Impacts of Produce Prescriptions and Medically Tailored Meals on Health Outcomes and Healthcare Utilization

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Dissertation Chapter Abstracts

The ***overall objective*** of this dissertation was to assess the impact of Food is Medicine policies on clinical outcomes and healthcare utilization among food-insecure individuals. The ***central hypothesis*** was that the provision of nutritious food through US healthcare systems to food-insecure Americans with or at risk of chronic disease will improve health at a cost-effective level. The ***long-term goal*** of this dissertation is to guide national policies regarding how Food is Medicine programs may be leveraged and expanded to improve health and wellbeing.

Chapter One

The Impact of Produce Prescriptions on Diet, Food Security and Cardiometabolic Health Outcomes: A Multi-Site Evaluation of Nine Produce Prescription Programs in the U.S.

Background: Produce prescriptions may play a role in improving cardiometabolic health by increasing fruit and vegetable (F&V) consumption yet impacts on clinical outcomes have not been evaluated in large-scale studies. The high prevalence of diet-related disease and adverse effects of food and nutrition insecurity underscore the need for larger evaluations. Our objective was to evaluate the impact of produce prescriptions on F&V intake, food security, self-reported health, and clinical biomarkers of cardiometabolic health including hemoglobin A1c (HbA1c), blood pressure (BP), and body mass index (BMI).

Methods: This is a multi-site, pre- and post-evaluation of 9 U.S. produce prescription programs, operated at 22 locations in 12 U.S. states, using individual-level data. The study included 3,881 individuals (2,064 adults aged 18+ years and 1817 children aged 2-17 years) with, or at risk for, poor cardiometabolic health recruited from health clinics serving low-income neighborhoods. Programs provided financial incentives via vouchers or electronic cards to purchase F&V at grocery stores or farmers markets (median value = $63 per month; program duration 4 – 10 months). F&V intake, food security, and self-reported health were measured using surveys; HbA1c, BP, and BMI for adults and BMI z-score for children were measured at clinics. Adjusted, multilevel mixed models were used to account for clustering by program location.

Results: After a median participation of 6.0 months, F&V intake increased by 0.83 (95% CI: 0.67, 1.00) and 0.21 (95% CI: 0.03, 0.39) cups per day among adults and children, respectively. The odds of being food-insecure

halved (odds ratio [OR]: 0.54 [0.45, 0.64]) and the odds of improving one category in self-reported health status more than doubled for both adults (OR: 2.05 [1.66, 2.52]) and children (OR: 2.52 [1.95, 3.26]). Among adults with HbA1c >=6.5%, HbA1c declined by -0.33 percentage points (-0.47, -0.20); among adults with stage I and II hypertension, systolic and diastolic BP declined by -8.62 mmHg (-10.44, - 6.81) and -4.97 mmHg (-6.00, -3.93), respectively; and among adults with overweight or obesity, BMI decreased by -0.34 kg/m^2 (-0.62, -0.07). Child BMI z-score did not change.

Conclusion: In this large-scale evaluation, produce prescription participation was associated with significant improvements in F&V intake, food security, and self-reported health for adults and children, and clinically relevant improvements in HbA1c, BP, and BMI for adults with poor cardiometabolic health. Findings support the potential for meaningful benefits of produce prescriptions and the need for large, randomized trials and further scaling of produce prescriptions.

Chapter Two

Evaluation of a Produce Prescription Program for Patients with Diabetes: A Longitudinal Analysis of Glycemic Control

Background: Produce prescriptions have shown promise to improve diabetes care, although most studies used small samples or lacked controls. Our objective was to evaluate impacts of a produce prescription program on glycemic control for patients with diabetes.

Methods: Participants included a non-random enrollment of 252 patients with diabetes who received produce prescriptions and 534 similar controls from two clinics in Hartford, CT. The start of the COVID-19 pandemic in March 2020 coincided with program implementation. Produce prescription enrollees received US $60/month vouchers for six months to purchase produce at grocery retail. Controls received usual care. The primary outcome was change in glycated hemoglobin (HbA1c) between treatment and controls at six months. Secondary outcomes included 6-month change in systolic and diastolic blood pressure (SBP and DBP), body mass index (BMI), hospitalizations, and emergency department admissions. Longitudinal generalized estimating equation models, weighted with overlap weights created by propensity scores, assessed changes in outcomes over time.

Results: At six months, there was no significant difference in change in HbA1c between treatment and control groups, with a difference of 0.13 percentage points (95% CI: -0.05, 0.32). No significant differences were observed for change in SBP (3.85 mmHg (-0.12, 7.82)), DBP (-0.82 mmHg (-2.42, 0.79)), or BMI (-0.22 kg/m^2 (-1.83, 1.38)). The incidence rate ratios for hospitalizations and emergency department visits were 0.54 (0.14, 1.95) and 0.53 (0.06, 4.72), respectively.

Conclusion: A 6-month produce prescription program for patients with diabetes, implemented during the onset of the COVID-19 pandemic, was not associated with improved glycemic control.

Chapter Three

Economic Analysis of Insurance Coverage of Medically Tailored Meals and Estimated Hospitalizations and Healthcare Expenditures in the US

Background: Medically tailored meals (MTMs) are associated with lower healthcare utilization among patients with complex diet-related diseases, but are not a covered benefit in Medicare or Medicaid. The potential impact of extending MTMs nationally remains unknown. The objective was to estimate one- and ten-year potential impacts on annual hospitalizations, annual healthcare expenditures, and overall policy cost effectiveness national MTM coverage for patients with diet-related disease and limited instrumental activities of daily living in Medicaid, Medicare, and private insurance.

Methods: This is a population-level, cohort policy simulation model estimated change in annual hospitalizations and healthcare expenditures from MTM coverage. 1,000 Monte Carlo simulations jointly incorporated uncertainty in model inputs for effect sizes, hospitalizations, healthcare expenditures, and program costs. We used a nationally representative sample from the 2019 Medical Expenditure Panel Survey of US adults age 18+ covered by Medicare, Medicaid, or private payers with at least one diet-sensitive condition and limitation in instrumental activities of daily living, representing an estimated 6.3 million individuals nationally. We modelled ten nutritionally tailored MTMs/week for an average of 8 months in each year of intervention. Outcomes were total hospitalizations, program costs, healthcare expenditures, and net policy costs.

Results: At baseline, mean (SD) patient age was 68.1 (16.6) years, 4.0 million (63.4%) were women, 4.2 million (66.7%) were non-Hispanic White, and 4.8 million (76.5%) received Medicare and/or Medicaid. Most common

eligibility diagnoses were diabetes, cardiovascular diseases, and cancer. If all 6.3 million eligible individuals received MTMs, an estimated 1,594,000 hospitalizations (95% UI: 1,297,000, 1,912,000) and $38.7 billion (24.9, 53.9) healthcare expenditures could potentially be averted in one year. Program costs were $24.8 billion (23.1, 26.8), for an associated net savings of $13.6 billion (0.2, 28.5) from a healthcare perspective. In 2019 dollars, ten years of the MTM intervention was anticipated to cost $298.7 billion (279.7, 317.4), potentially averting 18,257,000 hospitalizations (14,690,000, 22,109,000), and reducing healthcare expenditures by $484.5 billion (310.2, 678.4), for net savings of $185.1 billion (12.9, 377.8). Findings were robust in multiple sensitivity analyses.

Conclusion: National implementation of MTMs for patients with diet-sensitive conditions and activity limitations could potentially avert 1.6 million hospitalizations and save a net $13.6 billion annually.

Introduction and Rationale

"Food is Medicine" interventions are of rapidly growing interest to healthcare systems, payers, patients, and policymakers.[1-3] Food is Medicine programs integrate payment for or direct provision of healthy food to patients in coordination with a healthcare partner to improve diet-related health outcomes. Major examples include produce prescriptions and medically tailored meals (MTMs). Produce prescriptions offer free or discounted produce to ambulatory patients based on a range of eligibility criteria, whereas MTMs provide home-delivered, nutritious meals tailored to outpatients with severe chronic conditions and limitations in activities of daily living. Such programs hold great promise as potentially low-cost strategies to improve nutrition, food security, health, and quality of life, however research remains limited regarding how best to leverage Food is Medicine to improve clinical outcomes and healthcare utilization.

Rigorous empirical assessments of the efficacy of produce prescription programs on clinical outcomes and healthcare utilization are limited.[4,5] Most produce prescription program evaluations have been small pilots and meaningful results will require larger samples and/or pooled data across multiple programs. Most previous assessments of produce prescription programs have also lacked a control group and may have suffered from regression to the mean, especially when high-risk patients were recruited for participation.[3] Furthermore, some produce prescriptions had low levels of engagement, with few participants frequently redeeming vouchers at farmers' markets.[6] As compared to the produce prescription literature, several larger and more robust evaluations show promise for MTMs to rapidly improve health and lower healthcare costs for low-income individuals with advanced chronic disease, including diabetes, cardiovascular disease, end stage renal disease, HIV and cancer.[7-11] However, large randomized, controlled trials have yet to replicate results for both MTMs and produce prescription programs, although several RCTs are currently in progress throughout the U.S.

Intersection with Food Insecurity and Racial Disparities

Food insecurity is an acute symptom of poverty defined by the USDA as "the limited or uncertain availability of nutritionally adequate and safe foods," [12] and surged to historically high prevalence during the start of COVID-19 crisis.[13] While food insecurity remains a common metric in existing literature, *nutrition security*, defined by the USDA as "having consistent access, availability, and affordability of foods that promote well-being and prevent and treat disease," may be more relevant to health policy given the role of food access *and* nutrition on health outcomes.[14]

Nonetheless, food insecurity has been used in the majority of previous literature and has been strongly associated with poor health outcomes in the US.[15,16] For example, worse HbA1c, blood pressure, and BMI are associated with food insecurity as compared to food-secure individuals in the US, making diet-sensitive chronic

diseases like diabetes particularly challenging to manage.[17-20] The monthly spike in Emergency Department admissions among low-income individuals with diabetes during the last week of each month when food and finances are in short supply highlights the grave harm of food insecurity.[21,22] Food-insecure individuals often adopt rational coping strategies, such as delaying or forgoing medical care, [23,24] engaging in cost-related medication underuse, [25,26] [27] choosing between food and other basic needs such as utilities, and opting to consume low-cost, energy-dense foods to compensate for limited financial resources.[28] Within this context, it should not be surprising that healthcare utilization and total healthcare costs, including inpatient care, emergency care, surgeries, and drug costs, increase as food insecurity and malnutrition severity increases.[29,30-32] Furthermore, if individuals are choosing to consume low-cost, less healthy foods to cope with food insecurity, then nutrition education will often be insufficient for this population, and programs like MTMs or produce prescriptions offer a solution to access healthier foods.

In 2020 according to the USDA, 38.3 million Americans – including 11.7 million U.S. children – lived in food insecure households.[33] The food insecurity rates likely would have been much higher had it not been for substantial government aid during the first year of COVID-19, including robust increases in nutrition benefits, novel cash payments to households, and child tax credits (at the start of COVID-19 in spring of 2020 food insecurity shot up to historically high levels before aid reached American households later in the year).[33] However, even with the historical and bipartisan government assistance, by fall of 2020 when the USDA conducts its annual survey, major yet predictable disparities by race and ethnicity existed: while only 7% of white households experienced food insecurity, 22% of Black households and 18% of Hispanic household experienced food insecurity in 2020.[33]

Why might such racial disparities exist? The short answer, looking at America's history, is that slaves kidnapped from Africa built the U.S., and a civil war and several hundred years later this history continues to haunt our politics, economy, and social fabric. The combined effects of several hundred years of overt and systemic racism across the US economy, including but not limited to lynching, voting restrictions, redlining, the war on drugs and over policing, has compounded and created today's inequities in wealth, food insecurity, health, and mortality. [34-37] For example, in Boston in 2015, the average white family had $2.5 million in wealth, whereas the average Black family had $8.[38] Parts predominantly Black Roxbury have a life expectancy of less than 59 years – the shortest in all of Boston and shorter than most countries worldwide, while than half a mile away across Massachusetts Avenue, residents of Back Bay have city's highest life expectancy of almost 92 years.[39] Even in the "liberal" northern city of Boston, decades of systemic racism have permeated the economy and society, creating profound disparities in wealth and health.

Anti-black racism is not a requisite of systemic racism. Native Americans suffered genocide at the hands of the British and U.S. governments during colonization and westward expansion, the Chinese exclusion act barred the immigration of Chinese to America in 1882, Japanese Americans were rounded up in internment camps

during World War II, violence against Muslims and Arabic individuals rose after 9/11, and anti-Asian violence has increased notably during the COVID-19 pandemic. All of these forces can lead to significant consequences in the financial wellbeing and mental and physical health of non-White individuals in America. Thus, discussion of food insecurity and diet-related illness is incomplete without an acknowledgement of these histories.

The impact of overt and systemic racism is evident in the bodies of non-White U.S. adults. For example, according to the CDC, Non-Hispanic Black adults have the highest age-adjusted prevalence of obesity (49.9%), followed by Hispanic adults (45.6%), non-Hispanic White adults (41.4%) and non-Hispanic Asian adults (16.1%).[40] The CDC also reports that type 2 diabetes is highest among Native American adults and Black adults.[41] From 1999 – 2018, Non-Hispanic White individuals tended to have higher rates of optimal cardiovascular health than Mexican-American and Non-Hispanic Black individuals, although on average across the U.S. only 7% of U.S. adults had optimal health in 2017-2018.[42] Finally, disparities in dietary intake persist across race and ethnicity and have even widened as diet has improved slightly for non-Hispanic White adults, whereas it has remained unchanged for other racial groups.[43]

Other societal inequities and stigmas related to age, education, gender, income, and geographic location critically shape individual, family, and community access, convenience, and affordability around healthy food, diet quality, and diet-related health, forcing public health professionals to acknowledge the intersectionality of identities and how these can combine in unique ways for individuals and increase their risk of food insecurity and disease. For example, the CDC has reported that diagnosed type 2 diabetes is also highest among adults with less than a high school-level education and those experiencing poverty.[41] Diabetes prevalence is higher in rural areas as compared to urban areas in the U.S.,[44] and the prevalence of optimal cardiometabolic health is lower among Americans with lower education (5.0%) vs higher education (10.3%).[42] Research has also shown that a higher proportion of SNAP participants (indicating low-income) have poor diet scores (54%) as compared with higher-income individuals (29%).[45]

Intersection with COVID-19 and Health Disparities

The COVID-19 pandemic has further underscored the stark health disparities in a pre-existing epidemic of diet-related conditions, such as obesity, hypertension and type 2 diabetes, which are top risk factors for COVID-19 hospitalizations and deaths.[46,47] The U.S. now has a fast moving, infectious disease of COVID-19 layered over a slow-moving pandemic of diet-related illness. Unfortunately, both cardiovascular disease and COVID-19 are vascular inflammatory illnesses that exacerbate each other.[48] For example, nearly 61% of COVID-19 hospitalizations could have been avoided in U.S. with a healthier population at baseline without high prevalence of obesity, diabetes, hypertension, and heart failure.[49] Racial disparities again enter the equation at the intersection of diet-related illness and COVID-19: black adults have the highest prevalence of obesity in the

country, followed by Hispanic adults.[40] The CDC reports that American Indian, Hispanic, and Black adults are twice as likely to be hospitalized or die of COVID-19, even when accounting for age.[50] While poor diet and high prevalence of diet-related illness explains some of the COVID-19 mortality disparities by race/ethnicity, it cannot explain all of it, further highlighting the sustained impact of systemic racism throughout the healthcare system and economy.[51,52]

The Promise and Limitations of Food is Medicine to Improve Health Equities

In sum, the aforementioned and daunting challenges intersect with each other: food insecurity is associated with experiences of racism,[53] poor health outcomes [15,16] and higher healthcare costs [29,30]; disparities in food insecurity increased across racial and ethnic minority populations during 2020 [54]; disparities in COVID deaths by race/ethnicity continue today; and disparities in diet-related health may even worsen with sustained inflation and rising prices of groceries, making nutrition security even harder for low-income households across the U.S. Within this context, this dissertation lays down steppingstones to improve the scientific understanding of how nutrition interventions integrated into patient care may improve diet, health outcomes, and healthcare utilization for high-risk patients.

The COVID-19 crisis and disparities in food insecurity, diet, health and mortality underscore the important role Food is Medicine could play improving clinical care and health disparities by providing free healthy food to low-income patients with diet-related illness. For example, in the largest MTMs studies to date, participants receiving MTMs were more likely to be Black, more likely to have a disability, and more likely to be on Medicaid than the general U.S. adult population.[8,55] Chapter one of this dissertation represents the largest produce prescription study to date, in which participants were more likely to be non-Hispanic Black and Hispanic than the general U.S. population, plus were more likely to be enrolled in programs for low-income Americans like Medicaid, SNAP, and WIC. Thus, based on the demographic enrollment of previous Food is Medicine studies, these programs are well-positioned to improve health disparities. However, little is known if Food is Medicine programs will have differential impacts on health outcomes for different sub populations, for example by race / ethnicity, ability, and age, which will be the true test Food is Medicine's role at improving health inequities. For example, if programs are less effective for Black or Hispanic enrollees, then effort should be taken to further improve the programming. Evidence from chapter three of this dissertation does suggest that tailoring eligibility criteria to target high-need individuals, for example those with limited activities of daily living *and* food insecurity, will have greater per capita improvements in health outcomes and overall cost effectiveness.

While Food is Medicine has great potential to improve health inequities in clinical care, such programs are ultimately treatment focused, and cannot meaningfully impact root causes of poverty nor systemic racism. Furthermore, improving health equity through Food is Medicine is not a guaranteed outcome and depends on

which patient populations are prioritized in future policy. For example, many high-need, uninsured individuals are disconnected from the health care system and may not be able to access Food is Medicine services. Americans first and foremost need equitable access to the health care system for supportive screening, evaluation, and referrals, in addition to preventive clinical care and access to appropriate medications and procedures needed to treat the full spectrum of diet-related conditions. In Medicare, the only plans that offer Food is Medicine coverage are within private Medicare Advantage, which cost more than Part A and B and historically have enrolled a whiter and healthier population. Moving forward, Food is Medicine practitioners must evolve programs based on the latest science (to which this dissertation aims to contribute) and with input from participants with lived experience, and then pursue targeted policy opportunities to intentionally use Food is Medicine to improve health equities within the American healthcare system.

Chapter One

The Impact of Produce Prescriptions on Diet, Food Security and Cardiometabolic Health Outcomes: A Multi-Site Evaluation of Nine Produce Prescription Programs in the U.S.

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Under revisions at Circulation: Cardiovascular Quality and Outcomes

Introduction

One of every five deaths worldwide is attributable to suboptimal diet, more than any other risk factor including tobacco.[56] Suboptimal diet in the U.S. exerts a tremendous health burden, with more than 300,000 annual deaths from cardiovascular disease (CVD) and diabetes, and more than 8,000 new cancer cases attributable to suboptimal diet.[57,58] Most Americans do not meet guidelines for a healthy diet,[43] while population disparities in diet quality and health outcomes persist or have worsened among marginalized racial, ethnic, and low-income groups.[59,60] These challenges further intersect with food insecurity, which is strongly associated with poor health outcomes[15,16] and higher healthcare utilization and costs.[29,30]

Until recently, healthcare providers had few tools to address patient food and nutrition insecurity. However, rapidly evolving interest among healthcare systems, payers, patients, and policymakers in food is medicine interventions like produce prescriptions offer promising mechanisms to improve nutrition and health outcomes.[1] Produce prescriptions provide free or discounted produce, covered partly or fully by healthcare payers, to patients with or at risk for diet-related chronic diseases and often concomitant food insecurity.[1,3,5] These treatments recognize that the combination of financial incentives and nutrition education may be required to improve nutritional intake, especially for low-income populations. Early produce prescriptions were typically implemented at farmers' markets with more recent programs partnering with retail grocery to increase choice, convenience, and year-round access.[61]

A growing body of evidence suggests that produce prescriptions increases F&V intake, reduces food insecurity, and improves quality of life.[1,3,5,62] Yet, existing studies have been generally small pilots that evaluate a single program, and could be limited by publication bias, with only studies identifying positive effects being reported. Critically, evaluations on clinical biomarkers of cardiometabolic health such as glycated hemoglobin (HbA1c), blood pressure (BP), and body mass index (BMI) for patients with diet-related illness remain limited, with varying results.[3,5,62] Thus, more robust analyses from larger samples, including pooling data across multiple programs to reduce publication bias and increase generalizability, are critical to better understand the impact of produce prescriptions on various patient outcomes especially clinical outcomes.

To address these gaps in knowledge and inform the design of ongoing clinical and policy efforts, we evaluated the impact of produce prescriptions programs on F&V intake, food insecurity, self-reported health status, and clinical outcomes including HbA1c, BP, and BMI in a pooled analysis of nine programs. Findings are timely and relevant for both clinical practice and policy, including produce prescription pilot funding through the 2018 Farm Bill,[63] optional coverage of produce prescriptions by Medicare Advantage plans,[1] and ongoing Medicaid 1115 and 1915 waivers creating produce prescription pilots in several U.S. states.[64,65]

Methods

Population and Setting

Study participants included 1,817 children and 2,064 adults who participated in one of nine produce prescription programs at 22 sites across 12 U.S. states from 2014-2020. Eligibility criteria across programs included being at risk for poor cardiometabolic health (e.g., overweight/obesity, diabetes, or elevated blood pressure) for adults and having overweight / obesity for children, in addition to being food-insecure or being recruited from a health center serving a predominantly low-income neighborhood (see *Table 1* for detailed descriptions by program). Participants were referred by healthcare providers (physicians, medical assistants, nurses, or other members of the care team) to receive produce prescriptions operated by Wholesome Wave,[66] an organization dedicated to curbing the national burden of diet-related disease by improving affordability and access to healthy fruits and vegetables across the country. We included all produce prescription programs operated by Wholesome Wave that measured at least one biomarker in their programmatic data collection (ie, BMI / BMI z-score, HbA1c, or blood pressure). None of the included programs have been the subject of previous research or evaluation. The present study was reviewed by the Tufts Health Sciences IRB and determined not human subjects research as the analysis used retrospective, deidentified data provided from the programs.

Produce Prescription Intervention

After referral by a healthcare provider, participants were either enrolled at the clinic or at a clinic-hosted, community event with nutrition education classes. Enrolled participants received financial incentives (either paper vouchers or electronic cards) ranging from $15 - $300 per month (median = $63 per month) to purchase F&V at food retailers such as grocery stores and farmers markets (*Table 1*). Two of three pediatric programs and two of four adult programs scaled the produce prescription based on household size, although the dollars per household member differed by program (*Table 1*). Program duration ranged from 4 to 10 months. In addition to financial incentives, all pediatric and adult programs provided in-person or online nutrition education classes. Education varied from in-person, online, individual instruction and/or group lessons as well as tours of grocery stores.

Outcomes

Primary outcomes included changes in F&V consumption (cups/day), household food insecurity, HbA1c (%) among adults with baseline values >6.5%, and systolic and diastolic BP (mmHg) among patients with baseline values $\geq$130mmHg (systolic) and >80 mmHg (diastolic). Secondary outcomes included changes in self-reported health status, body mass index (BMI) among adults with overweight/obesity (BMI $\geq$25 kg/m^2) and BMI z-scores among children with overweight/obesity (BMI for sex and age $\geq$ 85th percentile). We hypothesized that among the biomarker outcomes, HbA1c and blood pressure would be most responsive to dietary changes over a several month program period, and thus were included as primary outcomes along with FV intake and food

insecurity. FV intake and food insecurity were included because they are the main targeted pathways throughout which improvements in health outcomes might occur.

