sourcing	Foods are pre-selected, often by an RDN or physician, as appropriate for meeting the dietary needs of the chronic disease being treated and/or prevented. Certain programs offer some flexibility for clients to choose the foods they prefer. Sourcing of food depends on the program; community food pantry programs will often use existing sourcing and distribution networks.	Households of four or fewer receive 20 to 30 pounds of fresh produce and 4 pounds of whole grains and legumes (low-sodium canned or dried). Households of five or more receive 40 to 60 pounds of fresh produce and 8 pounds of whole grains and legumes (low-sodium canned or dried). The Atlanta Community Food Bank supplies the food for the food pharmacy.
Food preparation and other program components	Because the food items provided are largely raw ingredients and whole foods, recipients need to prepare the food themselves. Programs sometimes include educational components, such as nutrition information brochures, nutrition counseling, and cooking classes.	Participants use the ingredients to prepare food at home. Ingredients are augmented with cooking classes in the hospital's teaching kitchen and nutrition classes taught by Grady Health dietitians. Participation in at least one cooking class and two nutrition sessions are required to maintain program eligibility.

# **Table 5: Medically Tailored Groceries in Practice, continued**

	Medically Tailored Groceries/Food Boxes: In General	Use Case: Grady Hospital Food as Medicine Prescription Program in partnership with Atlanta Community Food Bank: A Food Pharmacy
Food distribution and/or delivery	Participants pick up food on a regular basis at a set location. Home delivery is sometimes available. Food is often assembled in a pre-packaged box or bag.	The food pharmacy is located adjacent to the lobby of Grady Hospital. Participants can return for food every two weeks while they are enrolled in the program.
Duration	Medically tailored groceries are generally conceived as part of a long-term nutritional health management plan for patients experiencing food insecurity and diet- related chronic illnesses, like diabetes, pre- diabetes, and hypertension. The program's impact on participant health, with the exception of blood pressure, is often observed over months to years (not weeks). Programs strive for duration to match a patient's medical needs and allow for re- dosing as appropriate.	A health care provider (physician or allied professional) identifies the patient as meeting eligibility criteria and provides the referral.



**Produce prescriptions defined:** Produce is generally fresh but can also be canned or frozen if there is no added sugar, salt, or fat.<sup>102</sup> The redemption or pick-up site varies by program. An increasing number of commercial food retailers are serving as redemption sites in addition to farmers markets, which are the traditional access points for these programs. The definition of "produce" can also vary by program: most programs support access only to fruits and vegetables, while others have included legumes, grains, and more, blurring the distinction between produce prescriptions and medically tailored groceries.

Produce prescriptions are sometimes paired with services provided by RDNs, such as nutrition education, nutrition resources, supermarket tours, cooking classes, and medical nutrition therapy.

# **Table 6: Produce Prescriptions in Practice**

Use Case Provided by Andrea Talhami of DC Greens in Washington, DC				
	Produce Prescriptions: In General	Use Case: DC Greens in partnership with Giant Food, a grocery chain operating in Washington, DC		
Clients/ participants	<ul> <li>Produce prescription programs typically serve clients with diet-related health risks or conditions who are:</li> <li>food insecure or have other documented challenges in accessing nutritious foods; and</li> <li>able to shop for food and prepare meals.</li> </ul>	Participants are enrolled in a partner Medicaid managed care plan and have a diagnosis of hypertension, diabetes, or prediabetes. Medicaid enrollment is used as a proxy for food insecurity.		
Referral/ identification	Identification and referral of participants is performed by the health care provider or health insurance plan. Alternatively—and, especially when programs are operated outside of the clinical setting—participants may be eligible because they have previously been diagnosed with a health condition. Community providers will also sometimes provide screenings and assessments on-site. The prescription comes in the form of a paper prescription that can be redeemed for produce or electronic benefit (such as a debit card) with restrictions on where it can be used and what items it can cover.	Health care providers at partner clinics in DC assess program eligibility and issue a prescription, prompting participants to receive the benefit on their Giant Food bonus card.		
Food selection and sourcing	Eligible produce is generally fresh but can also be canned or frozen if there is no added sugar, salt, or fat. Some programs have expanded the benefit to include legumes, grains, and other items. Produce prescriptions grew, in part, out of farmers market voucher programs. They are often closely tied to farmers markets and sometimes explicitly aim to support local producers. The role of participant choice depends on the program. Generally, participants will use their benefit at eligible locations—which can include supermarkets, grocery stores, farmers markets, and other locations—and select the items that they want. Produce is sometimes pre-selected and pre- packaged, presented in a box or bag.	Participants receive \$80 per month on their Giant Food bonus card that can be spent on any fresh or frozen fruits and vegetables at participating Giant grocery stores.		

# **Table 6: Produce Prescriptions in Practice, continued**

	Produce Prescriptions: In General	Use Case: DC Greens in partnership with Giant Food, a grocery chain operating in Washington, DC
Food preparation and other services	Because the food items provided are largely raw ingredients and whole foods, participants need to prepare the food themselves. Programs sometimes include educational components, such as nutrition information brochures, nutrition counseling, and cooking classes.	Participants prepare the foods at home. There are no additional requirements to participate in the program, although a dietitian employed by the grocery store provides free consultations, and participants have the opportunity to participate in nutrition and cooking classes.
Food distribution and/or delivery	Prescription vouchers have monetary value and can be used at participating farmers markets or food retailers (corner stores, grocery stores, supermarkets, and pharmacies) to purchase produce. Accessibility often depends on the hours of the participating site and/or retail store— for example, prescriptions are often easier to redeem at a nearby supermarket than a weekly farmers market with limited hours. For programs where produce is pre-selected and pre-packaged, participants pick up produce on a weekly basis (sites often have limited hours or options). Some programs operate mobile markets (e.g., veggie vans).	Participants use their bonus card at checkout to pay for fresh and frozen fruits and vegetables at partnering Giant grocery stores.
Duration	Produce-prescription programs are generally conceived as part of a long-term nutritional health management plan for patients who are food insecure and at risk of or experiencing diet-related chronic illnesses like diabetes, prediabetes, and hypertension. The program's impact on participant health, with the exception of blood pressure, is often observed over months to years (not weeks). Programs strive for duration to match a patient's medical needs, generally at least six months, and allow for re-dosing as appropriate.	Participants enrolled in the program check in with their providers every three months to renew the benefit for up to one year.

# Other Interventions Within the Scope of Food is Medicine

In addition to medically tailored meals, medically tailored groceries, and produce prescriptions, the following interventions are also within this Action Plan's Food is Medicine definition and scope:

- Education or health care services when combined with an intervention that provides food, such as medically tailored meals, medically tailored groceries, or produce prescriptions. These services include nutrition education, lifestyle or other behavior change programs, cooking classes, and health care services like group visits for diabetes management.
- The addition of food provision or food purchasing power to existing food support programs when triggered by a health condition or health assessment. For example, a SNAP recipient might receive additional funds or subsidies for produce based on a nutritional assessment by a health care provider.

# Interventions Outside of this Report's Definition and Scope

Several Food is Medicine interventions clearly meet this Action Plan's definition. Identifying certain programs and services as out of its scope is more difficult. If nutrition is foundational to health, shouldn't every attempt to improve dietary quality be considered Food is Medicine? Wouldn't universal eligibility for the National School Lunch Program and a boost to the SNAP allotment, for example, do more for the nation's baseline health than any program limited to people living with certain health conditions? The answer, quite possibly, is yes. What about the implementation of a comprehensive income-support program that increased overall purchasing power for food and other necessities among low-income people? Again, likely yes. For example, unemployment insurance provided during the outset of the COVID-19 pandemic reduced rates of food insufficiency and food insecurity.<sup>103</sup> We may likewise see a significant reduction in food insecurity and a greater ability to obtain foods that support health from the temporary increase in the Child Tax Credit, enacted as part of the American Rescue Plan Act and is estimated to reduce child poverty by nearly 45%.<sup>104</sup>

The goal of this Action Plan is to help researchers, providers, policymakers, and communities better understand how to leverage nutrition within the current and near-future health care system to improve health outcomes and eradicate health disparities. Given the US federal budget's expenditure on health care—25% of GDP—it should be a national priority to identify when dietary interventions can meaningfully influence individual and population health.<sup>105</sup> The intersection between the health care and the food system is the scope of this Action Plan. This Action Plan is not meant to stand in for, replace, or undermine plans for broader systemic change in the health and food systems. It is instead intended to be complementary to such plans.

#### Given our goals, the following interventions are outside of the scope of this report:

- Administration of micronutrients (such as vitamins or other supplements) or a specific food because it contains a concentrated amount of a micronutrient. First, supplementation of micronutrients to address nutritional deficiencies identified in the clinical setting is generally accepted as part of health care—for example, someone with a documented deficiency of vitamin B12 will be able to receive a B12 prescription and generally have that supplement covered by insurance.<sup>106</sup> Second, prescribing a specific food to address health risks or health conditions, rather than a range of foods that reflect a healthy diet, is questionable—for example, carrots were once the only vegetable covered by WIC.<sup>107</sup> Furthermore, emphasizing specific foods as necessary for health can lead to significant environmental and social impacts production of those foods ramps up to meet variable demand.<sup>108</sup>
- Products administered in parenteral or enteral nutrition. These are products for patients who need complete or supplemental nutrition administered under the supervision of a doctor—for example, those who are unable to swallow. These products meet the Food and Drug Administration's definition of "medical foods," or foods that are defined by law as "formulated to be consumed or administered enterally under the supervision of a physician and intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on scientific principles, are established by medical evaluation."<sup>109</sup> Interventions that use these products are generally already integrated into health care, covered in many instances by Medicaid, Medicare, and private insurance.
- Existing federal nutrition and food support programs with the exception of WIC. Federal nutrition and food support programs, such as SNAP, are linchpins of food access in the United States, and this Action Plan frequently refers to them. However, enrollment in these programs does not depend on connection with the health care system, and, furthermore, food assistance is not typically tailored to health needs. Excluding these programs from the scope of this report is not intended to diminish their critical importance to health or to present Food is Medicine interventions as superior. Indeed, the research on these programs (discussed in Section V: Foundational Research) provides a critical foundation for Food is Medicine research to build on. What's more, the disconnect between health care and the operation of these programs has rendered them easier to use, resulting in less administrative burden when it comes to enrollment and benefit redemption than has historically been the case with programs more closely tied to health care like WIC.
- Nutrition education initiatives for individuals or health care clinicians that do not include the provision of food or enhanced support to purchase food. For individuals, initiatives that emphasize nutrition education or counseling alone are likely to disproportionately help those who have the discretionary resources to make the recommended changes. Patients with more limited resources may not be able to implement those changes without some form of tangible aid. This Action Plan focuses on interventions that reduce these inequities through the provision of material assistance. Regarding nutrition education, health care providers who are trained and incentivized to advise patients on the role of diet as it relates to treatment for health conditions play a critical role. Medical education and training contain significant gaps when it comes to nutrition and its use in disease treatment and management.<sup>110</sup> Medical schools are starting to take note, implementing a range of changes and programs.<sup>111</sup> These programs, however welcome, lie outside of the scope of this report.



The definition of Food is Medicine in this report is limited in order to facilitate actionable and specific recommendations for future research. However, individuals and families should be put in touch with all appropriate and effective programs and services that afford them the opportunity for a nutritious and culturally appropriate diet.

As the health care system evolves to provide more upstream interventions and preventive services, and the pathways for change via Food is Medicine interventions are further explored, its scope will also evolve. In putting forward this Action Plan, Food & Society at the Aspen Institute hopes to spur the creation and adoption of programs that redefine the boundaries of what is possible at the nexus of health care and food—to not only alter business as usual within the health care system but also to yield discoveries about the relationship between food and health that can inform and accelerate positive change beyond health care.

# **IV: Key Considerations for Food is Medicine Research**

This section introduces key considerations for research that pertain to food and nutrition, the health care system, and the intersection of these two critically important and complex fields. Many of these considerations are reflected in <u>Section VII: Recommendations</u>.

Food is Medicine research is challenged by the enormous complexity of its essential components: food and health. Future research needs to purposefully engage with and navigate the complexity at the intersection of these two components.

The provision of something so essential and meaningful as food, coupled with a complex health care system that is often difficult to navigate—and for some, difficult to trust—demands that research and interventions be subject to a heightened level of scrutiny in order to avoid missteps or potential harms. This requires a commitment to centering equity in research conception, design, execution, interpretation, dissemination, and translation.

Researchers must carefully consider the identity and perspectives of research participants as well as the intended intervention recipients—those who will benefit from the intervention beyond the research phase. Researchers must make decisions about research purpose and scope with a focus on equity. Practically, this means that researchers and funders should ask key questions that illuminate whether and how the information sought will be meaningful to the research participants, the field, and future policymaking. Examples of key questions that should be answered prior to research include:

- Who are the likely research participants, and who are the ultimate intended recipients of the proposed intervention? Are these two groups similar, and, if not, how do these differences affect the significance of the research results? Have individuals from both groups been engaged early and authentically in the process of research conception and design? Is the proposed research and intervention desired by these groups? Does the research team reflect the demographics and circumstances of these groups, and, if not, how will the team understand the full context in which the research is taking place?
- What foods does the intervention include? Are they appropriate and appealing for individuals from diverse backgrounds and cultures? Where personal choice is limited (for example, in the case of fully prepared meals), how do participant perspectives, preferences, and food-preparation abilities inform what is offered in the program?
- What level of engagement with health care does the research and intervention require? Are there barriers to this engagement for participants or for health care providers?
- Is the research appropriately powered to evaluate impact across different demographic groups?
- Is there a plan in place for flexibility in the research design to accommodate participant needs without compromising the integrity of the research?
- Is there a qualitative research component that can illuminate whether and why participants value and engage with the intervention?

In the existing Food is Medicine research, a number of peer-reviewed studies have found statistically significant improvements in food security, diet quality, and disease management.<sup>112</sup> Studies have also looked at hospitalizations and health care costs, finding significant reductions in inpatient admissions, emergency visits, and medical spending among those receiving Food is Medicine interventions.<sup>113</sup> Recipients also report feeling less stressed, cared for by health care providers, and more confident in their understanding of nutrition and healthy foods.<sup>114</sup> In patient surveys administered at one health system, the vast majority of patients screened for food insecurity found the screening and subsequent referral to food resources valuable.<sup>115</sup> This research is explored in more depth in <u>Section VI: Research on Food is Medicine Interventions</u>.

These findings indicate that Food is Medicine interventions can effect change on many important fronts. They can transform an individual's ability to alter diet to aid in disease management. They can reduce the number of traumatic and expensive hospitalizations. And they can improve patient-provider relationships.

Exploring the broader context of Food is Medicine interventions at the outset of research should result in the creation of programs and interventions that are:

- easy to access and adopt by the people who will ultimately use them, and
- easy to recommend and track for health care entities

For more on how to center equity in Food is Medicine research, see <u>Recommendations 1–7</u>.

#### Food and Health: What to Consider as Food is Medicine Interventions Are Designed, Tested, and Scaled

What drives food consumption and enables the attainment of health is heavily influenced by numerous biological, sociopolitical, and socioeconomic factors, complicating scientific analyses and understandings of causality. In conversations with advisors and other stakeholders, the following factors emerged as critical to keep in mind when designing interventions that can truly address long-standing health disparities through nutrition.

#### Food

- Food is a biological necessity. Simply put, people cannot live without food. Many countries explicitly recognize an individual's right to food.<sup>116</sup> The United States does not, but it has established numerous food-support programs over the past century.<sup>117</sup> In addition, specific nutritional needs and tastes change dramatically throughout one's lifespan. The first 1,000 days in a child's life are a particularly critical period in which nutritional deficiencies put children at risk of serious lifelong health complications and in which food preferences are formed that may persist throughout adulthood.<sup>118</sup>
- Food is an integral part of human culture. In addition to nutritional value, food has significant social value and meaning.<sup>119</sup> The preparation, consumption, and sharing of food is a fundamental part of participation in any society. Food is used, for example, to mark special occasions and religious festivals, solidify relationships, convey social status, support different ideologies, and promote and demonstrate cultural conformity.<sup>120</sup> The experience of food is also often deeply personal and familial, evoking specific emotions, moods, and memories.<sup>121</sup> Some studies have suggested that food-evoked emotions are one of the strongest predictors of food choice.<sup>122</sup>
- Food is political. Legacies of racism and nativism influence ideas about what people should eat, demonizing or exoticizing certain foods and complicating cultural relationships with traditional ways of eating.<sup>123</sup> The US government has, at times, actively interfered with food sovereignty—the ability for people to have "healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and [the] right to define their own food and agriculture systems."<sup>124</sup> For example, the US Department of Agriculture (USDA) has a long, well-documented history of discrimination against Black farmers that includes denying loans, delaying loan-processing times, and excluding Black farmers from federal insurance and disaster relief programs.<sup>125</sup> This has led to significant land loss among Black farmers, who now make up less than 2% of all farmers.<sup>126</sup> The federal government's forced removal of Indigenous communities from their lands along with brutal assimilationist policies disrupted traditional food systems and caused widespread food insecurity.<sup>127</sup> In some cases, federal food-support programs have played a role in worsening dietary patterns among Indigenous communities by promoting the consumption of ultra-processed foods in place of traditional foods.<sup>128</sup>
- **Caregivers are powerful nutrition gatekeepers.** Caregivers are often the primary people responsible for the diets of three important—and often nutritionally vulnerable—populations: children, people with disabilities, and older adults.<sup>129</sup> In the United States, caregiving responsibilities for these three groups disproportionately fall on women.<sup>130</sup> Childcare obligations also have spillover effects on the entire household, with parents and older siblings reducing their own food intake to shield young children from food insecurity.<sup>131</sup> Poor nutrition among older adults is associated with increased caretaking burdens.<sup>132</sup> Not only do older adults have limited capacity to cook and shop due to frailty, but they may also face unique challenges, such as oral health problems, loss of muscle tone that impacts chewing and swallowing, and changes in taste and smell that make food less appealing.<sup>133</sup>

• What someone consumes is rarely a straightforward choice. In addition to cultural factors, diet is dictated by what foods are accessible, affordable, and acceptable. Agricultural policy influences what foods are produced in the United States, and by whom.<sup>134</sup> Trade policy influences what is imported. Over 100 years of explicitly racist zoning and housing policies have influenced the location of grocery stores and other food vendors, the existence and accessibility of transportation systems, and the accumulation of wealth and economic opportunity that renders food affordable.<sup>135</sup> Marketing and advertising also have an outsized influence on shaping food tastes and driving demand, particularly among children and adolescents.<sup>136</sup> Research has found that fast-food companies and makers of unhealthy foods explicitly target advertising to Black and Latinx youth, increasing health disparities.<sup>137</sup> Beyond direct advertising and marketing, corporations and trade groups spend hundreds of millions of dollars each year to influence policy, including nutrition policies such as the Dietary Guidelines for Americans, the Farm Bill, and the Child Nutrition Reauthorization Act.<sup>138</sup>

The terms "food deserts" (limited access to healthy foods) and "food swamps" (inundation with fast food and unhealthy food options) are often used to characterize a neighborhood's food environment. However, some activists and scholars are now using the term "food apartheid"—defined as "the structural, political, and experiential limits on the availability of nutritious, healthy, affordable, and culturally appropriate foods, and/or limited or uncertain access to food"—to more aptly describe the intentional forces that shape food access and to acknowledge racial disparities.<sup>139</sup>

• **Messages about nutrition are often confusing and conflicting.** Even when people have the resources and desire to buy foods that support health, they are often confused about what to eat.<sup>140</sup> Nutrition research continuously evolves, sometimes contradicting previous findings (notable examples include low-fat diets, eggs, and soy protein). At the same time, the food industry intentionally sows confusion through industry-funded research and misleading marketing and advertising.<sup>141</sup> Research has found that exposure to conflicting nutrition information can result in "nutrition backlash," whereby people are less likely to trust nutrition science or follow healthy eating advice.<sup>142</sup> However, coordinated messaging is challenging as people receive nutrition information from a wide variety of sources, including health care providers, nutrition program providers (e.g., SNAP-Ed, WIC, and food pantry programs), friends, family, social media, news and magazine articles, television, salespeople, and food labels.<sup>143</sup> If well-equipped with nutrition knowledge and cultural competency, health care providers can be a driving force to help clarify messages and motivate healthy eating changes. Among the 54% of food consumers who receive nutrition advice from their provider about foods to eat and to avoid, 78% initiate some type of eating change.<sup>144</sup>

In the book *Pressure Cooker*: *Why Home Cooking Won't Solve Our Problems and What We Can Do About It*, Sarah Bowen, Joslyn Brenton, and Sinikka Elliot illustrate the pressures women navigate as they try to feed their families. Drawing on extensive interviews and ethnographic data, the book captures the complex range of circumstances around food and nutrition that Food is Medicine interventions try to address. These include a lack of financial resources, time, transportation, space, and equipment to cook, as well as the tensions and confusion around choosing the "right" foods, to name just a few. For example, in the book:

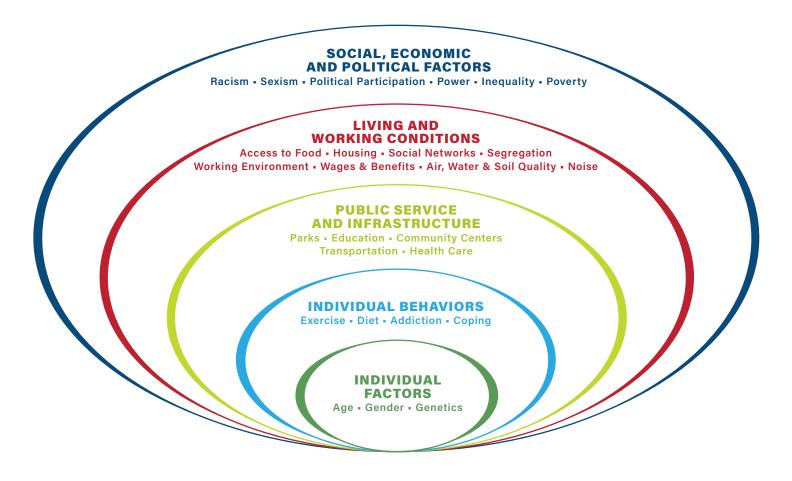
- Leanne, a mother of three, navigates a low-paying job in food service with unpredictable hours, a kitchen often infested with cockroaches, and a lack of transportation that makes grocery shopping and traveling to food pantries difficult. Though she likes to cook and takes great pride in making family meals, the lack of resources and time presents a challenge. She sometimes skips meals or eats less to ensure her family has enough food.
- Patricia, a grandmother trying to support her adult daughter and two grandchildren, puts meals together in the small hotel room where the family lives, with only a microwave, bathroom sink, and a very small food budget.
- Rae and her husband both work 40-plus hours a week and don't always have time to cook meals from scratch for their young son. Rae wants her family to be healthy but struggles to make sense of dietary advice that does not resonate with her family's traditional foodways or their identity as a Southern Black family.
- Rosario, who cooks traditional Mexican food for her family of three, negotiates mealtimes with children who sometimes reject the dinners she has made in favor of the "American" food their friends eat.

