

Written Statement for the Record
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Subcommittee on Health

Hearing on Investing in a Healthier America: Chronic Disease Prevention and Treatment

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Dear Chairman Jason Smith and Ranking Member Richard Neal, Health Subcommittee Chairman Vern Buchanan and Ranking Member Lloyd Doggett, and members of the House Ways and Means Subcommittee on Health, thank you for holding this hearing, "Investing in a Healthier America: Chronic Disease Prevention and Treatment." My name is Dr. Kevin Volpp, and I currently serve as the scientific lead for the American Heart Association's food is medicine (FIM) initiative, Health Care by Food (HCXF). I am also the founding Director of the Penn Center for Health Incentives and Behavioral Economics (CHIBE) and the Mark V. Pauly President's Distinguished Professor at the University of Pennsylvania's Perelman School of Medicine and the Wharton School.

For 20 years, I served as a part-time primary care doctor and hospitalist taking care of patients at the Philadelphia Veterans Affairs Medical Center. Many of my patients struggled with chronic diseases such as diabetes and congestive heart failure, which were exacerbated by their challenges finding affordable healthy food. As a behavioral economist, my work has largely focused on testing innovative ways of applying insights from behavioral economics in improving patient health behavior and clinician performance. Through my work with a variety of health plans, health systems, consumer companies, and individual patients, I have developed a deep understanding about what physicians, individuals, and families need to promote health, prevent disease, cure illness, and manage chronic health conditions. As a member of the American Heart Association's advocacy committee, I have worked to advance the organization's mission to be a relentless force for a world of longer, healthier lives for all.

As laid out in the AHA's presidential advisory on FIM,¹ AHA developed a call to action for the organization, as well as for the rest of the FIM research field, as we look toward strengthening the overall body of the work. Our call to action is the following:

- Define and determine the scope of FIM and its role in health care and strengthen the FIM evidence base across diverse populations to inform our collective understanding of the limitations to the existing evidence and the opportunities for incremental impact.
- In partnership with others, lead efforts to increase the rigor of FIM studies so that the field moves away from predominantly conducting pre-post studies in which causal inferences are difficult to draw to one that leads the field of nutrition research by using

¹ Volpp KG, et al. Food Is Medicine: A Presidential Advisory From the American Heart Association. *Circulation*. 2023;148:1417-1439.

experimental and quasi-experimental designs that support more robust and reliable conclusions.

- Bring behavioral science and human-centered design into FIM trials more systematically to increase engagement and ultimately both efficacy among those who choose to participate and population health effectiveness of interventions.
- Make concerted efforts to obtain funding for more rigorous, adequately powered longer-term studies to affect measured clinical outcomes. Conduct comparative effectiveness and cost-effectiveness studies, capturing tradeoffs between intervention costs and effectiveness to inform decisions on which FIM approaches to choose for different populations, outcomes, and settings.
- Use rapid-cycle innovation principles to improve program enrollment and engagement and to study design innovations such as adaptive study designs to accelerate learning from research studies.
- Embed FIM principles of research, including equity, transparency, rigor, quantitative/qualitative balance, dignity, and incorporating lived experience of patients and practitioners, to ensure that effective FIM interventions have reach, adoption, acceptability, and sustainability within the populations served.
- Create common data platforms and standardize data elements and metrics in FIM studies to facilitate comparisons across studies that could support the translation of research into policy.
- Catalyze partnerships across communities, food systems, health systems, commercial entities, and funding agencies to empower a patient-driven, health-for-all approach to mitigate food insecurity and to improve diet quality and health outcomes among the most disenfranchised.
- Leverage implementation science to examine questions on enrollment, dose, engagement, and adherence inclusive of health system or health plan integration. Identify and develop strategies to examine predictors of implementation success of individuals and incorporate these into program design.
- Expand complementarities of advocacy and policy work through cross-sector, community-engaged, inclusive coalitions at the regional and national levels, as well as governmental partnerships to create dialogue and build trust, collaboration, and collective action.
- Standardize professional education nationally to include nutritional science and FIM research to facilitate adoption of FIM best practices in clinical practice by the next generation of health professionals.

Why take a FIM approach to health care?

The connection between chronic disease and nutrition is undeniable. Our diets not only play a role in our risk of developing chronic diseases, but also can prevent, manage, and treat these diseases. Cardiovascular disease is the leading cause of death in the United States, and chronic diseases affected by nutrition including cardiovascular disease, stroke, and diabetes account for most of the nation's \$4.3 trillion in annual health care costs.² Cardiovascular disease alone accounts for 12 percent of total U.S. health expenditures, considerably more than any other disease.³ Heart disease and stroke cost the U.S. health care system \$216 billion annually and

² Martin AB, et al. National Health Expenditure Accounts Team. National health care spending in 2021: decline in federal spending outweighs greater use of health care: study examines national health care expenditures in 2021. *Health Aff (Millwood)*. 2023; 42:6–17.