Outcomes were measured at baseline and after program participation. Consumption of F&V was each assessed using semi-quantitative dietary questionnaires. One program used a 10-item F&V screener that assesses types of fruits (e.g., fruits, fruit juices) and vegetables (e.g., leafy greens, non-fried vegetables) in frequency (e.g, 3-4 times /week).[67] The remaining programs assessed the total daily, combined intake of fruits and vegetables separately in frequency (e.g., 3 times per day), in both frequency and portion size (e.g., 3 times per day, 0.5 cups each), or in servings per day (e.g., 3 servings per day). To harmonize data, we estimated the total intake of F&V in cups per day by combining data on frequency and portion size whenever available or assuming standard portion sizes from USDA MyPlate when portion size was not asked.[68] Wholesome Wave surveys did not assess any other components of the diet.

Food security was assessed using the USDA six-item food security module[12] or the validated Hunger Vital Sign.[69,70] These responses were harmonized to estimate presence or absence of household food insecurity as a binary measure.

Self-reported health status was assessed using the Center for Disease Control and Prevention's Healthy Days module in which participants select one of five health categories, ranging from excellent (category =1) to poor (category=5).[71] This measure has been validated in multiple studies as highly predictive of future health outcomes and total mortality.[72] Levels of HbA1c in blood were measured in standardized healthcare system laboratories; blood pressure, weight, and height were measured in the clinic as part of routine medical care or during a special visit to the clinic as part of program participation.

Covariates

Wholesome Wave registration surveys self-reported participants' age (continuous), biological sex (male/female) , race, ethnicity (white, non-Hispanic black, Hispanic, other), household size (number of people), and for child programs only; current household enrollment in the Supplemental Nutrition Assistance Program (SNAP) and Special Nutrition Program for Women, Infants and Children (WIC), health insurance coverage (Medicaid/CHIP, private, uninsured, other) and parent / caregiver employment (full time, part time, unemployed, other). While some programs measured additional covariates, we used all available, shared covariates measured across all programs in the analysis.

Statistical Methods

Changes in outcomes were measured as difference in values from baseline to the end of program participation. We used multi-level mixed models (ie, hierarchal models) that account for clustering of multiple measurements (ie, pre and post) within participants that are additionally clustered by program location. Our

models employed a random intercept for person and program location. Hierarchal linear models were used for continuous outcomes (F&V intake, clinical biomarkers) and generalized linear mixed models for binary and ordinal outcomes (food insecurity, health status). Analyses were conducted in adult and child populations separately, except for food insecurity which was analyzed at the household level. For outcomes assessed in adults (F&V intake and health status) or at the household level (food insecurity), fixed effects included age, sex, race/ethnicity, and household size; for outcomes assessed in children, fixed effects included age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, health insurance coverage, and parent / caregiver employment.

To account for missing data, we assessed patterns of missing data by comparing baseline characteristics and outcomes between participants with complete data and those missing at program end. No systematic differences between the two groups were identified, thus our primary analyses report the full case analyses. In sensitivity analyses, multiple imputation was conducted for outcomes with missing values. Multiple imputation was conducted separately for each outcome and incorporated all available variables that might help satisfy the missing at random assumption[73] including shared demographic covariates; baseline values of F&V intake, health status, food insecurity, and health outcomes; and indicator variables to account for clustering by program location.[74] We used 30 imputations as the Fraction of Missingness Indicator was less than 30 for all outcomes. We also conducted a sensitivity analysis excluding program locations with greater than 50% missingness of endpoint surveys.

A final sensitivity analysis assessed the impact of produce prescriptions on HbA1c among participants with baseline HbA1c ≥8.0%, on blood pressure among participants with baseline systolic BP ≥140 mm Hg or diastolic BP > 90 mm Hg, and on BMI among participants who were overweight or obese at baseline (BMI ≥ 30 kg/m^2 for adults; BMI for age and sex ≥ 95^{th} percentile for children). Stratified analyses were conducted to explore whether outcomes differed by (1) timing relative to the COVID-19 pandemic (whether the produce prescription program was completed prior to March 2020 or extended into the pandemic); and (2) participant characteristics including age (2-17, 18-64, 65+) , sex (as a biological variable), and race/ethnicity (as a self-reported, sociocultural construct which may reflect experiences of discrimination that worsen health), plus household size and household SNAP enrollment (characteristics that may impact a household's food needs).

Analyses were conducted in in Stata (version SE 17.0) by one investigator (K.H.) and replicated in SAS (version 9.4) by another (M.D). Due to testing of five primary outcomes, we used a Bonferroni corrected alpha=0.01 for statistical significance for primary outcomes.

Results

Participant Characteristics

Adults had a mean (SD) age of 54.4 (14.8) years, 70.7% were female, 29.8% were non-Hispanic White, and 45.1% were Non-Hispanic Black. Children had a mean age of 9.2 (4.2) years, 51.4% were female, 75.5% were Hispanic, and 62.7% were enrolled in SNAP. At baseline, mean (SD) F&V intake was 2.7 (1.9) cups/day among adults, and 3.4 (2.8) cups/day among children; and 56.3% of all households experienced food insecurity (*Table 3*).

The median monthly produce prescription received by adults was $43 (IQR: $31 - $60) with actual, observed program participation lasting for a mean (SD) of 6.4 (1.7) months, ranging from 1.0 – 10.0 months. The average adult participant spent 73.1% of their produce prescription dollars during program enrollment (the remainder was unspent). The median monthly amount received in pediatric programs was $112 (IQR: $85 - $133) with actual, observed program participation lasting for a mean (SD) 5.4 (1.9) months, ranging 2.0 – 9.4 months. The average child participant spent 77.1% of their produce prescription dollars during program enrollment.

Outcomes in Adults

Among all adults F&V intake increased by 0.83 cups per day (95% CI: 0.67, 1.00) (*Table 4*). Among all households, the odds of being food-insecure halved after program participation (odds ratio [OR]: 0.54 [0.45, 0.64]). Assessing clinical biomarkers of cardiometabolic health, HbA1c declined by -0.33 percentage points (95% CI: -0.47, -0.20) among those with HbA1c >=6.5% and by -0.61 percentage points (-0.81, -0.40) among those with HbA1c>=8.0%. Systolic and diastolic BP declined by -8.62 mmHg (-10.44, -6.81) and -4.97 mmHg (-6.00, -3.93), respectively, among those with stage I and II hypertension at baseline; and by -12.38 mmHg (-15.16, -9.60) and -9.81 mmHg (-12.09, -7.52) among those with stage II hypertension. BMI also significantly improved with a reduction of -0.34 kg/m^2 (-0.62, -0.07) among adults with overweight or obesity at baseline, and -0.49 kg/m^2 (-0.81, -0.16) among adults with obesity. Finally, program participation was associated with a doubling in the odds of improving one category in self-reported health status (OR: 2.05 [1.66, 2.52]). All adult primary outcomes passed the p=0.01 level of statistical significance required by the Bonferroni correction.

Outcomes in Children

Compared with baseline, F&V intake among children increased by 0.21 cups per day (95% CI: 0.03, 0.39) (*Table 4*). Household food insecurity also improved, as described above. Self-reported health significantly improved, with 2.5-fold higher odds of improving one category in self-reported health status (OR: 2.52 [1.95, 3.26]). No significant changes in BMI z-score were observed.

Sensitivity Analyses

Analyses using multiple imputation were similar to the main findings (*Table S2).* After dropping program locations with over 50% missing of endpoint data (did not affect HbA1c, SBP, DBP, or BMI analyses), full case

analyses were also similar to the main findings (*Table S3*). The exception was that child FV intake no longer met our Bonferroni correction for statistical significance (p=0.04). Exploratory stratified analyses identified minimal evidence of differential effects by participant subgroups (*Table S3-9*). Exceptions were signals around the impact of implementation during COVID-19, with greater improvements observed in F&V intake and HbA1c, among adult programs that occurred prior to COVID-19 (p for interaction all <0.05).

Discussion

In this multi-site, participant-level, pooled pre- and post- evaluation of nine produce prescription programs in 12 U.S. states, we identified statistically significant and clinically meaningful improvements in F&V intake, household food insecurity, HbA1c, BP, BMI and self-reported health status among adults; and in F&V intake, household food insecurity, and self-reported health status among children. There was no significant change in children's BMI z-score. This investigation provides the largest evaluation and strongest evidence to-date that produce prescriptions are associated with improved nutrition, food security, and self-perceived health among adults and children as well as key health outcomes among adults with suboptimal cardiometabolic health.

Our findings build upon and extend the results of previous studies on produce prescriptions. A recent systematic, scoping review of produce prescription studies found that 21 of the 22 studies published had identified improvements in F&V intake compared with baseline.[62] A pooled meta-analysis of five published produce prescription studies, totaling 1,039 adults, found a 0.8 cups/day (22%) increase in F&V consumption compared with baseline.[75] We identified a similar 0.83 cups/day increase among adults – a meaningful improvement given that less than 10% of American adults meet national F&V recommendations to consume 5-6 cups/day,[76] with a mean national intake of 2.3 cups/day.[77] The USDA estimates that an individual would need to spend $63 – 78 per month to meet the recommended daily FV intake,[77] and the median produce prescription of $48 per month for adults and $112 for children across programs would have provided financial support to reasonably increase FV intake.

Two reviews on interventions addressing food and nutrition insecurity in healthcare settings found few studies that assessed participant food insecurity, with only five studies using validated screeners, three of which found improvements in household food insecurity.[5,78] Given the observed improvements in both diet quality and food insecurity in our study, produce prescriptions appear to advance *nutrition security*, defined as having consistent access, availability, and affordability of foods that promote well-being and prevent and treat disease. This concept, embraced and prioritized by USDA,[79] highlights the central importance of access to not only calories, but to healthy foods and good nutrition.

Prior interventional studies of diet patterns support causal effects of increased F&V intake on HbA1c, BP, and BMI.[80-82] The health benefits of F&V appear to be derived from a complex set of dietary fiber (prebiotics), micronutrients, and phytochemicals, as well as potential replacement of less healthful foods in the diet.[83] Relatively few prior produce prescription studies have evaluated HbA1c, BP, or BMI, with mixed and inconsistent results often from pilot studies with smaller samples.[5,62] A meta-analysis of prior published studies identified reductions in HbA1c (-0.8% (95%CI: -1.6, -0.1); N=5 studies, 1,064 adults) and BMI (-0.6kg/m^2 (95%CI: -2.8,-0.3); N=3 studies, 215 adults).[75] By pooling individual-level data across 9 programs and 22 sites in 12 states, our study provides more robust evidence that produce prescriptions could be a promising component of clinical care for food insecure and/or low-income patients with poor cardiometabolic health.

While produce prescriptions were associated with improved child F&V intake and health status, our analysis of child BMI z-score did not reveal significant change. A review of childhood obesity prevention programs found that evidence for child weight loss was strongest for combined diet-physical activity interventions delivered in schools with both home and community components.[84] Produce prescriptions may need to be of longer duration or combined with additional components to impact child BMI-z-score. Nonetheless, the significant increase in F&V intake, reduction in household food insecurity, and improved self-reported health among children all support potential for meaningful impact on longer-term health outcomes. The improvement in these three outcomes alone is still a meaningful finding as the United States' healthcare system combats an epidemic of childhood obesity.

Among the adult programs, there is variation in produce prescription program designs within our dataset and published research,[5,62] and various programmatic factors may impact efficacy. For example, some programs increased benefits for each additional household member, and research suggests diminishing returns on F&V intake within larger households when the produce prescription value is not scaled by household size.[85] Some programs provided electronic cards, which may reduce stigma and increase consumer convenience.[86] The frequency, intensity, and quality of nutrition education and which retail or farmer's markets partners are included likely also impact efficacy (ie, multiple store locations, year-round availability, and convenient hours will increase accessibility). Future research will need to tease out which program designs are most likely to impact health outcomes.

Implications for Clinical Care

Low F&V intake is an established risk factor for multiple poor health outcomes, including higher risk of coronary heart disease, stroke, adiposity, and cancer.[58,87] In the U.S., more than 100,000 annual deaths from cardiometabolic disease are estimated to be attributable to insufficient F&V intake.[57] The estimated U.S. costs of obesity related illness, including diabetes, cardiovascular diseases, and obesity-related cancers are approximately

$1.7 trillion per year, equal to 9.3% of GDP.[88] By providing a structured intervention within the healthcare system, produce prescriptions could help combat these trends, as the magnitudes of the observed improvements in F&V intake, HbA1c, BP, and BMI in our study were each clinically meaningful.

The large observed improvements in food insecurity also have clinical implications. Food insecurity is strongly associated with poor health outcomes[15,16] and higher healthcare costs.[29,30] Food-insecure individuals often employ rational coping strategies that could harm their disease management, such as underusing medications[25] and choosing cheaper, unhealthful foods due to costs.[28] Food insecurity is also associated with worse glycemic control among individuals with diabetes[18] and Emergency Department admissions increase among low-income individuals with diabetes during the last week of the month, when food and finances are most often in short supply.[21] With the Covid-19 pandemic, stark disparities in household food insecurity have occurred by race/ethnicity, with 7.1% of White, non-Hispanic households experiencing food insecurity compared to 21.7% percent of Black, non-Hispanic households and 17.2% of Hispanic households.[89] Our new findings suggest that produce prescriptions substantially improve food security and may offset some of the adverse health inequities associated with food insecurity.

Implications for Policy

Historically, produce prescriptions have been primarily operated by community-based organizations supported by grants and donations, however, U.S. healthcare policy interest is rapidly growing, including payment for produce prescriptions within limited scopes of Medicare and Medicaid.[3] In 2020 Medicare Advantage plans began utilizing new Special Supplemental Benefits for the Chronically Ill,[90] which allow the optional coverage of up to $500 of produce prescriptions and other food programs per year to assist chronically ill enrollees in meeting nutritional needs. The Agriculture Improvement Act of 2018 established the Gus Schumacher Nutrition Incentive Program (GusNIP),[63] currently providing about $5 million per year in competitive grants for produce prescription implementation in healthcare settings. At the state-level, Section 1115 and 1915 demonstration waivers have allowed Medicaid programs in Massachusetts, North Carolina, Oregon, and California to pilot nutrition-focused interventions, including produce prescriptions, for high-risk patients.[64,65,91,92]

Private payers and insurance are also showing interest in produce prescriptions. Since 2019, John Hancock life insurance has offered customers premium discounts and monthly cash rebates to purchase fruits and vegetables in a national network of supermarkets.[93] Also in 2019, Kaiser Permanente announced Food for Life, a new priority to eliminate food insecurity among its 13 million members, which includes assistance in SNAP enrollment and ongoing randomized controlled trials of produce prescriptions and medically tailored meals.[94] However, given the overall limited coverage of produce prescriptions nationally, this treatment is unavailable to most Americans whom might benefit. Our new findings support the need for further testing and scaling of produce prescriptions, including in clinical settings and controlled trials, across a variety of patient populations.

Strengths

To our knowledge, this is the largest evaluation of produce prescriptions and health outcomes to date, increasing statistical power to detect impacts on dietary intake, health outcomes, and other clinically relevant endpoints. We pooled patient-level data from a broad range of locations, program designs, and healthcare partners, reducing the potential for publication bias and augmenting generalizability. We evaluated both adults and children, providing a range of findings across the life course. Findings for important, self-reported outcomes were complemented by supportive results based on objectively measured clinical biomarkers. Programs documented robust participant engagement as reflected by the mean redemption rates of ~75% of total available dollars over the 4 - 10-month intervention period. Findings were robust to several sensitivity analyses.

Limitations

The primary limitation is the absence of a control group, therefore the observed improvements in health outcomes could be attributable to regression to the mean and/or to other clinical factors like medication changes. On the other hand, the observed clinically and statistically meaningful improvements in diet quality, food security, health status, and biometrics all occurring concordantly support biologic plausibility. Missing data were common in some programs, which may lead to selection bias. However, sensitivity analyses with multiple imputation and exclusion of programs with over 50% missingness supported our primary results. FV intake was the only dietary component assessed, therefore we do not know if other dietary components improved or if detrimental substitutional effects occurred. Additionally, FV screeners that assess frequency only and not frequency plus portion size, as was the case in half the programs, may underestimate actual FV intake.[95] Finally, some programs were implemented during the COVID-19 pandemic which may have impacted their efficacy.

Conclusions

In this multi-site, participant-level analysis of nine produce prescription programs across 22 sites in 12 U.S. states that enrolled low-income or food insecure patients at risk for diet-related illness, program participation was associated with improvements in F&V intake, food insecurity, and self-reported health status among both adults and children, and clinically relevant improvements in HbA1c, BP, and BMI among adults. These findings provide important new evidence from a diverse set of programs for meaningful benefits of produce prescriptions, highlighting the need for clinical, policy, and healthcare payer and provider efforts to implement larger pilots and randomized designs of produce prescriptions.

Chapter Two

Evaluation of a Produce Prescription Program for Patients with Diabetes: A Longitudinal Analysis of Glycemic Control

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Under revisions at Diabetes Care

Introduction

More than 300,000 annual deaths from cardiovascular disease (CVD) and diabetes in the U.S. are attributable to suboptimal diet, underscoring the tremendous burden of diet-related illness.[57,58] Most U.S. adults do not meet the recommendations within the Dietary Guidelines for Americans, while marginalized racial, ethnic, and low-income groups tend to have worse overall diet quality.[59,60] These challenges further intersect with food insecurity, which is associated with poor health outcomes[15,16,29] and higher healthcare utilization,[30-32] as well as the COVID-19 pandemic, for which diabetes is a leading risk factor of COVID-19 hospitalization and death.[46,47,96] Healthcare providers have had few treatment tools to adequately address patient nutrition and food insecurity. However, there is growing interest and utilization among healthcare providers, payers, and patients in "food is medicine" interventions due to the high prevalence of diet-related disease in the U.S. and a growing focus on value-based care.[1] These healthcare-based interventions provide healthy food to patients for the treatment or prevention of disease and offer promising mechanisms to improve nutrition and health outcomes.[1,97] Produce prescriptions represent one of the most popular "food is medicine" models. Produce prescriptions support patients with diet-related illness by providing vouchers or electronic cards to redeem free or discounted fruits and vegetables (F&V) at retail grocery or farmers markets.[1-3,5,98,99] These interventions recognize that linking financial incentives with clinical care plans and nutritional education may be required to improve dietary intake, especially for low-income populations.

A growing body of evidence suggests that produce prescriptions increase F&V intake, reduce food insecurity, and improve quality of life.[1-3,5,98,99] Evaluations of produce prescriptions on glycemic control have been promising, with several studies showing improvements in glycated hemoglobin (HbA1c).[4,100-102] However, most of these prior analyses have been pre/post analyses without any external control group and may therefore be biased by regression to the mean or co-occurring changes in prognostic factors.[3] There is also growing healthcare policy interest in understanding if produce prescriptions programs can impact healthcare utilization, although this remains an understudied area.

In this study, we evaluated a 6-month produce prescription program comparing longitudinal changes in HbA1c between participants with diabetes and a weighted control group of similar patients. Secondary outcomes included changes in systolic blood pressure (SBP), diastolic blood pressure (DBP), and body mass index (BMI); as well as healthcare utilization including emergency department admissions and inpatient hospitalizations. To our knowledge, this is the largest produce prescription study to assess impacts on glycemic control among participants with diabetes as compared to a control group. Our study also contributes novel analyses on healthcare utilization. This research is relevant given recent flexibilities in Medicare Advantage plans to cover produce prescriptions, state-level pilots testing produce prescriptions in Medicaid managed care, [64,65] and recent

commitments by the USDA to improve nation-wide nutrition security,[63] which includes investments in produce prescriptions.[103]

Research Design and Methods

Population and Setting

Study participants included a non-random enrollment of 786 patients (252 enrolled in the Hartford Healthcare Produce Prescription Program, 534 controls) with type 1 or type 2 diabetes from two clinics at Hartford Hospital (Hartford, CT). Physicians and medical assistants were encouraged to identify and refer patients to the program who had a history of uncontrolled diabetes (HbA1c > 8.0%) and who were likely to be lower income and may experience food insecurity, based on zip code of residence. However, to assist meeting program enrollment numbers, a decision was later made to relax the HbA1c threshold to 6.5%. Participants also required at least one HbA1c measurement > 6.5% in the year prior to program start (Nov. 2018 – Oct. 2019) and at least one HbA1c measurement (of any value) during the program period (Nov. 2019 – Oct. 2020). Enrollment in the produce prescription program was from Nov 2019 to Mar 2020, with program implementation through Oct 2020. To create enrollment dates for the control group, we randomly assigned enrollment dates from the distribution of start dates for the treatment group (ranging from Nov. 2019 – Mar. 2020). Program implementation coincided with massive disruptions in the economy and clinical care during the first waves of the COVID-19 pandemic in the U.S.

We identified 534 individuals to serve as a control group from the clinics' electronic medical records, based on a sampling of patients who did not receive produce prescriptions, had at least one HbA1c measurement > 6.5% in the year prior to program start (Nov. 2018 – Oct. 2019), had at least one additional HbA1c measurement (of any value) during the program period (Nov. 2019 – Oct. 2020), and who lived in the same zip codes as the treatment group. This study was reviewed by the Tufts Health Sciences IRB and determined not human subjects research as the analysis used deidentified data on a completed program provided to the academic investigators by Hartford Healthcare.

Produce Prescription Intervention

The produce prescription program was operated by Wholesome Wave,[66] an organization dedicated to curbing the national burden of diet-related disease by improving affordability and access to healthy F&V. After referral to Wholesome Wave by their medical provider, patients received $60 per month for six months in the form of paper vouchers to purchase F&V at a local grocery retail chain. All patients received $60/month regardless of household size. Program implementers hypothesized that this value was sufficient to increase FV intake based on several years of operating similar programs in other U.S. settings. Vouchers were either received

at the clinic or mailed to participants (all vouchers were mailed after March 2020). As part of the intervention, Hartford Healthcare contracted a registered dietician nutritionist to lead group-based, grocery store tours with lessons on reading food nutrition labels and using the vouchers at check out. A launch event at the Diabetes Community Symposium (held on 11/2/2019) also provided an opportunity for additional nutritional education for participants in attendance, plus served as a recruiting event to enroll participants. After March 2020, all in-person nutrition education was cancelled and was not replaced with a remote option.

Because participant FV intake was not measured in the medical records, voucher redemption rates were the primary measure of program participation. To assess program participation, we used sales data from the retail grocery partner that reported the overall redemption rate of the produce prescriptions (ie, the percentage of received dollars that were spent on fruits and vegetables). To explore potential impacts of the COVID-19 pandemic on program participation, we also separately assessed redemption rates from Nov 2019 – March 2020 and April 2020 – September 2020.

Clinical Outcomes

Outcomes for participants and controls were extracted from Hartford Healthcare's electronic health records. The primary outcome was change in HbA1c from baseline to six months after program enrollment, comparing participants to controls. We also assessed changes in SBP, DBP, and BMI from baseline to six months between participants and controls as secondary outcomes. All existing measurements for HbA1c, blood pressure, and BMI were collected for participants and controls from 12-months prior to enrollment to 12-months post enrollment, allowing us to assess changes over time. We averaged biomarker measurements for any participant that had multiple measurements on the same day. All analyses utilized clinically measured data; weight and blood pressure measurements that were self-reported during telehealth appointments were excluded.

A final objective of our study was to assess if produce prescriptions may impact healthcare utilization. Secondary outcomes also included the total count of inpatient hospitalizations and emergency department admissions, separately, at six months after program enrollment. We report the incidence rate ratio for inpatient hospitalizations and emergency department admissions at six months after program enrollment for hypothesis testing. Healthcare utilization was drawn from the medical records and not obtained separately from claims data. As a member of the CareEverywhere network, Hartford Healthcare's electronic health records recorded healthcare utilization if a patient was admitted at other major health systems in Connecticut that use EPIC as their medical records platform.

Covariates

Demographic data were drawn from medical records, including age, biological sex (male, female), self-reported race/ethnicity (Non-Hispanic White, non-Hispanic Black, Hispanic, other), health insurance status

(Medicaid, Medicare, private / other), and self-reported smoking status (never, current, former). In addition, we obtained data on history of comorbidities (using ICD-10 codes) including congestive heart failure, cancer, chronic obstructive pulmonary disease, stroke, or renal disease, in addition to intensity of healthcare utilization including the number of clinic visits, clinical consults, outpatient visits, inpatient hospitalizations, and emergency department visits in the six months prior to program enrollment.