#### **Health Care**

• Health is multidimensional. There is now widespread recognition that social and environmental factors, not health clinical care, are primarily responsible for shaping individual and population health.<sup>145</sup> Dialogue on how to influence these broader factors is increasingly common among the World Health Organization, US federal health agencies, and health care providers and payers nationwide, creating new policy frameworks and investment paradigms.<sup>146</sup> A cornerstone of the literature around social determinants of health (the conditions in which people live, work, eat, and play) is that health disparities, or differences in health status among different groups of people, are complex and multifactorial; it is near-impossible to isolate any one factor and ignore their dynamic interrelations.<sup>147</sup> At the same time, addressing just one factor, such as food, could simultaneously improve many different health outcomes.

#### **Health is Multifactorial and Multidimensional**

This diagram depicts a variation of the socio-ecological model of health, which emphasizes the social, political, and environmental contexts that shape individual health. While the factors enumerated in the outer layers have a direct impact on the inner layers, the inner layers are often closest and most apparent to the individual. Many times, the socio-ecological model is used to show that it can be difficult to create meaningful change at the individual level without acknowledging and engaging these broader contexts; it is important that health interventions explicitly work across all levels.<sup>148</sup>



**Social Determinants of Health and Health-Related Social Needs:** The health care system has traditionally been designed to (and is currently best equipped to) respond to downstream impacts of the social determinants of health. Access to nutritious food, for example, is a social determinant of health, influenced by one's food environment and financial and social resources. The health care system is deeply intertwined with, but does not explicitly control, these factors. Yet it can, and increasingly does, respond to the lack of access to nutritious food—a health-related social need—resulting from these circumstances.<sup>149</sup>

Social Determinants of Health vs. Health-Related Social Needs			
Social determinants of health	The World Health Organization defines social determinants of health as "the conditions in which people are born, grow, live, work, and age," which are "shaped by the distribution of money, power, and resources." <sup>150</sup> These factors, including income, race, and education, are not positive or negative; however, they cannot be isolated from the dynamic and complex political realities in which they exist. Examples include income, as well as the policy choices, environmental factors, and social forces that make access to healthy living conditions and health care dependent on income and wealth.		
Health-related social needs	Health-related social needs are social risk factors for poor health outcomes (e.g., food insecurity). With an individual's permission, the health care system may seek to address health-related social needs through referral to or the provision of appropriate services (e.g., food). Examples include food insecurity, housing instability, lack of transportation, and lack of income.		

- Food insecurity is closely linked with increased rates of chronic disease and higher health care costs. Rates of food insecurity are higher among those with chronic diet-related illnesses. Using National Health and Nutrition Examination Survey data, one study consistently found statistically significant differences in the prevalence of food insecurity when comparing those with a diet-related health condition with their counterparts without that condition: diabetes (19.5% food insecurity prevalence among those living with diabetes vs. 11.5% food insecurity among those without that diagnosis), hypertension (14.1% vs. 11.1%), coronary heart disease (20.5% vs. 11.9%), congestive heart failure (18.4% vs. 12.1%), and obesity (14.3% vs. 11.1%).<sup>151</sup> Food insecurity is associated with higher health care utilization and significantly higher health care costs. Individuals who are food insecure have more hospitalizations and emergency department (ED) visits than their counterparts who are food secure, and they are more likely to be in the top 10% or even 2% of health care expenditures.<sup>152</sup>
- Access to health care is a persistent challenge. Even with significant policy changes over the past decade to expand health insurance coverage, 28.9 million non-elderly individuals were uninsured in 2019.<sup>153</sup> Those who are uninsured are disproportionately Black, Latinx, and Indigenous.<sup>154</sup> They are also disproportionately individuals without legal status.<sup>155</sup> Predicating access to Food is Medicine interventions on health insurance therefore poses a very real risk of excluding uninsured populations and further embedding health disparities.



- The US health care system is fragmented. The increasing use of private companies to administer publicly funded insurance, often through managed care plans, is exacerbating disparities in the range of benefits provided by Medicare and Medicaid, especially when it comes to nutrition. For example, of the 62 million people enrolled in Medicare, about 60% are enrolled in traditional ("fee-for-service") Medicare and have no access to a benefit that provides food. Among the 40% of Medicare beneficiaries who are enrolled in a managed care or Medicare Advantage program, only 39% had access to a meal benefit with access depending on whether their plan chose to cover the service.<sup>156</sup> Even if Food is Medicine interventions are implemented by one health care organization or insurer, there is no guarantee that individuals with the same needs will have the same access across individual states or nationwide.
- The provision of health care is not a guarantee of equitable treatment and attitudes. More than one in five patients report experiences of discriminatory treatment from medical professionals, with the majority of such discriminatory treatment relating to race or ethnicity.<sup>157</sup> Experiences of discrimination in the health care setting may mean that people of color are less likely to volunteer information about health-related social needs to their medical providers or trust their recommendations regarding Food is Medicine interventions.<sup>158</sup> For example, caregivers sometimes worry that disclosing food hardship will make them seem like unfit parents and could lead to a provider reporting them for child mistreatment.<sup>159</sup> Clinicians might preferentially screen some patients for food insecurity based on assumptions about who is food secure. They might refer some patients to interventions based on implicit assumptions, such as who is deserving of help, creating additional inequities. Linking Food is Medicine interventions to the health care system could mean that people of color receive them less often than white individuals with similar health profiles.



# **V: Foundational Research**

Section V provides an overview of the published, peer-reviewed research on health outcomes associated with food insecurity and federally funded food support programs—namely, the Supplemental Nutrition Assistance Program, the National School Lunch Program, Older Americans Act Nutrition Services Program, and the Special Supplemental Nutrition Program for Women, Infants and Children. The latter of which is a 50-year-old Food is Medicine program with valuable lessons for the field. Taken together, this research establishes an important foundation for Food is Medicine intervention research (Section VI: Research on Food is Medicine Interventions).

Though research on Food is Medicine interventions is still emerging, it continues to build on evidence that firmly establishes the connection between food insecurity and poor health outcomes, increased health care utilization, and increased health care costs. Likewise, evidence demonstrates the health impacts of providing food, most importantly through some of the country's key food support programs: the Supplemental Nutrition Assistance Program (SNAP), the National School Lunch Program (NSLP), Older Americans Act Nutrition Services Programs (OAANSP), and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Although WIC, unlike the other food support programs, meets this initiative's definition of Food is Medicine—enrollment requires nutrition assessment by a health professional—we have included it in foundational research because the program has been in existence for 50 years.

This section reviews the health outcomes associated with food insecurity as well as the health outcomes associated with the provisions of food support via SNAP, NSLP, OAANSP, and WIC. The team conducted Pubmed searches and requested information about relevant research from the Action Plan's network of advisors and stakeholders. The studies we included examine the association between food insecurity, SNAP, NSLP, OAANSP and WIC, and physical and/or behavioral health outcomes. They were conducted in the United States, written in English, and published in peer-reviewed journals within the past 25 years.

## **Food Insecurity and Health Outcomes**

A large and robust body of evidence links food insecurity to poor health outcomes. Being food insecure increases risk for a number of serious health conditions, is associated with higher health care utilization and costs, and motivates a range of coping behaviors that lead to poor health outcomes.

#### Food insecurity is associated with:

- Worsened mental health outcomes including depression,<sup>160</sup> anxiety,<sup>161</sup> and stress;<sup>162</sup>
- Worsened physical health outcomes including heart disease,<sup>163</sup> obesity,<sup>164</sup> diabetes,<sup>165</sup> hypertension,<sup>166</sup> and hyperlipidemia;<sup>167</sup>
- Poor health and developmental risk in children;<sup>168</sup>
- Health-damaging circumstances and behaviors including poor diet quality,<sup>169</sup> unhealthy weight control,<sup>170</sup> disordered eating,<sup>171</sup> poor diabetes self-management,<sup>172</sup> low medication;
- Adherence<sup>173</sup> and missed clinical visits;<sup>174</sup> and
- Increased health care utilization and costs including inpatient hospitalizations,<sup>175</sup> ED visits,<sup>176</sup> and prescription medications.<sup>177</sup>

Food insecurity is associated with worsened health outcomes through a number of pathways. Poverty is the primary cause of food insecurity; the two terms, however, are not synonymous. For example, there are households with incomes below the federal poverty threshold who are not food insecure and those with incomes above the federal poverty threshold who are.<sup>178</sup> Research has also identified several other factors associated with increased food insecurity, from individual and household characteristics—including household size and makeup, race and ethnicity (a proxy for experiences of discrimination), education, mental and physical health conditions, disability, and substance use—to macroeconomic trends such as low wages, high housing costs, high unemployment rates, and residential instability.<sup>179</sup> Indeed, all of these factors come into play when it comes to understanding the connection between food insecurity and health outcomes.

Food insecurity makes it harder to consume foods that support health, largely due to affordability and time constraints.<sup>180</sup> An unhealthy diet then leads to worsened health outcomes.<sup>181</sup> Episodes of food scarcity alternating with food availability can lead to undereating and binge eating which can in turn lead to insulin resistance.<sup>182</sup> The toxic stress of constantly worrying about having enough food to eat can impact mental health, anxiety, and depression. Faced with limited resources, individuals may not attend to their health needs in order to prioritize other pressing basic needs such as food, housing, and purchasing medications, causing health conditions to worsen over time.<sup>183</sup> In addition to trade-offs between purchasing food or medications, food insecure individuals who take medications on an empty stomach can experience adverse side effects and reduced medication efficacy.<sup>184</sup>

Researchers have also found that lack of food overall and the lack of culturally acceptable food give rise to feelings of deprivation and alienation, which can contribute to mental health issues, including increased stress, anxiety, and depression.<sup>185</sup> Stigma associated with accessing free meal sites and food resources also exacerbates poor mental health outcomes.<sup>186</sup>

# Food and Nutrition Support Programs and Health Outcomes: SNAP, NSLP, and OAANSP

While a lack of food is associated with poor health outcomes, the provision of food is associated with improved health outcomes. This section reviews the relevant research on the following federally funded food and nutrition support programs:

- Supplemental Nutrition Assistance Program (SNAP): SNAP is the country's largest and most flexible food support program, currently providing benefits to over 41 million individuals.<sup>187</sup> The estimated individual Average Monthly Benefit for Fiscal Year 2024 is \$202 and \$713 for a family of four.<sup>188</sup> SNAP benefits come with relatively few restrictions; they may be used to purchase any food items, except hot, ready-to-eat foods and alcoholic beverages, at eligible retailers.<sup>189</sup>
- National School Lunch Program (NSLP): NSLP is the country's second-largest food support program, providing meals to nearly 30 million school-age children.<sup>190</sup> NSLP accounts for roughly one-third of participants' daily caloric intake and, when combined with the School Breakfast Program, represents over half of participants' daily caloric intake.<sup>191</sup> NSLP meals must adhere to nutritional standards; these were significantly overhauled in 2010 with the passage of the Healthy, Hunger-Free Kids Act.<sup>192</sup>
- Older Americans Act Nutrition Services Program (OAANSP): The Nutrition Services Program, authorized under Title III of the Older Americans Act, provides states and US territories with grants to support senior nutrition services programs—namely, congregate and home-delivered nutrition programs.<sup>193</sup> The Congregate Nutrition Services program serves meals to older adults in places such as senior centers or faith-based settings, providing opportunities for socialization with others and health-promotion activities.<sup>194</sup> The Home-Delivered Nutrition Services program delivers meals to individuals who are homebound or otherwise have difficulty obtaining and preparing food for themselves.<sup>195</sup> Meals served using OAANSP funds must meet the current Dietary Guidelines for Americans.<sup>196</sup>
- All three programs are associated with lower health care utilization and positive health outcomes (see Table 7). However, these findings are not uniform across the peer-reviewed literature. Some studies have found mixed results, such as higher rates of obesity among SNAP participants, particularly when participants are compared with eligible nonparticipants (those who meet the program's eligibility requirements but are not enrolled). Understanding these mixed results requires a closer look at the key demographic characteristics, including the baseline health of those who do enroll in these programs. For example, those who participate in SNAP are more likely to be sick, food insecure, and in much worse financial situations than eligible nonparticipants.<sup>197</sup> Researchers note the difficulty of isolating the role of program participation in relation to primary outcomes, especially among populations who face manifold—and, often, hard-to-measure—social, economic, and health challenges.<sup>198</sup>



# **Changes to Federal Nutrition Programs during COVID-19**

COVID-19 brought significant changes to Federal Nutrition Assistance Programs, largely as a result of increased hunger across the country during the economic shutdowns in which millions of people no longer worked. Food insecurity was particularly high for Black households, which reported close to 20% food insufficiency in January 2021 (compared with 8% of white households). Significant changes to USDA programs included doubling the average monthly SNAP benefit (actual increases varied by location and household size), tripling the value of the monthly benefit in WIC for fruits and vegetables, enhanced flexibilities including the removal of the interview process for federal nutrition programs, and the development of entirely new programs like the Pandemic Electronic Benefit Transfer Program (P-EBT). The latter provided cash benefits for food, similar to SNAP, to families with children when they no longer had access to school meals during school closures. For a full list of USDA nutrition assistance program changes during COVID-19, see <u>here</u>.

Unfortunately, many of these changes to federal nutrition programs have since expired. Still, a lasting legacy of the COVID-19 era on federal nutrition programs was the creation of Summer EBT. This program was modeled after P-EBT and provides benefits to access free groceries to low-income families with school-aged children when schools are closed for the summer. More than 30 million children across America could benefit from Summer EBT. However, as of January 2024, 15 states led by Republican governors had rejected the free federal money for summer food for kids, further politicizing food and nutrition insecurity across the country. While 35 states have opted in to Summer EBT, those that did not include Alabama, Alaska, Florida, Georgia, Iowa, Idaho, Louisiana, Mississippi, Nebraska, South Carolina, South Dakota, Texas, Vermont, and Wyoming.

#### **Table 7: Food Support Programs and Health Outcomes**

An overview of the research on health outcomes related to three federally funded food and nutrition support programs: SNAP, NSLP, and OAANSP. Health outcomes—positive, negative, and mixed—are noted, as well as key findings about how these programs support health.

Research on SNAP and other federal nutrition programs is particularly challenging because randomized trials aren't feasible, legal, or ethical (with some exceptions within the USDA testing new program components, such as the Summer EBT pilot program).<sup>199</sup> Overall, people meeting the eligibility criteria in the United States are entitled to receive services from these programs. Most research compares participants with incomeeligible nonparticipants. This comparison is limited by selection bias, meaning that there are likely important characteristics influencing why someone enrolls in SNAP that make them different from someone with a similar income who doesn't enroll. Research findings can be difficult to interpret or at times contradictory. It's important to consider study design carefully in research on SNAP or other federal nutrition programs. Some studies aim to employ causal inference techniques, which attempt to measure factors influencing enrollment—the strongest approach. Other studies simply describe observed differences between participants and nonparticipants; these may not be causally linked to receiving SNAP benefits.<sup>200</sup>

SNAP				
Description	Health Outcomes	Additional Findings and Notes		
and most flexible food support program, currently providing benefits to over 40 million individuals. <sup>201</sup> <b>Eligibility criteria:</b> Eligibility factors include household income, household assets, immigration status, college enrollment status, and work status, but specific requirements vary by state. <sup>202</sup> <b>Foods available:</b> SNAP benefits come with relatively few restrictions; SNAP may be used to purchase food items, except hot, ready-to-eat food and alcoholic beverages, at eligible retailers. <sup>203</sup>	<ul> <li>Participation is associated with positive health outcomes:</li> <li>Improved diet quality<sup>204</sup></li> <li>Improved weight status<sup>205</sup></li> <li>Improved self-reported health status, and fewer sick days<sup>206</sup></li> <li>Improved physical health, growth, and development among young children<sup>207</sup></li> <li>Improved medication adherence and reduced nursing home and hospital admissions among older adults<sup>208</sup></li> <li>Lower health care use and health care costs<sup>209</sup></li> <li>Participation is also associated with mixed and poor health outcomes: <ul> <li>Higher rates of obesity<sup>210</sup></li> <li>Poorer dietary intake<sup>211</sup></li> <li>Higher cardiovascular disease mortality and diabetes mortality rates<sup>212</sup></li> <li>Unmet health care needs<sup>214</sup></li> </ul> </li> </ul>	<ul> <li>Potential pathways for positive health outcomes: <ul> <li>The provision of food leads to a reduction in food insecurity and frees up resources to address other basic needs and medications<sup>215</sup></li> <li>An increase in SNAP benefits has been shown to improve overall dietary intake in children<sup>216</sup></li> <li>SNAP can reduce the toxic stress and anxiety associated with food insecurity which is an important pathway through which food insecurity impacts health outcomes<sup>217</sup></li> <li>Enhanced purchasing power for groceries increases consumption of less nutritious fast food and restaurant meals<sup>218</sup></li> </ul> </li> <li>Potential pathways for mixed and poor health outcomes: <ul> <li>Baseline health is worse for SNAP participants when they enter the program and differences are not causally linked to participation<sup>219</sup></li> <li>SNAP benefit amounts are insufficient to purchase the relatively more expensive health outcomes<sup>220</sup></li> <li>SNAP benefits run out, particularly at the end of the month, leading to periods of undereating<sup>221</sup></li> <li>Higher rates of depression may be due to</li> </ul> </li> </ul>		

food insecurity and SNAP participation), or an unmeasured confounding variable<sup>223</sup>