³ Tsao CW, et al. Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association. *Circulation*. 2022;145:e153–e639.

cause \$147 billion in lost job productivity.⁴ Nutrition insecurity and unhealthy diets—characterized by a high intake of calories, sodium, added sugars, and saturated fat, and low intake of vegetables, fruits, and whole grains—significantly contributes to the development of cardiometabolic disease and chronic diseases more broadly. There are significant equity disparities as well, with higher rates of chronic disease mortality among those with low income, less education, and across different racial/ethnic populations. Black, Latino, and Native populations and low-income households, have higher rates of poor diet quality compared with the overall population.⁵ The COVID-19 pandemic has only exacerbated these disparities. Stable availability, access, affordability, and use of nutritious foods across the lifecycle can help reduce the risk of chronic diseases and help treat and manage chronic diseases. Unfortunately, many individuals in the United States are nutrition and food insecure⁶ and do not have access to affordable, nutritious food. There is a growing body of evidence that the health care system can be used to help patients access and consume healthy foods. To help address unhealthy diets and nutrition insecurity, evidence-based, cost-effective nutrition and food programs can be integrated into the health care system.

What is FIM?

FIM refers to a medical treatment or preventive intervention for patients with a diet-related health risk or condition and/or nutrition and food insecurity, to which they are referred by a health care provider, health care organization, or health insurance plan.⁷ Often these FIM interventions are coupled with medical nutrition therapy (MNT) and efforts to increase enrollment or participation in other federal and state safety net programs, and programs that address other social determinants of health (housing, education, transportation, social services, etc). There are distinct approaches that are described broadly as FIM, including but not limited to:

- Medically Tailored Meals (MTMs). MTMs are used to address diet-related diseases and food access among higher-risk individuals. MTMs provide home delivery of fully prepared meals designed by a registered dietician to meet the specific dietary needs of an individual living with one or more chronic diseases. This intervention is ideal for patients living with chronic diseases who are unable to shop for or prepare meals for themselves, such as patients following a hospitalization for congestive heart failure who are frail and have difficulty ambulating.
- Medically Tailored Groceries (MTGs). MTGs include a selection of groceries, such as vegetables, fruits, grains, beans, lean proteins and/or dairy prescribed by a registered dietitian nutritionist for a broader range of patients—those with diet-related acute and chronic conditions who can shop or pick up and prepare food at home. MTGs are part of a treatment plan for an individual with a defined medical diagnosis, confirmed by a health care provider or health plan. Food sourcing varies across programs and often incorporates community partners.
- Healthy Food Prescription Programs. Food prescription programs (also called produce prescription programs) incorporate food access directly into the patient-provider relationship which better enables patients to follow their providers' dietary advice. In these programs, providers "prescribe" fruits and vegetables, or other healthy foods, to at-risk patients in the form of coupons or vouchers for local farmers' markets, grocery stores,

⁴ Centers for Disease Control and Prevention. Health and Economic Costs of Chronic Diseases. Accessed online April 15, 2024. <https://www.cdc.gov/chronicdisease/about/costs/index.htm>.

⁵ Tsao CW, *ibid*.

⁶ Coleman-Jensen A, et al. Household Food Security in the United States in 2020. Economic Research Report No (ERR-298) pp. 2021.

⁷ Harvard University Center for Health Law and Policy Innovation. Accessed online April 15, 2024. <https://chlp.org/project/food-is-medicine/>.

or mobile markets. These programs are also typically accompanied by nutrition education and/or counseling and can be paired with services provided by registered dietitians or community health workers. Food prescription programs are typically offered to people living with chronic diseases that are exacerbated by unhealthy food and who have nutrition and food insecurity. Some food prescription programs have been funded through the farm bill reauthorization process. The 2018 farm bill provided \$250 million of mandatory funding for GusNIP, some of which is allocated for produce prescription pilots.

It is important to note that FIM complements other critical efforts to address food and nutrition security needs, such as supporting Supplemental Nutrition Assistance Program (SNAP), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the charitable food system (food banks and pantries), among others. However, it is distinct from these programs in that it is specifically targeted for people living with or at high risk of chronic disease, due in large part to diet, through health care settings.