Statistical Methods

We employed an overlap weight propensity score approach to weight the control and treatment group.[104] The propensity score was the probability that an individual enrolled in the produce prescription program given their measured covariates. This was estimated using logistic regression in which the outcome is selection into the treatment group and the explanatory variables are covariates that may predict the probability of treatment and confound the association between receipt of treatment and study outcomes. To calculate an individual's propensity score, we used a generalized linear mixed model with a random intercept for referral clinic to account for clustering by clinic.[105] Predictors included age, sex, race/ethnicity, health insurance status, smoking status; comorbidities including any history of congestive heart failure, cancer, chronic obstructive pulmonary disease, stroke, and renal disease; intensity of recent healthcare utilization including the number of clinic visits, clinical consults, outpatient visits, inpatient hospitalizations, and emergency department visits in the six months prior to program enrollment; and baseline values of HbA1c, SDP, DBP and BMI, defined as the closest measurement prior to program enrollment.

Overlap weights are a propensity score method in which treated patients are weighted by the probability of not receiving treatment (1 – propensity score) and controls are weighted by the probability of receiving the treatment (propensity score).[106] This approach mimics a randomized clinical trial by emphasizing those at clinical equipoise, and down-weighting individuals very likely to receive or not receive treatment. Another property of overlap weighting is that treatment and control groups will have perfect balance on all covariates included in the propensity score model. Results are similar to comparable methods like inverse probability treatment weights when treated and untreated groups are similar.

For our primary analysis, we used a weighted, linear generalized estimating equation (GEE) model to account for multiple measurements over time. At minimum, all study participants had a baseline HbA1c measurement (included in the propensity score model) and at least one HbA1c measurement during the program period. The model included an interaction term with treatment group and days since enrollment for each HbA1c measurement. All available covariates were included in the propensity score and weight creation; therefore, we did not adjust for these covariates in the GEE model. After fitting the models, we then estimated marginal means (aka least square means) at six months and conducted our hypothesis testing on the propensity score-weighted, difference in HbA1c at six months between treatment and control group. A secondary analysis used a similar

model but with an interaction term between treatment and the month of each HbA1c measurement to calculate the HbA1c change per month over the duration of the intervention period. These approaches were repeated for the secondary clinical outcomes SBP, DBP, and BMI. Finally, weighted GEE negative binomial models were used for healthcare utilization outcomes to estimate incidence rates in treatment and control group, and incidence rate ratio between treatment and control groups, in inpatient hospitalizations and emergency department visits during the 6-month produce prescription program. All analyses accounted for baseline outcome measurements by including them in the propensity score and overlap weight creation. Analyses were conducted in Stata 17 and used an alpha <0.05 for statistical significance.

Sensitivity Analyses

Sensitivity analyses included restricting the study population to individuals with uncontrolled diabetes at baseline, defined as HbA1c > 8.0%. We also estimated the change in HbA1c, blood pressure, BMI, and healthcare utilization at nine months after program enrollment (three months after receiving final vouchers) to capture more endpoint measurements after program completion and to explore if there were sustained program impacts. A final sensitivity analysis aimed to isolate the impacts of the COVID-19 pandemic shutdowns on program effectiveness. We stratified by whether HbA1c measurements were taken prior to March 20, 2020 (the date of the state-wide shutdown on CT) or during the COVID-19 pandemic. As HbA1c reflects the previous three-months of glycemic control, we incorporated a washout period and defined the COVID-19 impacted measurements as occurring after May 1, 2020. We then assessed monthly HbA1c change between treatment and control, separately, during both time periods (Nov 2019 – March 2020 vs. May 2020 – September 2020). Finally, we conducted an exploratory, pre/post stratified analyses of program participants and associations with HbA1c change by household size. Household size was measured by Wholesome Wave as part of program onboarding for participants only and it was not available for controls in the medical records.

Results

The intervention group included 252 produce prescription participants with a mean (SD) age of 60.6 years (13.7), 65.5% of whom were female and 84.8% were Hispanic adults *(Table 1).* The most common comorbidities were COPD (46.9%), congestive heart failure (24.2%), and renal disease (22.0%). Mean (SD) HbA1c at baseline was 8.82% (1.71). The control group included 534 individuals who did not receive produce prescriptions and had relevant HbA1c measures. Prior to weighting, individuals selected to be enrolled in the produce program, compared with controls not selected to be enrolled, were more likely to be on Medicaid vs. private insurance, of Hispanic ethnicity, female, and to have COPD, higher baseline HbA1c, higher baseline SBP, and a higher number of outpatient hospital visits in the prior 6 months *(Table 1)*. After the creation of propensity scores and overlap

weights, the weighted means and proportions at baseline between treatment and control were exactly balanced on each characteristic, with no differences between treatment and control groups *(Table 1)*.

During the program period, 90% of received produce dollars were redeemed at the partnering grocery retail locations. The redemption rate in the period prior to the onset of COVID-19 was 98%; and after April 2020, 85%. The nutrition education component of the intervention was stopped during the pandemic. Prior to COVID-19 shutdowns, only 5% of participants attended one in-person class and 9% attended one grocery store tour.

At six months, there was no significant difference in the change in HbA1c between treatment and control groups from baseline, with a difference of 0.13 percentage points (95% CI: -0.05, 0.32) (*Table 2*). Similarly, no difference was observed for change in SBP (3.85 mmHg (-0.12, 7.82)), DBP (-0.82 mmHg (-2.42, 0.79)), nor BMI (-0.22 kg/m^2 (-1.83, 1.38)). These findings were similar in analysis of month-to-month differences in change in HbA1c, SBP, DBP, and BMI between the intervention and control groups (*Figure 1, Figures S1-S3, Table S1*).

In the evaluation of healthcare utilization, hospitalizations and emergency department admissions in these patients were rare, with only 17 total hospitalizations and 5 emergency department admissions over the 6-month program period in all intervention and control patients combined (*Table 3*). The incidence rate ratios at 6-months for hospitalizations and emergency department visits associated with produce prescription receipt were 0.54 (0.14, 1.95) and 0.53 (0.06, 4.72), respectively, a non-statistically significant difference for both healthcare utilization outcomes.

Sensitivity Analyses

Among the subgroup with uncontrolled diabetes at baseline (HbA1c > 8.0%: 146 produce prescription participants, 208 controls), no differences were observed in 6-month change in HbA1c, SBP, DBP, or BMI between intervention vs. control groups (*Table S2*). The incidence rate ratio for hospitalizations in the intervention vs. control group was 0.20 (95% CI: 0.02, 1.60) (*Table S3)* and for emergency department admissions was (0.72 [0.06, 7.96]), both statistically non-significant differences. Similar findings were seen in analyses extending the follow-up to 9-months after enrollment (*Tables 2-3, S1-S2*). Stratified analyses by the onset of COVID-19 suggested no program impact among HbA1c measurements taken prior to the start of the pandemic (*Table S4*). However, only 203 out of 786 study participants had at least 3 months of program enrollment prior to March 20, 2020, and no produce prescription recipients completed the 6-month program prior to March 20, 2020. Exploratory analyses stratified by household size among participants only did not suggest any differential associations by household size between program participation and glycemic control (*Table S5*).

Conclusions

In this quasi-experimental, longitudinal study evaluating the impacts of a 6-month produce prescription program on 252 patients with diabetes compared with 534 controls, there were no statistically significant impacts on the primary outcome, HbA1c, nor secondary outcomes including blood pressure, BMI, inpatient hospitalizations, and emergency department admissions. Sensitivity analyses assessing impacts among those with uncontrolled diabetes at baseline and extending the analysis to nine months obtained similar results. A sensitivity analysis did not suggest early improvements in HbA1c with more limited durations of intervention (up to 3 months) prior to the COVID-19 shutdowns in the spring of 2020.

There are several possible explanations for our findings, in comparison to other studies which have suggested positive impacts of produce prescriptions on glycemic control, blood pressure, and BMI.[3,102] The first is that our study was strongly impacted by the unprecedented national disruptions in clinical care and economic and public safety instability from the early months of the COVID-19 pandemic. Patients were advised not to come into the clinic, and many received medical care via telehealth for the first time. In-store, nutrition education could not be continued as planned and vouchers were mailed to patients instead in-person pick-up at the clinic. During spring and summer of 2020, some participants likely experienced disruptions in work, when many were already in a precarious financial situation. Some participants likely shouldered new childcare demands and increased household food expenditures when schools closed. Many participants would have received stimulus checks and increased federal nutrition program benefits in the summer of 2020 during the time of our program, which would have offered more robust support than the produce prescription program. 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, it simply may be the case that $60 per month for F&V was not enough to impact glycemic control.

That this program was ineffective at improving glycemic control during a period coinciding with the start of the COVID-19 pandemic remains an important finding that may suggest modifications (e.g., larger doses or longer duration) could be required to support patients with poor glycemic control in future disruptive settings related to natural disasters from climate change, another pandemic, or economic downturns. The high overall redemption rate (90%) shows strong voucher utilization and suggests this population had a high, unmet need for additional resources to purchase FV. The redemption rate dropped from 98% prior to COVID-19 to 85% after the COVID-19 pandemic began (and even when seasonal changes from fall-winter to spring-summer might have predicted increased FV intake). This highlights the adverse effects of COVID-19 on program engagement, although an 85% redemption rate is still higher than in many previous produce prescription reports.[102]

The USDA estimates that an individual would need to spend $63 – 78 per month to meet their recommended daily FV intake.[77] Thus, the $60 monthly voucher could have provided reasonable financial

support for an individual to increase FV intake. On the other hand, the household size among participants ranged from 1-6 (median: 2), and the relative impact of the voucher on FV intake could decrease with higher household size if FV were shared among household members. Our exploratory analyses of pre/post HbA1c change did not suggest any significant differential association of the program with glycemic control when stratified by household size. In other pre-post studies of prescription produce programs with a median voucher amount of $43/month (IQR: 31-60), HbA1c was significantly reduced among patients with diabetes, but these studies lacked an external control comparison.[102] An ongoing randomized controlled trial in southern California is assessing how differential produce prescription values impact health outcomes among patients with diabetes, including adjusted to household size.[107]

There is wide variation in produce prescription programs among published research,[5,62] likely causing heterogeneity in findings across studies. For example, some programs may increase benefits for additional household members (ours did not), and research suggests diminishing returns on F&V intake within larger households when the produce prescription value is not scaled by household size.[85] Other components that may have impacted success include the frequency, intensity, and quality of nutrition education and which retail or farmer's markets partners are included (i.e., multiple store locations, year-round availability, and convenient hours will increase accessibility). Some previous produce prescription programs had more robust nutrition education or multiple classes;[4,5,108] in our study, the vast majority of participants (86%) did not attend the nutrition education event or grocery store tours, and these programs were cancelled following the onset of COVID-10. As such, our program should be interpreted as primarily a voucher-based program, and future research should aim to assess the impacts of financial incentives alone versus financial incentives in combination with nutrition education on participant health outcomes.

Our study employed a sufficiently large sample size, stronger methods than most previous evaluations, and targeted a high-risk population that should be responsive to dietary changes, which cautions that similar programs are not guaranteed to improve health outcomes. It is possible that the results of prior produce prescription analyses which did not incorporate controls have been influenced by regression to the mean, rather than a causal effect of the intervention.[3] However, in similar pre/post analysis in the present patient cohort (i.e., omitting the control group), we did not observe any improvement in clinical biomarkers, suggesting that this population and/or the time course of the intervention during COVID-19 may be relatively unique. Our findings suggest that future programs may require more touchpoints with participants, higher incentive values (and perhaps scaled by household size), longer duration, and/or more intensive nutrition education to have an impact on health outcomes.

The programmatic structures of produce prescriptions will be critical to understand as healthcare policy continues to gain a strong interest in produce prescriptions. Increasingly, states are leveraging flexibilities in Medicaid through Section 1115 waivers, 1915 waivers, and in lieu of services options to cover produce

prescriptions, and Medicare Advantage plans can provide up to $500 per year in optional benefits to cover produce prescriptions.[109] The USDA is currently providing $5 million per year in competitive grants for produce prescription implementation in healthcare settings[103] and recently announced a major expansion of this program.[110] Within this context, it is imperative that components of successful produce prescription models are identified and scaled in future research.

Our study has several strengths. To our knowledge, this is the largest interventional study employing a carefully constructed comparison group to evaluate the impacts of produce prescriptions on glycemic control and other risk markers among participants with diabetes. This is possibly the first, or at least among the earliest, produce prescription evaluations to assess impacts on healthcare utilization. The analysis utilized biomarker data from the electronic medical records that were measured by clinical staff, removing concerns of biases related to self-reported health measures. We collected data one-year prior to program enrollment and up to one-year after program enrollment, allowing us to capture more baseline and endpoint measurements, minimize missing data, and extend sensitivity analyses to nine months post enrollment. We employed weighted longitudinal models to assess trends over time between treatment and control groups, incorporating all available measurements within six and nine months after program enrollment to increase statistical precision. The analysis leveraged overlap weights to improve internal validity by accounting for confounding. Finally, employing overlap weights likely improved on the shortcomings of other propensity score techniques like matching, which may reduce sample size by excluding unmatched individuals, or inverse probability treatment weights, which may give more weight to outliers.

There are several limitations in our study. The healthcare, societal, financial, and nutritional disruptions of COVID-19 are the largest. Hartford Healthcare reduced their clinic operations from March – June 2020 and relied heavily on telehealth, meaning there were fewer lab measurements for both treatment and control during this period, leading to lower statistical precision. However, sensitivity analyses expanded our time horizon to nine months post enrollment, allowing the capture of additional endpoint data. Hartford Healthcare observed that emergency department admissions declined after March 2020, suggesting avoidance or fear of contracting COVID-19 (a trend seen nationwide)[111] and potentially underpowering the healthcare utilization analyses. The timing of lab measurements was based on provider judgment as part of routine clinical care and was not standardized for the study, and participants were more likely than controls to have a lab measurement on their enrollment date. This could contribute to differences in timing and frequency of outcome measures between the two groups and subsequently, bias results in unpredictable directions. The program did not assess FV consumption directly; however, redemption rates were recorded and averaged 90% over the course of the study. This was not a randomized controlled trial and cannot determine causality, although our methods aimed to leverage the most robust comparison group available with appropriate statistical power to detect associations for our primary outcome.

In summary, this quasi-experimental study found that a 6-month produce prescription program for predominantly lower-income patients with diabetes, implemented during the onset and first waves of the COVID-19 pandemic, was not associated with significant changes in HbA1c, BMI, BP, nor counts of inpatient hospitalizations and emergency department visits. These results were inconsistent with prior pre/post and pilot studies finding beneficial associations between produce prescriptions and glycemic control. As food is medicine programs expand in the U.S., future research should continue to assess the potential benefits and important programmatic components of produce prescriptions, utilizing strong study designs, so that successful models can be identified and scaled to improve health equity and quality of care.

Chapter Three

Economic Analysis of Insurance Coverage of Medically Tailored Meals and Estimated Hospitalizations and Healthcare Expenditures in the US

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Introduction

Despite suboptimal diet being a leading cause of morbidity and mortality in the U.S.,[57] the healthcare system has traditionally had few tools to connect high-risk patients to nutrition services.[1] This is rapidly changing with interest among healthcare systems, payers, patients, and policymakers in "food is medicine" interventions like medically tailored meals (MTMs) as a potential tool to improve nutrition security, health outcomes, and healthcare utilization for high-risk patients.[1,97] MTMs are fully prepared, nutritionally tailored, and generally home-delivered healthy meals for individuals living with advanced and costly diet-sensitive conditions, such as diabetes, heart failure, end-stage renal disease, HIV, and cancer. Programs generally provide ten weekly meals (lunch and dinner for five days per week), designed by a registered dietitian based on disease diagnosis and nutritional assessment.[112] MTM programs are often designed to treat individuals with lower income, food insecurity, and/or limitations in instrumental activities of daily living (IADLs) that make it difficult to prepare healthy meals.

In quasi-experimental interventions and pilot randomized controlled trials, patients receiving MTMs experience better disease management, fewer hospitalizations, emergency department admissions, and nursing home visits and have lower healthcare expenditures, compared to similar control patients. [8,9,55,113-115] Compared to matched patients not receiving MTMs, MTMs receipt has been associated with a 37% to 52% lower risk of hospitalization, 16% to 31% reduction in monthly healthcare expenditures, [8,9,55,113] and decreased net costs of ~$2,500 per patient year after paying for meal costs.[8,55]

MTMs, especially those evaluated in the literature, are generally provided by community-based organizations supported by grants, donations, and additional ad hoc restricted funding from Home Health Care Services benefits, Medicare Advantage programs, or state Section 1115 Waivers allowing coverage of MTMs.[2,3] MTMs are not currently a covered benefit in Medicaid nor Medicare. Bills at both state and federal levels have recently proposed expanded access to MTMs in Medicaid and Medicare, but these have not passed.[116,117] Availability of MTMs in federal programs depends on (a) whether regulatory flexibility or other special circumstances permit their inclusion, and, if permitted, (b) whether participating private healthcare entities choose to cover them.[1,2]

Given the limited coverage of MTMs nationally, this treatment is unavailable to most Americans who might benefit. To our knowledge, no previous research has modelled expected changes in healthcare expenditures and hospitalizations if MTMs were covered nationally by health insurance for the population routinely served by existing MTM organizations. The objective of this study was to estimate the one- and ten-year impacts of MTMs on hospitalizations, healthcare expenditures, and net costs among patients with diet-related diseases and limitations in instrumental activities of daily living (IADL) covered by Medicaid, Medicare, and private insurance.

Methods

Population and Setting

The study sample was drawn from the 2019 Medical Expenditure Panel Survey (MEPS), a nationally representative survey of healthcare utilization and costs among non-institutionalized US adults. MEPS provides detailed individual-level data including on age, sex, race/ethnicity, family income, geographic region, IADL limitations, medical conditions, healthcare utilization, and costs. This study was approved by Tufts Health Sciences Institutional Review Board and considered not-human subjects research based on use of publicly available, de-identified data. We followed the CHEERS guidelines throughout our analysis and reporting.

Patient Eligibility

We modeled eligible patients as adults age 18+ years covered by Medicare, Medicaid, or private payers and having both one or more diet-sensitive condition and one or more IADL limitation. Diet-sensitive conditions included diabetes, congestive heart failure, myocardial infarction, other heart disease, emphysema, and stroke as defined as priority conditions in the MEPS 2019 Combined File,[118] and non-melanoma cancer, chronic kidney disease, and HIV as defined by ICD-10 codes in the MEPS 2019 Medical Conditions File.[119,120] These diagnoses were selected because they reflect the patient populations in previous MTM research[7-11,55,113-115,121] and served by the national network of MTM providers.[112] IADL limitations were defined as a positive response to receiving help or supervision using the telephone, paying bills, taking medications, preparing light meals, doing laundry, or going shopping due to an impairment or health problem.[118]

MTM Intervention

We assumed meals were medically tailored and provided only for the index patient (i.e., no meals provided for other household members, as is common in most MTM insurance contracts). In practice, MTM organizations often create ten to fifteen meal plans per day, with Registered Dietician Nutritionists tailoring ratios of macronutrients and micronutrients for specific diagnoses, incorporating optimal quantities of healthy food groups such as fruits and vegetables, accounting for dietary preferences such as vegetarian options, and providing options for individuals who have challenges chewing solid foods. MTM dietary guidelines for common diagnoses are listed online by the Food is Medicine Coalition.[122]

We conducted a PubMed search for studies that measured the impact of MTMs on hospitalizations and/or healthcare expenditures in the United States in the past 20 years. Using the five studies identified, [8,9,55,113,123] we calculated the weighted average duration of MTM receipt, identified as an average of eight months of MTMs per patient per year *(Supplemental Table 3.1).* We also conducted an original meta-analysis to estimate policy effect sizes. By pooling findings from published interventional studies[8,9,55,113,123] using inverse variance-weighted meta-analysis with random effects *(Supplemental Table 3.2-3.3)*, MTM provision reduced annual healthcare

expenditures by 19.7% (95% CI: 6.9%, 32.4%) and annual hospitalizations by 47.0% (31.7%, 62.3%), compared with usual care. We further conservatively assumed that benefits of MTMs would occur only in the year of MTM provision, with no sustained or carry-over benefits into the following year.

Policy Costs

Annual MTM program costs included clinical screening costs and meal costs *(Table 3.1).* Screening costs were based on 2020 RD facility Medicare reimbursement rates for an initial, 15-min medical nutritional therapy at ~$30 per patient (ranges from $27.34 in Mississippi to $35.17 in Santa Clara County California).[124] Meal costs were based on 2019 insurance contracts from 10 major MTM organizations and include nutritional tailoring, ingredients, labor, administrative, and delivery costs, which yielded a pooled mean (SD) per meal cost of $9.30 (0.64). In our one-year and ten-year models, we calculated net policy costs as the sum of changes in healthcare expenditures attributable to MTM receipt and total MTM program costs.

For the 10-year policy model, we assessed historical trends in population size and annual healthcare expenditures among MTM-eligible patients from 2010-2019 using MEPS data. We adjusted each year's expenditures to 2019 USD[125] using log-linear regression stratified by insurance status for the eligible population, and used these inflation-adjusted trends to project 2020-2028 expenditures and population size from the 2019 MEPS data. Given the specific patient population eligible for MTMs, we chose this empirical forecasting approach using MEPS data rather than incorporating expected trends for the general US population. For the ten-year model, we assumed all eligible participants received meals for eight months per year in each year. We modeled an open cohort in which the population size for each year reflects people newly eligible entering and those who are no longer eligible leaving.

Simulation Model

We utilized a population-level, cohort policy simulation model to estimate the change in hospitalizations and healthcare expenditures that might occur from implementing an MTM policy compared to the status quo (ie, no new MTM policy), programmed in R (version 4.1.2). For one-year (2019) and ten-year (2019-2028) time horizons, model outputs included changes in annual inpatient hospitalizations and healthcare expenditures, MTM program costs and net policy costs from the healthcare perspective, separately analyzed among Medicaid, Medicare, dual eligible, and privately insured patients. Model inputs included annual hospitalizations and expenditures from MEPS, relative risks of hospitalizations and percent change in healthcare expenditures associated with MTM receipt, and MTM program costs *(Table 3.1).* MEPS survey weights were used to scale the sample to be nationally representative.

Simulations were repeated 1,000 times in each year so that probabilistic analyses jointly incorporated uncertainty in model inputs for hospitalizations, healthcare expenditures, effect sizes, and screening and meal

costs by drawing randomly from within the plausible range of each input during simulation. Estimates reflect the mean of 1,000 Monte Carlo simulations, with the 95% uncertainty interval defined as the 2.5th percentile to the 97.5th percentile of the simulations. Ten-year estimates summed separate simulations for each year (2019-2028) and assumed all eligible individuals received meals for eight months in each year, with 3% annual discounting of healthcare expenditures and MTM program costs

Secondary and Sensitivity Analyses

As some MTM contracts condition receipt on experiencing food insecurity, a secondary analysis restricted the patient population by adding food insecurity as an eligibility criterion for the one-year model (using 2017 MEPS data, the most recent dataset including food insecurity). Food insecurity is defined by the United States Department of Agriculture as "the limited or uncertain availability of nutritionally adequate and safe foods." [12] Multiple, one-way sensitivity analyses assessed robustness of findings to specific assumptions in our one-year model, including estimating potential impacts for individuals with diabetes and congestive heart failure only, as these represent the most diet-sensitive conditions among our eligibility criteria. A third one-year sensitivity analysis assumed only 50% of eligible patients received MTMs. A fourth sensitivity analysis estimated potential policy impact at the 2.5th 10th, 25th, 50th, 75th, 90th, and 97.5th percentiles of our effect size for change in healthcare expenditures associated with MTM receipt, holding constant all other inputs at their central estimate. Finally, we performed a threshold analysis to estimate the per meal cost at which the overall, one-year net policy costs would break even (ie, be zero), and a separate threshold analysis to estimate the minimum change in healthcare expenditures associated with MTM receipt for the overall policy costs to break even, holding constant all other inputs at their central estimate.