Description	Health Outcomes	Additional Findings and Notes
Enrollment: NSLP is the country's second-largest food support program, providing meals to nearly 30 million school-age children. <sup>224</sup> NSLP accounts for one- third of participants' daily caloric intake and, when combined with the School Breakfast Program, represents over half of participants' daily caloric intake. <sup>225</sup> Eligibility criteria: Any student attending a participating school can receive an NSLP lunch. <sup>226</sup> Students at or below 130% of the federal poverty level (FPL) can receive a free lunch, students at 130- 185% FPL can receive a reduced-price lunch, and students above 185% FPL can receive a low-cost full price lunch. <sup>227</sup> Foods available: NSLP lunches must meet federal nutrition standards and meal patterns; however, the specific foods served, and the methods of preparation, vary by school district. <sup>228</sup>	<ul> <li>NSLP participation (across all income categories) is associated with positive health outcomes:</li> <li>Improved weight status<sup>229</sup></li> <li>Improved self-reported health<sup>230</sup></li> <li>On average, it is the healthiest source of food in the American diet (as compared with restaurants, fast food, and meals at home).<sup>231</sup></li> <li>Healthy Hunger-Free Kids Act (HHFKA) nutrition standards, particularly, are associated with decreased overweight and obesity trends, as well as narrowed racial and ethnic disparities within those trends.<sup>232</sup></li> <li>Participation is also associated with mixed and poor health outcomes:</li> <li>Three studies found no association between NSLP participation and weight status or health outcomes<sup>233</sup></li> <li>Two studies found that participation was associated with worsened weight status<sup>234</sup></li> </ul>	<ul> <li>Potential pathways for positive outcomes:</li> <li>Meals provided through NSLP are more nutritious than meals from home or elsewhere, due to updated HHFKA standards<sup>235</sup></li> <li>HHFKA standards have increased consumption of fruits, vegetables, and whole grains<sup>236</sup></li> <li>Potential pathways for negative and mixed outcomes:</li> <li>Baseline health and other demographic characteristics of participants</li> <li>Negative weight associations were strongest for students who ate fewer lunches per week<sup>237</sup></li> <li>The difficulty of isolating the impact of NSLP given the significant role of other variables, such as income, food insecurity, and neighborhood food environment<sup>238</sup></li> <li>Changes in the composition of students who consume meals also make it difficult to isolate the impact of NSLP from other factors that impact the health status of NSLP participant groups<sup>239</sup></li> </ul>

Description	Health Outcomes	Additional Findings and Notes
Description Enrollment: 223 million meals were provided to 2.4 million older adults through the OAANSP in 2019. <sup>240</sup> Eligibility criteria: The only federal eligibility requirement is that a participant must be at least 60 years old; otherwise, eligibility is determined by states and local entities. <sup>241</sup> Foods available: Meals served using OAANSP funds must meet the current Dietary Guidelines for Americans, and each meal must provide at a minimum one third of the daily recommended Dietary Reference Intakes (as established by the Food and Nutrition Board of the National Academy of Sciences). <sup>242</sup>	<ul> <li>Participation in Congregate Nutrition Services programs is associated with positive health outcomes:</li> <li>Reduced hospital admissions overall, as well as ED visits that lead to hospital admission<sup>243</sup></li> <li>Fewer home health episodes<sup>244</sup></li> <li>Reduced nursing home admissions (effect was especially significant for low-income individuals)<sup>245</sup></li> <li>Participation in Home-Delivered Nutrition Services programs is associated with positive health outcomes:</li> <li>Improved ability for independent aging in place<sup>246</sup></li> <li>Improved dietary intake<sup>247</sup></li> <li>Decreased institutionalization<sup>248</sup></li> </ul>	<ul> <li>Potential pathways for positive outcomes:</li> <li>Congregate meal sites allow for socialization with peers.<sup>250</sup></li> <li>The provision of meals reduces the burden of food shopping and cooking, allowing individuals to remain in their homes as they age.<sup>251</sup></li> <li>The provision of meals supports the recovery process for individuals who have acute hospital episodes and leads to a reduction in food insecurity, freeing up resources to address other basic needs.<sup>252</sup></li> <li>Potential pathways for mixed outcomes:</li> <li>Baseline health and demographic characteristics of participants including increased risk of physical disability, chronic disease, and financial strain<sup>253</sup></li> <li>Some participants' nutritional intake may be limited to what they consume through OAANSP</li> </ul>
	<ul> <li>and poor health outcomes:</li> <li>One study found that participants were more likely to have a home health episode, admis- sion to skilled nursing facility, higher average Medicare expenditures, and ED visits leading to</li> </ul>	(one to two meals/day), which are not intended to or designed to meet participants' full nutri- tional needs. <sup>254</sup>

hospital admission<sup>249</sup>

# The First Large-Scale Food is Medicine Program: The Special Supplemental Nutrition Program for Women, Infants, and Children

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a well-established, federally funded Food is Medicine program that increases access to foods that support health for low-income families.<sup>255</sup> As the first national nutrition support program with eligibility criteria tied to the health care system, the program's operation and evolution offers important lessons for current and future Food is Medicine interventions: namely, that a limited food package can limit program appeal, and that administrative complexity can be a barrier to participation. The program also demonstrates that Food is Medicine interventions can be brought to scale, reduce disparities, and improve key health outcomes.

WIC is the country's third-largest food and nutrition support program, serving about 7 million people (1.63 million parents, 1.71 million infants, and 3.52 million children under 5) each month through the provision of food (via packages, vouchers, or credits), nutrition education, and referrals to social and health care services.<sup>256</sup>

Participants are low-income (between 100% and 185% of the federal poverty threshold depending on the state) and must be deemed at "nutritional risk" by a health professional.<sup>257</sup>

WIC meets the Action Plan's definition of a Food is Medicine intervention, as it includes both the provision of food and a nexus to the health care system:

- Provision of food: The WIC food package provides targeted, supplemental nutrition for pregnant people and their young children in order to improve health outcomes. There are seven different WIC food packages, each designed to meet specific nutritional needs at different stages of pregnancy and early childhood development: pregnancy, postpartum, breastfeeding, fully formula-fed (infants), partially breastfeeding (infants), fully breastfeeding (infants), and early childhood (ages 2–5).<sup>258</sup> WIC provides checks, vouchers, or an electronic benefit card that can be used to purchase eligible foods each month at an authorized store or farmers market.<sup>259</sup>
- Nexus to health care system: In order meet the nutritional risk eligibility requirement, WIC applicants undergo an assessment by a health professional (e.g., a physician, nurse, or nutritionist). The assessment is generally performed, at no cost to the applicant, at a local WIC clinic, but can also be conducted by other health professionals, such as the applicant's physician.<sup>260</sup> The assessment includes the applicant's height and weight, as well as a blood test for anemia.<sup>261</sup> The clinical criteria for nutritional risk varies by state, but typically includes a medical-based condition (such as being anemic, underweight, or having a history of poor pregnancy outcomes) or a dietary-based condition (such as having a poor diet).<sup>262</sup> Information collected during the assessment is used to select the appropriate food package, design nutrition education, and make referrals to additional service providers.<sup>263</sup>

#### Health Outcomes Associated with the WIC Program

WIC is widely recognized as one of the most effective nutrition programs in the United States.<sup>264</sup>

This report reviewed 11 studies that examine the impact of WIC participation on health Outcomes.<sup>265</sup> WIC participation is associated with:

- Decreased preeclampsia;<sup>266</sup>
- Increased length of gestation and birth weight;<sup>267</sup>
- Decreased preterm delivery and neonatal intensive care unit (NICU) stays;<sup>268</sup>
- Decreased infant mortality; and<sup>269</sup>
- Reduced racial disparities in maternal and birth outcomes (notably, preterm delivery, low birth weight, NICU admission, and infant mortality), particularly for Black pregnant people when compared with their white counterparts.<sup>270</sup>

Overall, WIC improves health outcomes through the provision of certain foods deemed particularly important for pregnant people and young children, as well as through increased purchasing power for health care due to lower food expenses.<sup>271</sup> A recent USDA review of WIC found that the program particularly improves the diet of young children (ages 2–4) compared with eligible nonparticipants, and that WIC participants consume fewer calories from added sugars and saturated fats than nonparticipants.<sup>272</sup> In addition to food, WIC also provides nutrition education, breastfeeding promotion and support, and referrals to health care and social services.<sup>273</sup> However, the studies reviewed by this Action Plan do not isolate the effects of the provision of food from the provision of the additional services.

# The evolution and administration of WIC offers important lessons for Food is Medicine interventions

1 In an intervention where the types of food provided are limited, participant choice and consideration of cultural preferences are important.

WIC was created in 1972 as a pilot program and later formalized as a national program in 1974.<sup>274</sup> Since WIC's inception, the WIC food package has undergone significant changes to better meet participants' needs. The food packages have evolved from a 1970s package that included infant formula, milk, cheese, eggs, cereal, and fruit juice to food packages that include a much wider variety of foods and are differentiated by the age and breastfeeding status of participants.<sup>275</sup> Even so, the National Academies of Science, Engineering, and Medicine noted as recently as 2017 that some foods in the WIC package were less preferred by people with different cultural backgrounds and that "expanding to allow more culturally suitable options merits consideration."<sup>276</sup> Fruit and vegetables, today one of the most popular and most redeemed foods in the WIC package, were introduced only in 1992—and then, only carrots were included, exclusively for breastfeeding parents.<sup>277</sup> A broader fruit and vegetable benefit for all participants, distributed as a voucher that allows participants to choose their own fruits and vegetables up to a specific dollar value, was not implemented until 2009.<sup>278</sup>

2 Administrative complexity in program enrollment and implementation is a barrier to program participation.

Prior to May 2020, many participants in WIC found it challenging to meet the program's eligibility and enrollment requirements. Enrollment and, in some cases, receipt of benefits required in-person visits at the local WIC office. Lack of transportation and childcare, wait times at the WIC office, and difficulty in scheduling appointments were all cited as barriers to participation.<sup>279</sup> The COVID-19 pandemic spurred major changes in WIC program administration as Congress gave USDA the authority to enact waivers for greater flexibility, most notably allowing states to issue benefits remotely rather than requiring participants to pick up their WIC EBT cards and/or paper vouchers, and allowing participants to enroll or re-enroll in WIC without in-person visits.<sup>280</sup> These and other waivers are still in effect, and advocates hope that many of these changes will be made permanent.

Redeeming WIC benefits also poses challenges. For example, stores are sometimes out of WIC-eligible foods, and cashiers who aren't knowledgeable about how to handle WIC transactions can delay checkouts, increasing the stigma that WIC participants experience.<sup>281</sup>

#### Key takeaways from WIC for future Food is Medicine intervention design

Fifty years of evolution in the structure and operation of WIC reveal factors that are key to maximizing participation in future Food is Medicine programs:

- Revisions to the food package underscore the importance of providing a wide variety of foods to accommodate cultural and personal preferences: if people don't consume the food because they don't like it, the program won't achieve the desired impact.
- WIC demonstrates the complexity of limiting food choice in an intervention, especially as interventions scale and become integrated into government programs. On one hand, each small change to the WIC food package involves months and in some cases years of scientific inquiry, preparation of official reports, and synthesis of public comment. This limits the program's nimbleness in responding to the latest advances in nutrition science. On the other hand, the program's notable health benefits are likely to be partially attributable to incentivizing healthy foods for participants.
- WIC's comprehensive range of services and supports means that a significant minority (41% of \$4.8 billion in 2021) are expended on non-food program components for participants, including nutrition education and breastfeeding support.<sup>282</sup> Other multi-component Food is Medicine interventions must consider the cost of non-food components as they scale.
- Finally, persistent challenges to enrolling in WIC and redeeming benefits illustrate the value of establishing simple eligibility criteria and enrollment processes for Food is Medicine interventions, as well as ensuring that interventions are easy to use.

### Specifically, as outlined by the USDA, WIC has achieved: 283

Birth Outcomes and Savings in Health Care Costs	Diet and Diet-Related Outcomes	Infant Feeding Practices	Other Positive Outcomes
<ul> <li>Longer pregnancies</li> <li>Fewer premature births</li> <li>Lower incidence of low birth weight;</li> <li>Fewer infant deaths;</li> <li>A greater likelihood of receiving prenatal care; and</li> <li>Savings in health care costs from \$1.77 to \$3.13 for every \$1 spent in WIC within the first 60 days after birth</li> </ul>	<ul> <li>A more nutrient-dense diet</li> <li>Decline in the rate of iron deficiency anemia from 7.8% in 1975 to 2.9% in 1985, which the Centers for Disease Control and Prevention is partly due to WIC participation</li> </ul>	<ul> <li>Increased likelihood of breast-feeding after having received information about it from the WIC clinic</li> <li>WIC breastfeeding policy and program activities were strengthened in the early 1990s</li> <li>Between 1996 and 2001, the percentage of WIC mothers breastfeeding in the hospital increased by almost 25%, from 46.6 to 58.2%</li> <li>Between 1996 and 2001, the percentage of WIC infants breastfeeding at six months of age increased by 61.2%, from 12.9 to 20.8%</li> <li>Infants who are fed infant formula, 90% received iron-fortified formula, which is recommended for nearly all non-breastfed infants for the first year of life</li> </ul>	<ul> <li>Improved rates of childhood immunization and of having a regular source of medical care</li> <li>Improved vocabulary scores for children of mothers who par- ticipated in WIC prenatally</li> <li>Significantly improved memory for children enrolled in WIC after the first year of life</li> <li>Higher hemoglobin levels and lower risk of maternal obesity at the onset of the subsequent pregnancy for women who received postpartum benefits</li> <li>Increased likelihood of children having a regular provider of medical care;</li> <li>Improved growth rates</li> </ul>

#### **From Foundational Research to Food is Medicine Interventions**

The promise of Food is Medicine interventions relies on two key assumptions: first, that inconsistent access to food has a negative impact on health, and second, that programs that increase access to healthy foods can promote positive health outcomes. This overview of the country's largest food support programs establishes that Food is Medicine research builds on a body of evidence that firmly supports the finding that food insecurity is associated with a wide array of poor physical and mental health outcomes, as well as with increased health care utilization and spending. In addition, research on existing food support programs (SNAP, NSLP, OAANSP, and WIC) begins to demonstrate that the provision of food is generally associated with improved health outcomes.

# **VI. Research on Food is Medicine Interventions**

This section examines the published, peer-reviewed research on medically tailored meals, medically tailored groceries, and produce prescriptions—the three primary categories of Food is Medicine interventions described in <u>Section III: Food is Medicine Defined</u>. It provides an overview of what has been tested and how, for what purposes, and in what populations. Overall, this section summarizes what the research demonstrates about the impact and effectiveness of Food is Medicine and identifies the gaps that remain.

Over the past decade, research on Food is Medicine has transformed the field and laid the groundwork for conversations about its widespread adoption. The research demonstrates that Food is Medicine interventions are not only replicable and scalable but also effective. All three interventions examined in this report have been shown to reduce food insecurity, improve dietary intake, and support mental health. Across multiple studies, medically tailored meals, medically tailored food, and produce prescriptions have been associated with improved clinical outcomes including weight (body mass index), blood pressure, and blood sugar control (HbA1c). However, results vary with intervention design, duration, and target population. Some studies have reported no significant impacts on health outcomes. Multiple studies of medically tailored meals have documented reductions in health care utilization, including fewer hospitalizations and ED admissions, significant reductions in health care expenditures, and even reduced mortality. Overall, most Food is Medicine research studies to date have been pre-post pilots or quasi-experimental studies, although new randomized controlled trials are accelerating and are providing the highest quality evidence. Qualitative assessments, in which researchers learn about the perspectives and experiences of participants and stakeholders, have become increasingly common across all interventions, yielding critical insights about program design and implementation, participant satisfaction and engagement, in addition to health care provider perspectives.

As the research tables in this report demonstrate, the volume and rigor of research has increased with each year. This trend is set to continue with an impressive number of forthcoming studies and ongoing research that explores a vast range of health care, patient, and health condition-specific outcomes.

The opportunities for investigation also continue to expand as exciting new programs and policy innovations are implemented across the country. The challenge now is ascertaining how best to propel rigorous, high-impact, translatable research that can quickly bring necessary reforms to the health care and food systems.

The findings in this section are drawn exclusively from the published, peer-reviewed research conducted in the United States through December 1, 2023. In addition to undergoing the rigors of the peer-review and publication process, this research is readily available to and requested by those making key decisions about Food is Medicine program design, implementation, and funding. It is important to note, however, that this focus omits many important facets of the larger body of evidence on the efficacy and value of Food is Medicine, including forthcoming studies, conference presentations, gray literature, and other reports. In addition, the resources required to research the health impact of Food is Medicine interventions and seek publication in a peer-reviewed journal are not available to all program implementers. One goal of this Action Plan is to encourage the deployment of additional resources to ensure that future research engages a wide range of perspectives and captures the full impact of Food is Medicine interventions.

#### The Impacts of the COVID-19 Pandemic on Food is Medicine Research

Since the publication of the first Food is Medicine Action Plan, the world emerged from the worst of the COVID-19 pandemic. The toll was unfathomable, with over 1 million people killed by the virus in the United States. It's now clear that high, existing rates of diet-related illness is one of several factors responsible for the large number of deaths in the United States.<sup>284</sup> For example, a study estimated if the United States had a cardiometabolically healthy population with low levels of diabetes, hypertension, heart disease and obesity, then nearly two-thirds of the COVID-19 hospitalizations could have been prevented.<sup>285</sup> Vice versa, a COVID-19 infection can also worsen management of cardiovascular illnesses like diabetes, and the interconnectedness of COVID-19 and diet-related illness remains a concern today.<sup>286</sup>

The destabilizing events of the pandemic have critical implications for Food is Medicine research. It's important to remember that many recently published studies evaluated programs that occurred during the COVID-19 pandemic. The economic shutdowns starting in March 2020 brought unprecedented disruptions in clinical care and the economy. Patients were advised to avoid unnecessary medical appointments, and many received medical care via telehealth for the first time. Millions of households experienced disruptions in work and shouldered new childcare demands and increased household food expenditures when schools closed. Nearly all Americans received stimulus checks and federal nutrition programs like SNAP and WIC expanded benefits, and an entirely new program, Pandemic EBT, was created for children who no longer had access to school meals.<sup>287</sup> All this occurred as disruptions in the food supply chain limited availability of certain products and increased prices at retail grocery stores. In the context of this instability and the relationships between COVID-19 and chronic diseases, it's easy to imagine that many Food is Medicine programs would be have been affected in one way or another.



#### **Important Concepts in Food is Medicine Research**

Several key concepts are critical to understanding Food is Medicine research, both in contextualizing the current body of evidence related to efficacy and in identifying opportunities to purposefully build on this evidence in the future.

# **Baseline Health**

It is critical to understand the baseline health of the target population. Generally, the worse the overall health of the participant, the faster researchers can expect to see changes in outcomes for health conditions that are highly sensitive to diet. For example, a diabetic participant who has a baseline HbA1c of 10.0 and cannot shop and cook for themselves due to a disability is more likely to see an improvement after six months of medically tailored meals than a diabetic patient who has a baseline HbA1c of 6.5 and can shop and cook for themselves. Similarly, if a participant has very few health care costs at baseline, then the program is less likely to reduce already low health care costs.

# Intensity of Intervention

The intensity of the intervention refers to how much food is provided, often measured on a per-week basis. This key concept can also include what kind of food is provided, as well as how long food is provided (also referred to as duration). Programs that target all aspects of a healthy diet, such as medically tailored meals or medically tailored groceries, are more likely to improve health quickly than fruits and vegetables alone. And programs that last for an extended period of time—generally, six-plus months are more likely to produce measurable health outcomes. Household size also matters in determining the intensity of the intervention, as food will be shared within a household.<sup>288</sup> For example, if a recipient of medically tailored meals is a parent with three children and the family is food-insecure, the recipient will likely share food with their children, thereby reducing the intensity of the intervention for the intended recipient. However, if meals are scaled for household size and the children also receive meals, the parent is more likely to fully consume each meal.

# Adherence

Study results must be interpreted within the context of program adherence, participation, and engagement. Very low adherence rates bias the results toward the null hypothesis of no program impact. For example, if participants are redeeming only half of their produce prescription vouchers at a farmers market because it is open only on Saturdays and not conveniently located, then they are receiving a substantially less intensive intervention than intended. In contrast, if the program is available at multiple access points with convenient hours and locations and participants redeem more vouchers, they will receive a more intensive intervention that is more likely to achieve the intended outcome. Other issues that may have an impact on adherence include throwing or giving away intervention food—these issues, too, can be addressed through program design. While the medical literature often refers to adherence as "compliance," this suggests that the participant was not meeting program expectations when, in reality, the program may have been poorly designed, inconvenient, or unwelcoming for participants.

#### **Outcome of Interest**

The outcome being measured impacts the amount of time in which results can be expected. For example, HbA1c and blood pressure may be highly sensitive to changes in diet. A Food is Medicine intervention may have a significant impact on HbA1c or blood pressure within four to six months; however, the same program may not have a meaningful impact on BMI for one to two years.