The interest in FIM programs and their increasing use within health care has been in part ahead of the research, driven in large part by organizations and advocates who have worked to develop service delivery programs to meet the nutritional needs of people living with chronic diseases. Within the past several years, health care integration of FIM interventions has become increasingly common. FIM programs are growing, which allows for more researchers to assess the effectiveness of the implementation of different FIM approaches.

Already there has been tremendous momentum at the state and federal level. State Medicaid agencies may currently apply for waivers (i.e., Section 1115 demonstration waiver and 1915(b) waiver) to test new FIM approaches, including MTMs and produce prescription programs, and nearly a dozen states have begun to take advantage of these opportunities for innovation. The administration has called for testing MTMs in Medicare, expanding and enhancing Medicare coverage of nutrition and obesity counseling (MNT), and increasing funding for nutrition research, and have held multiple convenings on FIM as part of the National Strategy on Hunger, Nutrition, and Health. The Centers for Medicare and Medicaid Services (CMS) now requires hospitals to screen patients for needs related to food insecurity, housing, transportation, and other social determinants of health. Medicare Advantage plans already voluntarily offer supplemental benefits that include food assistance and FIM-like benefits (MTMs, MTGs, produce prescription), but this is an emerging area with limited information about its utilization. The Department of Health and Human Services (HHS) is currently developing common measures and a framework for evaluating FIM set to be released by the fall. Finally, produce prescription programs and pilots continue to grow in numbers, including at the Indian Health Service and Department of Veterans Affairs.

Strengths and Room for Improvement in FIM Research

FIM programs have commonly been evaluated as part of small-scale studies and pilot projects conducted using local resources that are generally not scalable. The HCXF initiative is funding smaller studies with a goal of addressing implementation challenges that would limit the potential for scalability and then will fund larger studies. HCXF has also identified populations to prioritize in research, including the acutely ill, patients with recent hospital discharges, high-risk pregnant women, and alternative paths or wrap-arounds for glucagon-like peptide 1 drugs (GLP-1), drugs. We are also prioritizing having geographically and ethnically and racially diverse populations as participants in the initiative.

Of the studies on FIM programs, the literature on MTMs is the most well-developed, with a number of rigorous study designs and results that examine clinical outcomes and health care

utilization and spending. MTMs are associated with improved health outcomes for people living with chronic diseases such as diabetes, heart failure, HIV, and chronic liver disease. Patients on medically tailored meals have reported higher quality of life scores, lower rates of food insecurity, and improved diet quality.^{8,9} MTM are also associated with reduced hospital admissions and overall health care costs.^{10,11} The research suggests that produce prescription programs are effective at increasing fruit and vegetable consumption^{12,13} and reducing household food insecurity.¹⁴ The studies conducted on food prescription programs have found that some of these programs are associated with improved health outcomes and reduced health care burden including decreased hemoglobin A1C levels¹⁵ and lower body mass index.¹⁶ While modeling studies have suggested that food prescription programs may prevent cardiovascular disease and diabetes, these have typically had to make assumptions about the longer term effects of short-term interventions that may or may not end up being confirmed.¹⁷

In general, many of the FIM studies that have been conducted using pre-post examination of a group that received an intervention without comparison groups; the measured impact of such interventions may be overstated since they do not account for the general tendency of measured outcomes to regress to the mean.¹⁸ Furthermore, only a small number of randomized controlled trials have been done and those that have been done with few exceptions are small and typically not tested using a scalable infrastructure. More broadly, there are important questions to answer regarding the intensity of FIM interventions, the duration, delivery, the role of patient preferences and choice, the incorporation of educational or behavioral strategies or coaching in addition to food permission, the testing of comparative effectiveness of ways to change behaviors and habits, and of cost effectiveness. More testing using infrastructure that can be replicated and scaled will be particularly important in determining ways to create solutions that could be deployed widely across the United States.

While there have been studies showing no significant results, this further illustrates the importance of carefully considering study design, and various implementations that take into account the lived experience of the populations most likely to benefit. The recent negative study by Doyle et al tested a very specific intervention, in which participants had to drive to an on-site food pharmacy to pick up their food on a bi-weekly basis and did not have a great many options

⁸ Ishaq O, et al. Food as medicine: A randomized controlled trial (RCT) of home delivered, medically tailored meals (HDMTM) on quality of life (QoL) in metastatic lung and non-colorectal GI cancer patients. *Journal of Clinical Oncology*. 2016;34.

⁹ Berkowitz SA, et al. Medically Tailored Meal Delivery for Diabetes Patients with Food Insecurity: a Randomized Cross-over Trial. *J Gen Intern Med*. 2019;34:396-404.