For the ten-year model, sensitivity analyses included alternative annual discounting rates of 0% and 5% and incorporating a second year of sustained reductions in healthcare expenditures among 15% of MTM recipients without requiring MTMs in the second year.

Results

Eligible Patients

In 2019, we estimated that approximately 6.3 million U.S. adults would have been eligible to receive MTMs in Medicare, Medicaid and private insurance based on having at least one diet-sensitive disease and IADL limitation (*Table 3.2)* with a mean (SD) patient age of 68.1 (16.6) years, in which 63.4% were women and 66.7% were non-Hispanic White. Median (IQR) household income was 192.3% (93.5%, 372.1%) of the poverty line, and 76.5% of patients were covered by Medicare and/or Medicaid. The most common eligibility diagnosis was diabetes, followed by cardiovascular disease and cancer *(Table 3.2).* Mean (SD) annual healthcare expenditures

in 2019 were $31,134 ($34,749) per person, including 0.98 (1.68) ED visits and 0.54 (0.94) hospitalizations per person per year, consistent with the expected high severity of illness and healthcare utilization in this patient population.

Estimated One-Year Effects

If all eligible individuals received MTMs, then MTM program costs, including clinical screening and meals, would cost $24.8 billion (23.1, 26.8) and an estimated 1,594,000 hospitalizations (95%UI: 1,297,000, 1,912,000) and $38.7 billion (24.9, 53.9) in healthcare expenditures would potentially be averted in one year *(Table 3.3).* Most (77.0%) of the healthcare expenditure savings would occur in Medicare and Medicaid, totaling $29.8 billion (22.2, 38.2). Summed across all healthcare payers, the policy was estimated to be potentially net cost saving at $13.6 billion (0.2, 28.5). By payer subsets, one-year possible policy cost savings were estimated at $3.1 billion (-2.9, 9.5) for private payers, $3.4 billion (-5.4, 12.1) for Medicare, $1.7 billion (-1.1, 5.1) for Medicaid, and $5.9 billion (-1.9, 14.1) for dual eligible. In probabilistic analyses combing all insurance strata, the intervention was associated with net cost-savings in >97% of the simulations *(Figure 3.1).*

One-Year Sensitivity Analyses

When adding food insecurity as an eligibility criterion, eligibility decreased from 6.3 to 1.9 million individuals. Compared to the original population, this smaller population was younger and more likely to be non-Hispanic Black or Hispanic, have lower household income, and be dual-eligible *(Table 3.2).* Baseline annual ED admissions, hospitalizations, and healthcare expenditures were slightly higher than for the base-case population, although these differences were not statistically significant. In this smaller population, our model estimated that MTMs would potentially avert 506,000 hospitalizations (95%UI: 398,000, 654,000) and $13.0 billion (7.9, 18.9) in healthcare expenditures in one year, with a net policy cost savings of $5.5 billion (0.7, 11.1) *(Table 3.3).*

2.8 million individuals in the primary population had diabetes. Among this population our model estimated that MTMs could potentially avert 701,000 hospitalizations (95%UI: 524,000, 911,000) and $19.3 billion (12.2, 27.3) in healthcare expenditures in one year, with a net policy cost savings of $10.9 billion (3.6, 18.8). 1.7 million individuals had congestive heart failure, and among this population our model estimated that MTMs receipt was associated with a potential reduction of 530,000 hospitalizations (95%UI: 737,000, 705,000) and $10.9 billion (6.3, 15.6) in healthcare expenditures in one year, with a net policy cost savings of $5.8 billion (3.6, 18.8). The three secondary populations were anticipated to have between 139% - 173% greater per capita net policy cost savings than the primary population (*Supplemental Table 3.4)*.

Assuming only 50% coverage of eligible participants in the primary population, the policy was estimated to potentially prevent 798,000 hospitalizations (95%UI: 648,500, 956,000) and $19.4 billion (12.5, 26.9) in healthcare expenditures, with a net policy savings of $6.9 (0.1, 14.2) in one year. For the one-year policy to be

cost-neutral rather than cost-saving, the estimated per meal cost would need to double from $9.20 to $18.89 and the change in healthcare expenditures associated with MTM receipt would need to decline by over one third, dropping from 19.7% to 12.7%. Across the uncertainty range from the 2.5^{th} – 97.5^{th} percentile of the effect size for change in healthcare expenditures associated with MTM receipt, the majority of scenarios would be anticipated to be cost-savings, with the potential for significantly greater benefits than are reported in our primary findings (*Supplemental Figure 3.1*). However, it remains possible that the policy may have a net positive cost if the true effect of MTM receipt on change in healthcare expenditures is below the 14^{th} percentile of our effect size uncertainty range.

Estimated Ten-Year Effects

Based on observed national trends with 2019 as the base, we assumed that from 2020-2028, the eligible patient population would increase annually by 1.0% among privately-insured individuals, 2.1% in Medicare, 3.0% in Medicaid, and 5.7% in dual eligible; and that per patient inflation-adjusted healthcare expenditures would increase by 1.5% annually among privately-insured individuals, 1.7% in Medicare, 3.5% in Medicaid, and 3.9% in dual eligible. In 2019 dollars, ten years of the MTM intervention was estimated to potentially cost $298.7 billion (95%UI: 279.7, 317.4), reduce hospitalizations by 18,257,000 (14,690,000, 22,109,000) (*Table 3.4*), and reduce healthcare expenditures by $484.5 billion (310.2, 678.4) *(Supplemental Table 5),* for a net cost savings of $185.1 billion (12.9, 377.8) from an insurer perspective, in which the target population received MTMs for eight months per year in each of the ten years modelled *(Table 3.4).*

Ten-Year Sensitivity Analyses

Applying either 5.0% discounting or no discounting of costs, $441.2 billion (95%UI: 282.7, 617.7) and $558.4 billion (357.3, 782.1) in healthcare expenditures would potentially be adverted, respectively *(Supplemental Table 3.5).* The net 10-year cost savings were $143.7 billion (-11.8, 319.4) for 5.0% discounting and $260.7 billion (62.7, 481.5) for no discounting *(Table 3.4).* Assuming benefits of MTMs persisted into a second year for 15% of individuals (and with 3% discounting), the estimated ten-year potential net cost savings was $231.5 billion (41.2, 441.4).

Discussion

Combining nationally representative data on patient eligibility and healthcare utilization with evidence from interventional studies of MTMs, our simulation model estimated that full national coverage of MTMs in Medicare, Medicaid, and private insurance for patients with both a diet-sensitive condition and IADL limitation could meaningfully reduce annual hospitalizations and healthcare expenditures. Among 6.3 million eligible high-

risk recipients, MTMs could possibly prevent 1.6 million annual hospitalizations. Furthermore, after accounting for the costs of identifying and referring patients to MTM organizations and providing ten weekly meals for an average of eight months annually, the policy is anticipated to be associated with a net savings of $13.6 billion over one-year and $185.1 billion over ten-years. These findings were robust to a range of sensitivity and scenario analyses.

Alignment with Prior Research

The provision of prepared meals through healthcare first arose as a palliative measure for patients with AIDS under the Ryan White Comprehensive AIDS Resources Emergency Act in 1990, at a time when few effective treatments for HIV existed. The potential utility of MTMs in clinical care is now supported by interventional studies observing improved diet quality, food security, and disease management when high-risk patients with diet-sensitive conditions receive MTMs.[113-115,121,126] MTMs have been associated with reduced depressive symptoms and fewer dilemmas between paying for either food, healthcare or prescriptions.[121] Receipt of MTMs is also associated with improved disease management. For example, among patients with HIV receiving MTMs, antiretroviral therapy adherence increased; and among patients with diabetes, diabetes self-management improved.[121,126] These prior findings suggest that MTMs may improve health through several pathways including improved nutrition, improved food security, better financial wellbeing, reduced stress and anxiety, and improved medication adherence and self-management.

Other research supports additional mechanisms by which MTMs could reduce hospitalizations and lower healthcare expenditures. For example, patients with advanced cirrhosis and ascites required fewer weekly paracenteses and experienced improved ascites-specific quality of life after three months of MTMs.[114] Among patients with recent heart failure hospitalization, 1 month of MTMs improved clinical symptom and quality of life scores on the Kansas City Cardiomyopathy Questionnaire.[113] In a recent randomized controlled trial, 600 patients hospitalized with chronic heart failure were assigned to receive either usual hospital meals or medically tailored meal plans, nutritional counseling, and if necessary, supplemental IV nutrition. The tailored nutritional support led to a 56% reduction in mortality at thirty days.[127] Although provided in-hospital rather than home-delivered, this trial supports the benefits of comprehensive, tailored nutritional support for high-risk patients.

Interpretation of Results

We modelled MTM provision to patients with severe comorbidities and limitations to independence, and these findings should not be generalized to a healthier population nor to a less intensive nutrition intervention. We do not anticipate similar results would be expected for individuals with the same diagnoses who do not have limited IADLs. Our main analysis is based on full coverage of all eligible individuals to provide a best-case policy scenario. In practice, it would take time for MTM services to scale and serve all eligible patients. Thus, our

scenario analysis of 50% coverage is an alternative benchmark for comparison. Scaling of MTMs could increase program efficiency and reduce costs, leading to greater net savings. Conversely, scaling could be associated with lower nutritional quality or tailoring of meals, reducing efficacy. These possibilities need to be evaluated with empirical research. Nonetheless, the robustness of our results suggests that national MTM coverage would be expected to be effective and cost-savings under a range of circumstances if appropriately targeted, including adding food insecurity as a criterion for eligibility or focusing only on patients with diabetes or congestive heart failure. Sensitivity analyses suggest that further targeting to these higher need populations may result in greater per capita cost savings, but lower population level cost savings as fewer people are eligible. Finally, the primary goal of MTMs is to provide high-quality medical care for vulnerable patients, and the observed reductions in hospitalizations and expenditures do not incorporate potential additional benefits in patient-related quality of life, disease progression, caregiver wellbeing, and population-level health equity.

Health Policy Relevance

This investigation leverages national data and interventional findings to estimate the health and economic impacts of MTM expansion within Medicaid, Medicare, and private insurance. The findings support policy expansion of access to MTMs by adopting health policy reforms. Several states are currently piloting expanded MTM access, including a $6 million pilot in California for patients with heart failure;[128] a $149 million pilot of Flexible Services in Massachusetts which covers nutrition and housing programs including MTMs among Medicaid patients;[64] and a similar $650 million 1115 waiver in North Carolina's Medicaid program that allows payment for MTMs.[65] Multiple private payers are experimenting with MTMs through charitable donations and grants.[112] Kaiser Permanente, the largest HMO in the U.S., is undertaking a large controlled trial of MTMs for high-risk patients.[129] At the federal level, the Medically Tailored Home-Delivered Meal Demonstration Pilot Act of 2021 has been introduced to direct Medicare to implement and evaluate MTMs with similar bills recently introduced at the state level.[116,117] As of 2020, Medicare Advantage plans may also choose to provide MTMs to certain beneficiaries. Despite this accelerating use of MTMs, access depends on buy-in from state-level Medicaid administrators or managed care plan leadership and is therefore limited by geography and/or insurance carrier. The current limitations in national coverage present an opportunity to improve health if future policies expand MTM access, with an additional opportunity to improve health equity if such policies prioritize low income and/or food-insecure patients. Our findings support the promise of MTM programs, the need for their timely implementation, scaling, and evaluation in both public and private healthcare.

The COVID-19 pandemic has further highlighted the need to invest in prevention and treatment of nutrition-sensitive chronic conditions with a focus on health equity. The U.S. Centers for Disease Control and Prevention has documented diet-related conditions including diabetes, cardiovascular diseases, chronic kidney disease, cancers, and obesity as leading risks for COVID-19 hospitalizations and deaths.[130] Our research suggests

that expanding MTM access should be considered as one healthcare strategy to improve care for high-risk patients with diet-related conditions.

Strengths

We incorporated national data on eligible patients and healthcare utilization and expenditures, increasing generalizability. Effect sizes were derived from interventional studies of MTMs, and MTM program costs from insurance contracts between MTM providers and healthcare systems. Patient eligibility criteria were aligned with prior research studies and existing MTM programs. Our policy model included probabilistic sensitivity analyses across 1,000 Monte Carlo simulations to jointly incorporate uncertainty and report a range of plausible outcomes, while additional one-way sensitivity analyses tested the impact of specific assumptions on the results. We estimated both one-year and ten-year outcomes, providing a range of clinically and policy-relevant time horizons.

Limitations

Although all included MTM studies were interventional, most were quasi-experimental, with carefully constructed rather than randomized control groups. However, existing randomized trials of MTMs that assessed other health outcomes[113-115,127] support the estimated benefits from the quasi-experimental interventions. Published literature was insufficient to incorporate other outcomes that may be impacted by MTMs, for example emergency department admissions, nursing home admissions, and patient quality of life. Published MTM evaluations report up to two years of intervention, and our ten-year estimates could be either over- or underestimates of cost savings, depending on whether efficacy strengthens or wanes over time. The eligible population analyzed represents an open cohort, with some newly entering eligible patients and others exiting due to loss of eligibility or mortality. Finally, our base-case 10-year analysis assumed no carry-over benefits of receiving MTMs, which could underestimate policy benefits if some MTM recipients have lasting improvements in health after one year of intervention.

Conclusions

Our simulation model of a nationally representative MTM eligible population with diet-sensitive conditions and IADL limitations estimates that coverage for MTMs in Medicare, Medicaid and private insurance could potentially avert 1.6 million hospitalizations and save a net $13.6 billion from the healthcare perspective in the first year. These findings are timely and relevant to inform increasing state, federal, and private payer interest in implementing Food is Medicine interventions like MTMs to address diet-related chronic illness in the US.

Conclusion

Produce Prescriptions

Chapter one of this dissertation built on previous research to reaffirm that participation in produce prescription programs is associated with improved FV intake, food insecurity and self-reported health status. Critically, chapter one provides new, important evidence that produce prescription programs can also improve health outcomes. The analyses found clinically meaningful and statistically significant improvements in biomarkers of cardiometabolic health among adults with poor health at baseline in the largest produce prescription analysis to date pooling individual level data from 22 produce prescription locations across 12 U.S. states. These improvements were even larger among adults with obesity, uncontrolled diabetes, and stage II hypertension at baseline. Pooling data across multiple program locations and designs operated in over ten U.S. states improved the generalizability of these findings. However, the study is limited due to the lack of a control group and possible regression to the mean, thus changes could have occurred by chance or due to cooccurring factors such as lifestyle or medication changes. Nonetheless, the findings suggest that produce prescription could be an important part of clinical care for select patients and supports the need and feasibility for large trials and demonstration projects. This study is relevant given the growing US policy focus on produce prescription programs, including the new GusNIP Produce Prescription Program as part of the 2018 Farm Bill, Medicaid pilots of produce prescriptions in multiple U.S. states, and new optional coverage of produce prescriptions in Medicare Advantage plans.

Chapter two offered a deep dive into one of the Wholesome Wave programs included in the chapter one pooled analysis, namely the Hartford Healthcare Produce Prescription Program. Short of a randomized controlled trial, this study utilized one of the best designs available to evaluate the program and contributed to the literature by employing a stronger research design and larger sample size than most of the existing produce prescription research on clinical biomarker outcomes. Chapter two is also the first study to assess healthcare utilization among diabetic participants in a produce prescription program, another notable contribution to the produce prescription research base. Unfortunately, across all outcomes assessed, no impacts on health or healthcare utilization were detected as compared to the control group, even though the Hartford Healthcare program targeted patients with a history of uncontrolled diabetes (which is one of the patient populations most responsive to dietary interventions).

The chapter two evaluation of the Hartford Healthcare Produce Prescription provides an opportunity to explore if regression to the mean may have occurred in chapter one because this study leveraged a comparison group and was included in the pre/post, pooled analyses. Interestingly, even the pre/post analyses of participants only within the Hartford Healthcare program found no program impact. Had the pre/post analyses found a significant improvement in HbA1c whereas the propensity score weighted analyses did not, this would show that

regression to the mean had occurred in at least one of the chapter one programs. While it is impossible to know if regression to the mean occurred within the other programs included in chapter one, it is encouraging that regression to the mean cannot explain the seemingly contradictory null findings in chapter two, which leveraged a robust quasi-experimental study design. In fact, the inclusion of the Hartford Healthcare program with the pooled analyses of chapter one brings the effect estimates for HbA1c, BMI, and BP down closer to the null hypothesis.

The null results of the Hartford Healthcare program counters the optimism found in the chapter one results, however chapter two findings could be unique to the historical moment of the early COVID-19 pandemic outbreak in the U.S. Nonetheless, the null findings should give produce prescription program implementers and policy makers pause and recognize that not all Food is Medicine programs are designed equally, nor is it a guarantee that they will work even within a high-risk population. Programmatic components such as benefit amount, scaling benefits by household size, using card technology, and maximizing convenience and choice among retail partners for participants will likely impact program efficacy and should be explored by future research.

In sum, chapters one and two are relevant to non-profit organizations, health care administrators, physicians, patients, retail grocery partners and policy makers across the US who are interested in operating produce prescription programs. Findings from these chapters provide both optimism for the potential benefits of produce prescriptions, balanced with caution and pause for reflection on what programmatic aspects may be required to effectively improve health outcomes.

Strengths and Limitations of Quasi Experimental Designs

Chapters one and two leveraged quasi experimental study designs, which have several pros and cons as compared to the standard of randomized controlled trials (RCTs). Quasi-experimental studies evaluate the association between an intervention and an outcome in which the intervention is not randomly assigned. Common quasi experimental studies regression discontinuity designs, interrupted time series analyses, instrumental variable analyses, and non-randomized evaluations with a constructed comparison group. These studies all have the benefit of being pragmatic options when the logistics for a randomized trials are not feasible or are unethical, plus can retroactively measure policy changes with appropriate selection of existing datasets. Quasi-experiments are particularly efficient when studying long-term impacts of policy change or dietary intake on disease incidence in settings in which a randomized control trial would be too expensive and infeasible to conduct for years at a time. Even in shorter-term contexts, quasi-experimental studies are less expensive and time consuming than a randomized trial. Quasi-experimental studies can also be leveraged to evaluate rapid outbreaks or safety concerns that require urgent responses that cannot wait for a RCT to be planned and implemented. Finally, quasi-experimental studies often have increased generalizability as they evaluate the real-world effectiveness of an

intervention implemented by hospital staff or government programs for example, rather than the efficacy of an intervention implemented by research staff under highly controlled research conditions.

There are two main shortcomings of quasi-experiments. The first is selection bias, which refers to systematic differences between the intervention and control groups that are related to the outcome of interest. Selection bias can be introduced by the investigator when creating comparison groups if the treatment group and control group are drawn from differing populations. Second, other factors outside of the policy or intervention being evaluated may impact the results, a phenomenon known as historical bias.

There are additional concerns for quasi experimental studies. Retrospective data are frequently leveraged and may be incomplete, difficult to obtain, or were collected for other purposes. For example, electronic record data is collected primarily for billing and health care decision making, with research as a secondary objective, thus there may be missing variables for a study or high levels of missingness among variables that are measured. In retrospective studies in which investigators are attempting to measure former exposures, recall bias may also be a concern. The quality of data may vary in different time periods, resulting in measurement error. Finally, maturation bias can occur when natural changes over time influence the study outcome, for example seasonality, study fatigue, or aging.

Appropriately controlling for confounding is a concern in quasi-experimental studies. When following subjects before and after an intervention, confounding by time is specific concern and can occur when confounders have values that change over time, for example age, clinical biomarkers like BMI, BP, and HbA1c, diet, or smoking status. This is of greater importance in longer studies in which values of time-varying confounders are more likely to change and impact the outcome of interest, and in scenarios in which time varying confounding is influenced by past exposure. Failure to appropriately account for confounding by time can result in over-adjustment bias. This occurs when an investigator controls for a time-varying variable that is both a mediator and confounder, which partially blocks the effects of a past exposure on the outcome that is mediated through that variable. Statistical techniques like inverse probability treatment weights and G estimation can account for time varying confounding influenced by past exposure in quasi-experimental studies and provide unbiased treatment effects.[131] Finally, like all observational studies, the internal validity of quasi experimental studies can be impacted by residual confounding of unmeasured confounders.

There are study design and implementation factors that can limit both RCTs and quasi-experimental studies. For example, policy or program implementation can impact the efficacy of the intervention or policy being studied, resulting in “non-compliance” or loss to follow-up. Thus, for both RCTs and quasi-experiments it is critical to obtain implementation and utilization data and to budget resources for end point data collection. These concerns arose in chapter one of my dissertation in which Wholesome Wave surveys had high rates of missing program end data, and in chapter two, in which the redemption rate of produce prescriptions within the Hartford Healthcare Produce Prescription Program decreased slightly during the COVID-19 pandemic.

Measurement error is always a concern and if non-differential, could bias results towards the null hypothesis. If differential measurement error is present, it could bias results in unpredictable ways (ie, towards the null or away from the null). Testing bias, in which knowing the results of a previous test may influence the results on a latter test, is a concern in both RCTs and quasi experimental studies and highlights the importance of blinding, when feasible. A similar concept of observation bias could threaten the internal validity of both RCTs and quasi experimental studies and describes the scenario in which the intervention group could be more likely to improve when they are aware of being observed.

Several strategies can be used to improve the internal validity of quasi-experimental studies. The most important is using a well-constructed control group drawn from the same source population, which can assist in accounting for seasonal changes, historical bias and regression to the mean. Statistical techniques like matching or propensity score weights can help create comparable control groups, providing greater plausibility of detecting a true treatment effect (for example, chapter two of this dissertation). Multisite studies are preferable as they generally have stronger external validity when testing an intervention at multiple locations and communities (for example, chapter one of this dissertation). Studies that can analyze dose-response relationships between the treatment and outcome of interest can also add greater evidence of a treatment effect (for example, a higher produce prescription dollar value may have greater impacts on health outcomes).

Leveraging multiple measurements over time before and after a policy change or intervention increases the internal validity of a quasi-experimental study and improves statistical power. For this reason, interrupted time series studies are a common quasi-experimental design and sometimes are the only option available to study nationwide nutrition or health policies. In these longitudinal studies, pre-intervention outcome data establish an underlying trend that is assumed to continue had the intervention not been implemented. Thus, any change in the outcome trend during the post-intervention period is determined to be the treatment effect. Interrupted time series analyses typically work best for outcomes that are likely to change soon after an intervention is introduced. Both interrupted time series and other types of longitudinal studies allow an investigator to assess changes within groups over time, and when a control group is available, to compare changes across groups over time (as was done in chapter two). If sufficient follow-up data are available, investigators can also assess if treatment effects end when the intervention is removed or if benefits are sustained over time (this approach was also incorporated into the chapter two analyses). Finally, for all longitudinal studies, analyses must account for clustering arising from repeat measurements on individuals, for example with GEE or HLM models (otherwise standards errors will be incorrectly small), and sample size calculations should account for design effects due to clustering.

Covariate Adjustment in Chapters One and Two

Chapters one and two adjusted for covariates in distinct ways. Chapter one adjusted for covariates in a pre/post study without a control group, whereas chapter two leveraged propensity score weights to balance potential confounders between the treatment and control groups. The following section adds more detail than was in the manuscripts describing the rationale of these two approaches.

In general, there are several scenarios to adjust for variable even when one is not particularly worried about confounding, for example in a pre/post study without a control group (ie, chapter one), within a randomized trial, in mediation analysis, or simply to improve the overall model prediction. The first reason would be to increase the precision of the main predictor. Even in randomized controlled trial, where the main predictor's beta should be unbiased with a sufficiently large sample size, investigators sometimes choose to adjust for other variables as they can potentially improve statistical precision with an appropriate number of known or probably confounders. (Other investigators may choose to only control for measured covariates in a randomized trial that have imperfect balance after randomization). However, model overfitting, in which an investigator adds too many variables into a statistical model, can worsen precision through increased collinearity and fewer degrees of freedom. The negative impacts of overfitting are even more pronounced when added variables are unlikely to be true confounders, so care should be taken to evaluate if covariates are probable confounders before adding them to a model.