# Sample Size

Some of the existing Food is Medicine studies, particularly those focused on produce prescriptions, have small sample sizes. A small sample reduces a study's ability to observe the true impacts of an intervention. The larger the sample, the lower the statistical uncertainty and the more precise the study's findings. A power calculation allows a researcher to predict the minimum sample size required to be confident that a study will capture the impact of the intervention. If a study is underpowered, it may not be worth conducting. Furthermore, conducting it may even be unethical. With smaller groups of study participants, qualitative research can yield critical insights into program design, implementation, and acceptability.

# **Regression to the Mean**

This is a well-documented phenomenon that can occur if a variable is extreme at baseline. Over time, the variable will move closer to the population mean, independent of any intervention. Regression to the mean is most likely to affect results in a prepost pilot study without a control group. In this scenario, data may seem to report a significant effect when in fact there is none, or the effect is much smaller than the results suggest. Food is Medicine studies are particularly susceptible to regression to the mean, especially when the eligibility criteria target high-risk patients with high baseline measurements in biomarkers or health care utilization. For example, if all participants in a study have very high blood pressure, many blood pressure values will improve next time they are measured by random chance. This may have nothing to do with the intervention but rather with changes in stress, sleep, medications, exercise, and other factors.

# **Selection Bias**

This form of systematic error can arise when enrolling participants in a study—those who enroll or remain in a study may differ from those who do not enroll (or the control group) in meaningful ways other than access to the intervention or exposures under investigation. For example, while it may seem reasonable to compare SNAP participants with eligible nonparticipants, a number of factors—such as financial distress, poor baseline health, and household demographics—influence whether or not someone participates in SNAP in the first place, and those factors can then influence study outcomes.

Sometimes these factors can be measured as confounders and accounted for within study design and analysis. Yet ignoring these factors when selecting control groups can bias the results of the study, failing to capture the true effects of the intervention or exposure. The potential for selection bias also arises when those who do not complete the study differ from those who do in a meaningful way. For example, if those who did not complete a produce prescription study lived the farthest away from the distribution site, the study results could overstate the impact of the intervention in favor of those who lived closer, failing to capture its full impact. A well-run randomized control trial is one way to remove concerns of selection bias.

# Table 8: Summary of all Medically Tailored Meal Studies with Quantitative MethodsPublished in the United States through December 1, 2023, by Outcomes, Study Design,and Sample Size

#### Color codes+

Sample size	
< 100	< 100
≥ 100	≥ 100

+Each green cell in the summary table represents a study with a positive association with the assessed outcome, signifying a positive effect on health outcomes. The darker green cells represent a larger sample size for a positive finding. Each gray cell in the summary table represents a study with a null or no effect finding. The darker gray cells represent a larger sample size for a null or no effect finding.

Tai	s among Medically lored Meals† 2015-2023)	Randomized controlled trials	Quasi-experimental studies (with comparison groups)	Pre/post studies and single-arm, longitudinal studies (no comparison group)
	Food insecurity <sup>289, 290, 291</sup>			
Nutrition & Social Risk	Dietary intake/ quality <sup>292, 293, 294, 295, 296, 297</sup>			
	Quality of life <sup>298, 299, 300</sup>			
	HbA1c or glucose management <sup>301, 302, 303</sup>			
Clinical Outcomes	Blood pressure <sup>304, 305</sup>			
	Weight/BMI <sup>306, 307, 308,309, 310,311</sup>			
	Hospitalization/ inpatient visit <sup>312, 313, 314,</sup> <sup>315, 316, 317, 318, 319</sup>			
	ED visit <sup>320, 321, 322, 323, 324</sup>			
Health Care Utilization	Readmission/ <sup>325</sup> Rehospitalization			
	Other health care utilization <sup>#, 326, 327, 328, 329</sup>			
	Health care cost <sup>330, 331,</sup> 332, 333, 334, 335			
	Mortality <sup>336, 337</sup>			
	Other <sup>*338, 339, 340, 341</sup>			

† This table includes all published medically tailored meal studies that used quantitative statistical methods conducted in the United States that were published prior to December 1, 2023. Randomized trials reflect the strongest study design. Within a given column for each of the three study designs, studies with large sample sizes (marked by a dark green shade) reflect a higher degree of certainty in the findings. A single study may have multiple outcomes marked in the table. In addition, some studies include more than one target population, in which case outcomes were marked for each population. However, any secondary analyses or exploratory analyses not described in a study's abstract were excluded from this table. Positive associations labeled in green are determined by the standard statistical significance of p < 0.05 or 95% confidence interval not containing 0 (continuous) or 1 (categorical).

#Other health care utilization includes admission to skilled nursing facilities, paracenteses, emergency transportation, and length of stay

\*Other outcomes include mental health, functional status, malnutrition, volume overload, diabetes self-management, antiretroviral treatment adherence, and lipid profile (e.g., small dense low-density lipoprotein cholesterol, total cholesterol, and lipoprotein A).

#### **Medically Tailored Meals Peer-Reviewed Literature: A Closer Look**

Research on medically tailored meals (MTMs) has advanced rapidly, with increasing rigor and study size. This research is leading the way on demonstrating measurable decreases in health care utilization and spending, along with improvements in clinical outcomes across several health conditions. Forthcoming research will continue to probe these exciting results with even larger, longer studies, randomized trials, and evaluations of MTM programs in Section 1115 Waivers that allow Medicaid coverage for Food is Medicine programs in several states, while also looking at new patient populations, such as those with cancer or high-risk pregnancies.

No. of quantitative and qualitative studies:	23
No. of quantitative studies with control or comparison group:	12/20
No. of quantitative studies with sample over 100:	15/20
Duration range:	two weeks to 18+ months
Intensity range:	50-100% of daily dietary intake

Health conditions: type 2 diabetes, HIV/AIDS, heart failure, chronic liver disease, diabetes, cancer, end-stage renal disease, patients receiving hemodialysis treatment, chronic obstructive pulmonary disease, congestive heart failure

**Patient populations:** urban, suburban, Medicare and Medicaid beneficiaries, low-income, food-insecure, older adults ages 65+, patients with limitations in activities of daily living, children participating in Head Start programs, home care clients

**Outcomes:** mortality, inpatient admissions, ED visits, admissions to a skilled nursing facility, readmission rates, health care costs (inpatient, outpatient, ED, pharmacy, emergency transportation), Healthy Eating Index scores, diet quality (18-item Multifactor Screener), food insecurity, BMI, frailty/disability, Katz Index of Independence in Activities of Daily Living, health-related quality of life, cost-related medication underuse, competing demands between food and medicine, hypoglycemia (self-reported), hemoglobin A1c (HbA1c), optimal blood sugar range, diabetes distress, diabetes self-efficacy, depressive symptoms, internalized HIV stigma, ART adherence, chronic liver disease-specific outcomes (paracenteses per person/week, measures of liver function, diuretic dose, quality-of-life symptom inventory), interdialytic weight gain, plasma phosphorous, absolute volume overload, DETERMINE nutritional risk score, heart failure-specific outcomes (Kansas City Cardiomyopathy Questionnaire, cardiac biomarkers), qualitative insights and process metrics, including patient satisfaction, food preferences, and program adherence

**Strength of research design:** The evidence base for MTMs is the most robust (i.e., more strong quasiexperimental studies and RCTs) among the three Food is Medicine interventions examined in this report, yet the volume of studies ultimately remains small. Of the 20 quantitative studies, seven are randomized trials and 12 use comparison groups. Compared with other Food is Medicine categories, the MTM literature has few qualitative studies (only three studies), suggesting more work could be done to learn directly from the perspectives and experiences of participants, clinicians, and other stakeholders.

**Intervention design:** Intervention design across studies varies as well, making it difficult at times to draw comparisons across studies. For example, program length ranged from two weeks to over 18 months, and the number of meals provided per day varied from one to three meals per day. Recent RCTs have provided fewer meals per week and for shorter durations than earlier quasi-experimental studies. Most programs also provided meals for the entire household, although this was not the case in every study. Meals were generally home-delivered, but one intervention required that participants pick up meals. Meals were sometimes complemented with nutrition counseling.

Across the spectrum of Food is Medicine interventions, MTMs are the most intensive for service providers requiring the preparation and, often, home delivery of food—and therefore the most expensive. Organizations often prepare 10+ meal plans per day to address specific dietary guidelines for different diagnoses, cultural and personal preferences, and food allergies. MTMs reduce many barriers that program participants face such as costs and affordability, time and convenience, dietary knowledge, skills in food preparation, and transportation. However, for the intervention to be effective, factors such as cultural acceptability, palatability, and household dynamics are critical to MTM program design.<sup>342</sup>

**Program participants:** Historically, medically tailored meals have been provided to populations with highly complex health profiles. Programs have emphasized immediate treatment of urgent health needs, with little minimal emphasis on prevention and only one study in a pediatric population. Nearly all studies feature the same core inclusion criterion: a diagnosis of one or more serious, nutrition-related or nutrition-sensitive medical conditions. Half of the studies also use income or food security as an inclusion criterion, further compounding the clinical, nutritional, and social risk factors of study participants.

Generally, participants were extremely sick and many struggled to shop and cook independently. They already faced significant health risks and had high baseline health care costs. Therefore, it is unwise to extrapolate MTM study outcomes to the general population or even to those with high health care usage and costs who are not at serious nutritional risk and have difficulties with activities of daily living.<sup>343</sup>

**Medically tailored meals and equity considerations:** Medically tailored meals remove several logistical and financial barriers to food access. The provision of meals also serves as a point of social contact and support when home-delivered. While choice is more limited as compared with a produce prescription program (participants can often choose fruits and vegetables at retail grocery stores that fit their personal and cultural preferences), many of the meal providers participating in these studies strive to use recipes that reflect the food traditions of their client populations. It is important that studies note when and how client preferences and tastes are incorporated into intervention design as this can play a key role in overall adherence. We also encourage researchers to measure if meals are being consumed and shared with other household members.

To date, research on MTMs has evaluated health outcomes and health care utilization for the principal program participant. In practice, many medically tailored meal organizations provide meals to the entire household. These interventions may rely on the meals serving the nutritional needs of everyone in the household, allowing the principal program participant to consume most or all of the food that was intended for them. Future research should evaluate the importance of providing meals to the full household as well as the range of benefits experienced by other household members.

Another key practice of many of the meal providers participating in these studies is access to as-needed nutrition counseling. Participants can work with RDNs to help them stay with a diet that may be unfamiliar, understand why MTMs are important for their health, schedule consumption of meals around taking medication, and make appropriate choices about what to eat outside of the meals if the intervention doesn't provide full daily nutrition or once the intervention ends. Research has yet to explore the full range of these benefits or the impact of different program components.

#### Key Takeaways:

Due to the wide range of program designs and conditions included in the MTM research, it is difficult to compare across studies and make overarching conclusions. However, two key themes are emerging: (1) MTMs can reduce health care utilization and even mortality in specific circumstances with patients with advanced chronic disease, most promisingly among patients with a recent heart failure hospitalization. More research is needed to better understand which specific populations might see this reduction in health care utilization and duration of MTMs is required. Reduced health care utilization is not a guaranteed outcome and will likely be program-specific. (2) Even among patient populations that do not see immediate reductions in health care utilization, MTMs can result in important health gains, both physical and mental, and improve the management of diet-related illness.

**Unanswered questions:** Research has yet to comprehensively evaluate optimal intervention intensity (the amount of food provided), impacts of specific dietary plans, or the duration for different health conditions and levels of acuity. Research could also identify which participants could transition to a less-intensive medically tailored groceries or produce prescription program and maintain health outcomes, on what timeline, and under what circumstances. Similarly, research should investigate what happens to meal recipients' diet and health once the intervention ends, and if health benefits are maintained once programs end. Finally, more qualitative analyses could provide important insights into how programs could enhance participant engagement.

# **Medically Tailored Meals**

# Table 9: Medically Tailored Meals Peer-Reviewed Literature

Author	Study Design	Intervention	Key Findings
Boxer <sup>344</sup> (2023)	Randomized controlled trial n = 655 adults with at least one of the following diet-sensitive conditions: heart failure, cancer, COPD, diabetes, chronic kidney disease, chronic liver disease	Participants were randomized to receive either two or four weeks of one MTM per day	<ul> <li>In both groups, the Katz activities of daily living scores improved</li> <li>In both groups, there was no change in ED visits or rehospitalizations</li> <li>In the two-week group, HADS changed from 5.4 to 4.8 (p = 0.005) and the DETERMINE nutritional risk score changed from 7.2 to 6.4 (p = 0.0006), but there was no change in the four-week group</li> <li>There was no statistically significant difference across all outcomes between the two-week and four-week MTM program</li> </ul>
Kelly <sup>345</sup> (2023)	Qualitative study using surveys and interviewsn = 22 participants completed interviewsn = 529 participants completed surveysAdults with one or more of six health conditions: heart failure, cancer, chronic obstructive pulmonary disease, diabetes mellitus, chronic liver disease/ cirrhosis, or chronic kidney disease discharged from one of two hospitals in the Denver/ Boulder area between April 2020 and June 2021 during the COVID-19 pandemic	Two to four weeks of MTMs, one meal per day, post-discharge from a hospital	<ul> <li>Participants were very satisfied with the program, reporting that they had sufficient healthy food to eat, the meals were convenient and easy to prepare</li> <li>Participants recommended that nutrition education and greater flexibility in quantity and frequency of food would improve their experience</li> </ul>
Nguyen <sup>346</sup> (2023)	Retrospective cohort study with two comparison groups Seniors ages 65+ enrolled in Medicare Advantage n = 742 with a recent heart failure hospitalization for MTMs (n= 2,834 for 2019 comparisons; n = 455 for 2020/2021 comparisons) n = 756 with other hospitalization for MTMs (n = 6,665 for 2019 comparisons; n = 523 for 2020/2021 comparisons)	MTMs for up to four weeks post hospital discharge (total of 56 to 84 meals) Patients selected meals from menus offered by Mom's Meals	<ul> <li>Among those with heart failure, MTMs were associated with lower odds of combined 30-day death and rehospitalization compared with the no meals-2021/2022 cohort (odds ratio = 0.55, p &lt; 0.001) but was not significant compared with the no-meals 2019 cohort (odds ratio = 0.86, p = 0.12)</li> <li>Among those without heart failure, MTMs were associated with lower combined 30-day death and rehospitalization when compared with the no-meals 2019 (odds ratio = 0.64, p &lt; 0.001) and the no-meals 2021/2022 (odds ratio = 0.48, p &lt; 0.001) cohorts</li> </ul>
Belak <sup>347</sup> (2022)	Matched retrospective cohort pilot study n = 39 adults with heart failure, food insecurity, and at high risk for readmission compared to n=117 similar, matched comparisons Due to missing data, analytical sample was only 22 to 26 participants for biomarkers	Three months of MTMs at three meals per day, plus nutrition counseling with a dietitian after discharge from hospital Participants could have one session per month with the dietitian	<ul> <li>No impacts on BMI or blood pressure</li> <li>Dietary intake improved (more fruit and milk, fewer chips) among the 11 participants with prepost dietary data</li> </ul>

# Table 9: Medically Tailored Meals Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
Brophy-Herb <sup>348</sup> (2022)	<b>Randomized controlled trial</b> n = 299 preschoolers ages 3–6 recruited from Head Start programs	12 weeks of home-delivered, medically supportive meals provided by Meals on Wheels, plus provision of cooking/ serving resources	<ul> <li>Dietary intake significantly improved, including daily consumption of fruit, fruit juice, and red and orange vegetables</li> <li>Total vegetable consumption, family meal frequency, and BMI z-score did not change</li> </ul>
Clark <sup>349</sup> (2022)	Pre-post study without a comparison group n = 154 adults with type 2 diabetes using continuous glucose- monitoring devices	28 days of meal delivery with three meals per day plus meals for household members The meal program occurred during the COVID-19 pandemic from June–September 2020 Participants selected meals of their choice	<ul> <li>Average time in optimal blood sugar range improved by 6.8% (p &lt; 0.001) and odds of achieving a 70+% time in range increased (odds ratio = 2.55, p = 0.051)</li> <li>Average glucose management index improved by 0.21% (p &lt; 0.001)</li> <li>Benefits were not sustained after the meal program ended</li> </ul>
Galiatsatos <sup>350</sup> (2022)	<b>Pre-post pilot study</b> n = 84 adults ages 60+ recruited form an urban medical center with a prior hospitalization in the past year with a diagnosis of diabetes, hypertension, heart failure, and/or chronic obstructive pulmonary disease	Meals on Wheels provided three months of daily meal delivery Monday–Friday Meals met the American Heart Association and American Diabetes Association standards The intervention also included home safety inspection and modification, free medical supplies, and daily social engagement with a check-in on medications, post-hospital health appointments, appetite, and well-being	<ul> <li>Total hospital expenditures while on meals were \$435,258 as compared with \$1,445,637 (p &lt; 0.01) during the three months prior to enrollment, a 70% decrease in costs, largely due to a reduction in intensive care unit admissions</li> <li>Costs at six months and 12 months after enrollment remained lower than the six-month and 12-month periods prior to enrollment (p &lt; 0.05)</li> <li>Significant reduction in hospital admissions (142 in the three months before enrollment versus 37 in the three months after enrollment, p &lt; 0.001), but an increase in emergency room visits that did not result in hospitalizations (41 versus 122, p &lt; 0.001)</li> </ul>
Go <sup>351</sup> (2022)	Three-arm randomized controlled trial n = 1,977 adults with heart failure, diabetes, or chronic kidney disease being discharged from a hospital admission n = 993 received medically tailored meals; n = 497 received virtual nutritional counseling; n = 984 controls	Up to 10 weeks of MTMs with one meal per day per person in the household (mean program length was 6.9 weeks)	<ul> <li>MTMs did not reduce all-cause hospitalization at 90 days after discharge, and no additional benefit was observed with virtual nutritional counseling</li> <li>MTMs were associated with lower mortality (adjusted hazard ratio: 0.65, p &lt; 0.05) and fewer hospitalizations for heart failure (adjusted hazard ratio: 0.53, p &lt; 0.05), but not for diabetes-related hospitalizations (adjusted hazard ratio: 0.75, p &gt; 0.05)</li> </ul>
Hager <sup>352</sup> (2022)	Cohort policy simulation model US adults with limitations in instrumental activities of daily living and at least one diet-related chronic disease Estimated nationwide eligible population was 6.3 million adults	Modeled policy of eight months of MTMs per year with 10 meals per week, not scaled for household members	<ul> <li>If all eligible individuals received MTMs for eight months per year, an estimated 1.6 million hospitalizations and \$38.7 billion in health care expenditures could potentially be averted in one year</li> <li>Accounting for MTM program costs, the policy would be expected to have cost savings at \$13.6 billion per year, with most savings occurring in Medicare and Medicaid</li> </ul>

