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

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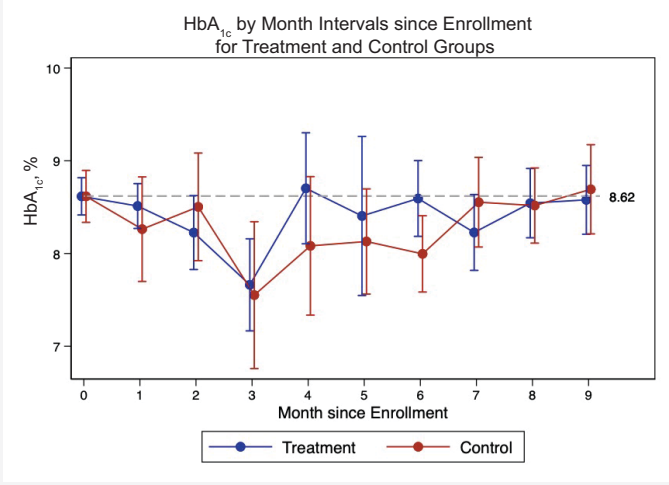
252 patients with diabetes received produce prescriptions of $60 / month for 6 months.

Longitudinal analyses using overlap propensity score weights compared changes in HbA_{1c} with 534 controls.

Program implementation coincided with the first wave of COVID-19 in spring 2020.



At 6 months, there was no significant difference in HbA_{1c} between treatment and control groups.

ARTICLE HIGHLIGHTS

- Produce prescriptions offer patients free fruit and vegetables and have shown promise in improving diabetes care, although most previous studies used small samples or lacked controls.
- The objective of this study was to evaluate the impacts of a produce prescription on glycemic control for patients with diabetes.
- Compared with weighted controls, patients receiving a 6-month produce prescription during the onset of the COVID-19 pandemic did not have improved glycated hemoglobin.
- Future research should assess which programmatic components of produce prescriptions are most likely to improve health outcomes, although findings may be unique to the start of COVID-19 in the U.S.

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

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OBJECTIVE

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

RESEARCH DESIGN AND METHODS

Participants included a nonrandom enrollment of 252 patients with diabetes who received a produce prescription and 534 similar control participants from two clinics in Hartford, Connecticut. The start of the COVID-19 pandemic in March 2020 coincided with program implementation. Produce prescription enrollees received vouchers ($60 per month) for 6 months to purchase produce at grocery retail. Controls received usual care. The primary outcome was change in glycated hemoglobin (HbA_{1c}) between treatment and control at 6 months. Secondary outcomes included 6-month changes in systolic (SBP) and diastolic blood pressure (DBP), BMI, hospitalizations, and emergency department admissions. Longitudinal generalized estimating equation models, weighted with propensity score overlap weights, assessed changes in outcomes over time.

RESULTS

At 6 months, there was no significant difference in change in HbA_{1c} between treatment and control groups, with a difference of 0.13 percentage points (95% CI −0.05, 0.32). No significant difference was 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). Incidence rate ratios for hospitalizations and emergency department visits were 0.54 (0.14, 1.95) and 0.53 (0.06, 4.72), respectively.

CONCLUSIONS

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.

More than 300,000 annual deaths resulting from cardiovascular disease and diabetes in the U.S. are attributable to suboptimal diet, underscoring the tremendous burden of diet-related illness (1,2). Most U.S. adults do not meet the recommendations within the Dietary Guidelines for Americans, and marginalized racial, ethnic,

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See accompanying article, p. 1140.

and low-income groups tend to have worse overall diet quality (3,4). These challenges further intersect with food insecurity, which is associated with poor health outcomes (5–7) and higher health care use (8–10), as well as the COVID-19 pandemic, during which diabetes has become a leading risk factor of COVID-19 hospitalization and death (11–13).

Health care providers have few tools to adequately address patient nutrition and food insecurity. However, there is growing interest in and use of "food-is-medicine" interventions among health care providers, payers, and patients as a result of the high prevalence of diet-related disease in the U.S. and a growing focus on value-based care (14). These health care–based interventions provide healthy food to patients for the treatment or prevention of disease and offer promising mechanisms to improve nutrition and health outcomes (14,15). 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 fruit and vegetables (F&V) at retail grocery or farmers markets (14,16–20). These interventions recognize that linking financial incentives with 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 (14,16–20). Evaluations of the impacts of produce prescriptions on glycemic control have been promising, with several studies showing improvement in glycated hemoglobin (HbA_{1c}) (21–23 and K. Hager, Z. Li, B. Ling, D. Mozaffarian, K. Chui, P. Shi, S.B. Cash, S. Folta, F.F. Zhang, unpublished observations). However, most analyses have been pre/post studies without controls and may have been biased by regression to the mean or co-occurring changes in prognostic factors (17). There is also growing health care policy interest in understanding if produce prescription programs can affect health care use, although this remains an understudied area.