In chapter one, the primary research question was to examine individual-level change in outcomes associated with produce prescription participation. With no control group and thus no differential distributions of confounding variables across comparison groups, there is no strict need to control for time-constant variables to limit confounding. Yet, there are some minor benefits to including potential confounders in the model. In the case of chapter one, adding covariates slightly improves statistical precision, although the difference was minimal and did not meaningfully change the results. Another reason to adjust for covariates in a pre/post study is to move away from a "variable-focused" paradigm and to a "model-focused" paradigm. In chapter one, while the inclusion of non-time-varying factors did not significantly impact the effect estimate, it does improve the overall model's prediction. This is important if a researcher uses marginal means or predicted means from the model to compute an individual's estimated outcome value. (In fact, chapter two used marginal means to report the difference in HbA1c between treatment and control at 6 months after program enrollment). The one drawback of adding potential confounders in a pre/post study would be losing a degree of freedom for each additional covariate added to the model; however, the chapter one sample size was sufficiently large and thus the inclusion didn't impact statistical inference. Either way, the results were similar with and without the added potential confounders, and an investigator could reasonably select either approach.

A final rationale to add covariates into a model is to isolate partial effects in mediation analyses. For example, imagine that Z is a partial mediator in the relationship X➡Y. To parse out the direct effect of X on Y through Z as a mediator, an investigator could add Z as a covariate in the regression model. This was done as an exploratory analysis within chapter one for a separate Tufts Friedman School produce prescription modelling study (outside the scope of this dissertation) to see if FV intake had a direct impact on HbA1c change independent of BMI mediated impacts on HbA1c.

Chapter two leveraged a propensity score weighting approach instead of "standard" controlling for confounding by adding covariates in the main regression model to account for differences between the treatment and control groups. The primary benefits of this approach are that overlap weights create both improved statistical precision and perfect covariate balance on potential confounders. This latter point mimics an important attribute of randomized controlled trials and acknowledges that an even distribution of a measured confounder across two groups cannot bias results. However, as compared to randomized trial, propensity score overlap weights can only create balance on measured covariates. Since an individual's propensity score is the probability of receiving treatment based on observed covariates used in the propensity score creation, not only do propensity scores take into consideration the impact of potential confounders on the outcome of interest, but also measure their collective prediction of receiving treatment in the first place. While these represent the theoretical rationale of using propensity scores in chapter two, interestingly, conducting the analyses without the propensity score weights (and instead using the predictors of the propensity score model as covariates in the main regression model) did not meaningfully change the results in the chapter two analyses.

Medically Tailored Meals

The final chapter in this dissertation is the first study to leverage available data to estimate the health and economic impacts of MTM expansion within Medicaid, Medicare, and private insurance to patients with diet-related, chronic disease and limitations in instrumental activities of daily living. Coverage for MTMs is not a mandated benefit within Medicaid or Medicare, but there is growing interest in health insurance coverage of MTMs, including recent legislation at the state and federal levels.[116,117] In practice, given the lack of national reimbursement and relatively few, small scale non-profit organizations scattered across the US, the service is unavailable to the vast majority of Americans. This type of modelling study complements existing literature by estimating national impacts of expanded MTM coverage while testing different underlying assumptions, thereby offering policymakers a range of plausible outcomes to guide decision making.

Chapter three compliments the program evaluations within the Wholesome Wave studies with a distinct methodology that modelled impacts of MTM expansion within Medicare, Medicaid, and private insurance for

patients with diet-related illness and limitations in activities of daily living. Chapter three provides useful predictions based on the best available data and incorporates the uncertainty inherent in all the model inputs. While the effect sizes for the impact of MTMs on healthcare utilization are derived from relatively few studies, it is encouraging that a recent abstract accepted for presentation at the upcoming American Public Health Association annual meeting in November 2022 described a randomized controlled trial of MTMs for patients with congestive heart failure which found a significant reduction in hospitalizations identical to the effect size derived from our meta-analysis of previous studies.[132] Chapter three highlights that MTMs could play a significant role in clinical care and U.S. health policy for patients with advanced diet-related illness, especially if future RCTs continue to confirm the effect sizes used in the chapter three model. This type of modelling exercise is highly useful for policy makers weighing the pros and cons of funding future programs, demonstration projects, or even legislation.

Future Questions and Methods

There are several key areas to explore in future research that build off this dissertation. To me personally, understanding the impacts of the benefit dollar value, program duration, and household size on produce prescription efficacy are among the most interesting. Additionally, future research should explore if produce prescriptions have a larger impact on health outcomes if benefits could be redeemed for other healthy food purchases like whole grains, nuts and beans, in addition to fruits and vegetables only. Similarly, within medically tailored meal research there is an opportunity to test dietary patterns and meal composition to improve the degree of medically tailoring to maximize impact on health outcomes.

Overall, future food is medicine evaluations should employ stronger methods, in particular among produce prescription evaluations. It is hard to imagine how a future pre/post study could meaningfully add to the literature, especially once the chapter one manuscript is published, which represents by far the largest new produce prescription evaluation to date. Randomized trials are the gold standard, but the propensity score weighting methods used for chapter two can easily be adapted for other settings. Some food is medicine programs may also lend themselves well to a regression discontinuity design if using a strict biomarker cutoff value for program eligibility and enrollment. Finally, the chapter one analyses taught me that maximal funding and staff effort should be exerted to eliminate missing data during program implementation and data collection. No matter how strong the study design missing data will limit internal validity, even in a randomized controlled trial, and limiting the impacts of missing data should be a priority in study design.

Impact on Policy

The research in this dissertation has already impacted U.S. health and food policy developments. Most notably, the chapter three manuscript on MTM expansion was shared with the Congressional Budget Office and

after reviewing the manuscript, the CBO economists agreed that MTMs could be cost savings if appropriately targeted. This means that the CBO would score future MTM legislation as cost-savings, which presents a real opportunity to advance policy as Rep. Jim McGovern has introduced legislation to create a large MTM pilot within Medicare. Scoring the bill as cost savings significantly increases the likelihood that the legislation would pass. Rep. McGovern also organized a congressional visit to the Tufts University Friedman School of Nutrition Science and Policy in spring 2022 in which findings from chapter one and chapter three were shared. Dissertation findings have also been incorporated into letters from the National Produce Prescription Collaborative to the Biden administration in preparation for the White House Conference on Hunger, Nutrition and Health.

Finally, I was able to build on the research within this dissertation through my work as a writer on the consensus report compiled by the Task Force on Hunger, Nutrition and Health co-led by Tufts University in preparation for the White House Conference.[133] Recommendations to expand medically tailored meal and produce prescription access to Americans with diet-related illness made it into the final National Strategy on Hunger, Nutrition and Health, highlighting the potential for this research to expand in the coming decade, and most importantly, the potential of such research and policy to improve the health and wellbeing of millions of Americans.

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As chair of my committee, Dr. Mozaffarian connected me with numerous and significant opportunities, including working as writer on the report by the Task Force on Hunger, Nutrition and Health in preparation for the White House Conference on Hunger, Nutrition and Health, gaining a leadership role on the National Produce Prescription Collaborative steering committee, sharing research with the Congressional Budget Office, meeting with a delegation of the U.S. House of Representatives at Tufts, and helping to coordinate the Flexible Services Medically Tailored Meal Consortium, an exciting research initiative that I plan to be involved with after graduation. I also owe improvements in my scientific writing to Dr. Mozaffarian for all the detailed edits he provided the past 2 years. I'm grateful to Dr. Zhang who connected me with additional research opportunities within the larger produce prescription evaluation team and instilled the importance of checking data quality, interrogating methods, and replicating results. Dr. Wong was instrumental in the MTM modelling paper and thesis proposal preparations, and throughout the entire process was a grounding force in this work. Finally, Dr. Berkowitz's deep command of study designs, causal inference and communicating the nuance of scientific findings improved aspects of all the dissertation chapters.

Finally, I would also like to thank all my other coauthors involved in my dissertation papers for their contributions, in particular Dr. Peilin Shi, Dr. Ken Chui, Dr. Fred Cuddhea, and Brianna Lauren for their collaboration in the statistical analyses and modelling, and to Zhongu Li and Sylara Cruz for making it all happen within the large research teams.

Tables and Figures

Table 1: Description of Participant Eligibility and Program Structure of Pooled Wholesome Wave Produce Prescription Programs

	Participants Eligibility		*Incentive and Program Structure*					
Program Name	**Population**	**Eligibility**	**US State**	**Healthcare Partner***	**Monthly Produce Prescription Dollars**	**Duration (months)**	**Setting**	**Delivery Model**
2016 Los Angeles Target FVRx Program	Pediatric	Children age 2-18 at risk for developing chronic disease as determined by their healthcare provider based on being overweight or obese and/or having poor nutrition or food insecurity.	CA	Eisner Health	$180 for a household of 2 $210 for a household of 3 $270 for a household of 4 $300 for a household of 5+	6	Grocery (Target) and farmers' markets	Voucher
2017 Three-State Target FVRx Program	Pediatric	Children age 2-18 at risk for developing chronic disease as determined by their healthcare provider based on being overweight or obese and/or having poor nutrition or food insecurity.	CA, TX, FL	Eisner Health (CA), Hermann Memorial (TX), Jessie Trice Health Center (FL)	$90-120 for a household of 2 $150-210 for a household of 3 $180-270 for a household of 4 $270-300 for a household of 5+	6-9	Grocery (Target) and farmers' markets	Voucher
2018-2019 Chobani Reward Card Program	Pediatric	Children age 2-18 with household food insecurity. Overweight or obesity was not a requirement for eligibility.	NY, ID	Chenango Memorial Health (NY), Family Health Services (ID)	$60	6-7	Grocery	Card
2014 Blue Cross Blue Shield Program	Adult	Adults with a diagnosis of diabetes in Minneapolis, MN recruited from a community health center serving a low-income neighborhood.	MN	Northpoint Health and Wellness, CentraCare Health System	$30 per household member	4	Grocery, farmers market	Voucher
2019 Humana	Adult		FL	Community Health Centers of Pinellas	$15	8	Grocery (Walmart)	Card

Reloadable Gift Card Program		Eligibility criteria required food insecurity and at least one chronic disease. Participants were referred from a Federally Qualified Health Center.						
2019 Ohio Department of Health Produce Voucher Program	Adult	Adults with diabetes or pre-diabetes. Although food insecurity or low-income was not a criteria, participants were recruited from health centers in low-income neighborhoods.	OH	Community Health and Wellness Partners of Logan County, Hopewell Health Centers of Athens County	$30 per household member up to four members	10	Grocery, farmers' market	Voucher
2020 Ohio Department of Health Produce Voucher Program	Adult	Adults with diabetes or pre-diabetes. Although food insecurity or low-income was not a criteria, participants were recruited from health centers in low-income neighborhoods.	OH	Community Health and Wellness Partners of Logan County, Hopewell Health Centers of Athens County	$90	10	Grocery, farmers' market	Voucher
2020 Hartford Healthcare Funded Program	Adult	HbA1c greater than 6.5% and receiving care at one of two Hartford Healthcare clinics. While food insecurity and income were not eligibility requirements, participants were recruited from zip codes with higher levels of poverty and many of the participants are on Medicaid.	CT	Hartford Healthcare	$60	6	Grocery	Voucher
2020 Multi-State, Weight Watchers Produce Rx Program	Adult	Adults with overweight or obesity referred by health centers in 9 states.	FL, NC, GA, MN, CO, CA, TX, NY	Broward Community Health (FL), Grady Health (GA), UNC Charlotte (NC), CEAP Health Partner (MN), Behavioral Health Services (CA), Mental Health Center of Denver (CO), Weight Watchers only (TX, NY)	$50	6-9	Primarily grocery (Walmart) with some sites using home delivery or food panty	Card, with one site using vouchers and one site using an online app.

*Some healthcare partners recruited participants from multiple clinics within their system.
Programs that occurred in years 2014 - 2017 had two to three in-person nutrition education and cooking demonstration events at which participants received produce prescriptions for the next two to three months. Starting in 2018, Wholesome Wave dropped the attendance of classes as a condition to receive the next round of produce prescriptions, and instead offered optional nutrition education in partnership with universities through the Expanded Food & Nutrition Education Program or through the clinic's own nutritional programming

Table 2: Baseline Characteristics of 3,881 Participants in 9 Produce Prescription Programs across 22 US Sites

Characteristic*	**Adult Population N=2064**	**Child Population N=1817**
Age, *years,* mean (SD)	54.4 (14.8)	9.27 (4.2)
Female, N (%)	1,459 (70.7)	929 (51.4)
Race/Ethnicity, N (%)	Non-Hispanic White: 615 (29.8) Non-Hispanic Black: 929 (45.1) Hispanic: 441 (21.4) Other: 75 (3.6)	Non-Hispanic White: 159 (9.2) Non-Hispanic Black: 227 (13.1) Hispanic: 1,308 (75.5) Other: 39 (2.3)
Household Size, *number of people,* mean (SD)	2.7 (1.6)	4.6 (1.4)
Household SNAP Enrollment, N (%)		1,073 (62.7)
Household WIC Enrollment, N (%)		1,428 (82.6)
Insurance Status, N (%)		Medicaid, CHIP: 1,358 (79.0) Private: 67 (3.9) Uninsured: 196 (11.4) Other: 95 (5.5)
Parent / Caregiver Employment, N (%)		Full-time (40 hrs/wk): 318 (18.5) Part-time (<40 hrs/wk): 416 (24.3) Unemployed: 652 (38.0) Other: 329 (19.2)
	Baseline Outcome Measurements	
FV Intake, *cups per day,* mean (SD)	2.7 (1.9)	3.4 (2.8)
Food Insecurity, N (%)	1,305 (65.8)	737 (49.4)

HBA1c, *%,* mean (SD)	8.7 (1.8)	
Systolic Blood Pressure, *mm Hg,* mean (SD)	144.5 (13.6)	
Diastolic Blood Pressure, *mm Hg,* mean (SD)	87.5 (7.4)	
Body Mass Index, Kg/m^2, mean (SD)	37.3 (8.3)	
Body Mass Index z-score for sex and age, *z-score,* mean (SD)		1.9 (0.5)
Health Status, N (%)	Excellent: 59 (3.3) Very Good: 214 (12.0) Good: 685 (38.4) Fair: 675 (37.8) Poor: 152 (8.5)	Excellent: 117 (15.4) Very Good: 189 (24.9) Good: 325 (42.8) Fair: 99 (13.0) Poor: 30 (3.9)

Abbreviations: SNAP = Supplemental Nutrition Assistance Program, WIC = Special Supplemental Nutrition Assistance Program for Women, Infants, and Children, HbA1c = glycated hemoglobin

* Sociodemographic variables are listed when they were measured in all adult or child programs (ie, SNAP, WIC, insurance status and employment were not assessed in all adult programs). Sample size for some sociodemographic variables do not add up to the number of participants enrolled as participants skipped survey questions in the baseline survey; sample size for participants with baseline values in outcome measures was 1290 (adults FV intake), 1745 (children FV intake), 1,785 (adults self-reported health), 760 (children self-reported health), 1,982 (adults food insecurity), 1491 (children food insecurity children), 741 (HbA1c), 419 (SBP), and 439 (DBP), 762, (adults BMI), 953 (children BMI z-score). No program measured all outcomes.

Table 3: Pooled Changes in F&V Intake, Food Insecurity, and Health Outcomes Associated with Produce Prescription Program Participation.

Outcome	Population at Baseline	N	Pre Unadjusted Mean (SD) or %	Post Unadjusted Mean (SD) or %	Estimate (95% CI)*	P-value
				All Adults		
Fruit and Vegetable Intake, *cups per day*	All adults, age 18+ years	715	3.54 (2.88)	3.89 (2.25)	0.83 (0.67, 1.00) †	<0.0001
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	All adults, age 18+ years	738	Excellent: 2.5% Very Good: 10.4% Good: 39.1% Fair: 39.6% Poor: 8.4%	Excellent: 4.7% Very Good: 16.4% Good: 42.6% Fair: 31.6% Poor: 4.7%	2.05 (1.66, 2.52)	<0.0001
				All Children		
Fruit and Vegetable Intake, *cups per day*	All children, age 2-17 years	1070	3.47 (2.83)	3.73 (2.19)	0.21 (0.03, 0.39) †	0.003
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	All children, age 2-17 years	486	Excellent: 13.5% Very Good: 23.5% Good: 44.2% Fair: 14.3% Poor: 4.5%	Excellent: 23.5% Very Good: 31.2% Good: 34.9% Fair: 7.3% Poor: 3.1%	2.52 (1.95, 3.26)	<0.0001
				All Households		
Food Insecurity, *odds ratio (binary)* ‡	Households	1816	Yes: 56.3% No: 43.7%	Yes: 48.2% No: 51.8%	0.54 (0.45, 0.64) †	<0.0001
				Adults with Poor Cardiometabolic Health at Baseline		
HbA1c, *(%)*	Adults with HbA1c $\geq$ 6.5%	605	8.74 (1.80)	8.42 (1.88)	-0.34 (-0.46, -0.20) †	<0.0001
Systolic Blood Pressure, *mmHg*	Adults with systolic BP $\geq$ 130 mm Hg	310	140.23 (13.59)	135.97 (16.47)	-8.79 (-10.54, -7.04) †	<0.0001

Diastolic Blood Pressure, mmHg	Adults with diastolic BP ≥ 80 mm Hg +	329	87.05 (7.21)	82.15 (9.46)	-4.96 (-5.99, -3.94) †	<0.0001
Body Mass Index, k*g/m2*	Adults with BMI ≥ 25 kg/m2	570	37.16 (8.20)	36.80 (7.96)	-0.34 (-0.62, -0.07)	0.014
			Adults with Very Poor Cardiometabolic Health at Baseline			
HbA1c, *(%)*	Adults with HbA1c ≥ 8.0%	361	9.76 (1.65)	9.15 (1.89)	-0.61 (-0.81, -0.40)	<0.0001
Systolic Blood Pressure, *mmHg*	Adults with systolic BP ≥ 140 mm Hg	160	153.83 (12.19)	142.32 (17.34)	-12.38 (-15.16, -9.60)	<0.0001
Diastolic Blood Pressure, mmHg	Adults with diastolic BP ≥ 90 mm Hg +	93	95.86 (7.03)	86.45 (10.65)	-9.81 (-12.09, -7.52)	<0.0001
Body Mass Index, k*g/m2*	Adults with BMI ≥ 30 kg/m2	467	39.23 (7.53)	38.76 (7.43)	-0.49 (-0.81, -0.16)	<0.0001
			Children with Overweight and Obesity at Baseline			
Body Mass Index z-score for age and sex, *z-score*	Children age 2-18 with BMI percentile for age and sex ≥ 85th percentile	577	1.94 (0.51)	1.92 (0.62)	-0.01 (-0.04, 0.03)	0.401
			Children with Obesity at Baseline			
Body Mass Index z-score for age and sex, *z-score*	Children age 2-18 with BMI percentile for age and sex ≥ 95th percentile	408	2.19 (0.40)	2.16 (0.54)	-0.01 (-0.06, 0.03)	0.603

***** Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Pediatric analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status.
† p<0.001 for the 5 co-primary outcomes, all passing the Bonferroni-corrected alpha=0.01 for statistical significance.
‡ Two programs assessed food insecurity *"within the past 12 months",* meaning the endpoint surveys captured the entire program period plus several months prior to enrollment.

Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for program location and for within-person repeat measures (i.e., pre and post).

Table S1: Missingness at Program End by Outcome and Wholesome Wave Program

Program	Sample Size at Baseline	FV Intake	Food Insecurity	HbA1c	SBP	DBP	BMI	BMI z-score	Health Status
2016 Los Angeles Eisner FVRx Program	535	365/509 (28.3%)	382/533 (27.7%)	--	--		--	--	360/502 (27.9%)
2017 Three-State Target FVRx Program	1176	620/978 (36.6%)	638/1195 (41.7%)	--	--		--	539/799 (32.5%)	--
2018-2019 Chobani Reward Card Program	286	150/258 (41.9%)	--	--	--		--	80/154 (48.1%)	150/258 (41.9%)
2014 Blue Cross Blue Shield Program	102	76/92 (17.4%)	58/101 (42.6%)	58/78 (25.6%)	39/45 (13.3%)	41/47 (12.8%)	76/90 (15.6%)	--	58/101 (42.6%)
2019 Humana Reloadable Gift Card Program*	505	--	64/328 (80.5%)	36/40 (10%)	34/35 (2.86%)	43/44 (2.27%)	61/73 (16.4%)		68/363 (81.3%)
2019 Ohio Department of Health Produce Voucher Program	241	94/113 (16.8%)	95/113 (15.9%)	177/177 (0%)	113/113 (0%)	116/116 (0%)	230/230 (0%)	--	--
2020 Ohio Department of Health Produce Voucher Program	186	126/186 (32.3%)	117/173 (32.4%)	120/132 (9.1%)	83/99 (16.2%)	83/102 (18.6%)	143/164 (12.8%)	--	126/186 (32.3%)
2020 Hartford Healthcare Funded Program*	321	--	108/321 (66.4%)	244/290 (15.9%)	--		--	--	108/321 (66.4%)
2020 Multi-State, Weight Watchers Produce Rx Program	809	437/759 (42.4%)	443/806 (45%)	--	56/56 (0%)	56/56 (0%)	78/78 (0%)	--	419/801 (47.7%)

Percent missingness is in (). Sample size varies by outcome within program as some participants skipped survey questions and some partner clinics within a given program where unable to share clinical biomarkers.
*Humana and Hartford programs had disruptions in the final survey administration due to the COVID-19 pandemic (impacted health status and food insecurity missingness, but not clinical biomarkers as these were measured and shared by clinical partners).

Table S2: Pooled Changes in F&V Intake, Food Insecurity, and Health Outcomes Associated with Produce Prescription Program Participation using Multiple Imputation

Outcome	Population at Baseline	N	Estimate (95%CI)
	All Adults		
Fruit and Vegetable Intake, *cups per day*	Adults, including parents / caregivers from pediatric programs	1,150	0.85 (0.68, 1.02) †
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	Adults, including parents / caregivers from pediatric programs	1,772	1.62 (1.30, 2.02)
	All Pediatrics		
Fruit and Vegetable Intake, *cups per day*	Children (all age 2-18)	1,745	0.26 (0.06, 0.45) †
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	Children (all age 2-18)	760	2.37 (1.70, 3.31)
	All Households		
Food Insecurity, *odds ratio (binary)* ‡	Households	3,428	0.63 (0.52, 0.76) †
	Adults with Poor Cardiometabolic Health at Baseline		
HbA1c, *(%)*	Adults with HbA1c $\geq$ 6.5%	709	-0.29 (-0.42, -0.16) †
Systolic Blood Pressure, *mmHg*	Adults with systolic BP $\geq$ 130 mmHg	348	-8.38 (-10.13, -6.62) †
Diastolic Blood Pressure, mmHg	Adults with diastolic BP $\geq$ 80 mmHg	368	-4.94 (-5.96, -3.92) †
Body Mass Index, kg*/m2*	Adults with BMI $\geq$ 25kg/m2	635	-0.36 (-0.64, -0.09)

Adults with Very Poor Cardiometabolic Health at Baseline			
HbA1c, *(%)*	Adults with HbA1c ≥ 8.0%	418	-0.58 (-0.78, -0.38)
Systolic Blood Pressure, *mmHg*	Adults with systolic BP ≥ 140 mmHg	186	-11.10 (-13.84, -8.37)
Diastolic Blood Pressure, mmHg	Adults with diastolic BP ≥ 90 mmHg +	108	-9.43 (-11.70, -7.16)
Body Mass Index, kg*/m2*	Adults with BMI ≥ 30kg/m2	520	-0.52 (-0.85, -0.19)
Children with Overweight and Obesity at Baseline			
Body Mass Index z-score for age and sex, *z-score*	Children age 2-18 with BMI percentile for age and sex ≥ 85th percentile	953	-0.01 (-0.06, 0.04)
Children with Obesity at Baseline			
Body Mass Index z-score for age and sex, *z-score*	Children age 2-18 with BMI percentile for age and sex ≥ 90th percentile	674	-0.03 (-0.09, 0.04)

*Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Pediatric analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status.
† $p<0.01$ for the 5 co-primary outcomes, all passing the Bonferroni-corrected alpha=0.01 for statistical significance.
‡ Two programs assessed food insecurity *"within the past 12 months",* meaning the endpoint surveys captured the entire program period plus several months prior to enrollment.

Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for program location and for within-person repeat measures (i.e., pre and post).

Table S3: F&V Intake, Food Insecurity, and Health Outcomes Associated with Produce Prescription Program Participation Excluding Locations with >50% Missingness of Endpoint Outcomes

Outcome	Population at Baseline	N	Estimate (95%CI)*
	All Adults		
Fruit and Vegetable Intake, *cups per day*	Adults, including parents / caregivers from pediatric programs	577	0.80 (0.62, 0.99) †
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	Adults, including parents / caregivers from pediatric programs	408	2.23 (1.68, 2.97)
	All Pediatrics		
Fruit and Vegetable Intake, *cups per day*	Children (all age 2-18)	944	0.20 (0.00, 0.39) †
Health Status, *odds ratio of improving one category from poor (5) to excellent (1)*	Children (all age 2-18)	425	2.68 (2.04, 3.54)
	All Households		
Food Insecurity, *odds ratio (binary)* ‡	Households	1,754	0.52 (0.44, 0.63) †
	Children with Overweight and Obesity at Baseline		
Body Mass Index z-score for age and sex, *z-score*	Children age 2-18 with BMI percentile for age and sex $\geq$ 85th percentile	517	-0.01 (-0.05, 0.02)

*Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Pediatric analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status.
† $p<0.001$ for the co-primary outcomes (passing the Bonferroni-corrected alpha=0.01 for statistical significance) with the exception of child FV intake ($p=0.04$).
‡ Two programs assessed food insecurity *"within the past 12 months",* meaning the endpoint surveys captured the entire program period plus several months prior to enrollment.
Only outcomes that included at least one program location with >50% missingness are listed. Of the 22 program locations, 4 locations assessing adult FV intake were dropped, 1 location for child BMI-z-score, 2 locations for child FV intake, 8 locations for food insecurity, and 8 locations for adult health status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for program location and for within-person repeat measures (i.e., pre and post).

Table S4: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by if Program Implementation Occurred before or during the COVID-19 Pandemic

	Program before COVID-19		Program during COVID-19		
	n	Effect size (95% CI)	n	Effect size (95% CI)	P for interaction
FV intake (adults)	168	1.76 (1.43 to 2.10)	547	0.55 (0.36, 0.73)	<0.0001
Food insecurity	1,211	0.49 (0.39, 0.61)	605	0.63 (0.47, 0.84)	0.31
Health status (adults)	126	2.70 (2.16, 3.38)	612	1.98 (1.57, 2.49)	0.26
HbA1c (≥6.5%)	268	-0.50 (-0.70, -0.29)	337	-0.20 (-0.38, -0.02)	0.03
SBP (≥ 130 mmHg)	184	-8.99 (-11.5, -6.50)	126	-8.09 (-10.7, -5.48)	0.63
DBP (≥ 80 mmHg)	197	-4.91 (-6.33, -3.49)	132	-5.05 (-6.54, -3.56)	0.89
BMI (≥ 30kg/m2)	364	-0.33 (-0.54, -0.12)	206	-0.37 (-1.04 to 0.31)	0.90

"*During COVID-19*" is defined as any produce prescription program that operated after March 2020. All child programs ended prior to March 2020.
Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).

Table S5: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by Household Size for Adults

	1 Person		2 People		3+ People		P for interaction
	n	Effect size (95% CI)	n	Effect size (95% CI)	n	Effect size (95% CI)	
FV intake	148	0.66 (0.35, 0.98)	216	0.84 (0.56, 1.13)	351	0.89 (0.64, 1.15)	0.58
Health status	166	2.49 (1.58, 3.93)	222	1.67 (1.14, 2.45)	350	2.19 (1.62, 2.96)	0.27
HbA1c (≥6.5%)	158	-0.23 (-0.52, 0.06)	216	-0.43 (-0.63, -0.23)	231	-0.31 (-0.54, -0.08)	0.51
SBP (≥ 130 mmHg)	63	-9.44 (-14.95, -3.94)	111	-7.74 (-10.2, -5.23)	136	-8.96 (-11.60, -6.35)	0.76
DBP (≥ 80 mmHg)	61	-4.51 (-7.23, -1.79)	114	-5.56 (-7.29, -3.83)	154	-4.71 (-6.18, -3.23)	0.71
BMI (≥ 30kg/m2)	111	-0.61 (-1.31, 0.09)	200	-0.31 (-0.61, -0.01)	259	-0.25 (-0.73, 0.23)	0.64

Adult analyses control for age, sex, and race/ethnicity.
Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).
Food insecurity not included as it was measured at the household level.

Table S6: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by Household Size for Children

	2-3 People		4 People		5+ People		P for interaction
	n	Effect size (95% CI)	n	Effect size (95% CI)	n	Effect size (95% CI)	
FV intake	197	0.38 (-0.04, 0.79)	326	0.00 (-0.32, 0.31)	547	0.29 (0.03, 0.55)	0.38
Health status	91	3.03 (1.07, 8.54)	163	1.88 (1.21, 2.93)	233	2.80 (1.26, 6.26)	0.27
BMI z-score	106	0.06 (-0.00, 0.11)	161	-0.08 (-0.16, -0.00)	310	0.01 (-0.04, 0.06)	0.03

Children analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).
Food insecurity not included as it was measured at the household level.

Table S7: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by Age

	Children 2-17		Adults 18-64		Adults 65+		P for interaction
	n	Effect size (95% CI)	n	Effect size (95% CI)	n	Effect size (95% CI)	
FV intake (adults)	---	---	559	0.78 (0.59, 0.98)	156	1.00 (0.69, 1.32)	0.28
FV intake (children)	1070	0.21 (0.03, 0.39)	---	---	---	---	---
Food insecurity	996	0.40 (0.31, 0.52)	620	0.72 (0.53, 0.97)	200	0.48 (0.28, 0.82)	0.04
Health status (adults)	---	---	560	2.09 (1.65, 2.65)	178	2.05 (1.32, 3.19)	0.55
Health status (children)	487	2.50 (1.93, 3.23)	---	---	---	---	---
HbA1c (≥6.5%)	---	---	407	-0.32 (-0.51, -0.14)	198	-0.34 (-0.52, -0.17)	0.89
SBP (≥ 130 mmHg)	---	---	238	-9.10 (-11.18, -7.01)	72	-7.05 (-10.8, -3.30)	0.35
DBP (≥ 80 mmHg)	---	---	276	-4.66 (-5.80, -3.52)	53	-6.57 (-9.05, -4.08)	0.18
BMI (≥ 30kg/m2)	---	---	438	-0.41 (-0.76, -0.06)	132	-0.12 (-0.44, 0.20)	0.39

Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Children analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).

Table S8: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by Sex

	Female		Male		P for interaction
	n	Effect size (95% CI)	n	Effect size (95% CI)	
FV intake (adults)	537	0.89 (0.70, 1.08)	178	0.65 (0.34, 0.97)	0.22
FV intake (children)	544	-0.02 (-0.29, 0.25)	526	0.45 (0.22, 0.69)	0.01
Food insecurity	1115	0.52 (0.42, 0.65)	701	0.57 (0.43, 0.76)	0.61
Health status (adults)	559	2.02 (1.59, 2.56)	179	2.15 (1.40, 3.31)	0.78
Health status (children)	237	2.91 (1.22, 6.92)	250	2.18 (1.53, 3.11)	0.41
HbA1c (≥6.5%)	370	-0.44 (-0.61, -0.27)	235	-0.15 (-0.38, 0.07)	0.04
SBP (≥ 130 mmHg)	200	-9.14 (-11.3, -7.03)	110	-7.67 (-11.10, -4.27)	0.45
DBP (≥ 80 mmHg)	220	-4.20 (-5.39, -3.02)	109	-6.50 (-8.51, -4.50)	0.04
BMI (≥ 30kg/m2)	376	-0.39 (-0.76, -0.01)	194	-0.25 (-0.62, 0.12)	0.64
BMI z-score (≥ 85th percentile)	298	-0.02 (-0.06, 0.02)	278	0.00 (-0.06, 0.06)	0.58

Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Children analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).

Table S9: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by Race/Ethnicity

	Non-Hispanic White		Non-Hispanic Black		Hispanic		P for interaction
	n	Effect size (95% CI)	n	Effect size (95% CI)	n	Effect size (95% CI)	
FV intake (adults)	311	0.81 (0.59, 1.04)	309	0.77 (0.49, 1.05)	64	1.39 (0.82, 1.96)	0.13
FV intake (children)	82	0.17 (-0.37, 0.71)	73	0.61 (-0.06, 1.28)	892	0.21 (0.01, 0.41)	0.54
Food insecurity	301	0.81 (0.54, 1.22)	403	0.35 (0.23, 0.53)	1050	0.52 (0.41, 0.66)	0.01
Health status (adults)	311	2.06 (1.37 to 3.09)	309	2.19 (1.60 to 2.99)	64	1.80 (1.14 to 2.83)	0.80
Health status (children)	76	2.44 (1.18, 5.04)	4	---	395	2.51 (1.89, 3.33)	0.70
HbA1c ($\geq$6.5%)	311	-0.47 (-0.65, -0.29)	62	-0.01 (-0.63, 0.60)	208	-0.21 (-0.44, 0.01)	0.07
SBP ($\geq$ 130 mmHg)	199	-9.34 (-11.8, -6.84)	89	-8.43 (-11.0, -5.82)	11	0.18 (-8.80, 9.16)	0.17
DBP ($\geq$ 80 mmHg)	204	-5.81 (-7.15, -4.47)	96	-3.66 (-5.52, -1.80)	18	-3.67 (-8.10, 0.77)	0.15
BMI ($\geq$ 30kg/m2)	386	-0.30 (-0.57, -0.02)	133	-0.53 (-1.38, 0.33)	35	-0.41 (-1.16, 0.33)	0.80
BMI z-score ($\geq$ 85th percentile)	47	-0.17 (-0.37, 0.02)	57	0.06 (0.02, 0.09)	462	0.00 (-0.04, 0.04)	0.02

Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Pediatric analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).

Table S10: Pooled Changes in Outcomes Associated with Produce Prescription Participation Stratified by SNAP Enrollment

	SNAP participants		Non-SNAP participants		P for interaction
	n	Effect size (95% CI)	n	n	
FV intake (adults)	117	1.43 (1.01 to 1.85)	151	1.38 (1.05 to 1.72)	0.87
FV intake (children)	666	0.23 (-0.08 to 0.55)	404	0.20 (-0.01 to 0.42)	0.88
Food insecurity	736	0.37 (0.27, 0.50)	542	0.63 (0.44, 0.89)	0.01
Health status (adults)	106	1.66 (0.97 to 2.84)	121	4.89 (2.62 to 9.12)	0.08
Health status (children)	294	2.22 (1.60, 3.09)	192	3.06 (2.05, 4.58)	0.14
BMI z-score ($\geq 85^{th}$ percentile)	363	-0.01 (-0.05, 0.03)	199	-0.02 (-0.09, 0.06)	0.80

Adult sample size and outcomes are limited to programs that measured SNAP enrollment. Adult and household analyses were adjusted for age, sex, race/ethnicity, and household size. Pediatric analyses were adjusted for age, sex, race/ethnicity, household size, SNAP enrollment, WIC enrollment, insurance coverage, and parent / caregiver employment status. Hierarchal Linear Models were used for continuous outcomes and Generalized Linear Mixed Models for categorical outcomes with random effects for Wholesome Wave program location and random effects for repeat measures on individuals (ie, pre and post).

Chapter 2 Tables and Figures

Table 2.1: Characteristics of Produce Rx Participants and Controls

Characteristics	**Treatment** (n=252)	**Control** (n=534)	**Standardized mean difference**	**Treatment, weighted** (n=252)	**Control, weighted** (n=534)	**Standardized mean difference, weighted**
Age at enrollment, *years*, mean (SD)	61 (13.6)	58.4 (14.2)	0.19	60.4 (10)	60.4 (7.2)	0.0
Female, n (%)	164 (65.1)	293 (54.9)	0.21	164 (61.7)	293 (61.7)	0.0
Race/ethnicity, n (%)						
Non-Hispanic white	8 (3.2)	89 (16.7)	-0.46	8 (4.9)	89 (4.9)	0.0
Non-Hispanic black	16 (6.3)	92 (17.2)	-0.34	16 (8.7)	92 (8.7)	0.0
Hispanic	218 (86.5)	317 (59.4)	0.64	218 (81.0)	317 (81)	0.0
Other	8 (3.2)	32 (6.0)	-0.13	8 (4.6)	32 (4.6)	0.0
Insurance status, n (%)						
Medicaid	123 (48.8)	205 (38.4)	0.21	123 (45.1)	205 (45.1)	0.0
Medicare	113 (44.8)	226 (42.3)	0.05	113 (46.4)	226 (46.4)	0.0
Private insurance / Other	16 (6.3)	103 (19.3)	-0.39	16 (8.5)	103 (8.5)	0.0
Cigarette smoking, n (%)						
Never smoked	121 (48.0)	260 (48.7)	-0.01	121 (47.2)	260 (47.2)	0.0
Former smokers	95 (37.7)	183 (34.3)	0.07	95 (36.7)	183 (36.7)	0.0
Current smokers	36 (14.3)	91 (17.0)	-0.08	36 (16.1)	91 (16.1)	0.0
Comorbidities, n (%)						
Myocardial Infarction	38 (15.1)	71 (13.3)	0.05	38 (14.4)	71(14.4)	0.0
Congestive Heart Failure	61 (24.2)	125 (23.4)	0.02	61 (23.9)	125 (23.9)	0.0
Cancer	21 (8.3)	42 (7.9)	0.02	21 (7.3)	42 (7.3)	0.0
COPD	119 (47.2)	203 (38)	0.19	119 (44.4)	203 (44.4)	0.0
Stroke	26 (10.3)	63 (11.8)	-0.05	26 (10.4)	63 (10.4)	0.0
Renal Disease	57 (22.6)	132 (24.7)	-0.05	57 (22.3)	132 (22.3)	0.0
Bariatric Surgery	2 (0.8)	11 (2.1)	-0.11	2 (1.0)	11(1.0)	0.0
Cardiometabolic Markers at Enrollment, mean (SD)						
HbA1c, %	8.8 (1.7)	8.2 (2.1)	0.29	8.6 (1.1)	8.6 (1.2)	0.0

SBP, mmHg	136.5 (18.3)	134 (18.5)	0.15	136.2 (13.0)	136.2 (9.4)	0.0
DBP, mmHg	74.5 (10.9)	74.5 (11.4)	0.01	74.5 (7.8)	74.5 (5.3)	0.0
BMI, kg/m2	32.6 (7.0)	33.1 (8.4)	-0.05	32.5 (5.1)	32.5 (3.9)	0.0
				.		
Healthcare Utilization 6-months prior to enrollment, mean (SD)						
# ED visits	0.01 (0.08)	0.01 (0.07)	0.05	0.00 (0.04)	0.00 (0.03)	0.0
# Inpatient hospitalizations	0.01 (0.10)	0.05 (0.26)	-0.19	0.02 (0.09)	0.02 (0.07)	0.0
# Outpatient office visits	0.8 (1.6)	0.7 (1.7)	0.08	0.8 (1.1)	0.8 (0.7)	0.0
# Outpatient hospital visits	1.8 (0.4)	1.5 (0.5)	0.24	3.3 (2.4)	3.3 (1.6)	0.0
# Clinical consults	2.2 (2.6)	1.7 (2.4)	0.19	2.0 (1.7)	2.0 (1.2)	0.0

Table 2.2: Change in Hba1c, Blood Pressure, and Body Mass Index between Treatment and Control Groups

Outcome	6-Month			9-Month		
	Change in Treatment	Change in Control	Between Group Difference	Change in Treatment	Change in Control	Between Group Difference
	mean (SE)	*mean (SE)*	*β (95% CI)*	*mean (SE)*	*mean (SE)*	*β (95% CI)*
HbA1c, *%*	-0.11 (0.06)	-0.24 (0.07)	0.13 (-0.05, 0.32)	-0.13 (0.06)	-0.19 (0.08)	0.06 (-0.13, 0.25)
SBP, *mmHg*	-0.93 (1.14)	-4.78 (1.67)	3.85 (-0.12, 7.82)	-0.41 (1.61)	-4.44 (1.54)	4.03 (-0.34, 8.40)
DBP, *mmHg*	-2.61 (0.61)	-1.79 (0.55)	-0.82 (-2.42, 0.79)	-2.48 (0.58)	-1.61 (0.54)	-0.87 (-2.42, 0.67)
BMI, kg/m^2	-0.02 (0.57)	0.20 (0.59)	-0.22 (-1.83,1.38)	-0.13 (0.57)	0.38 (0.58)	-0.51 (-2.10, 1.08)

N=252 in treatment group, N= 534 in control group

Results are from longitudinal, generalized estimating equation models applying overlap weights created from propensity scores. All measures taken from baseline to 6 months were included in the 6-month analysis; all measures taken from baseline to 9 months were included in the 9-month analysis. Produce prescription program lasted 6 months for each participant.

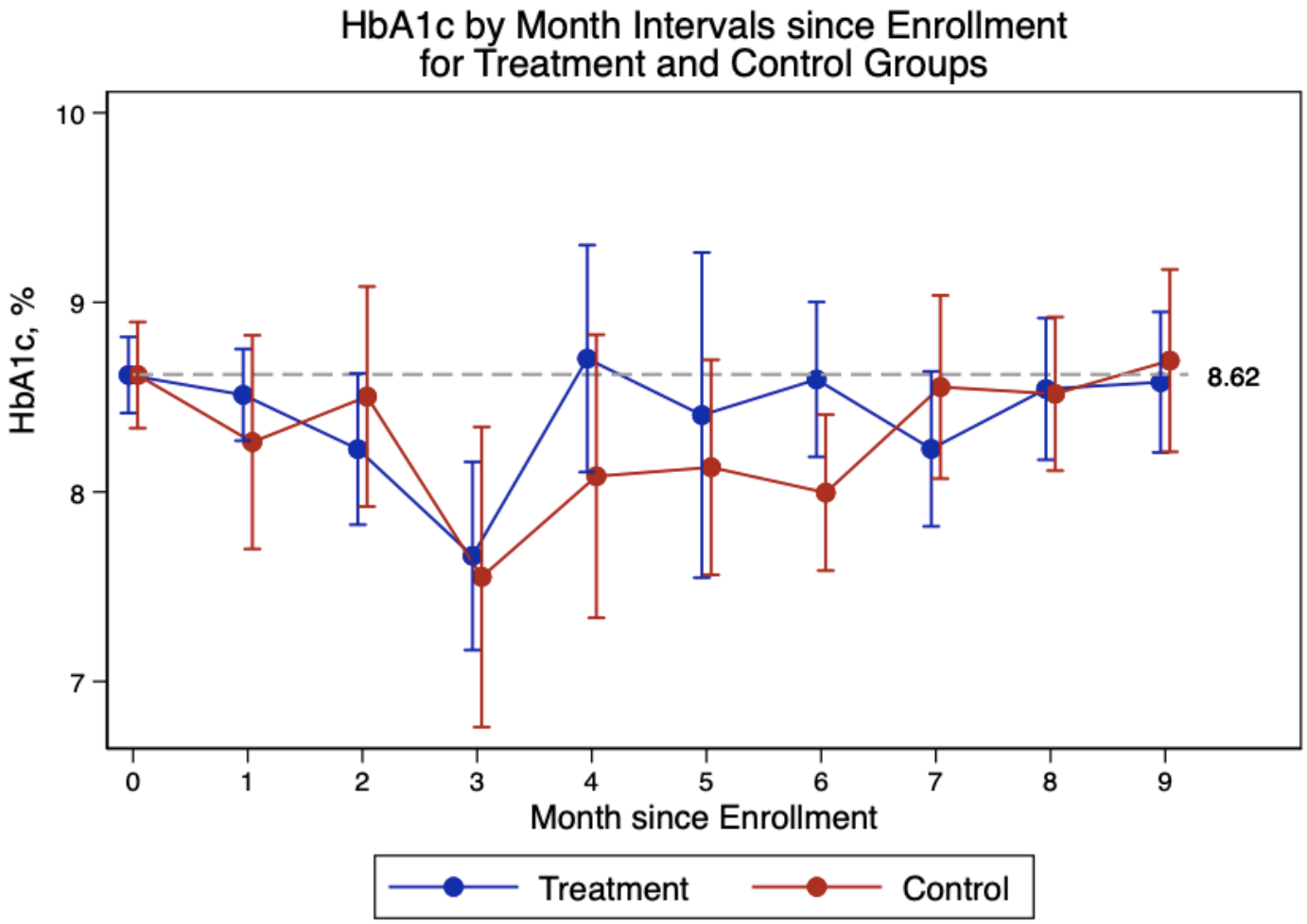
Table 2.3: Incidence Rates of Inpatient Hospitalizations and Emergency Department Admission associated with Program Participation at 6- and 9- months after Enrollment

Time Interval	Treatment		Control		Incidence Rate Ratio (95%CI)
	Count	Incidence Rate (SE)	Count	Incidence Rate (SE)	
Inpatient Hospitalizations					
6-month	3	0.01 (0.01)	14	0.02 (0.01)	0.54 (0.14, 1.95)
9-month	5	0.02 (0.01)	24	0.03 (0.01)	0.54 (0.20, 1.50)
Emergency Department					
6-month	1	0.01 (0.01)	4	0.01 (0.00)	0.53 (0.06, 4.72)
9-month	3	0.01 (0.01)	5	0.01 (0.00)	1.27 (0.30, 5.32)

N=252 in treatment group, N= 534 in control group

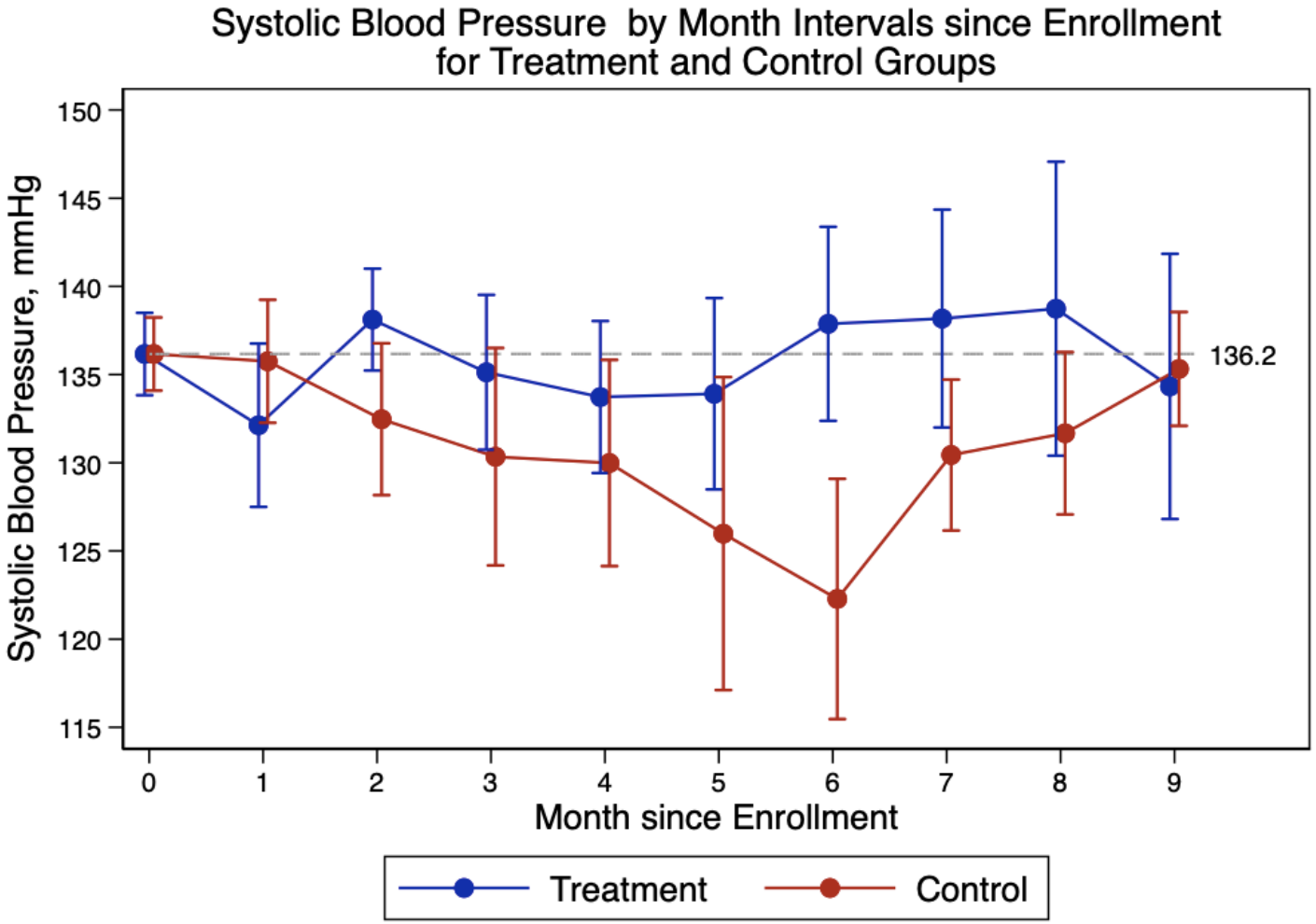
Results are from negative binomial generalized estimating equation models using overlap weights created from propensity scores. Models describe the incidence rate ratio (ie, relative risk) of hospitalization or emergency department admissions between treatment and control groups. With overlap weights applied, the mean count of inpatient hospitalizations and emergency department admissions within the 6-months prior to enrollment is equivalent for treatment and control groups. Produce prescription program lasted 6 months for each participant.