# Table 9: Medically Tailored Meals Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
Juckett <sup>353</sup> (2022)	<b>Retrospective chart review</b> n = 130 adults over age 65	Home-delivered meals that met general nutrition recommendations but were not medically tailored Participants choose meals from a list of options	<ul> <li>Older adults who selected their own meals chose meals that were significantly lower in protein, potassium, fat, and calories</li> <li>Coordinating meal selection with the help of RDNs may improve nutritional intake</li> </ul>
Kunvik <sup>354</sup> (2021)	Three-arm randomized controlled trial n = 67 adults ages 65+ comprising home care clients, caregivers, and care recipients n=22 in the protein-rich meal group n=24 regular meal group; n=21 control group	Participants were randomized into three groups: (1) protein- rich meal, snack, and bread; (2) regular meal; and (3) control group with no meals for eight- week home meal service	<ul> <li>At eight weeks, protein-rich home meal service increased protein intake at 9.4 g/d (p &lt; 0.05) compared with other groups</li> <li>Protein-rich home meal service increased calcium intake (169.9 mg/d (p &lt; 0.05) and improved the Sit-to-Stand Test at -4.8 seconds (p &lt; 0.05) compared with controls</li> <li>No change was observed in self-reported, health-related quality of life in treatment groups as compared with control group</li> </ul>
Perez <sup>355</sup> (2021)	Pre-post pilot study without a comparison group n = 20 patients with kidney failure on hemodialysis	One month of MTMs, tailored to have a low-sodium content, with three meals per day	<ul> <li>MTMs were associated with clinically relevant improvements in:</li> <li>Interdialytic weight gain (-0.82 kg; p &lt; 0.001)</li> <li>Systolic blood pressure (-18.0 mmHg; p &lt; 0.001); diastolic blood pressure (-5.9 mmHg; p = 0.008)</li> <li>Plasma phosphorus (-1.55 mg/dL; p = 0.005)</li> <li>Absolute volume overload (-1.08L; p = 0.025)</li> </ul>
Sakr-Ashour <sup>356</sup> (2021)	<b>Cross-sectional study</b> n = 1,227 adults ages 67+ n = 620 home-delivered meal recipients; n = 607 matched comparisons	Home-delivered meals provided through OAANSP Meals were not fully medically tailored but did adhere to USDA MyPlate guidelines	<ul> <li>Healthy Eating Index (HEI) 2010 scores of meal participants were lower on days when meals were not delivered (52.5 v. 63.4, p &lt; 0.0001)</li> <li>Less than 20% of home-delivered meal participants and comparison met the USDA recommended intake for fruit, vegetables, dairy, and protein</li> </ul>
Tapper <sup>357</sup> (2020)	<b>Pilot randomized trial</b> n = 40 adults with cirrhosis and ascites (chronic liver disease)	MTM delivery program: four weeks of meals and eight weeks of follow-up	<ul> <li>MTM group vs. standard of care group:</li> <li>Required fewer paracenteses</li> <li>Quality of life improved more</li> <li>Spent fewer days in the hospital</li> </ul>
Berkowitz <sup>358</sup> (2020)	Semi-structured interviews n = 20 adults diagnosed with type 2 diabetes with HbA1c > 8.0%	MTM delivery program: 12 weeks of meals	Participants were generally satisfied with MTM They emphasized the importance of receiving culturally appropriate food and reported improved quality of life, ability to manage diabetes, and stress reduction Participants also suggested combining MTM and other programs with additional financial assistance, particularly with medications
Berkowitz <sup>359</sup> (2019) JAMA	Retrospective cohort study with near/far matching n = 1,020 adults Intervention: 499 existing MTM program clients	MTM delivery program: average of 12.4 months of meals	<ul> <li>MTM group vs. matched cohort:</li> <li>49% fewer inpatient admissions</li> <li>72% fewer admissions to skilled nursing facilities</li> <li>16% reduction in health care costs</li> </ul>

### Table 9: Medically Tailored Meals Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
Berkowitz <sup>360</sup> (2019) J. Gen. Int. Med.	<b>Randomized cross-over trial</b> n = 42 adults diagnosed with type 2 diabetes with HbA1c > 8.0%	MTM delivery program: 12 weeks "on-meals" (intervention) and 12 weeks "off-meals" (control)	<ul> <li>"On-meals" group vs. "off-meals" group:</li> <li>Increased Healthy Eating Index 2010 score by +31.4/100</li> <li>Reduced food insecurity from 62% to 42%</li> <li>Reduced hypoglycemia from 64% to 47%</li> <li>Fewer days when mental health interfered with quality of life</li> </ul>
Henstenburg <sup>361</sup> (2019)	Retrospective chart review n = 103 adults, existing MTM program clients with complex health conditions who filled out the 2016 Client Satisfaction Survey	MTM delivery program: at least six months of meals	<ul> <li>Decreased hospitalizations (p = 0.0077)</li> <li>BMI was stable (median decrease of 0.04) and did not vary by diagnosis</li> </ul>
Berkowitz <sup>362</sup> (2018)	Retrospective matched cohort n = 3,077 adults, dually eligible for Medicaid and Medicare; members of a managed care plan Separate matched cohorts: MTM recipients: n = 133, n = 1,002 nonrecipients Non-tailored food: n = 624 recipients, n = 1,318 nonrecipients	MTM delivery program and non- tailored food delivery program: at least six months	<ul> <li>MTM group vs. matched cohort:</li> <li>70% fewer ED visits</li> <li>72% fewer uses of emergency transportation</li> <li>52% fewer inpatient admissions</li> <li>Lower medical spending (-\$570)</li> <li>\$220 in net health care cost savings</li> <li>NTF group vs. matched cohort:</li> <li>44% fewer ED visits</li> <li>38% fewer uses of emergency transportation</li> <li>Lower medical spending (-\$156)</li> </ul>
Hummel <sup>363</sup> (2018)	Randomized controlled trial n = 66 adults ages 55+ with a history of systemic hypertension; discharged to home following hospital admission for acute decompensated heart failure	MTM delivery program: four weeks of meals, with 12 weeks of follow-up	<ul> <li>Intervention vs. control:</li> <li>Similar Kansas City Cardiomyopathy Questionnaire summary scores</li> <li>Increased Kansas City Cardiomyopathy Questionnaire clinical summary scores (p = 0.053)</li> <li>Fewer 30-day heart failure readmissions (p = 0.06) and days rehospitalized within that timeframe (p = 0.055)</li> </ul>
Palar <sup>364</sup> (2017)	Pre-post study without a comparison group n = 56 adults, existing Project Open Hand clients with HIV and/ or type 2 diabetes and income under 300% FPL	MTM pick-up program: six months of meals	<ul> <li>Nutritional measures:</li> <li>Decreased food insecurity (p &lt; 0.0001)</li> <li>Decreased consumption of fatty foods (p = 0.003)</li> <li>Decreased consumption of sugary foods or drinks (p = 0.006)</li> <li>Fewer depressive symptoms (p = 0.028)</li> <li>Decreased binge drinking (p = 0.008)</li> <li>Decreased number of participants reporting giving up health care for food (p = 0.029) or food for health care (p = 0.007)</li> <li>HIV group: increased ART adherence (p = 0.046)</li> <li>Type 2 diabetes group: decreased diabetes distress (p &lt; 0.001); increased perceived diabetes self-management scores (p = 0.007); decreased BMI (p = 0.035)</li> </ul>

### Table 9: Medically Tailored Meals Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings	
DiMaria-Ghalili <sup>365</sup> (2015)	Cross-sectional descriptive study n = 171 adults, MTM program clients who completed Client Satisfaction Survey Comparison: National Survey of Older Americans Act Participants respondents n = 191, 272 from the Northeast n = 622,410 from urban/suburban areas	MTM delivery program (duration not specified)	<ul> <li>MTM recipients vs. National Survey of Older Americans Act Participants:</li> <li>More likely to rate the program highly (p &lt; 0.01</li> <li>Reported healthier eating (p &lt; 0.01); improved health (p &lt; 0.01); satisfaction with taste (p &lt; 0.01); and satisfaction with variety (p &lt; 0.01)</li> </ul>	
Gurvey <sup>366</sup> (2013)	Retrospective matched cohort n = 698 adults, members of a Medicaid Managed Care Organization Intervention: = 65 existing MTM program clients Comparison: n = 633 matched nonrecipients	MTM delivery program: at least six months of meals	<ul> <li>Intervention vs. comparison:</li> <li>Lower mean monthly health care costs (\$28k vs. \$41k)</li> <li>Lower mean monthly inpatient costs (\$220k vs. 132k)</li> <li>Lower HIV/AIDS mean monthly costs (\$37k vs. \$17k)</li> <li>Fewer monthly ED visits (p = 0.0001)</li> <li>Fewer monthly inpatient visits (p = 0.0001)</li> <li>Shorter monthly inpatient length of stay (p = 0.0008)</li> <li>Lower percentage of individuals discharged to home (p = 0.0001)</li> </ul>	

### **Research Table Acronyms**

AIDS	Acquired Immunodeficiency Syndrome	HbA1c	Hemoglobin A1c
ART	Antiretroviral Therapy		Human Immunodeficiency Virus
BMI	Body Mass Index	MTM	Medically Tailored Meal
	Blood Pressure	NSOAAP	National Survey of Older Americans Act Participants
CDC	Centers for Disease Control and Prevention	NTF	Non Tailored Food
CSA	Community Supported Agriculture		Randomized Control Trial
DSME	Diabetes Self-Management Education	Rx	Prescription
ED	Emergency Department	SD	Standard Deviation
	Federal Poverty Level		Socioeconomic Status
FQHC	Federally Qualified Health Center	SNAP	Supplemental Nutrition Assistance Program
			Special Supplemental Nutrition Program for Women, Infants, and Children

Table 10. Summary of all Medically Tailored Groceries Studies with Quantitative Methods Published in the United States through December 1, 2023, by Outcomes, Study Design, and Sample Size

#### Color codes+

Sample size			
< 100	< 100		
≥ 100	≥ 100		

+Each green cell in the summary table represents a study with a positive association with the assessed outcome, signifying a positive effect on health outcomes. The darker green cells represent a larger sample size for a positive finding. Each gray cell in the summary table represents a study with a null or no effect finding. The darker gray cells represent a larger sample size for a null or no effect finding.

Outcomes among Medically Tailored Groceries <sup>†</sup> (2015-2023)		Randomized controlled trials	Quasi-experimental studies (with comparison groups)	Pre/post studies and single-arm, longi- tudinal studies (no comparison group)
Nutrition &	Food insecurity <sup>367, 368, 369, 370,371</sup>			
Social Risk	Dietary intake/quality <sup>372, 373, 374,</sup> 375, 376, 377			
	HbA1c or glucose management <sup>378, 379, 380, 381</sup>			
Clinical Outcomes	Blood pressure <sup>382, 383</sup>			
	Weight/BMI <sup>384, 385, 386, 387, 388</sup>			
Health Care Utilization	Readmission/ rehospitalization <sup>389</sup>			
	Health Care cost <sup>390</sup>			
	Other*391, 392, 393, 394, 395, 396			

+ This table includes all published medically tailored food studies that used quantitative statistical methods conducted in the United States that were published prior to December 1, 2023. Randomized trials reflect the strongest study design. Within a given column for each of the three study designs, studies with large sample sizes (marked by a dark green shade) reflect a higher degree of certainty in the findings. A single study may have multiple outcomes marked in the table. In addition, some studies include more than one target population, in which case outcomes were marked for each population. However, any secondary analyses or exploratory analyses not described in a study's abstract were excluded from this table. Positive associations labeled in green are determined by the standard statistical significance of p < 0.05 or 95% confidence interval not containing 0 (continuous) or 1 (categorical).

\*Other outcomes include cancer treatment completion rate, viral suppression, CD4 cell counts, food efficacy, physical activity, health status, mental health, diabetes self-efficacy and medication adherence, and preventative services utilization

#### **Medically Tailored Groceries Peer-Reviewed Literature: A Closer Look**

Medically tailored groceries—sometimes called healthy food boxes, healthy food packages, food pharmacies, or hospital/clinical food pantries—blend components from MTMs and produce prescriptions. Recipients receive preselected, disease-specific food but need to prepare and cook meals on their own. Many medically tailored grocery programs are located within health care facilities; others require participants to pick up food at community organizations; and a few offer home delivery. Medically tailored groceries are associated with decreases in food security and improvements in dietary quality. And several, though not all, studies have found improvements in disease-specific outcomes. During the COVID-19 pandemic, there was a large growth in medically tailored grocery (MTG) programs, with many qualitative and implementation studies specific to the COVID-19 response by health care systems. Forthcoming research will continue to explore a variety of different program designs—such as the type of food provided, the amount of food provided, duration, and home delivery—among different patient and geographic populations.

No. of quantitative and qualitative studies:	25
No. of quantitative studies with control or comparison group:	4/14
No. of quantitative studies with sample over 100:	10/14
Duration range:	two to 12 months

**Health conditions:** type 2 diabetes, prediabetes, cancer, hypertension, hyperlipidemia, cancer, HIV/AIDS, hypertension, heart disease, other unspecified chronic conditions.

**Intensity range:** Many studies don't specify and others report different metrics. Ranges from 25%–33% of dietary intake, to a grocery value of \$230/month, to 12 meals per household member every other week, to 40 lbs. per clinic visit.

**Patient populations:** urban, suburban, rural, food insecure, uninsured, Medicaid enrollee, households with children, households impacted by COVID-19, low-income below 130% of federal poverty line

**Outcomes:** food security, dietary intake, hemoglobin A1c (HbA1c), diabetes self-management, diabetes selfefficacy, medication adherence, hypoglycemic episodes, BMI, blood pressure, physical activity, depression scores, patient experience and satisfaction, health care provider experience and satisfaction, program utilization, COVID-19 pandemic-related stress, patient characteristics predicting higher program engagement, quality of life, cancer treatment completion rates, HIV management, CD4 count **Strength of research design:** The quantitative evidence base for medically tailored groceries is still emerging, with only two randomized controlled trials. As compared with the MTM literature, fewer studies use control groups. Most are pilot studies, exploring program implementation and laying the groundwork for larger, more rigorous investigations. Recently, the MTG literature has seen a growth in qualitative studies analyzing facilitators and barriers to program implementation and learning directly from the experience of program participants.

**Intervention design:** Medically tailored grocery interventions frequently include community-based food pantries or clinic-based food pantries but may also include Community Supported Agriculture (CSA) shares or home-delivered groceries. Grocery items are generally unprepared, whole, or minimally processed foods. In some interventions, grocery items were presented as a "package" or "food bag," limiting client choice, while others allowed participants to choose what they wanted from a variety of pre-selected items. MTG programs allow for a high degree of medical tailoring for specific conditions and benefit from providing healthy items across food groups. Participants generally pick up grocery items on a weekly or biweekly basis and interventions run from two to 12 months. Many programs feed the entire household but differ in how they scale food for additional household members. Medically tailored groceries are less resource-intensive than medically tailored meals, meaning that they are usually less expensive per program participant than a MTM intervention.

In studies of medically tailored groceries, there was greater variation in program elements than in studies of medically tailored meals. This includes a wide range of diversity in populations, intensity, duration, nutritional composition, type of distribution, and educational components, making it harder to define each intervention and compare its impact across different populations, settings, and outcomes.

**Program participants:** Within the existing medically tailored groceries literature, there is a range of medical conditions, with diabetes and prediabetes being the most common. Food insecurity is generally a key inclusion criterion, including among the most recent programs created in response to the COVID-19 pandemic. One clinic-based program had a "no questions asked" policy, welcoming any patient who wanted assistance with food. Participants in medically tailored grocery programs were generally able to shop and cook for themselves, distinguishing this group from some participants in medically tailored meal studies.

**Medically tailored groceries and equity considerations:** Most programs required participants to pick up food, often at a community-based organization or clinic with more limited hours than retail grocery stores. By design, these programs assume participants have the time, kitchen equipment, and knowledge to prepare meals. Three programs provided home-delivered groceries. Some programs have pre-packaged food boxes or bags, while food pantry models offer participants some choice in food offerings. Several programs included education components, ranging from an educational booklet with recipes to several weeks of intensive classes and nutrition counseling.



### Key Takeaways:

The medically tailored groceries literature is less established than the medically tailored meals literature, with fewer randomized trials and quasi-experimental studies with comparison groups. Studies have not yet explored the impacts on health care utilization and health care costs. Similar to the MTM literature, due to the wide variation in program design and patient population, it's challenging to compare across studies or make definitive conclusions on efficacy. Several studies have shown promising impacts on health outcomes, yet the largest trial to date did not find a significant impact on diabetes management. Recent studies have focused on program implementation and learning directly from participants about facilitators and barriers to program engagement.

**Unanswered questions:** Future research MTGs should investigate intervention design, especially to increase participant engagement to ensure that participants are routinely picking up food or having it consistently delivered. Similar to the MTM literature, the MTG literature has large gaps in knowledge regarding the ideal program intensity (what percentage of dietary intake is provided), scaling the amount of food based on household size, and how to address participant tastes, preferences, and convenience considerations (location, transportation, physical ability, and the like). These critical design features are worthy of independent investigation—for example, how much food provided and for how long yields optimal results for different health conditions? Or does allowing for participant choice increase program satisfaction and adherence?

Research also needs to investigate what happens when participants bring food home—do they have the time, knowledge, skills, and tools to prepare meals? Who helps them and shares food with them? How are foods used to support the needs of others in their community? Which foods are participants able to easily incorporate into their cooking? What resources do groceries free up and how does this translate into other gains such as extra disposable income?

Finally, as with medically tailored meals, research needs to explore what happens to participants when the intervention ends and whether health outcomes can be sustained.

## **Medically Tailored Groceries**

### **Table 11: Medically Tailored Groceries Peer-Reviewed Literature**

Author	Study Design	Intervention	Key Findings
Crusan <sup>397</sup> (2023)	Qualitative interviews n = 15 adult patients recruited from a community health clinic identifying as Latinx and managing a chronic disease	Dietary Approaches to Stop Hypertension (DASH diet) medically tailored food kits	<ul> <li>Food kits with all fresh fruits and vege- tables were the preferred model by two- thirds of participants</li> <li>Themes included a preference for fresh fruits and vegetables over frozen or canned items; common barriers to accessing produce included time, money, and trans- portation</li> </ul>
Finkel <sup>398</sup> (2023)	Qualitative interviews n = 24 participants n = 10 program stakeholders	Clinic-to-community emergency food assistance program developed in response to food insecurity during the COVID-19 pandemic Participants received approximately 40 pounds of pre-packaged groceries, including vegetables, fruit, whole grains, dairy, and protein twice per month, pick- up or delivery	<ul> <li>Pandemic-related demands and reduced resources motivated participation</li> <li>Convenience, safety with masks and social distancing, and ease of access facilitated program retention</li> <li>Participants valued fresh produce and diversity of foods</li> <li>Stakeholders identified aligned values, flexibility, and communication as key to successful partnerships</li> </ul>
Luo <sup>399</sup> (2023)	<b>Cross-sectional study</b> n = 400 individuals with cancer and incomes below 130% FPL	Hospital-based, therapeutic food pantry with support from dietitians to select food	<ul> <li>More than half of participants did not have access to a vehicle or public transportation to access grocery stores</li> <li>Fewer than half of the participants reported eating fruits and vegetables on a daily basis</li> <li>Participants reported interference of cancer with work, lack of energy, difficulty affording food, and sleep problems</li> </ul>
Rivera <sup>400</sup> (2023)	Single-arm pilot feasibility trial n = 13 food-insecure adults ages 35–75 with hypertension	Medically tailored groceries (adhering to Mediterranean diet) and kitchen toolkits Dietitian provided cooking instructions, nutrition education, and disease management classes in a 16-week program	<ul> <li>On average, participants attended 19 out of 22 classes</li> <li>Patients were highly satisfied with cooking classes and food delivery</li> <li>Food security significantly improved (p &lt; 0.05) and dietary quality trended positively (p &gt; 0.05)</li> <li>Mean systolic and diastolic blood pressure decreased on average by 6.4 mmHg and 2.9 mmHg (both p &gt; 0.05)</li> </ul>
Woo Baidal <sup>401</sup> (2023)	Quasi-experimental, longitudinal cohort study n = 44 food-insecure households with children under age 6 receiving care at a New York City clinic n = 132 comparisons	Every-other-week food pantry visits for six months with approximately 12 meals per household member Foods were aligned with USDA MyPlate guidelines Cooking demonstrations with nutrition education and recipes occurred at food pantry visits	<ul> <li>Median attendance was 10 out of 14 sessions</li> <li>Food insecurity decreased at the twomonth and six-month follow-ups among participants</li> <li>Compared with control group:</li> <li>Participants had smaller increases in BMI z-score for children (-0.31, p &lt; 0.05) and BMI for adults (-0.68, p &lt; 0.05)</li> <li>Each attended session was associated with a smaller increase in BMI z-score (-0.03, p &lt; 0.05)</li> </ul>