¹⁰ Berkowitz SA, et al. Association Between Receipt of a Medically Tailored Meal Program and Health Care Use. *JAMA Intern Med*. 2019;179:786-793.

¹¹ Berkowitz SA, et al. Meal Delivery Programs Reduce The Use Of Costly Health Care In Dually Eligible Medicare And Medicaid Beneficiaries. *Health Aff (Millwood)*. 2018;37:535-542.

¹² Bhat S, et al. Healthy Food Prescription Programs and their Impact on Dietary Behavior and Cardiometabolic Risk Factors: A Systematic Review and Meta-Analysis. *Advances in Nutrition*. 2021.

¹³ Marcinkevage J, Auvinen A and Nambuthiri S. Washington State's Fruit and Vegetable Prescription Program: Improving Affordability of Healthy Foods for Low-Income Patients. *Prev Chronic Dis*. 2019;16:e91.

¹⁴ Ridberg RA, et al. A Pediatric Fruit and Vegetable Prescription Program Increases Food Security in Low-Income Households. *J Nutr Educ Behav*. 2019;51:224-230.e1.

¹⁵ Bryce R, et al. Participation in a farmers' market fruit and vegetable prescription program at a federally qualified health center improves hemoglobin A1C in low-income uncontrolled diabetics. *Prev Med Rep*. 2017;7.

¹⁶ Cavanagh M, et al. Veggie Rx: an outcome evaluation of a healthy food incentive programme. *Public Health Nutr*. 2017;20:2636-2641.

¹⁷ Lee Y, et al. Cost effectiveness of financial incentives for improving diet and health through Medicare and Medicaid: A microsimulation study. *PLoS Med*. 2019;16:e1002761.

¹⁸ Doyle J, et al. Effect of an Intensive Food-as-Medicine Program on Health and Health Care Use: A Randomized Clinical Trial. *JAMA Intern Med*. 2024;184:154-163.

with regards to their meal choices.¹⁹ Lack of effectiveness in one specific intervention does not negate that other differently designed interventions may be effective, and both negative and positive studies provide important learnings that inform future research studies.

A common challenge and barrier to system transformation has been that among the wide variety of programmatic interventions at the intersection of food and health, most exist on a small and siloed scale. Different hospitals, payors, and health care providers have approached these programs in various ways, without any clear or standardized set of implementation approaches likely to be capable of scaling nationally. To create more generalizable approaches, there would ideally be coordination between HHS and the United States Department of Agriculture (USDA) with support for research from the National Institutes of Health (NIH) and involvement of public-private partnerships both to facilitate the testing of scalable ideas and to provide financial support. Current FIM interventions do not consistently include the perspectives and voice of potential participants, which can reduce engagement by those who are offered the programs and thereby diminish their impact. In FIM studies that are focused on improving health outcomes or reducing health care utilization, careful assessment of cost effectiveness should be conducted as this will be important in informing decisions about public or private health insurance coverage. Finally, research can also help us understand how to increase uptake and engagement, and thereby full utilization of FIM programs, to maximize their potential impact on health and health care costs.

Strengths of Medical Nutrition Therapy Research

As noted previously, MNT is often part of a FIM intervention. MNT research has shown it to be a cost-effective, evidence-based intervention to manage chronic conditions, especially obesity, diabetes, and cardiovascular disease.^{20,21,22} CMS defines MNT as “nutritional diagnostic, therapy, and counseling services for the purpose of disease management, which is usually conducted by a registered dietitian (RD) or nutrition professional.” MNT services involve in-depth individualized nutrition assessment and use the Nutrition Care Process (NCP) to manage disease. This intervention is also designed to improve a patient’s nutritional knowledge of their health condition and diet behavior. Coverage for MNT varies depending on the insurance provider. For Medicare and Medicaid, MNT services are reimbursable for certain populations. Medicare Part B only covers MNT and other related services for patients diagnosed with diabetes, non-dialysis kidney disease or patients within 36 months post kidney transplant, who are referred by a physician and when services are provided by a registered dietitian (RD) who is enrolled as a Medicare provider. Medicare covers three hours of MNT the first year of treatment and up to two hours of MNT for each subsequent year. While the costs for these services are reimbursable for patients with diabetes or chronic kidney disease, MNT services are not reimbursed through Medicare for patients with pre-diabetes or other chronic conditions (e.g., hypertension, obesity, CVD, etc.). Medicaid coverage for MNT for adults and children varies from state to state and some states do not recognize RDs as approved Medicaid providers. States are required by federal law to provide “mandatory” benefits including services like inpatient and outpatient hospital services, physician services, laboratory and x-ray services, and other “optional” benefits like

¹⁹ Doyle J, *ibid.*

²⁰ Anderson JM. Achievable Cost Saving and Cost-Effective Thresholds for Diabetes Prevention Lifestyle Interventions in People Aged 65 Years and Older: A Single-Payer Perspective. *Journal of the Academy of Nutrition and Dietetics.* 2012;112:1747-1754.