Figure 2.1: HbA1c (%) by Month Intervals since Enrollment for Treatment and Control Groups



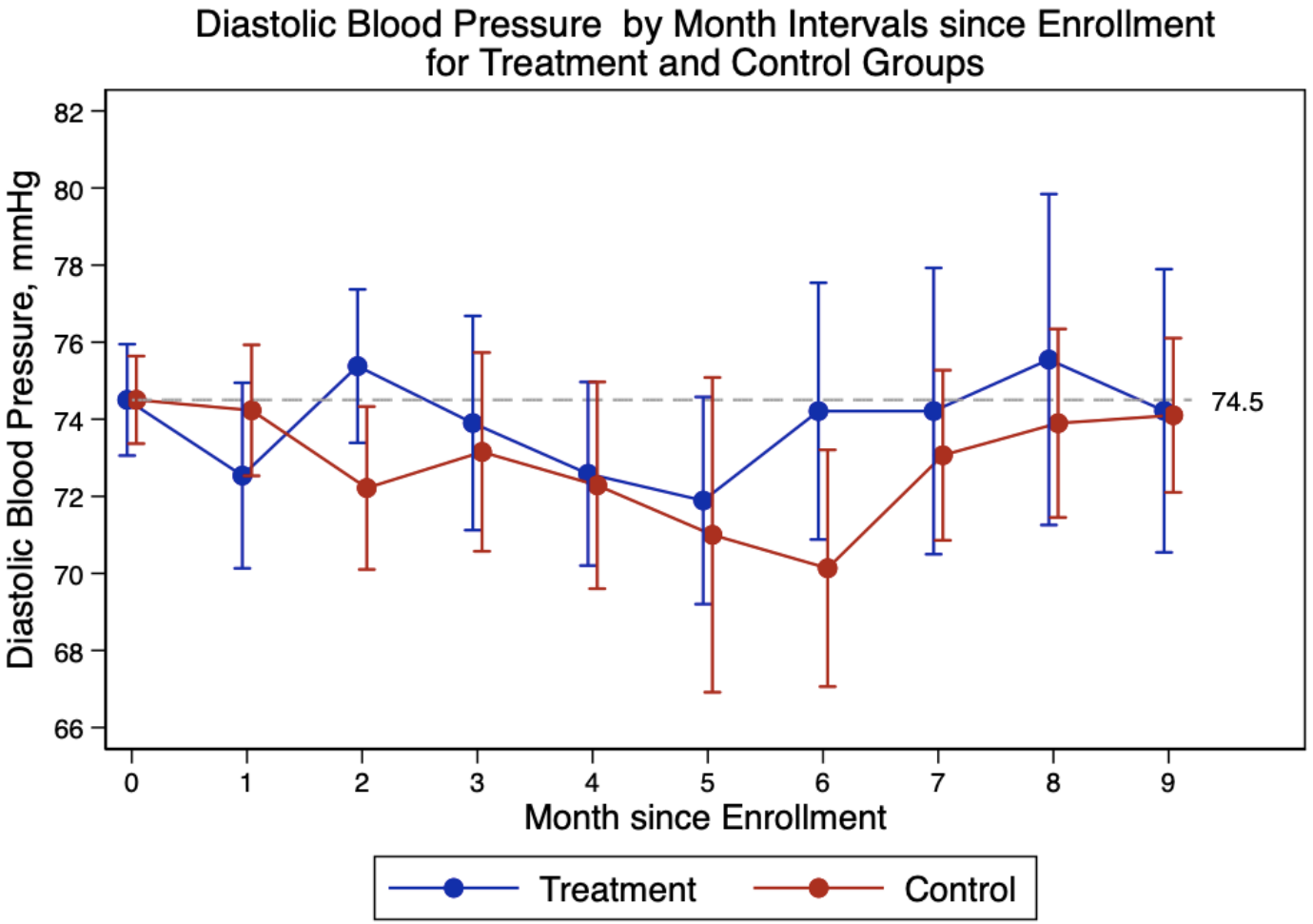
Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean HbA1c in treatment (blue) or control (red) group within a monthly interval, e.g., baseline, within 1st month, within 2nd month, etc. Bars represent 95% confidence intervals. With overlap weights applied, the mean Hba1c at baseline is equivalent for treatment and control groups. Confidence intervals are smallest at baseline because every participant in the treatment and control groups have a baseline measurement.

Figure S2.1: Systolic Blood Pressure by Month Intervals from Weighted GEE Regression for all Participants



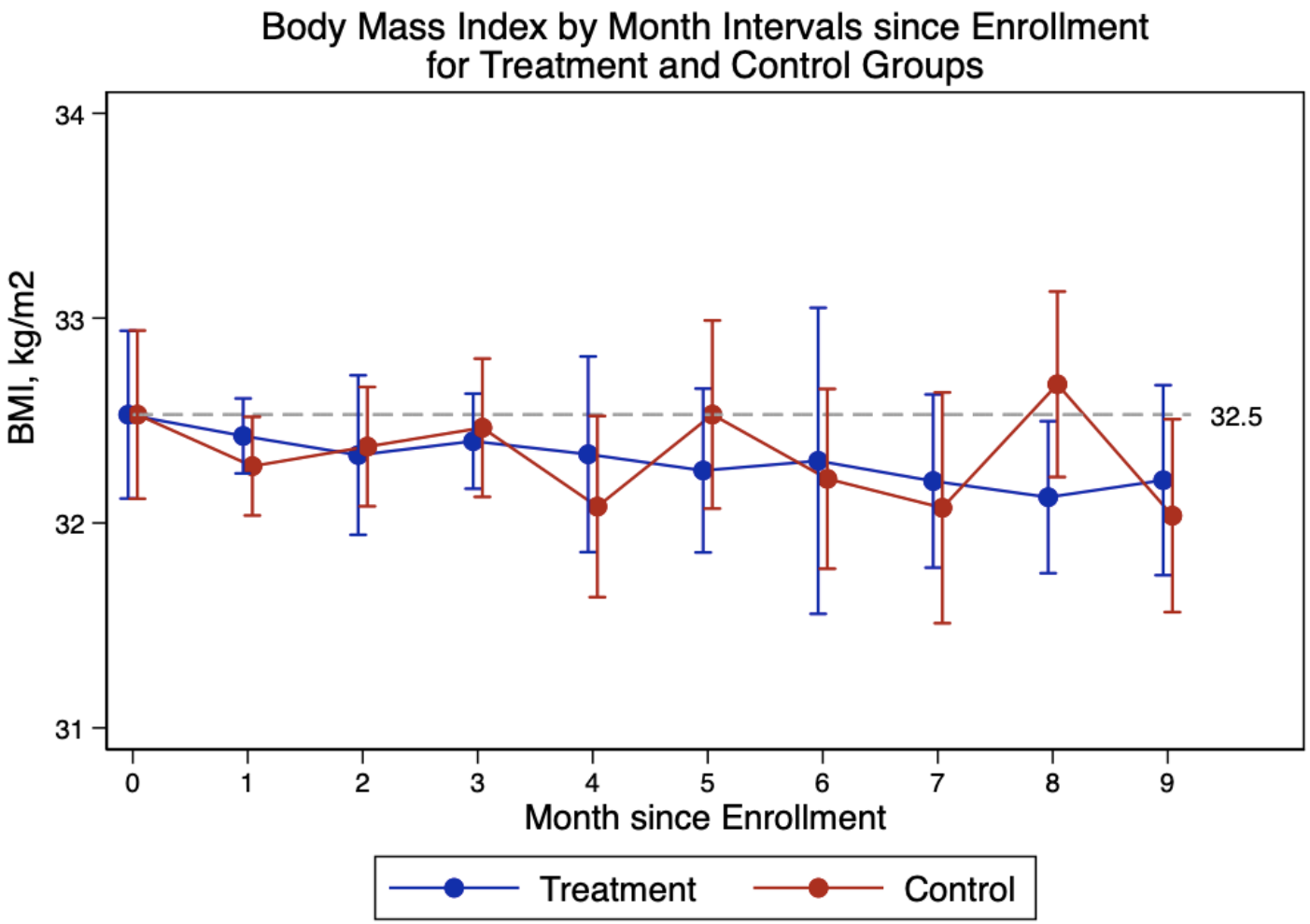
Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean SBP in treatment (blue) or control (red) group within a monthly interval, e.g., baseline, within 1st month, within 2nd month, etc. Bars represent 95% confidence intervals. With overlap weights applied, the mean SBP at baseline is equivalent for treatment and control groups. Confidence intervals are smallest at baseline because every participant in the treatment and control groups have a baseline measurement.

Figure S2.2: Diastolic Blood Pressure by Month Intervals from Weighted GEE Regression for all Participants



Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean DBP in treatment (blue) or control (red) group within a monthly interval, e.g., baseline, within 1st month, within 2nd month, etc. Bars represent 95% confidence intervals. With overlap weights applied, the mean DBP at baseline is equivalent for treatment and control groups. Confidence intervals are smallest at baseline because every participant in the treatment and control groups have a baseline measurement.

Figure S2.3: Body Mass Index by Month Intervals from Weighted GEE Regression for all Participants



Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean BMI in treatment (blue) or control (red) group within a monthly interval, e.g., baseline, within 1st month, within 2nd month, etc. Bars represent 95% confidence intervals. With overlap weights applied, the mean BMI at baseline is equivalent for treatment and control groups. Confidence intervals are smallest at baseline because every participant in the treatment and control groups have a baseline measurement.

Table S2.1: Change in HbA1c between Treatment and Control Group from Baseline to 9 Months by Month since Enrollment

Month since Enrollment	**Total number of measurements**	**Change in HbA1c in Participants** *Weighted Mean (SE)*	**Change in HbA1c in Controls** *Weighted Mean (SE)*	**Between Group Difference** *Weighted Mean (95% CI)*
0	786	8.617(0.102)	8.617(0.143)	0.000(-0.345,0.345)
1	927	-0.012(0.019)	-0.057(0.048)	0.045(-0.055,0.146)
2	1059	-0.057(0.030)	-0.067(0.058)	0.010(-0.117,0.137)
3	1166	-0.150(0.038)	-0.153(0.064)	0.003(-0.143,0.150)
4	1268	-0.099(0.044)	-0.183(0.069)	0.084(-0.077,0.245)
5	1347	-0.115(0.060)	-0.206(0.070)	0.091(-0.089,0.271)
6	1486	-0.113(0.062)	-0.246(0.070)	0.134(-0.049,0.317)
7	1654	-0.142(0.060)	-0.228(0.078)	0.086(-0.106,0.278)
8	1858	-0.134(0.059)	-0.216(0.077)	0.081(-0.108,0.271)
9	2045	-0.126(0.057)	-0.188(0.079)	0.063(-0.128,0.253)

Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores. Separate regression models were run for each time period and included all available HbA1c measurements starting from enrollment to the end of each month. Produce prescription program lasted 6 months for each participant. With overlap weights applied, the mean Hba1c at baseline is equivalent for treatment and control groups.

Table S2.2: Change in Hba1c, Blood Pressure, and Body Mass Index between Treatment and Control Groups for Participants with HbA1c > 8.0% at Enrollment

Outcome	6-Month			9-Month		
	Change in Treatment	Change in Control	Between Group Difference	Change in Treatment	Change in Control	Between Group Difference
	mean (SE)	*mean (SE)*	*β (95% CI)*	*mean (SE)*	*mean (SE)*	*β (95% CI)*
HbA1c, *%*	-0.23 (0.11)	-0.35 (0.10)	0.12 (-0.18, 0.41)	-0.34 (0.10)	-0.27 (0.12)	-0.06 (-0.37, 0.24)
SBP, *mmHg*	-0.02 (1.33)	-3.36 (2.62)	3.34 (-2.42, 9.10)	0.01 (1.83)	-2.69 (2.28)	2.702 (-3.017,8.42)
DBP, *mmHg*	-2.13 (1.25)	-1.32 (1.13)	-0.81 (-4.10, 2.49)	-1.61 (1.39)	-0.95 (1.12)	-0.65 (-4.16, 2.85)
BMI, kg/m^2	-0.08 (0.11)	-0.15 (0.12)	0.07 (-0.26, 0.39)	-0.20 (0.14)	-0.23 (0.14)	0.04 (-0.35, 0.43)

N=146 in treatment group, N= 208 in control group

Results are from longitudinal, generalized estimating equation models using overlap weights created from propensity scores. All measures taken from baseline to 6 months were included in the 6-month analysis; all measures taken from baseline to 9 months were included in the 9-month analysis. Produce prescription program lasted 6 months for each participant.

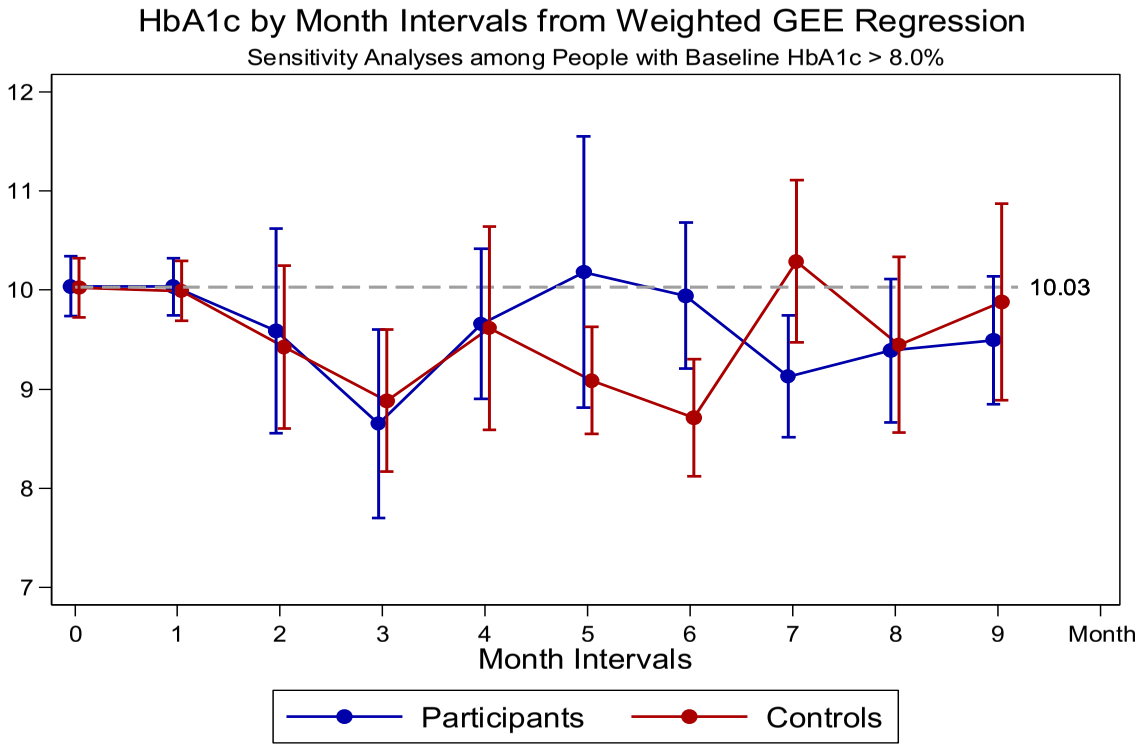
Table S2.3: Incidence rate of inpatient hospitalizations and emergency department admission associated with program participation at 6- and 9- months after enrollment

Time Interval	Treatment		Control		Incidence Rate Ratio (95%CI)
	Count	Incidence Rate (SE)	Count	Incidence Rate (SE)	
Inpatient Hospitalizations					
6-month	1	0.01 (0.01)	8	0.04 (0.01)	0.20 (0.02,1.60)
9-month	3	0.02 (0.01)	17	0.07 (0.02)	0.32 (0.09,1.14)
Emergency Department					
6-month	1	0.01 (0.01)	2	0.01 (0.01)	0.72 (0.06, 7.96)
9-month	3	0.02 (0.02)	3	0.02 (0.01)	1.44 (0.29, 7.14)

N=146 in treatment group, N= 208 in control group

Results are from negative binomial generalized estimating equation models using overlap weights created from propensity scores. Models describe the incidence rate ratio (ie, relative risk) of hospitalization or emergency department admissions between treatment and control groups. With overlap weights applied, the mean count of inpatient hospitalizations and emergency department admissions within the 6-months prior to enrollment is equivalent for treatment and control groups. Produce prescription program lasted 6 months for each participant.

Figure S2.4: HbA1c by Month Intervals from Weighted GEE Regression among participants with HbA1c > 8.0% at Enrollment



Results are from longitudinal, generalized estimating equation model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean HbA1c in treatment (blue) or control (red) group within a monthly interval, e.g., baseline, within 1st month, within 2nd month, etc. Bars represent 95% confidence intervals. With overlap weights applied, the mean Hba1c at baseline is equivalent for treatment and control groups. Confidence intervals are smallest at baseline because every participant in the treatment and control groups have a baseline measurement.

Chapter 3 Tables and Figures

Table 3.1: Inputs for Policy Simulation Model to Estimate One-Year and Ten-Year Change in Hospitalizations and Healthcare Expenditures Attributable to Provision of MTMs and Net Policy Costs

Input	Data Source
Annual inpatient admissions and healthcare expenditures stratified by insurance status	• Medical Expenditure Panel Survey administered by the Agency for Healthcare Research and Quality.[118]
Estimated policy effect sizes	• Original meta-analysis of five published MTM studies that assessed impacts of MTM receipt on inpatient hospitalizations and/or healthcare expenditures [8,9,55,113,123] **(eTable 2-3).** • Effect sizes include pooled relative risks of inpatient hospitalizations and percent change in healthcare expenditures.
MTM costs from insurance contracts	• Original survey to Food is Medicine Coalition organizations [112] administered August – September of 2021. • The survey included questions on 2019 annual meals delivered, participants served, organization expenditures, and monthly meal costs from insurance contracts. • 11 organizations responded of the 15 organizations asked to complete the survey.
Screening and referral costs	• Medicare reimbursement rates for an initial Medical Nutrition Therapy assessment by a Registered Dietician Nutritionist.[124] • This is a one-time, added cost for each eligible MTM recipient in each year of the policy simulation model.

Table 3.2: Sample Description of Individuals Eligible to Receive Medically Tailored Meals in the United States by Eligibility Criteria using data from the Medical Expenditure Panel Survey

Variable	Primary Population: Non-institutionalized US adults with nutrition sensitive disease, and IADL limitations	Secondary Population: Non-institutionalized US adults with nutrition sensitive disease, IADL limitations, and food insecurity
Population Size, n	6,309,998*	1,887,681†
Age, years mean (SD)	68.1 (16.6)	60.5 (15.5)
Female, n (%)	4,001,494 (63.4)	1,202,453 (63.7)
Race and Ethnicity, n (%)	Non-Hispanic White: 4,208,527 (66.7) Non-Hispanic Black: 898,846 (11.3) Hispanic: 710,456 (14.2) Asian: 193,736 (3.7) Other or Multiple: 298,434 (4.7)	Non-Hispanic White: 851,344 (45.1) Non-Hispanic Black: 479,471 (25.4) Hispanic: 364,322 (19.3) Non-Hispanic Asian: 73,620 (3.9) Other or Multiple: 118,924 (6.3)
Ratio of Family Income to Poverty Line, Mean (SD) Median (IQR)	 2.8 (2.7) 1.9 (0.9, 3.7)	 2.6 (2.5) 1.3 (0.8, 2.2)
US Census Region, n (%)	Northeast: 1,124,402 (17.8) Midwest:	Northeast: 290,703 (15.4) Midwest:

	1,273,829 (20.2) South: 2,487,704 (39.4) West: 1,424,064 (22.6)	575,742 (30.5) South: 683,341 (36.2) West: 337,895 (17.9)
Insurance Status, n (%)	Private: 1,485,365 (23.5) Medicare: 2,571,563 (40.7) Medicaid: 697,293 (11.1) Dual eligible: 1,555,779 (24.7)	Private: 352,996 (18.7) Medicare: 598,395 (31.7) Medicaid: 307,692 (16.3) Dual eligible: 628,598 (33.3)
Disease Diagnosis‡, n (%)		
	Diabetes: 2,830,507 (44.9) Congestive Heart Failure: 1,693,284 (26.8) Myocardial Infarction: 1,345,389 (21.3) Other Heart Disease: 2,304,133 (36.5) Stroke: 2,279,549 (36.1) Cancer: 2,345,823 (37.2) Emphysema: 672,761 (10.7) Chronic Kidney Disease: 82,030 (1.3) HIV: 37, 860 (0.6)	Diabetes: 977,819 (51.8) Congestive Heart Failure: 366,210 (19.4) Myocardial Infarction: 369,985 (19.6) Other Heart Disease: 734,308 (38.9) Stroke: 420, 953 (22.3) Cancer: 458,706 (24.3) Emphysema: 303,917 (16.1) Chronic Kidney Disease: 30,203 (1.6) HIV: 22,652 (1.2)

Annual ED Admissions,		
Mean (SD)	0.98 (1.68)	1.09 (1.8)
Median (IQR)	0 (0,1)	0 (0,2)
Annual Hospitalizations,		
Mean (SD)	0.54 (0.94)	0.59 (1.0)
Median (IQR)	0 (0,1)	0 (0,1)
Annual Healthcare Expenditures,		
Mean (SD)	$31,134 ($34,749)	$33,634 ($48,978)
Median (IQR)	$20,107 ($8,856, $38,965)	$19,153 ($6,392, $41,460)

*Based on 667 individuals in the 2019 MEPS survey.
†Based on 244 individuals in the 2017 MEPS survey.
‡ Totals do not equal 100% as eligible individuals may have multiple comorbidities.