### Table 11: Medically Tailored Groceries Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
DePuccio <sup>402</sup> (2022)	Qualitative study with semi-structured interviews n = 20 patients n = 20 health care providers and medical center administrators n = 11 food bank staff	Patients and their family members receive fresh produce once weekly from one of 16 participating food pantries affiliated with a regional foodbank	<ul> <li>Barriers were provider time constraints and competing demands, inadequate physician feedback regarding patients' program use, patient transportation barriers, and stigma associated with food pantry use</li> <li>Implementation facilitators included pro- gram champions at clinics and screening and referral coordination between clinics and Mid-Ohio Farmacy</li> </ul>
Frazier <sup>403</sup> (2022)	Description of program implementation Patients visiting at a medical clinic in Chicago, Illinois	Self-serve, no-questions-asked food pantries open 24 hours a day, seven days a week to everyone in the medical center during COVID-19 pandemic	<ul> <li>Food pantry served 18,600 individuals from March 2020 to November 2021 during COVID-19 pandemic</li> <li>Traffic was highest in a phlebotomy wait- ing area and a cafeteria pantry</li> <li>A "no-barriers" model suggests that food pantry systems might re-examine struc- tural barriers (i.e., income or neighborhood requirements) to access services</li> </ul>
Gany <sup>404</sup> (2022)	Three-arm randomized controlled trial n = 117 food-insecure patients with cancer at four New York City safety-net cancer clinics	Arm One patients received pre-packaged grocery bags (five lunches and five dinners) for six months once per week at a food pantry Arm Two patients received a monthly \$230 debit card for six months Arm Three patients received a weekly commercial grocery delivery (five lunches and five dinners) for six months	<ul> <li>The debit card group had the highest cancer treatment completion rate (94.6%), followed by food delivery (82.5%), and then pantry only (77.5%)</li> <li>Food-security scores improved significantly in all arms but did not differ across arms</li> <li>Depression and quality-of-life scores improved significantly in the pantry and delivery arms</li> </ul>
Reinoso <sup>405</sup> (2022)	Description of program implementation n = 112 food-insecure patients at Eskenazi Health Center Pecar in Indianapolis, Indiana	Medically tailored, clinic-based food pantry with nutrition education group visits (eight-week sessions) Patients also received referrals to community food pantries and federal nutrition programs	<ul> <li>At program end, 73% of participants reported consuming three+ servings of fruits per day compared with 56% at enrollment</li> <li>58% of participants reported consuming four+ servings of vegetables per day compared with 45% at enrollment</li> <li>Dashboard for social determinants of health data collection and a team-based workflow reduced burdens on providers</li> </ul>
Tanumihardjo406 (2023)	Description of program implementation n = 4,112 patients visiting Providence Milwaukie Hospital in Portland, Oregon, which serves a population with high rates of food insecurity and chronic conditions	Medically tailored food pantry with community teaching kitchen with diabetes self-management education, culinary nutrition education, and patient navigation to community referrals	<ul> <li>Lessons learned for success included:</li> <li>Foster health system and organizational support to pilot and sustain the program</li> <li>Flexibility to adapt programming to meet evolving needs of communities served</li> <li>Increase the use of reimbursable services while cultivating relationships with mission-driven donors and foundations</li> </ul>
Yu <sup>407</sup> (2022)	Pre/post study without a comparison group n = 191 HIV patients with food insecurity in Humboldt, Napa, or San Joaquin counties in California	Home-delivered meals or meal kits on a weekly basis contributed to 30% of clients' daily nutritional needs Patients could receive an additional monthly pantry box with nonperishable grocery items, if needed	<ul> <li>After one year, the proportion of patients with CD4 ≥ 500 increased from 48.5% to 66.7% (p = 0.031)</li> <li>Patients reporting food security increased significantly from 0% to 62.1% (p &lt; 0.001)</li> <li>For each six months of enrollment, there were 91.2% increased odds (p = 0.002) of viral suppression and an increase in CD4 count of 32.2 cells/mm3 (p = 0.010)</li> </ul>

### Table 11: Medically Tailored Groceries Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
Mirsky <sup>408</sup> (2021)	Description of program implementation n = 18 food-insecure patients with chronic diseases	Pre-packaged bags with plant-based foods, recipes, and in-person nutrition education by a dietitian	<ul> <li>Partnerships with food banks providing food and logistical support is beneficial</li> <li>Shelf-stable items reduce the need for freezer and refrigerator costs and space</li> <li>To support growth, programs need more data capture, research and evaluation, fundraising, and team building</li> </ul>
Walker <sup>409</sup> (2021)	Description of program implementation           n = patients with food insecurity and chronic disease, residing in a large metropolitan region in Ohio	Patients and their family members receive fresh produce once weekly from one of 16 participating food pantries affiliated with a regional foodbank	<ul> <li>51% of referred patients visited a food pantry at least once</li> <li>Patients who were older (p &lt; 0.001), had diabetes (p = 0.03), and had previously visited a food pantry (p &lt; 0.001) were more likely to visit a food pantry</li> </ul>
Sastre <sup>410</sup> (2021)	<b>Retrospective chart review</b> n = 542 admitted patients identified as food insecure	Vouchers for medically tailored food for food-insecure patients at discharge: one time (study period of 12 months)	38% of patients redeemed vouchers; among patients who redeemed vouchers, the average number of hospital readmis- sions was 7% lower than for those who did not redeem vouchers
Cheyne <sup>411</sup> (2020)	Pre-post pilot without a comparison group n = 192 adults with clinical history of prediabetes	Diabetes-appropriate food packages and text-based education: monthly, six-month assessment of a 12-month intervention	<ul> <li>Improved food security, dietary intake, physical activity, health status, and de- pression scores (p &lt; 0.001 for each)</li> <li>BMI did not change significantly</li> </ul>
Paolantonio <sup>412</sup> (2020)	Nested cohort study n = 33 food-insecure cancer patients (SNAP participants were not eligible)	Unrestricted* supplemental food voucher for food-insecure cancer patients: monthly for six months *\$230/month debit card with only restrictions on cigarettes, alcohol, and cash back	<ul> <li>On average, patients spent 77% of unrestricted voucher funds on items categorized as "healthy," with the largest portion spent on animal protein (22%), fruits (15%), and vegetables (13%)</li> <li>70% of patients reported eating most or all of the food themselves</li> </ul>
Hickey <sup>413</sup> (2020)	<b>Mixed-methods evaluation</b> n = 504 patients with self- reported/clinic-reported food insecurity	Pediatric clinic-based food pantry: three- day supply of food (no limit or frequency reported), 22-month study period	No significant relationship between access- ing the pantry and preventative service completion for up-to-date immunization status, completed lead screening, or completed developmental screening at 27 months of age
Aiyer <sup>414</sup> (2019)	Pre-post mixed-methods evaluation without a comaprison group n = 172 food-insecure adults	Produce distributions: 30 pounds of fresh produce and four "Food Rx-friendly" nonperishable food items every two weeks for nine months	<ul> <li>Food insecurity decreased from 100% at baseline to 10.2% at visit three and 5.9% by visit 12</li> <li>Perceived helpfulness of provided foods in improving dietary behaviors: fruits = 94.4%, vegetables = 90.6%, lean proteins = 85.2%, whole grains = 82.1%, low-fat dairy = 73.4%</li> </ul>
Feinberg <sup>415</sup> (2019)	Pre-post pilot without a comparison group n = 112 patients with type 2 diabetes HbA1c ≥ 8.0%)	Food pharmacy program for adults with type 2 diabetes: monthly for 12 months	<ul> <li>HbA1c decreased from 9.6% to 7.5%</li> <li>Health care spending for participants insured by Geisinger (n = 37) dropped by 80%</li> <li>Operational cost of ~\$2,400 per patient a year</li> </ul>

### Table 11: Medically Tailored Groceries Peer-Reviewed Literature, continued

Author	Study Design	Intervention	Key Findings
Greenthal <sup>416</sup> (2019)	<b>Semi-structured interviews</b> n = 30 patients, 89 providers	Hospital-based food pantry: up to two times a month	Patients: alleviated some concerns about stigma and inspired greater confidence in food quality
			• Providers: supported hospital-based food pantry and made frequent referrals; expressed a desire for additional training related to food insecurity
Ferrer <sup>417</sup> (2019)	<b>Pilot RCT</b> n = 58 adults with type 2	Medically tailored grocery pick-up for adults with type 2 diabetes: two times a	• HbA1c decreased by 3.1% in the interven- tion group vs. 1.7% in the control group
	diabetes (HbA1c > 9%)	month for six months	<ul> <li>(p = 0.012)</li> <li>Starting the Conversation Diet scores improved in the intervention group (p &lt; 0.001)</li> </ul>
			<ul> <li>BMI was unchanged in both groups</li> </ul>
Seligman <sup>418</sup> (2018)	RCT n = 568 food pantry clients with HbA1c ≥ 7.5%	Diabetes-appropriate food package program at food banks: 11 food packages over six-month period	<ul> <li>No significant difference between interven- tion and control groups in HbA1c; within the intervention group, HbA1c decreased significantly among those who fully en- gaged vs. partially engaged (p = 0.02).</li> </ul>
			<ul> <li>Statistically significant improvements in the intervention compared with the control group: food security (p=0.03), food stability (p=0.01), fruit and vegetable in- take (p=0.04), and trade-offs between food and diabetes supplies (p=0.03)</li> </ul>
Wetherill <sup>419</sup> (2018)	Pre-post pilot with no comparison group n = 43 patients at a health clinic with hypertension, diabetes, and/or hyperlipidemia	Pilot clinic-based food pharmacy to support chronic disease self- management: monthly food packages over seven-month study period	<ul> <li>Significant improvement in daily dietary fiber intake; slight increase in daily fruit and vegetable intake</li> </ul>
			Mean food security did not change
			• Among participants who had high blood pressure at enrollment (n = 17), diastolic blood pressure significantly improved
Gany <sup>420</sup> (2016)	Nested cohort study n = 351 patients at five cancer clinics	Hospital-based food pantry for low- income cancer patients: weekly food packages over four-month period	• The median number of return visits after initial visit was two and the mean was 3.25 (SD = 3.07)
			• Younger patients used the pantry less, immigrant patients used the pantry more, and prostate cancer and stage IV cancer patients used the pantry more
Seligman <sup>421</sup> (2015)	Pre-post pilot with no compar- ison group	Diabetes-appropriate food package program at food banks: monthly food	• Mean HbA1c decreased from 8.11% at baseline to 7.96% at follow-up (p < 0.001)
-	n = 687 food pantry clients with self-reported diabetes diagnosis and/or HbA1c $\geq$ 6.5%	packages over six-month period	• Diabetes self-efficacy and medication adherence increased; fruit and vegetable intake increased
			• 88% of participants reported that they preferred the diabetes food box to regular food pantry options

### Table 12. Summary of all Produce Prescription Studies with Quantitative Methods Published in the United States through December 1, 2023, by Outcomes, Study Design, and Sample Size

#### Color codes+

Sample size			
< 100	< 100		
≥ 100	≥ 100		

+Each green cell in the summary table represents a study with a positive association with the assessed outcome, signifying a positive effect on health outcomes. The darker green cells represent a larger sample size for a positive finding. Each gray cell in the summary table represents a study with a null or no effect finding. The darker gray cells represent a larger sample size for a null or no effect finding.

Outcomes among	Produce Prescription Programs <sup>†</sup> (2013-2023)	Randomized controlled trials	Quasi-experimental studies (with comparison groups)	Pre-post studies and single-arm, longi- tudinal studies (no comparison group)
Nutrition &	Food insecurity <sup>422, 423, 424, 425, 426</sup>			
Social Risk	Fruit and vegetable intake/ dietary quality <sup>427, 428, 429, 430, 431, 432,</sup> 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443			
	HbA1c or glucose management <sup>444, 445, 446, 447, 448,</sup> <sup>449, 450</sup>			
Clinical Outcomes	Blood pressure <sup>451, 452, 453, 454, 455, 456, 457</sup>			
	Weight/BMI458, 459, 460, 461, 462, 463, 464, 465, 466, 467			
Health Care Utilization	ED visits or acute care utilization468,469			
	Hospitalization470			
	Other <sup>*471, 472, 473, 474, 475, 476</sup>			

This table includes all published produce prescription studies that used quantitative statistical methods conducted in the United States that were published prior to December 1, 2023. Randomized trials reflect the strongest study design. Within a given column for each of the three study designs, studies with large sample sizes (marked by a dark green shade) reflect a higher degree of certainty in the findings. A single study may have multiple outcomes marked in the table. In addition, some studies include more than one target population, in which case outcomes were marked for each population. However, any secondary analyses or exploratory analyses not described in a study's abstract were excluded from this table. Positive associations labeled in green are determined by the standard statistical significance of p < 0.05 or 95% confidence interval not containing 0 (continuous) or 1 (categorical).

\*Other outcomes include healthful food purchasing practices, knowledge of fresh fruit and vegetable preparation, self-reported health status, lipid profile, quality of life, preterm delivery, and breastfeeding.

### **Produce Prescriptions Peer-Reviewed Literature: A Closer Look**

Produce prescription research is the most common within the Food is Medicine literature. Produce prescription programs have become a national movement, with millions of dollars in dedicated federal funding each year through the GusNIP Produce Prescription Grant Program, new pilot programs within the Veterans Administration and Indian Health Service, and programs in several states implemented through Medicaid Section 1115 Waivers. The research on these interventions demonstrates improvements in food security and dietary intake while emerging research focuses on the impacts of clinical outcomes like BMI, blood pressure, and HbA1c. Yet even with a high volume of studies, there remain very few randomized trials confirming the efficacy of programs. The volume and scope of forthcoming research is exciting—in particular, studies will evaluate impacts within federally funded programs, representing an unprecedented scale.

No. of quantitative and qualitative studies:	59
No. of quantitative studies with control or comparison group:	9/35
No. of quantitative studies with sample over 100:	14/35
Duration range:	four weeks to two years
Intensity range:	\$5 to \$270/month

Health conditions: type 2 diabetes, prediabetes, obesity, childhood obesity, cancer, hypertension, pregnancy, hyperlipidemia, unspecified chronic conditions

**Patient populations:** urban, suburban, rural, food-insecure, uninsured, Medicaid enrollee, children, pregnant women, patients at federally qualified health centers, GusNIP participants, residents of low-income counties, SNAP participants

**Outcomes:** food insecurity, dietary intake (primarily fruit and vegetable consumption), preterm birth weights, infant weight, breastfeeding, blood pressure, hemoglobin A1c, BMI, nonadmission ED visits, ED admission, hospitalizations, cost-effectiveness in terms of quality adjusted life years saved, exercise, stress and anxiety, self-reported health status, self-reported mood, sleep, pain and depression statuses, fruit and vegetable purchasing behavior, COVID-19 anxiety, nutrition knowledge, participant experience and satisfaction, barriers to participation, health care provider experience, implementation metrics including redemption rates, implementation learnings and best practices

**Strength of research design:** The research on produce prescriptions is the most prolific among both quantitative and qualitative studies in the Food is Medicine literature. Most evaluate diet, food insecurity, and process metrics such as participation rates, redemption rates, and participant satisfaction. While studies have shown promising results for improving cardiometabolic health, most studies lack a comparison group, and many are small pilots. Yet a recent produce prescription analysis included the largest sample size of any Food is Medicine study and pooled data from programs across the United States, finding beneficial impacts on health outcomes across a wide range of settings and communities. The literature includes only two randomized control trials, so early findings suggesting beneficial impacts on clinical outcomes such as blood pressure, blood sugar control (HbA1c), and weight will need to be confirmed in future, larger trials. There are only two produce prescription studies assessing health care utilization, with mixed results.

More so than the literature on medically tailored meals or groceries, the produce prescription research has excelled in qualitative and community-based research. Many recent studies include the perspectives of participants through interviews and focus groups, during program planning and implementation, or through voice and video recordings in which participants document their personal experiences. The literature also includes qualitative studies that highlight health care provider, nutrition educator, and health policy maker perspectives and contain key insights for program implementation and replication. The produce prescription literature includes the only studies that explicitly use community-based participatory research approaches, whereby participants and community members are actively involved in program design, metrics, and evaluation.

**Intervention design:** The monetary value of prescriptions varied widely, from a \$5 coupon to \$270 per month loaded onto an electronic card used at retail grocery. The duration also varied widely, from four weeks to two years. It can be hard to evaluate and compare the intensity of interventions, as prescriptions were not always scaled for household size and redemption rates were at times low or unreported. Many programs, in particular earlier studies in the literature, provided paper vouchers that could be redeemed only at farmers markets, which generally operate on a weekly and seasonal basis, limiting opportunities for participants to redeem vouchers. However, programs are increasingly making it possible to redeem prescriptions at retail stores using convenient electronic cards at checkout, including large grocery retailer chains, pharmacies, and smaller local grocery stores. Many of the produce prescription programs featured in the literature also included an educational component, such as nutritional counseling, cooking classes, and health education classes.

**Program participants:** Among programs targeting specific medical diagnoses, most interventions enrolled participants who had or were at risk for type 2 diabetes and/or cardiovascular disease. Fewer focused on child nutrition and pregnancy. Most interventions explicitly included food insecurity as a criterion for eligibility or recruited patients from safety net clinics. Finally, during the COVID-19 pandemic, several new programs were started that were less prescriptive and were open to a wide range of low-income patients, regardless of their specific medical condition.

**Produce prescriptions and equity considerations:** Among the three intervention types examined in this report, produce prescriptions generally are the cheapest and most efficient to operate, especially with emerging card technology that allows programs to scale across large retail grocery chains. This also maximizes participant choice in that they can choose where to pick up food and select items that meet their personal and cultural preferences. In addition to physical vouchers and debit cards, one program tried an online ordering platform while another provided the option for delivery. Online ordering and delivery may make produce prescriptions more accessible and easier to use for people with transportation challenges and work- or child care-related time constraints.

On average, produce prescriptions provide less food and have the lowest cash value. The relatively low cost of the intervention makes produce prescriptions easier to scale to more people and to broader patient populations.



#### Key Takeaways:

Like the research on medically tailored groceries, the research on produce prescriptions reveals significant differences in intervention design—namely, prescription amount, program duration, and program convenience—making it hard to draw meaningful conclusions about effectiveness. Low participation and/ or redemption rates and many pre-post studies without comparison groups compound this challenge. Yet recent studies have shown promising impacts on managing clinical biomarkers for adverse cardiometabolic health, like weight, blood pressure, and blood sugar control. To have an impact on clinical outcomes, future trials would likely be more successful by maximizing participant redemption rates, scaling incentives by household size, and providing a sufficiently high monthly value for six months or more.

**Unanswered questions:** Research must investigate questions such as how to best operationalize produce prescription programs and how to maximize redemption rates. Research should understand the household effects of produce prescriptions and, importantly, what happens when the program ends. Researchers should also investigate which patient populations are most likely to benefit, minimum effective duration and intensity of interventions, cost effectiveness, the role of nutrition education, and the potential benefit of produce beyond fruits and vegetables (i.e., whole grains, nuts, seeds, beans, and legumes). Regardless of the research question, more studies with strong comparison groups will advance the produce prescription field in the years to come.