²¹ Sikand G, et al. Clinical and cost benefits of medical nutrition therapy by registered dietitian nutritionists for management of dyslipidemia: A systematic review and meta-analysis. *Journal of Clinical Lipidology.* 2018;12:1113-1122.

²² Troyer JL, McAuley WJ and McCutcheon ME. Cost-effectiveness of medical nutrition therapy and therapeutically designed meals for older adults with cardiovascular disease. *Journal of American Dietetic Association.* 2010;110:1840-1851.

prescription drugs, case management, physical therapy, and occupational therapy, which can also be covered by Medicaid. However, coverage for nutritional services is not outlined specifically by Medicaid on the list of mandatory or optional benefits.

MNT is used in a variety of programs that may include FIM interventions or could be augmented with FIM interventions in various programs that counsel on diet for people with or at risk of developing diabetes or heart disease. Efforts are being made at the federal level to increase access of MNT to vulnerable populations. For the past few Congresses, legislation has been introduced to expand MNT access. The first of which was introduced in 2017. As noted previously, the administration has called for expanding coverage of MNT in Medicare.

Conclusion

Chronic conditions and unhealthy diets are inextricably linked, and health disparities remain all too pervasive. FIM interventions within the health care system is a promising approach in helping patients access and consume healthy foods that could improve health outcomes for people living with chronic diseases. Important research gaps, however, continue to exist in our knowledge base on what FIM interventions would be the most effective.

The AHA's HCXF initiative is committed to helping generate the evidence and tools needed in the health sector to design and scale cost-effective FIM programs. Working with patients and partners in government, academia, health care, industry, and community-based organizations, the HCXF initiative will accelerate the rate of innovation to unlock solutions to these most complex challenges.

The AHA supports efforts to increase prioritization of nutrition and equitable access to healthy, affordable food in the health care delivery system and to connect patients with community resources that improve access to and consumption of healthy food.²³ By increasing coverage for nutrition services through health insurers like Medicare and Medicaid and expanding existing food and nutrition programs, patients can be connected with the resources they need to prevent, treat and manage chronic diseases that drive health care costs across the United States. The AHA further supports efforts to expand investments in nutrition and FIM research, and in existing programs that address food and nutrition insecurity.

About Health Care by Food™ (HCXF)

In conjunction with the White House Conference on Hunger, Nutrition, and Health in 2022, the American Heart Association and The Rockefeller Foundation launched the Health Care by Food initiative to strengthen the evidence base for FIM. Our vision is to accelerate a future in which millions of patients receive the benefit of a more holistic approach to diet and health, health care professionals and practitioners know how FIM programs can help prevent and manage disease, and payors have sufficient, objective cost-effectiveness evidence for reimbursing FIM programs. The initiative will provide the large-scale clinical evidence required to help identify, support and implement the most viable FIM strategies as a covered benefit through public and private health insurance.

Launched in Spring 2023, the HCXF initiative is made up of over 257 leading researchers across the country in diverse academic fields, including the support of dozens of experts who comprise

²³ American Heart Association. Strategies to Address Socioeconomic and Racial and Ethnic Disparities in Chronic Diseases by Incorporating Food and Nutrition Programs into the Primary Healthcare Setting. June 2022. Accessed online April 15, 2024. <https://www.heart.org/-/media/Files/About-Us/Policy-Research/Policy-Positions/Access-to-Healthy-Food/Medical-Nutrition-Therapy-Policy-Statement-2022.pdf>.

nine volunteer task forces that are examining issues ranging from health equity and common measures for FIM, community engagement and implementation science, behavioral science, cost effectiveness, human-centered design, and evaluation of the Medicaid waivers, among other issues. Already the HCXF initiative has funded over \$8 million in 23 research grants that are testing the clinical effectiveness of different FIM interventions in diverse patient populations with diabetes, hypertension, cardiovascular disease, and high-risk pregnancy. The initiative is also funding an implementation analysis of the high and low redemption rates in the Gus Schumacher Nutrition Incentives Program (GusNIP) program through the Gretchen Swanson Center for Nutrition. Together, these grants involve researchers from more than 20 academic institutions, 27 community-based organizations, and a number of national corporations with participation throughout much of the United States. These promising short-term and smaller studies will inform larger, scalable research studies.