Table 3.3: Estimated One-Year Averted Hospitalizations, Savings in Healthcare Expenditures, and Net Policy Costs Savings Attributable to Provision of MTMs by Eligibility Criteria

Insurance	**Population Size**	**Averted Annual Inpatient Hospitalizations** (95% UI)	**Savings in Annual Healthcare Expenditures in Billions of USD** (95% UI)	**MTM Program Costs in Billions of USD** (95% UI)	**Net Policy Cost Savings in Billions of USD** (95% UI)
		Non-institutionalized US adults with nutrition sensitive disease, and IADL limitations			
Private	1,485,365	290,000 (173,000, 419,000)	$8.9 (2.7, 15.7)	$5.9 (5.1, 6.7)	$3.0 (-2.8, 9.4)
Medicare	2,571,562	712,000 (455,000, 1,013,000)	$13.4 (4.4, 22.7)	$10.1 (8.8, 11.6)	$3.3 (-5.3, 12.1)
Medicaid	697,292	195,000 (102,000, 327,000)	$4.5 (1.5, 8.0)	$2.8 (2.4, 3.2)	$1.6 (-1.2, 5.0)
Dual eligible	1,555,779	397,000 (241,000, 579,000)	$11.9 (4.0, 20.7)	$6.1 (5.3, 7.0)	$5.7 (-1.7, 14.0)
Total	**6,309,998**	**1,594,000 (1,297,000 1,912,000)**	**$38.7 (24.9, 53.9)**	**$24.8 (23.0, 26.6)**	**$13.6 (0.3, 28.5)**
		Non-institutionalized US adults with nutrition sensitive disease, IADL limitations, and food insecurity			
Private	330,587	78,000 (37,000, 126,000)	$2.7 (0.5, 5.8)	$ 1.3 (1.1, 1.5)	$ 1.4 (0.7, 4.3)
Medicare	587,828	167,000 (86,000, 272,000)	$3.1 (1.0, 5.5)	$ 2.3 (2.0, 2.6)	$ 0.8 (-1.3, 3.2)
Medicaid	286,066	117,000 (76,000, 171,000)	$2.8 (0.6, 5.8)	$ 1.1 (0.9, 1.3)	$ 1.7 (-0.4, 4.6)
Dual eligible	683,200	144,000 (76,000, 228,000)	$4.4 (1.4, 8.0)	$ 2.7 (2.3, 3.0)	$1.8 (-1.1, 5.3)
Total	**1,887,681**	**506,000 (398,000, 654,000)**	**$13.0 (7.9, 18.9)**	**$7.4 (6.9, 8.0)**	**$5.6 (0.8, 11.1)**
		Non-institutionalized US adults with diabetes and IADL limitations			
Private	636,320	118,000 (62,000, 183,000)	$4.3 (1.2, 7.9)	$1.9 (2.1, 1.6)	$2.4 (-0.7, 6.1)
Medicare	1,001,345	304,000 (180,000, 463,000)	$5.6 (1.9, 9.5)	$3.0 (2.5, 3.4)	$2.6 (-1.2, 6.5)
Medicaid	368,460	63,000 (24,000, 120,000)	$2.5 (0.7, 4.6)	$1.1 (0.9, 1.2)	$1.4 (-0.3, 3.5)
Dual eligible	824,381	216,000 (123,000, 326,000)	$7.0 (2.3, 12.4)	$2.4 (2.1, 2.8)	$4.6 (-0.1, 10.0)
Total	**2,830,506**	**701,000 (524,000, 911,000)**	**$19.3 (12.2, 27.3)**	**$8.4 (7.8, 9.1)**	**$10.9 (3.6, 18.8)**

Non-institutionalized US adults with congestive heart failure and IADL limitations

Private	374,445	77,000 (31,000, 128,000)	$2.5 (0.7, 4.5)	$1.1 (0.9, 1.3)	$1.4 (-0.4, 3.4)
Medicare	871,058	288,000 (168,000, 436,000)	$5.0 (1.7, 8.7)	$ 2.6 (2.2, 2.9)	$2.4 (-0.8, 6.1)
Medicaid	119,035	37,900 (24,000, 57,000)	$0.7 (0.2, 1.5)	$0.4 (0.3, 0.4)	$0.4 (-0.1, 1.1)
Dual eligible	330,745	127,000 (68,000, 196,000)	$2.6 (0.8, 5.0)	$1.0 (0.8, 1.1)	$1.6 (-0.2, 4.0)
Total	**1,695,293**	**530,000 (373,000, 705,000)**	**$10.9 (6.3, 15.6)**	**$5.0 (4.6, 5.4)**	**$5.8 (1.3, 10.6)**

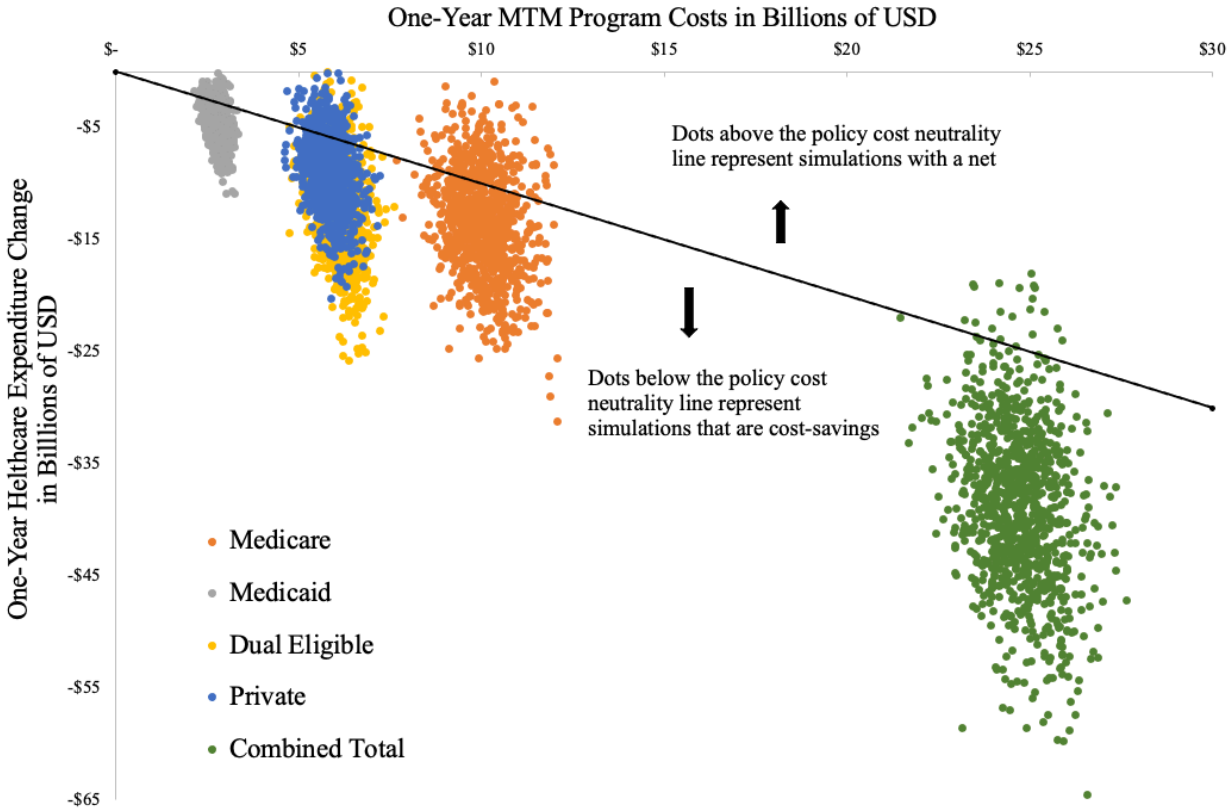
Estimates are the mean of 1,000 Monte Carlo simulations with the 95% uncertainty interval defined as the 2.5th percentile to the 97.5th percentile of the simulations. The policy simulation model runs 1,000 Monte Carlo simulations using inputs and their uncertainties from 2019 Medical Expenditure Panel Survey, relative risks of annual hospitalizations and annual percent change in healthcare expenditures associated MTM receipt, screening costs and meal costs. Hospitalizations are rounded to the nearest 1,000 and healthcare expenditures are rounded to the nearest $100,000,000.

Table 3.4: Estimated Ten-Year Averted Hospitalizations and Net Policy Cost Savings Attributable to Provision of MTMs, by Discounting Approach

Insurance	10-Year Averted Hospitalizations (95% UI)	*No Discounting of Future Costs* 10-Year Net Policy Cost Savings in Billions of 2019 USD (95% UI)	*3% Discounting of Future Costs (primary analysis)* 10-Year Net Policy Cost Savings in Billions of 2019 USD (95% UI)	*5% Discounting of Future Costs* 10-Year Net Policy Cost Savings in Billions of 2019 USD (95% UI)
Private	3,029,000 (1,812,000, 4,385,000)	$62.2 (-$27.1, 156.4)	$45.5 (-32.8, 127.3)	$36.0 (-34.0, 110.4)
Medicare	7,836,000 (5,008,000, 11,144,000)	$52.1 (-62.4, 164.7)	$30.2 (-69.4, 128.2)	$17.6 (-73.3, 107.4)
Medicaid	2,226,000 (1,169,000, 3,748,000)	$31.1 (-12.1, 81.5)	$22.6 (-14.8, 66.2)	$17.7 (-16.4, 57.4)
Dual eligible	5,166,000 (3,132,000, 7,519,000)	$115.2 (-16.9, 260.0)	$88.0 (-27.0, 213.5)	$72.4 (-32.0, 186.6)
Total	**18,257,000 (14,690,000, 22,109,000)**	**$260.7 (62.7, 481.5)**	**$185.1 (12.9, 377.8)**	**$143.7 (-11.8, 319.4)**

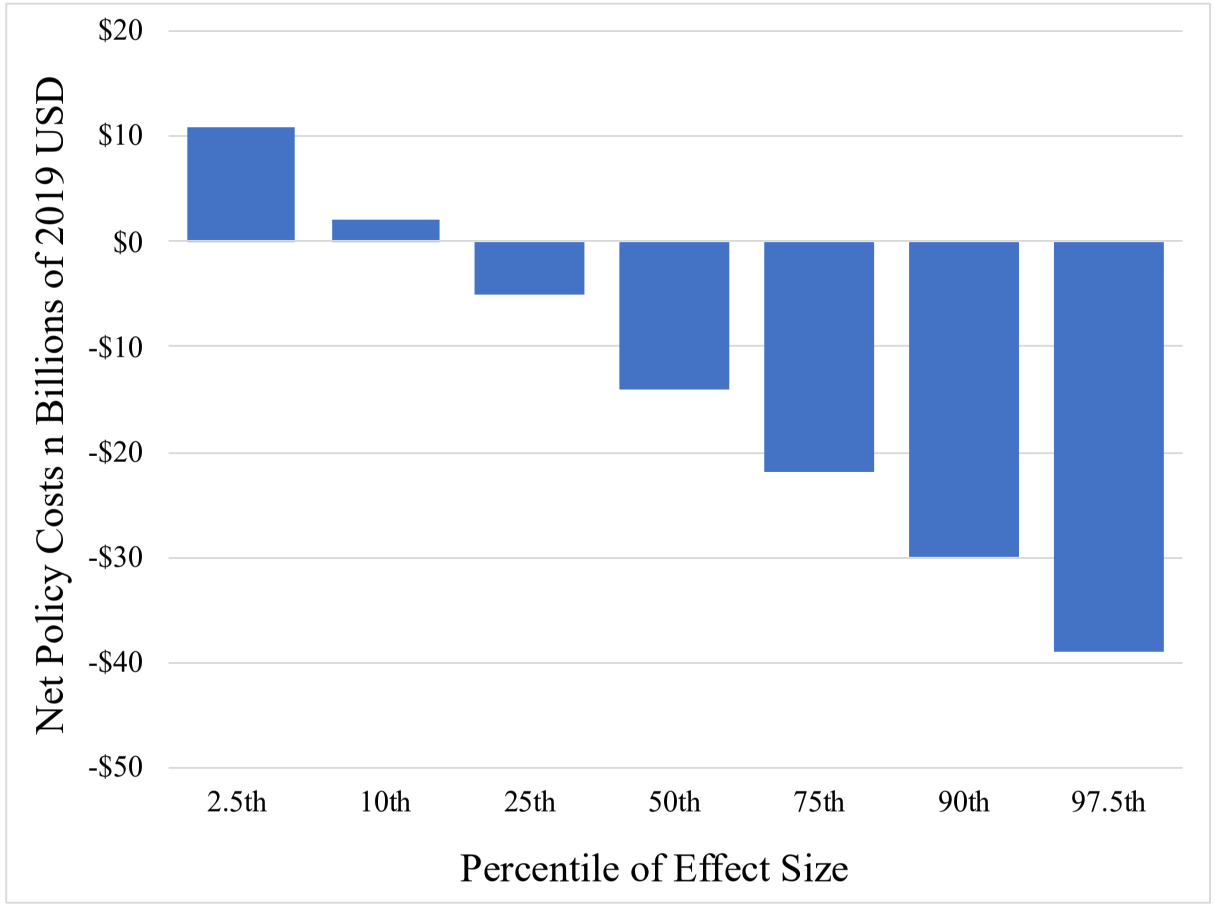
In each of the ten years, the eligible population was assumed to receive 8 months of medically tailored meals per year. Estimates are the mean of 1,000 Monte Carlo simulations with the 95% uncertainty interval defined as the 2.5th percentile to the 97.5th percentile of the simulations. The policy simulation model runs 1,000 Monte Carlo simulations using inputs and their uncertainties from 2019 Medical Expenditure Panel Survey, relative risks of annual hospitalizations and annual percent change in healthcare expenditures MTM receipt, screening costs and meal costs. The policy simulation model was run separately and then summed for each of the ten years (2019-2028) to obtain final estimates. Baseline distributions of hospitalizations and healthcare expenditures for years 2020-2028 were estimated using the historical rate of change in population size and healthcare expenditures from 2010-2019 for the target population. Hospitalizations are rounded to the nearest 1,000 and healthcare expenditures are rounded to the nearest $100,000,000.

Figure 3.1: Model Simulations of One-Year MTM Policy Costs and Potential Change in Healthcare Expenditures Associated with MTM Receipt, by Health Insurance Status



Each dot represents one of 1,000 simulations, stratified by insurance status. Dots below the cost neutrality result in policy cost savings, while dots above the line have positive net policy costs. The policy simulation model runs 1,000 Monte Carlo simulations using inputs and their uncertainties from 2019 Medical Expenditure Panel Survey, relative risks of annual hospitalizations and annual percent change in healthcare expenditures associated MTM receipt, screening costs and meal costs.

Figure S3.1: Net Annual Policy Costs by Percentile of Effect Size for Reductions in Healthcare Utilization Associated with Medically Tailored Meal Receipt



Percentiles are equivalent to the following one-year change in healthcare expenditures associated with eight months MTM receipt: 2.5th = -6.9%; 10th = -11.4%; 25th = -15.3%; 50th= -19.7% (central estimate); 75th= -24.1%; 90th= -28.0%; 97,5th = -32.4%. Healthcare expenditures would need to be reduced by 12.6% for the policy to be cost neutral, equivalent to the 14th percentile of the effect size uncertainty range for change in healthcare costs associated with MTM receipt. Effect size estimates are from an original metanalysis of all known studies assessing the association between MTM receipt and inpatient hospitalizations and/or healthcare expenditures conducted in the U.S. in the past 20 years.

Table S3.1: Weighted Average of the Observation Period and MTM Intervention Lengths in Previous Studies

Study	Number of MTM recipients in the intervention group	Observation Period	MTM Intervention Length
Berkowitz 1 [55]	499	21.4 months	12.4 months
Berkowitz 2 [8]	133	19.1 months	17.8 months
Gurvey [9]	65	6.0 months	6.0 months
Hummel [113]	33	3.0 months	1.0 month
Weighted Average	**730**	**18.8 months**	**12.2 months**

The weighted average observation time and MTM intervention length included all known studies assessing the association between MTM receipt and inpatient hospitalizations and/or healthcare expenditures conducted in the U.S. in the past 20 years. The study by Horton[123] did not specify the average observation period nor intervention length.

Table S3.2: Meta-Analysis of Previous Studies that Assessed the Impact of MTM Receipt on Inpatient Hospitalizations and Healthcare Expenditures

Study	Relative Risk of Inpatient Hospitalization Associated with MTM receipt	Standard Error
Berkowitz 1[55]	0.51	0.16
Berkowitz 2[8]	0.48	0.16
Hummel[113]	0.68	0.19
Gurvey[9]	0.51	0.13
Pooled Effect	**0.53**	**0.08**

Results from inverse variance meta-analysis with random effects that included all known studies assessing the association between MTM receipt and inpatient hospitalizations and/or healthcare expenditure in the U.S. in the past 20 years. Only one study[8] reported the impact of MTMs on emergency department admissions (in a second study,[9] the authors stated that their results for emergency department admissions were "inconclusive"). Therefore, we did not incorporate MTM impacts on emergency department admissions in our analysis as they would have been dependent on a single study.

Table S3.3: Meta-Analysis of Previous Studies that Assessed the Impact of MTM Receipt on Inpatient Hospitalizations and Healthcare Expenditures

Study	Percent Change in Annual Healthcare Expenditures Associated with MTM receipt	Standard Error
Berkowitz 1[55]	-17.0%	5.3%
Berkowitz 2[8]	-16.0%	5.7%
Horton[123]	-24.0%	8.3%
Gurvey[9]	-31.0%	9.0%
Pooled Effect	**-19.7%**	**6.5%**

Results from inverse variance meta-analysis with random effects that included all known studies assessing the association between MTM receipt and inpatient hospitalizations and/or healthcare expenditure in the U.S. in the past 20 years.

Table S3.4: Per Capita, One-Year Estimated Averted Hospitalizations, Savings in Healthcare Expenditures, and Net Policy Cost Savings Attributable to Provision of MTMs by Eligible Population

Insurance	**Population Size**	**Per Capita Averted Inpatient Hospitalizations** (95% UI)	**Per Capita Savings in Healthcare Expenditures** (95% UI)	**Per Capita Net Policy Cost Savings**
	Primary Population: Non-institutionalized US adults with nutrition sensitive disease, and IADL limitations			
Private	1,485,365	0.19 (0.12, 0.28)	$5,920 (1,800, 10,560)	$2,090 (-1,960, 6,390)
Medicare	2,571,562	0.28 (0.18, 0.40)	$5,250 (1,710, 8,820)	$1,320 (-2,110, 4,710)
Medicaid	697,292	0.28 (0.15, 0.47)	$6,310 (2,150, 11,470)	$2,490 (-1,600, 7,270)
Dual eligible	1,555,779	0.26 (0.15, 0.37)	$7,460 (2,570, 13,300)	$3,770 (-1,200, 9,100)
Total	**6,309,998**	**0.25 (0.15, 0.37)**	**$6,090 (3,940, 8,540)**	**$2,230 (50, 4,530)**
	Non-institutionalized US adults with nutrition sensitive disease, IADL limitations, and food insecurity			
Private	330,587	0.23 (0.11, 0.38)	$7,860 (1,490, 17,380)	$4,168 (-1,280, 10,170)
Medicare	587,828	0.28 (0.15, 0.46)	$5,100 (1,700, 9,350)	$4,160 (-1,380, 10,400)
Medicaid	286,066	0.41 (0.26, 0.60)	$9,440 (2,090, 20,270)	$1,290 (-640, 3,860)
Dual eligible	683,200	0.21 (0.11, 0.33)	$6,290 (2,050, 11,790)	$2,410 (-230, 5,790)
Total	**1,887,681**	**0.27 (0.14, 0.42)**	**$6,670 (4,180, 10,010)**	**$3,090 (690, 5,602)**
	Non-institutionalized US adults with diabetes and IADL limitations			
Private	**636,320**	0.19 (0.10, 0.29)	$6,740 (1,880, 12,370)	$3,770 (-1,050, 9,580)

Medicare	**1,001,345**	0.30 (0.18, 0.46)	$5,560 (1,870, 9,480)	$2,580 (-1,200, 6,450)
Medicaid	**368,460**	0.17 (0.07, 0.33)	$6,660 ($1,960, $12,550)	$3,700 (-910, 9,560)
Dual eligible	**824,381**	0.26 (0.15, 0.40)	$8,550 (2,770, 14,990)	$5,580 (-160, 12,140)
Total	**2,830,506**	**0.25 (0.19, 0.32)**	**$6,838 (4,330, 9,650)**	**$3,870 (1,290, 6,660)**
		Non-institutionalized US adults with congestive heart failure and IADL limitations		
Private	374,445	0.21 (0.08, 0.34)	$6,650 (1,904, 12,120)	$3,680 (-1,130, 8,970)
Medicare	871,058	0.33 (0.19, 0.50)	$5,780 (1,970, 10,010)	$2,800 (-931, 7,010)
Medicaid	119,035	0.31 (0.20, 0.48)	$6,080 (1,450, 12,300)	$3,110 (-1,534, 9,280)
Dual eligible	330,745	0.38 (0.21, 0.59)	$7,950 (2,400, 15,040)	$4,970 (-470, 11,970)
Total	**1,695,293**	**0.31 (0.22, 0.42)**	**$6,420 (3,770, 9,210)**	**$3,443 (-770, 6,238)**

Estimates are the mean of 1,000 Monte Carlo simulations with the 95% uncertainty interval defined as the 2.5th percentile to the 97.5th percentile of the simulations. The policy simulation model runs 1,000 Monte Carlo simulations using inputs and their uncertainties from 2019 Medical Expenditure Panel Survey, relative risks of annual hospitalizations and annual percent change in healthcare expenditures associated MTM receipt, screening costs and meal costs. Hospitalizations are rounded to the nearest 1,000 and healthcare expenditures are rounded to the nearest $100,000,000.

Table S3.5: 10-Year Savings in Healthcare Expenditures Attributable to MTM Receipt by Discounting Approach

Insurance	*No Discounting of Future Costs* **10-Year Savings in Healthcare Expenditures in Billions of 2019 USD** (95% UI)	*3% Discounting of Future Costs (primary analysis)* **10-Year Savings in Healthcare Expenditures in Billions of 2019 USD** (95% UI)	*5% Discounting of Future Costs* **10-Year Savings in Healthcare Expenditures in Billions of 2019 USD** (95% UI)
Private	$125.9 (38.2, 220.8)	$109.2 (33.3, 191.7)	$99.6 (30.2, 174.7)
Medicare	$168.7 (56.0, 285.6)	$146.9 (48.7, 248.6)	$134.3 (44.5, 227.0)
Medicaid	$64.2 (20.9, 114.8)	$55.8 (18.2, 99.7)	$50.7 (16.6, 90.8)
Dual eligible	$199.6 (67.2, 346.8)	$172.6 (58.1, 299.9)	$156.8 (52.8, 272.5)
Total	**$558.4 (357.3, 782.1)**	**$484.5 (310.2, 678.4)**	**$441.2 (282.7, 617.7)**

In each of the ten years, the eligible population was assumed to receive 8 months of medically tailored meals per year. This table reports potential savings in healthcare expenditures only and does report the net policy costs. Estimates are the mean of 1,000 Monte Carlo simulations with the 95% uncertainty interval defined as the 2.5th percentile to the 97.5th percentile of the simulations. The policy simulation model runs 1,000 Monte Carlo simulations using inputs and their uncertainties from 2019 Medical Expenditure Panel Survey, relative risks of annual hospitalizations and annual percent change in healthcare expenditures MTM receipt, screening costs and meal costs. The policy simulation model was run separately and then summed for each of the ten years (2019-2028) to obtain final estimates. Baseline distributions of hospitalizations and healthcare expenditures for years 2020-2028 were estimated using the historical rate of change in population size and healthcare expenditures from 2010-2019 for the target population. Hospitalizations are rounded to the nearest 1,000 and healthcare expenditures are rounded to the nearest $100,000,000.

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