In this study, we evaluated a 6-month produce prescription program comparing longitudinal changes in HbA_{1c} 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 BMI, as well as health care use, including emergency department admissions and inpatient hospitalizations. To our knowledge, this is the largest produce prescription study to assess the impacts on glycemic control among participants with diabetes compared with a control group. Our study also contributes novel analyses on health care use. This research is relevant given recent flexibility in Medicare Advantage plans to cover produce prescriptions, state-level pilots testing produce prescriptions in Medicaid managed care (24,25), and recent commitments by the U.S. Department of Agriculture (USDA) to improve nationwide nutrition security (26), which includes investment in produce prescriptions (27).

RESEARCH DESIGN AND METHODS

Population and Setting

Study participants included a nonrandom enrollment of 786 patients (252 enrolled in the Hartford Healthcare Produce Prescription Program and 534 control participants) 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 (HbA_{1c} >8.0%) and who were likely to be lower income and experience food insecurity, based on zip code of residence. To assist meeting program enrollment goals, a decision was later made to relax the HbA_{1c} threshold to 6.5%. Study participants were also required to have at least one HbA_{1c} measurement >6.5% in the year before program start (November 2018 to October 2019) and at least one HbA_{1c} measurement (of any value) during the program period (November 2019 to October 2020). Enrollment in the produce prescription program was from November 2019 to March 2020, with program implementation through October 2020. To create enrollment dates for the control group, we randomly assigned enrollment dates from the distribution of start dates for the treatment group. Program implementation coincided with disruptions in the economy and clinical care during the onset of the COVID-19 pandemic in the U.S.

We identified 534 patients with diabetes to serve as control participants from the electronic health record (EHR), based on a sampling of patients who did not receive the produce prescription, had at least one HbA_{1c} measurement >6.5% in the year before program start, had at least one additional HbA_{1c} measurement (of any value) during the program period, and lived in the same zip codes as the treatment group. This study was reviewed by the Tufts Health Sciences Institutional Review Board and determined not to be human subjects research because the analysis used retrospective deidentified data on a completed program.

Produce Prescription Intervention

The produce prescription program was operated by Wholesome Wave (28), 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 6 months in the form of paper vouchers to purchase F&V at a local grocery retail chain. All patients received $60 per month regardless of household size. Program implementers hypothesized that this value was sufficient to increase F&V intake based on operating similar programs in other U.S. settings. Vouchers were received at the clinic or mailed to participants (all vouchers were mailed after March 2020). A registered dietitian led 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 2 November 2019) provided additional nutritional education for participants. After March 2020, all in-person nutritional education was cancelled and was not replaced with a remote option.

Because participant F&V intake was not measured in the EHR, voucher redemption rates were the primary measure of program participation. To assess redemption rates, we used sales data from the retail grocery partner to report the percentage of received dollars that were spent on F&V. To explore the potential impacts of the COVID-19 pandemic on program participation, we also separately assessed redemption rates from November 2019 to March

2020 and April 2020 to September 2020.

Clinical Outcomes

Outcomes for participants and control participants were extracted from the Hartford Healthcare EHR. The primary outcome was change in HbA_{1c} from baseline to 6 months after program enrollment, comparing participants with control participants. We also assessed changes in SBP, DBP, and BMI as secondary outcomes. All existing measurements for HbA_{1c}, blood pressure, and BMI were collected for participants and control participants from 12 months before enrollment to 12 months postenrollment. Both clinics followed identical protocols for biomarker measurement and used the same laboratory for HbA_{1c} tests. All analyses used 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 affect health care use. Secondary outcomes also included the total count of inpatient hospitalizations and emergency department admissions, separately, at 6 months after program enrollment. We report the incidence rate ratio for inpatient hospitalizations and emergency department admissions at 6 months after program enrollment for hypothesis testing. Health care use was drawn from the EHR and not from claims data. As a member of the CareEverywhere network, the Hartford Healthcare EHR recorded health care use if a patient was admitted at another health system using EPIC as its medical records platform.

Covariates

Demographic data were drawn from medical records, including age, biological sex (male or female), self-reported race/ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic, or other), health insurance status (Medicaid, Medicare, or private/other), and self-reported smoking status (never, current, or former). In addition, we obtained data on history of comorbidities (using ICD-10 codes), including congestive heart failure, cancer, chronic obstructive pulmonary disease (COPD), stroke, or renal disease, in addition to intensity of health care use, including the number of clinic visits, clinical consults, outpatient visits, inpatient hospitalizations, and emergency department visits in the 6 months before program enrollment.

Statistical Methods

We used an overlap weight propensity score approach to weight the control and treatment groups (29). The propensity score was the probability that an individual would be enrolled in the produce prescription program, given the patient's measured covariates. This was estimated using logistic regression, in which the outcome was selection into the treatment group and the explanatory variables were covariates that may have predicted the probability of treatment and confounded the association between treatment and 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 (30). Predictors included age, sex, race/ethnicity, health insurance status, and smoking status; comorbidities, including any history of congestive heart failure, cancer, COPD, stroke, or renal disease; intensity of recent health care use, including the number of clinic visits, clinical consults, outpatient visits, inpatient hospitalizations, and emergency department visits in the 6 months before program enrollment; and baseline values of HbA_{1c}, SDP, DBP, and BMI, defined as the closest measurement before program enrollment.