## **Produce Prescriptions**

Author	Study Design	Intervention	Key Findings
Cullen <sup>477</sup> (2023)	Qualitative study using phone interviews n = 31 caregivers of pediatric participants who visited clinics	CSA program with weekly boxes of local, organic produce for 12 weeks at two urban, academic pediatric outpatient care sites	<ul> <li>Four themes emerged regarding barriers to food access during the pandemic:</li> <li>Fluctuations in price, availability, and quality of food</li> <li>Financial strain of households</li> <li>Faster consumption with all family members at home</li> <li>Shopping challenges, including COVID-19 infection fears, store closures, and limited childcare</li> <li>Increased SNAP allotments were particularly useful, and delays of mailed WIC benefits were challenging</li> </ul>
Folta <sup>478</sup> (2023)	Qualitative interviews n = 8 clinic staff from five primary care "safety net" clinics	Produce prescription programs operated by Wholesome Wave	<ul> <li>The ability to provide a tangible benefit to patients was a motivating factor in adoption for clinic staff</li> <li>Flexible integration into clinic workflows facilitated program implementation</li> <li>Challenges included changes to the workflow and extra staff time; clinic staff were skeptical about the sustainability of both the benefits to patients and the ability to continue the program at their clinics</li> </ul>
Hager <sup>479</sup> (2023)	Pooled, pre/post study without a comparison group n = 3,881 individuals (2,064 adults ages 18+ and 1,817 children ages 2–17 years) with, or at risk for, poor cardiometabolic health recruited from clinics serving low-income neighborhoods from 22 locations in 12 US states from 2014–2020	Produce prescriptions using vouchers or electronic cards at grocery stores and farmers markets (median = \$63/month; duration: four to 10 months)	<ul> <li>Among adults with diabetes, HbA1c declined by -0.29 percentage points (p &lt; 0.05)</li> <li>Among adults with hypertension, systolic and diastolic blood pressure declined by -8.38 mmHg (p &lt; 0.05) and -4.94 mmHg (p &lt; 0.05)</li> <li>Among adults with overweight or obesity, BMI decreased by -0.36 kg/m2 (p &lt; 0.001); child BMI z-score did not change</li> </ul>
Hager <sup>480</sup> (2023)	Quasi-experimental longitudinal study with a weighted comparison group n = 252 program participants with history of uncontrolled diabetes who were likely to have lower incomes based on zip code of residence Comparison group (n = 534) met same criteria but were not enrolled	Vouchers (\$60 per month) for six months to purchase produce at grocery retail Program enrollment finished spring 2020 and was disrupted by the COVID-19 pandemic	<ul> <li>No significant difference in change in HbA1c or blood pressure between treatment and comparison groups at six months</li> <li>Incidence rate ratios for hospitalizations and ED visits were 0.54 (p &gt; 0.05) and 0.53 (p &gt; 0.05), again no significant difference</li> </ul>
Imuro <sup>481</sup> (2023)	Pre-post study without a comparison group n = 303 adult patients with prediabetes or type 2 diabetes, 90% reported Mexico as their country of origin	Weekly prescriptions distributed to patients during visits (12 total) to provide recommended 21 servings of vegetables per week	<ul> <li>Among adults with diabetes, mean change in HbA1c was -0.3 (p = 0.01); for patients with baseline HbA1c ≥ 7%, mean change was -0.45 (p = 0.01)</li> <li>Significant reduction in systolic blood pressure for participants with hypertension at baseline at -4.2 mmHg (p = 0.001)</li> <li>Improvements in food security, self-reported ratings of sleep, mood, pain, and measures of depression (all p &lt; 0.001), anxiety (p = 0.045), and stress (p = 0.002)</li> </ul>

Author	Study Design	Intervention	Key Findings
Johnson <sup>482</sup> (2023)	Qualitative interviews and thematic analysis n = 13 clinicians who referred families to a produce prescription program	Fresh produce delivered to homes of families at risk for food insecurity every other week for eight weeks (four deliveries total)	<ul> <li>The program offered a tangible resource to address food insecurity, building trust and strengthening clinician self-efficacy in addressing families' concerns</li> <li>Incorporation of a produce prescription intervention was feasible and well-accepted by pediatric primary care clinicians</li> </ul>
Mayfield <sup>483</sup> (2023)	Pre/post study without a comparison group	Enrolled participants received \$40/ month at a supermarket chain	<ul> <li>The odds of nonadmission ED visits were lower at pro- gram end (odds ratio = 0.76, p &lt; 0.05)</li> </ul>
	n = 711 adult patients with Medicaid insurance	Average program enrollment was 203 days	<ul> <li>Among patients with "none to mild" on the Charlson Comorbidity Index (CCI), a 36% reduction in the odds of nonadmission ED utilization was observed (OR = 0.64; p &lt; 0.05)</li> </ul>
			• Among the CCI "moderate to severe" subsample, no signif- icant reduction in ED utilization was observed
Stotz <sup>484</sup> (2023)	Mixed-methods: surveys, semi- structured interviews, and one	GusNIP nutrition incentive and produce prescription programs	Roles and responsibilities of educators extended beyond providing curriculum-based nutrition education
	<b>focus group</b> n = 41 nutrition educators who		Partnerships with collaborating cross-sector organizations     were essential
	work with the USDA GusNIP, Nutrition Incentive, and Produce Prescription programs		• Recruitment and promotion of education services could be improved
Stroud <sup>485</sup> Pre/post study without a comparison group       (2023)     n = 40 rural adult patients with type 2 diabetes		24-week delivery-based produce prescription with culturally tailored recipes	• Mean HbA1c decreased from 7.6% to 7.1% (p = 0.001)
	n = 40 rural adult patients with		<ul> <li>Perceived stress decreased (p = 0.01)</li> <li>Weight and BMI decreased post-intervention but did not reach statistical significance (p = 0.09 for both)</li> </ul>
			• No significant change in food insecurity
Wang <sup>486</sup>	Microsimulation policy	Proposed policy of providing long-	• The policy would:
(2023)	<b>modeling</b> n = US adults with diabetes and food insecurity ages 40–79	term produce prescriptions valued at \$42/month to all US adults with diabetes and food insecurity	• Prevent 292,000 cardiovascular disease events and gain 260,000 quality-adjusted life-years over a 30-year period
			• Be highly cost-effective from a health perspective, with an incremental cost-effectiveness ratio of \$18,100/quality-adjusted life-year saved
			• Yield cost-savings from a societal perspective, accounting for impacts on the economy and worker productivity
Ylitalo <sup>487</sup> (2023)	Pre/post study without a comparison group	Four to six weekly, 1.5-hour cooking classes with shared meals,	<ul> <li>Observed increases in cooking self-efficacy (p &lt; 0.001) and diet-related self-management strategies (p &lt; 0.001)</li> </ul>
	n = 33 adult patients recruited from a health care clinic	education, and produce delivery	• Participants attended 66% of sessions
Abel <sup>488</sup>	Retrospective, cross-sectional	Food-insecure patients were	50% redeemed at least one voucher
(2022)	study n = 242 patients referred to a pro- duce prescription program at an academic medical center between June and November 2019	offered a \$10 or \$20 voucher for fruits and vegetables to use at four Greenmarkets	<ul> <li>Patients given \$20 were significantly more likely to redeen their prescriptions than patients given \$10 (63% vs. 44%, p &lt; 0.01)</li> </ul>
			• Prescription redeemers were significantly more likely to have food insecurity (p < 0.01), and have elevated hemoglobin A1C than non-redeemers (6.3 vs. 5.5%, p < 0.001)
			• Distance, time constraints, and forgetting or losing prescriptions were common barriers, while convenience facilitated redemption

Author	Study Design	Intervention	Key Findings
Auvinen <sup>489</sup> (2022)	Semi-structured web-conference or telephone interviews n = 19 stakeholders, including program administrators, clinicians, food retailers, food policy lawyers, and health policy analysts involved in the design, implementation, or evaluation of produce prescription programs	Produce prescription programs in the United States	Interviewees viewed produce prescriptions positively, with potential to address health equity by improving patients' diets, food security, disease management, financial securi- ty, and experiences with the health care system
Brown <sup>490</sup> (2022)	Mixed-methods: registration survey and qualitative interviews n = 1,472 caregivers participated in the program, among whom 31 were interviewed	CSA program with free boxes of produce distributed weekly	<ul> <li>Caregivers were surprised to learn about the program</li> <li>Caregivers felt that it reinforced the hospital's commitment to "whole health" and perceived it to be safer than other food program settings during the COVID-19 pandemic</li> <li>Important features included allowing families to self-select into programming, ease and efficiency of use, kindness of staff, and confidentiality</li> </ul>
Esquivel <sup>491</sup> (2022)	Semi-structured telephone interviews n = 25 parents/caregivers and 34 children (ages 2–18), English- speaking, residents of Waianae Coast of Oahu, screened positive for food insecurity, and had overweight or obesity	Monthly \$50 vouchers for six months with n-person or online redemption at local farmers markets and online food hubs	<ul> <li>Facilitators included program convenience, health center/ pediatrician endorsement, and positive communications with farmers market vendors</li> <li>Key motivators for program participation included the promotion of child well-being, financial support for fami- lies, and positive impacts on families</li> <li>Barriers to participation included conflicting schedules of farmers markets</li> </ul>
Fischer <sup>492</sup> (2022)	Mixed-methods study: pre and post quantitative surveys and qualitative interviews n = 25 food-insecure families with children ages 0–5 at risk for overweight or obesity	Families received a biweekly delivery of seasonal, local produce (8 lbs.) for one year	<ul> <li>12-month retention was 60% with 77.5% of the produce consumed</li> <li>80.5% of participants said they tried a new food</li> <li>Fruit and vegetable intake improved (p &lt; 0.05)</li> <li>Four themes emerged from qualitative interviews of participants: (1) reduced food hardship; (2) support for family-driven behavioral change; (3) increased economic flexibility,;and (4) increased opportunities for family bonding</li> </ul>
Joseph⁴ <sup>93</sup> (2022)	Pre/post study without a compar- ison group n = 33 adults patients with hyper- tension, diabetes, hyperlipidemia, or obesity; self-reported desire to increase fruit and vegetable intake in diet; and referred by a primary care provider	A 10-week program with \$10 vouchers for weeks one-five, and \$20 for weeks six-10 at farmers markets	<ul> <li>38% of individuals lost weight during the program</li> <li>Mean daily self-reported fruit and vegetable intake increased from the baseline by 0.43 cups but was not statistically significant (p = 0.14)</li> <li>A statistically significant improvement in quality of life (p = 0.03) and increased social interaction occurred as a result of the attending the farmers market</li> </ul>
Lyonnais <sup>494</sup> (2022)	Mixed-methods study: pre- and post-quantitative surveys and qualitative interviewsn = 93 participants recruited from low-resourced communities in six rural North Carolina counties; 10 participants completed surveysSemi-structured interviews among n = 3 health educators, n = 6 food retailers, and n = 7 participants	Sets of four or eight, \$5 vouchers were distributed to participants	<ul> <li>18.4% redemption rate; no change in fruit and vegetable consumption</li> <li>Most respondents indicated that they visit farmers markets more (78.3%) and indicated that they tried a new farmers market (72.7%) after the program</li> <li>Health educators and food retailers who participated felt that the initiative benefited their operations and wanted to partner with the program again</li> </ul>

Author	Study Design	Intervention	Key Findings
Lyonnais <sup>495</sup> (2022)	Mixed-methods study: pre- and post-quantitative surveys and qualitative interviews n = 125 participants recruited from counties with low socioeconomic status; program eligibility criteria and length varied by participating sites	A series of \$5 vouchers, at least \$20 total, to redeem for fresh fruits and vegetables from participating local farmers markets, grocers, and food stands	<ul> <li>Overall voucher redemption rate was 52%</li> <li>There was a 0.29 cup/day increase in self-reported fruit intake from pre- to post-intervention (p = 0.031)</li> <li>Qualitative analyses indicated that participants enjoyed the financial benefits of the program and wanted it to continue</li> </ul>
Newman <sup>496</sup> (2022)	Process evaluation with a qualitative comparative case study approach n = 15 program implementers, nutrition educators, and farmers market managers were interviewed in focus groups and nutrition education classes were observed	Three Georgia produce prescription programs: \$1 per household member per day for six months redeemable at farmers markets	<ul> <li>Creating accessible programming encouraged participation</li> <li>Provider dedication to the program was important</li> <li>Participants' challenging life circumstances made participation difficult</li> <li>Program sustainability was a concern</li> </ul>
Saxe-Custack <sup>497</sup> (2022)	Semi-structured telephone interviews n = 56 caregivers of children in a produce prescription program from August 2018 and March 2019 in a pediatric clinic in Flint, Michigan	One \$15 prescription for fresh produce, redeemable at the downtown farmers market or local mobile market, to every patient during office visits in a pediatric clinic	<ul> <li>Themes include:</li> <li>Families face regular constraints in food access and experience stressful food insecurity; prescription program increased food access and adjusted shopping habits</li> <li>Consequences of COVID-19 included increased anxiety in food shopping and food insecurity</li> </ul>
Slagel <sup>498</sup> (2022)	Quasi-experimental study with two comparison groupsAdults who were SNAP-eligible or food insecure and had one or more of the following diagnoses: (a) overweight and obesity; (b) diabetes; (c) prediabetes; (d) hy- pertension; and (e) hyperlipidemiaIntervention group n = 31 Comparison group (nutrition edu- cation only) n = 13 Control group n = 16	Intervention group received \$1 per day per household member, redeemable at a farmers market, two SNAP-Ed programs, one finan- cial literacy program, and monthly health screenings	<ul> <li>Participants increased the frequency of consuming dark green vegetables, intervention (0.36 ± 0.72); nutrition education (0.14 ± 0.33); controls (-0.09 ± 0.19); cups/day (p &lt; 0.05)</li> <li>Participants improved their ability to afford utilities (intervention = 33%; nutrition education = 0%; controls = 10%; p &lt; 0.05)</li> </ul>
Slagel <sup>499</sup> (2022)	Mixed-methods: qualitative interviews and quasi-experimental evaluation         n = 46 eligible adults for the         Supplemental Nutrition Assistance         Program-Education (SNAP-Ed) from         3 Georgia counties) with at least one diet-related condition	Intervention group received a monthly produce prescription of \$1/day per household member for 6 months, redeemable at farmers markets	<ul> <li>All groups described price-conscious food purchasing and limited farmers markets/CSA experience at baseline</li> <li>Intervention group reported improved knowledge and perception of farmers markets or CSA settings and prefer- ence for fresh and local produce</li> <li>Both intervention and nutrition-education groups report- ed increased motivation to purchase and cook fruits and vegetables</li> </ul>
Stevenson <sup>500</sup> (2022)	Process description and evaluation Community with high levels of poverty and food insecurity	Participants received vouchers (\$40/ month for four months) to spend at stores	<ul> <li>Lessons learned from implementation include:</li> <li>Engage in a rigorous participatory planning process with all community partners allowing adequate time to establish service agreements and a voucher system with vendors</li> <li>Engage potential program participants in different ways and spaces throughout the community</li> </ul>

Author	Study Design	Intervention	Key Findings
Stotz <sup>501</sup> (2022)	Descriptive survey and semi- structured interviews Health care providers from all 18 GusNIP-funded produce prescription programs; n=34 (survey only) and n=16 (survey and interview)	GusNIP produce prescription programs	<ul> <li>Operational challenges included lack of time/staff, difficulty with provider/patient engagement (some related to COVID-19), steep learning curve during implementation, and data sharing and research requirements</li> <li>Important to have full-time staff member in clinic responsible for implementing program</li> <li>Satisfaction with positive patient experiences and outcomes</li> <li>Appreciation for rigorous program evaluation to establish sustained funding and to advance policies</li> </ul>
Stroud <sup>502</sup> (2022)	Process description and evalu- ation n = 4,691 rural and uninsured patients receiving care from three safety-net clinics	Patients self-selected salvaged and gleaned produce at clinics provid- ed by a national organization and local food bank	<ul> <li>Program combined disease management and food-waste reduction</li> <li>Patients were connected with produce at their primary care clinic</li> <li>Areas for expansion and improvement included provision of nutrition education and culinary support and formal evaluation</li> </ul>
Thomson <sup>503</sup> (2022)	Qualitative descriptive study with focus groups n = 24 Black and Latinx adults at risk for food insecurity who were potential participants for a future produce prescription program	A potential program intended to provide weekly produce boxes and nutrition and cooking classes	<ul> <li>Fresh food accessibility was limited by cost, household size, and transportation but enhanced by food pantries, budgeting, and education</li> <li>Deterrents included unhealthy diets driven by cultural and familial norms; but weight loss and awareness of comorbidities were positive motivators</li> <li>Preference for local produce and cooking classes as components of a program; but concerns about low participation due to the stigma of receiving aid</li> </ul>
Zack <sup>504</sup> (2022)	Mixed-methods: baseline and follow-up survey and qualitative interviews n = 1,075 patients from the health center referred to the market; phone interviews were conducted among 45 participants	A health-center-based market provided fresh produce to patients and the public Participants received approximately 25 pounds of produce per visit	<ul> <li>37.1% of participants attended the market at least one time</li> <li>Barriers included limited time (28%), work conflicts (23%), and not knowing market location/date (22%)</li> <li>Healthy foods motivated attendance</li> </ul>
Zimmer <sup>505</sup> (2022)	Mixed-methods: bimonthly survey and semi-structured phone interviews n = 150 program participants with food insecurity	Weekly delivery of regionally sourced produce and pre-packaged meals during the COVID-19 pandemic from March 2020 to October 2021	<ul> <li>Program promoted healthy dietary habits, enhanced financial well-being, and alleviated logistical barriers to accessing food and cooking</li> <li>Partnerships between health care providers, community organizations, farmers, and participants are needed for future produce prescription programs and must consider participant needs and program sustainability</li> </ul>
Martin <sup>506</sup> (2021)	A photovoice study including focus groups and thematic analysis n = 28 participants recruited to a CSA program	Participants pick up produce shares from health centers weekly for 18 to 22 weeks Participants pay \$5 per week using cash or SNAP benefits for a weekly share of fresh produce valued at \$23 (net benefit = \$18/week).	<ul> <li>Participants viewed the program as supporting positive changes to their physical and social health and facilitating learning about new foods, cooking, and agriculture.</li> </ul>
Slagel <sup>507</sup> (2021)	Quasi-experimental study with two comparison groups n = 54 adults who were SNAP- eligible or otherwise underserved, with a diagnosis of one or more of five diet-related chronic conditions: (1) overweight and obesity; (2) diabetes; (3) prediabetes; (4) hypertension; and (5) hyperlipidemia	Participants received \$1 a day per household member, redeemable up to once a week at local farmers markets, plus nutrition education and health screenings	<ul> <li>77.3% of participants completed the program and spent nearly 90% of their prescription dollars</li> <li>Intervention group increased fruits and vegetables intake at 0.81 servings/day vs0.25 servings/day for controls (p &lt; 0.05)</li> <li>Intervention group increased knowledge of fresh fruit and vegetable preparation compared with the control group (p &lt; 0.05)</li> </ul>

Author	Study Design	Intervention	Key Findings
Veldheer <sup>508</sup> (2021)	Pre/post study without a comparison group n = 97 adults with type 2 diabetes, HbA1c ≥ 7.0%, and BMI ≥ 25 kg/m <sup>2</sup>	Produce prescription program with DSME: \$28–\$140/month in vouchers for seven months	<ul> <li>HbA1c decreased by 1.3% (p &lt; 0.001); reductions were associated with higher voucher redemption rates (p = 0.032) and a change in diabetes medications (p = 0.003)</li> <li>Changes in blood pressure and BMI were not statistically significant</li> <li>Average redemption rate using intent-to-treat was 53%;</li> </ul>
Slagel <sup>509</sup> (2021)	Non-randomized, parallel, controlled trial	Produce prescription voucher program with expanded nutrition education: seven-month	<ul> <li>redemption was significantly and positively associated with higher dollar amounts (p &lt; 0.001)</li> <li>Increased frequency of consuming vegetables, healthful food purchasing practices, and the ability to afford more hills (p = utilizing) (p = 0.01)</li> </ul>
	n = 36 food-insecure adults with a diet-related health condition	education: seven-month intervention (voucher amount not specified)	<ul> <li>bills (e.g., utilities) (p &lt; 0.05)</li> <li>Changes in food security, clinical biomarker, and biometric measures were not significant</li> </ul>
Bryce <sup>510</sup> (2021)	Pilot RCT n = 128 adults with HbA1C > 8.0%	Produce prescription debit card program at FQHC farmers market: up to \$80 for four months	As compared with control, no statistically significant differences in any outcome metrics (HbA1c, BMI, or blood pressure), but a small effect size for HbA1c
			<ul> <li>Pre-post within intervention group, HbA1C decreased sig- nificantly (p = 0.006), with a small- to medium-effect size</li> </ul>
Ridberg <sup>511</sup> (2021)	Pre/post study with historical comparison group	For pregnant WIC recipients: \$40 fruit and vegetable vouchers	• Food security increased (p $\leq$ 0.001), intervention vs. comparison
	n = 592 pregnant adults enrolled in WIC	(distributed with WIC vouchers) over 14-month study period	Average intake frequency of whole fruit, salad, total fruit, and combined fruits and vegetables were higher for inter- vention group vs. comparison
			• Compared with births in historical control group (n = 2,299), odds of preterm delivery were 37% lower in intervention group (p = 0.18)
Burrington <sup>512</sup> (2020)	Pre/post study without a comparison group n = 10 families with low SES with one or more children at risk for chronic disease	Produce prescription pilot with online ordering and nutrition education in rural setting: weekly credit (\$15–\$25, depending on family size) for five months	<ul> <li>Redemption of online produce credit was 94% and class attendance was 80%</li> <li>The program increased confidence with cooking, tasting new foods, and following new fruit- and vegetable-based recipes; average fruit and vegetable intake rose for children to five+ servings/day; confidence, culinary skills, and food literacy increased slightly</li> </ul>
York <sup>513</sup> (2020)	Pre/post study without a comparison group	Organic vegetable distributions: weekly pick-up of vegetables for	No statistically significant change in HbA1c
(2020)	n = 21 Latinx adults with self- reported diagnosis of type 2 diabetes	12 weeks	<ul> <li>Reduced systolic (p = 0.03) and diastolic (p = 0.01) blood pressure</li> </ul>
Orsega-Smith <sup>514</sup>	Pre/post study without a comparison group	Clinic-based mobile market produce distribution: 15–25 lbs. per	Adult fruit and vegetable intake significantly increased
(2019)	n = 41 food-insecure adults with one of the following: Medicaid	month of produce for one year	<ul> <li>Child fruit consumption also significantly increased, but there was no difference in child vegetable consumption</li> <li>Fruit and vegetable purchase avoidance based on cost</li> </ul>
	enrollee, overweight, or have two or more children		decreased (from 65.0% to 51.2%)
Berkowitz <sup>515</sup> (2019)	Randomized controlled trial n = 41 adults with obesity or overweight recruited from a community health center in central MA	Participants were randomized to receive a weekly box of local fruits and vegetables as a CSA share from Jun – Nov. The control group received a financial incentive of equal value.	<ul> <li>The intervention improved Healthy Eating Index scores b 4.3 points relative to control group (p=0.03).</li> <li>Food insecurity was lower in intervention group (RR = 0.68).</li> </ul>
Saxe-Custack <sup>516</sup> (2019)	Non-controlled longitudinal intervention trial n = 114 caregiver–child pairs	Produce prescription voucher program at two pediatric clinics: \$15 vouchers (no limit reported) for six months	<ul> <li>Increased child-reported mean daily intake of whole fruit (p = 0.03)</li> <li>Increase in total fruit intake (including fruit juice) and vegetable intake was not significant</li> </ul>

Author	Study Design	Intervention	Key Findings
Emmert-	Longitudinal, repeated-measures	Vegetable voucher (part of a	Increased consumption of fruits and vegetables
Aronson <sup>517</sup> (2019)	n = 49 FQHC patients with	behavioral pharmacy program): \$10/week for 16 weeks	• Changes in diastolic blood pressure and acute care utilization were not significant
	behaviorally mediated clinical concerns and/or food insecurity		• Acute care utilization decreased by 77%
Ridberg <sup>518</sup> (2019)	Pre/post study without a comparison group n = 578 low SES households with children acco 2, 18 who were	Farmers market produce prescription program: \$0.50 to \$1 per person per day for four to six months	<ul> <li>72% of households increased their summative food security score</li> <li>In adjusted regression models, participants had higher shares corrective fine or aim clinical visite corrected</li> </ul>
	children ages 2–18 who were clinically obese or overweight		change scores with five or six clinical visits, compared with one or two visits, and education level of caretaker
Ridberg <sup>519</sup> (2019)	Retrospective cohort study n = 883 children; overweight or obese	Farmers market produce prescription program: \$0.50-\$1 per household member per day in vouchers that could be redeemed up to giv times	<ul> <li>Increase from first to last visit in the percentage of federal dietary guidelines being met was 93% to 100% for fruits, 64% to 70% for vegetables, and 78% to 86% for combined fruits and vegetables</li> </ul>
		up to six times	Dose propensity of 0.32 cups for each additional visit
			Average voucher redemption was 59%
Marcinkevage <sup>520</sup> (2019)	Mixed-methods process and outcome evaluation	SNAP-based nutrition-incentive prescription for supermarkets: \$10	Overall redemption rate was 54.4%
(2015)	n =144 adults; SNAP enrollment	voucher each week for up to six months	<ul> <li>88.9% of participants reported that the program was easy to use; 86.8% reported increased ability to afford balanced meals</li> </ul>
			<ul> <li>88.2% reported eating more fruits and vegetables; 71.5% reported managing their health conditions better; and 81.2% reported improvement in meeting nutrition, diet-re- lated, or meal plan goals</li> </ul>
Schlosser <sup>521</sup> (2019)	<b>Qualitative interviews</b> n = 23 food-insecure adults with hypertension diagnosis	Farmers market produce prescription program for hypertension: \$40 a month for three months	Transportation issues shaped shopping and eating     patterns and limited participant ability to access farmers     markets
			• Limited and unstable income shaped participant shopping and eating behavior before, during, and after participation
			Consider structural constraints in program design
Joshi <sup>522</sup> (2019)	Mixed-methods process evaluation	Farmers market produce prescription program for hypertension: \$40 a month for	• Implementation: seven diverse providers screened 266 pa- tients over three months; 224 were enrolled; over \$14,500 of vouchers were redeemed
		three months	• Identify and involve multiple key decision-makers; use nonclinical staff; and develop a routine communication plan to address implementation issues
Izumi <sup>523</sup> (2018)	Mixed-methods evaluation n = 9 FQHC patients who	Discount CSA program for FQHC patients: weekly pick-up for 23	• 78% of respondents indicated that the CSA program improved their health or health behaviors
	completed survey	weeks	• Proportion of members who thought they ate as many vegetables as they thought they should rose from 17% to 67%
			• Focus group (n = 15) participants said program improved diet quality and provided instrumental, informational, and emotional support
Trapl <sup>524</sup>	Pre/post study without a	Farmers market produce	Daily fruit consumption increased (p < 0.001)
(2018)	comparison group	prescription program for hypertension: \$40 a month for	• Daily vegetable consumption increased (p < 0.001)
	n = 137 food-insecure adults with hypertension diagnosis	three months	• Farmers market visits and voucher redemption were not associated with fruit and vegetable consumption
			86% voucher redemption
Bryce <sup>525</sup>	Pre/post study without a	Produce prescription program for	• Average HbA1C decreased from 9.54% to 8.83% (p = 0.001).
(2017)	comparison group n = 65 adults; type 2 diabetes diagnosis or HbA1c > 6.5	diabetes: \$10 a week for up to four weeks	• Weight and blood pressure did not change (p > 0.05)

Author	Study Design	Intervention	Key Findings
Cavanagh <sup>526</sup> (2017)	Retrospective pre-post with control using medical records n = 54 adults; low SES, hypertensive, obese, and/or diabetic	Mobile market produce prescription program: weekly \$7 fruit and vegetable vouchers for at least five weeks	<ul> <li>Mean BMI decreased by 0.74 kg/m2, versus 0.35 kg/m2 in control (p = 0.02)</li> </ul>
Trapl <sup>527</sup> (2017)	Mixed-methods evaluation n = 40 pregnant adults; < 24 weeks gestation; adults residing within high poverty area	Farmers market produce prescription program for pregnant adults: four \$10 vouchers for 16 weeks.	<ul> <li>56% of participants redeemed at least one voucher; redemption didn't vary significantly by model of care or by perceived barriers to fruit and vegetable intake</li> <li>Living closer to a farmers market increased redemption (88.1%)</li> <li>Providers (n = 10) indicated that the program created opportunities to talk about diet</li> </ul>
Omar <sup>528</sup> (2017)	<b>Pre-post with no comparison</b> group n = 27 adults with BMI > 25	Farmers market debit card produce prescription program: up to \$40 on a rechargeable debit card over 12 weeks and \$20 boxed food delivery for completing program	<ul> <li>78% of participants reported an increase in their daily intake for fresh fruits and vegetables, with an average increase of 2 cups/day</li> <li>Biometrics (n = 16): five had weight loss and five had improvements in blood pressure</li> </ul>
George <sup>529</sup> (2016)	Pre-post with qualitative evaluation n = four low SES families; patients at weight-loss clinic; children overweight and/or obese	Farmers market produce prescription with medical student mentor: four \$50 vouchers for eight weeks	<ul> <li>On average, families spent \$40.68 of vouchers and reported one weekly produce item going unused</li> <li>Transportation and unpredictable work schedules were major barriers for both families and mentors</li> <li>Integrating medical student nutritional mentoring into the program was feasible and conferred benefits to families, students, and vendors</li> </ul>
Chrisinger <sup>530</sup> (2016)	Pre-post with no comparison group n = 353 families	Farmers market produce prescription program: \$10 voucher for 16 weeks	<ul> <li>Significant increase in children's fruit and vegetable consumption reported by parents</li> <li>Rx redemption rates were low (36%), likely due to logistical factors</li> </ul>
Goddu <sup>531</sup> (2015)	Implementation evaluation	Multi-site produce prescription program: \$5 coupon off \$20 purchase at Walgreens and \$10 voucher for local farmers markets	<ul> <li>Value and convenience of the prescription are strong determinants of use</li> <li>A small and diverse coordinating team is key</li> </ul>
Watt <sup>532</sup> (2015)	Quasi-experimental prospective study with comparison group n = 61 pregnant (first trimester), low SES, Latinx adults	Farmers market produce prescription program for Latinx, pregnant, low-income adults: weekly vouchers (amount not reported) for six months	<ul> <li>Intervention vs. comparison:</li> <li>More likely to breastfeed (p = 0.07)</li> <li>Infants more likely to pass the ages and stages developmental screen (p = 0.06)</li> <li>More likely to have significant improvements in diet, exercise, and depression (p ≤ 0.05)</li> <li>No association with infant weights</li> <li>Significant variation in redemption rates</li> </ul>
Friedman <sup>533</sup> (2014)	Mixed-methods, community- based participatory researchn = 44 adults; diagnosed with type 2 diabetes; enrolled in diabetes education programn = 13 providers	Farmers market produce prescription program for diabetes: \$1 coupons for farmers market (no limit reported) for 22 weeks	<ul> <li>80% of the prescriptions were spent on the same day the patients received them; patients enjoyed social aspects of the market</li> <li>Provider communication about diet decreased over time</li> </ul>
Freedman <sup>534</sup> (2013)	Mixed-methods evaluation n = 41 low SES adults diagnosed with type 2 diabetes	FQHC-based farmers market produce prescription program for diabetes: \$25 vouchers at baseline, \$25 at midpoint, and \$40 at follow- up over 22-week period	• Increased daily fruit and vegetable consumption (p = 0.07)



### Conclusion

The 107 studies reviewed in this section demonstrate that Food is Medicine interventions are associated with improved dietary intake, improved health status, improved disease-specific health outcomes and biomarkers, decreased depression, decreased trade-offs between food and medication, decreased health care utilization and spending, and more. However, the strength of the research varies and, ultimately, many studies have small samples, low retention rates, and no control or comparison groups. Fortunately, recent studies are increasingly using large samples, stronger study designs, and more mixed-methods approaches that include qualitative interviews and focus groups. There is also significant variation across intervention categories— while the MTM studies employ on average the more rigorous research designs, the produce prescription research is the most voluminous. The literature on medically tailored groceries falls somewhere in between: while there are fewer studies, two-thirds included a control or comparison group. Moreover, drawing conclusions within each category or across all categories is nearly impossible given significant variation in program design (intensity, duration, delivery, etc.) and participant demographics (health condition, food security status, economic status, etc.).

Since the first publication of this Research Action Plan, there have been nine published Food is Medicine review articles. All US Food is Medicine studies included in these recent review articles were also included in this edition of the report. The review articles are listed in the table below and allow those interested to take a deeper dive into the state of the Food is Medicine field by focus area.

### **Food is Medicine Reviews**

Author	Study Title	Year Published	Journal
Cafer, et al.535	Examining the context, logistics, and outcomes of food prescription programs: a scoping review	2023	Research in Social and Administrative Pharmacy
Muleta, et al. <sup>536</sup>	Pediatric produce prescription initiatives in the US: a scoping review	2023	Pediatric Research
Chen, et al.537	Food as medicine? Exploring the impact of providing healthy foods on adherence and clinical and economic outcomes	2022	Exploratory Research in Clinical and Social Pharmacy
Newman, et al. <sup>538</sup>	Current landscape of produce prescription programs in the US	2022	Journal of Nutrition Education and Behavior
Fleury, et al. <sup>539</sup>	The nutritional issue of older people receiving home-delivered meals: a systematic review	2021	Frontiers Nutrition
Little, et al. <sup>540</sup>	Promoting healthy food access and nutrition in primary care: a systematic scoping review of food prescription programs	2021	American Journal of Health Promotion
Bhat, et al. <sup>541</sup>	Healthy food prescription programs and their impact on dietary behavior and cardiometabolic risk factors: a systematic review and meta-analysis	2021	Advances in Nutrition
Veldheer, et al. <sup>542</sup>	A systematic scoping review of how health care organizations are facilitating access to fruits and vegetables in their patient populations	2020	Journal of Nutrition

This section outlined what the research can tell us about a variety of Food is Medicine programs and interventions. Importantly, it also highlighted remaining unknowns and critical research questions. <u>Section VII</u> of the Research Action Plan builds on this foundation and includes specific recommendations to advance Food is Medicine research. It focuses on the research questions that need to be asked and the types of studies that need to be conducted to help create a more complete picture of Food is Medicine interventions. Addressing these questions and studies can further illustrate how Food is Medicine programs can be most effective across a range of demographics and types of participants.

### **VII. Recommendations**

The current body of research on Food is Medicine interventions has shifted the national dialogue around nutrition and health. From Congress to state legislatures, from the US Department of Agriculture to state Medicaid programs, the government is promoting, testing, and expanding Food is Medicine interventions, compelled by the future of a healthier nation and a more effective and cost-efficient health care system.

The proliferation of Food is Medicine interventions and their increasing use within health care has been conducted mostly ahead of the research. It is driven in large part by nonprofits and advocates on the ground who developed creative programs to meet the nutrition-related needs of people living with chronic illness. But, particularly within the past five years—and since the first version of this Action Plan was released—health care integration of Food is Medicine interventions is increasingly common. As a result, a new wave of interest and investment in exploring the full impact of Food is Medicine offers opportunities to sustainably support and scale access to the most effective interventions.

- Assist researchers in design and process to ensure equity is embedded throughout the research continuum
- Identify key considerations to ensure that research design and processes are robust and appropriate for yielding the most valuable and actionable information
- Identify the most urgent questions that have yet to be explored
- Describe how funders and government agencies can support the most valuable research in the field
- Discuss complementary programs and research that have major implications for nutrition and health, both within and beyond the health care system.

The core principles that inform these recommendations are equity, attention to research design and potential for translation, purposeful investment of resources, and contextualization of Food is Medicine within broader systems and institutions. Alignment with these principles will advance a future in which:

- Everyone has the food that will allow them to live a healthy, dignified life according to their specific needs.
- Effective, appropriate Food is Medicine interventions are integrated into the US health care system nationwide, providing access to a wide range of proven interventions.
- All Food is Medicine research centers equity through the research continuum so that interventions empower individuals and communities and are effective across demographic groups.

#### **Equity Throughout the Food is Medicine Research Continuum**

The incidence of diet-related chronic disease in the United States compels us to urgently identify the most effective Food is Medicine interventions. **We must know what interventions work, for whom, and for how long**. We must understand interventions in context, both of the individual and the household receiving the intervention, as well as the broader ecosystem of communities, programs, and policies that dictate nutrition access across the lifespan.

Using equity principles to guide all phases of the Food is Medicine research process is critical to the strategic deployment of limited financial and human resources.

If equity is not a central principle that guides the concept and execution of research, research risks irrelevance at best—and, at worst, can do real harm, by further embedding the systemic racism and inequitable access that has long run throughout both the food and health systems.

Centering equity in Food is Medicine research means that all Americans can come to a deeper understanding of the many factors—political, historical, cultural, personal—that influence everyone's relationship to food and its impact on health, and then act on that new understanding.

"For our country and our children to reach their highest potential, we must not only keep food on the table, but also aim for everyone to enjoy nutritious and affordable food that contributes to their overall health."

----US Department of Agriculture Secretary Tom Vilsack

The authors of the *Food* is *Medicine Research Action Plan* recognize that all research is subject to practical constraints of funding, time, purpose, and capacity. It won't always be practical to apply every recommendation to every research endeavor. But in many cases, protocols and plans can shift in meaningful ways to ensure greater alignment with equity principles.

Throughout 2023, and starting with the release of the first Action Plan in January 2022, a core group of advisors—as well as broader Food is Medicine discussions led by Food & Society at the Aspen Institute—have intensively refined the new recommendations. The streamlined, timely, and revised recommendations reflect critical considerations and processes—as well as still unanswered questions—that will ensure Food is Medicine research advances health equity: a fair and just opportunity for everyone to be as healthy as possible, with the aim of reducing and ultimately eliminating disparities in health and its determinants that adversely affect excluded or marginalized groups.<sup>543</sup>

The updated and completely revised recommendations below represent the work of 18 months of virtual and in-person meetings with leading Food is Medicine researchers, implementers, practitioners, and study evaluators representing all areas of the United States across a wide variety of health care sectors, populations, and areas of focus. They build on the initial recommendations of the 2022 Action Plan, offering a streamlined version and steps that will advance the field as a whole.

#### **Designing Equity-Centered Food is Medicine Research**

- 1 Food is Medicine research should make health equity central to its methods, conduct, and outcomes because diet-related illnesses and their risk factors are major drivers of health disparities.
- 2 Researchers should seek out and include the perspectives of community members who are eligible to receive the intervention in question. At the same time, researchers and funders should seek out a broad variety of perspectives and partnerships with Food is Medicine implementers.
- 3 Research teams should surface and identify their team members' perspectives and potential biases, and fully engage all team members and partners in study design, planning, and decision-making.
- 4 Teams should monitor study recruitment and retention to ensure that the study population fully represents the population being targeted for the intervention. Participants should also be properly compensated for their time.

#### **Funding Equity-Centered Food is Medicine Research**

- Funders and researchers must ensure that there are adequate resources for the time and necessary steps required for true equity-centered research. This includes time for study planning and training to ensure that researchers fully listen to community and practitioner voices and effectively integrate equity principles into the research design framework.
- 6 Congress should provide the National Institutes of Health with significant funding dedicated to Food is Medicine research. The NIH should also leverage its own resources to continue its path-breaking work in emphasizing and expanding Food is Medicine research, including by establishing Food is Medicine Centers of Excellence.
- Health care payers should partner with government agencies and one another to enable more cross-disciplinary Food is Medicine research that is ambitious and builds in equity-centered evaluation components from the outset, especially for high-impact opportunities like state Medicaid waiver programs.

#### **Food is Medicine Study Design**

- 8 Eligibility and inclusion criteria for interventions should fully reflect the diversity of the community being studied.
- Qualitative research, which examines the perceptions and experiences of participants, clinicians, and program implementers, should be an essential component of new proposals. Human-centered design also prioritizes these values. Qualitative and human-centered research should include culturally reflective methodologies that support diverse perspectives and attempt to understand the "why" behind quantitative results. At the same time, quantitative analyses should leverage comparison groups, either through randomized trials or quasi-experimental approaches, to compare outcomes among those who participate in Food is Medicine programs and similar patients who do not. These studies will provide the strongest evidence and allow successful models to scale.
- Studies should be designed to test what types of interventions work, at what dose, for what population, and for what duration. For example, researchers can assess the health impacts of providing food interventions plus nutrition education versus providing food interventions alone. The findings will build the case for health plans and payers to adopt, scale, and tailor coverage for highly effective Food is Medicine interventions.

### Food is Medicine Metrics to Advance Clinical and Policy Decision-Making

- Food is Medicine research should measure a broad set of health outcomes so that research metrics will fully capture the effects of interventions on individual and population health. These could include changes in diet, quality of life, clinical outcomes, mental health, engagement with health care, health care utilization, and cost-effectiveness. Assessed outcomes should reflect the needs and desires within a community, including participants and their care team, and not simply reflect the interests of researchers.
- Researchers and experts from the fields of health care, nutrition, public health, and dietetics, as well as Food is Medicine providers and advocacy organizations, should identify a set of meaningful metrics that can be incorporated across Food is Medicine research design and evaluation. Health care practitioners should use standardized metrics and validated tools when possible for specific health conditions. Previously developed toolkits, such as the Nutrition Incentive Hub's Core Metrics Toolkit, may be a helpful starting point for metrics development.

#### Food is Medicine Research Outcomes that Will Support a Common Agenda

- Research that focuses on prevention and not solely on managing diet-related disease should be expanded—especially for populations, such as children, that can benefit greatly from a prevention model.
- Researchers should explore, and funding should be available to assess and evaluate, the wider spillover effects of Food is Medicine interventions on improving the health and nutrition security of entire households and not just study participants.
- (1) As part of the effort to build momentum toward integrating Food is Medicine and health care, health care organizations and payers should increasingly highlight data on the cost-effectiveness of Food is Medicine interventions for specific populations.

### **Coordinating and Strengthening Related Federal Policy Efforts**

- Government agencies and researchers should coordinate within and across departments to combine data on health outcomes and health care utilization (i.e., from Medicaid, Medicare, and the Veterans Health Administration) with enrollment and benefits data from the US Department of Agriculture and federal nutrition programs. This will allow researchers to evaluate health outcomes among Food is Medicine participants and within the general population.
- Food is Medicine research should continue to examine the ripple effects of other outcomes that more broadly address social drivers of health, such as reduced social isolation, household economic stability, and improved mental health in addition to Food is Medicine's impacts on local food systems.
- Building on the recommendations from the 2022 White House Conference on Hunger, Nutrition, and Health, the US Department of Health and Human Services should continue to lead and coordinate efforts across federal agencies to explore the impact of Food is Medicine interventions on health outcomes, health care utilization, and cost-effectiveness. HHS should guide federal investments in Food is Medicine research and encourage interagency collaboration. These investments could include cross-sector organizations and agencies working with specific populations like older adults and other vulnerable populations such as pregnant and postpartum women or those with disabilities. New collaborations will accelerate the integration of evidence-based Food is Medicine interventions across government programs and health care providers.

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**Food & Society at the Aspen Institute** brings together leaders and decision-makers in the food and beverage industry and the public health community—scientists, nutritionists, environmentalists, entrepreneurs, chefs, restaurateurs, farmers, and food makers of all kinds—to find solutions to production, health, and communications challenges in the food system. The goal is for people of all income levels to eat better and more healthful diets—and to enjoy them bite by bite.

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