Overlap weighting is a propensity score method in which treated patients are weighted by the probability of not receiving treatment (1 − propensity score) and control participants are weighted by the probability of receiving the treatment (propensity score) (31). 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 those of comparable methods like inverse probability treatment weighting when treated and untreated groups are similar.

We used a weighted linear generalized estimating equation (GEE) model with an independent correlation structure to account for multiple measurements over time. All study participants had a baseline HbA_{1c} measurement (included in the propensity score model) and at least one HbA_{1c} measurement during the program period. The model included an interaction term with treatment group and days since enrollment for each HbA_{1c} 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 (i.e., least square means) and conducted our hypothesis testing on the propensity score–weighted difference in HbA_{1c} at 6 months between treatment and control groups. A secondary analysis used a similar model but included an interaction term between treatment and months since enrollment for HbA_{1c} measurements to calculate the HbA_{1c} change per month during 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 health care use outcomes to estimate incidence rates in treatment and control groups and incidence rate ratios 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 $\alpha < 0.05$ to indicate statistical significance.

Sensitivity Analyses

Sensitivity analyses included restricting the study population to individuals with uncontrolled diabetes at baseline, defined as $HbA_{1c} > 8.0\%$. We also estimated changes in HbA_{1c}, blood pressure, BMI, and health care use at 9 months after program enrollment (3 months after receiving final vouchers) to capture more end point measurements after program completion and 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 HbA_{1c} measurements were taken before 20 March

2020 (the date of the statewide shutdown in Connecticut) or during the COVID-19 pandemic. Because HbA_{1c} reflects the previous 3 months of glycemic control, we incorporated a washout period and defined the COVID-19–affected measurements as occurring after 1 May 2020. We then assessed monthly HbA_{1c} change between treatment and control groups, separately, during both time periods (November 2019 to March 2020 vs. May 2020 to September 2020). Finally, we conducted exploratory pre-/poststratified analyses of household size association with HbA_{1c} change among program recipients. Household size was measured by Wholesome Wave as part of program onboarding for the treatment group and was not available for control participants.

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% of whom 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) HbA_{1c} at baseline was 8.82% (1.71). The control group included 534 individuals who did not receive the produce prescription and had relevant HbA_{1c} measures. Before weighting, individuals selected to be enrolled in the program, compared with control participants, were more likely to be female and have Medicaid versus private insurance, Hispanic ethnicity, COPD, higher baseline HbA_{1c}, 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 groups 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 before the onset of COVID-19 was 98%; after April 2020, it was 85%. The nutritional education component of the intervention was stopped during the pandemic, and only 5% of participants attended one in-person class and 9% one grocery store tour during the full program period.

At 6 months, there was no significant difference in the change in HbA_{1c} 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), or BMI (−0.22 kg/m^2; −1.83, 1.38). These findings were similar in analyses of month-to-month differences in change in HbA_{1c}, SBP, DBP, and BMI between the intervention and control groups (Fig. 1, Supplementary Figs. 1–3, and Supplementary Table 1).

In the evaluation of health care use, hospitalizations and emergency department admissions in these patients were rare, with only 17 total hospitalizations and five 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 (95% CI 0.14, 1.95) and 0.53 (0.06, 4.72), respectively, a nonstatistically significant difference for both outcomes.

Sensitivity Analyses

In the subgroup with uncontrolled diabetes at baseline (HbA_{1c} >8.0%; 146 produce prescription participants and 208 control participants), no difference was observed in 6-month change in HbA_{1c}, SBP, DBP, or BMI between intervention and control groups (Supplementary Table 2). The incidence rate ratio for hospitalizations in the intervention versus control group was 0.20 (95% CI 0.02, 1.60) (Supplementary Table 3), and for emergency department admissions, it was 0.72 (0.06, 7.96). Similar findings were seen in analyses extending follow-up to 9 months after enrollment (Tables 2 and 3 and Supplementary Tables 1 and 2). Stratified analyses by the onset of COVID-19 suggested no program impact on HbA_{1c} measurements taken before the start of the pandemic (Supplementary Table 4). However, only 203 of 786 study participants had at least 3 months of program enrollment before 20 March 2020, and no produce prescription recipients had completed the 6-month program before 20 March 2020. Exploratory analyses stratified by household size among participants only did not suggest any differential association by household size between program participation and glycemic control (Supplementary Table 5).

CONCLUSIONS

In this quasiexperimental longitudinal study evaluating the impacts of a 6-month produce prescription program on 252 patients with diabetes compared with 534 control participants, there were no statistically significant impacts on the primary outcome, HbA_{1c}, or 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 9 months showed similar results. A sensitivity analysis did not suggest early improvements in HbA_{1c} with more limited durations of intervention (up to 3 months) before the COVID-19 shutdowns in spring 2020.

There are several possible explanations for our findings, in comparison with other studies that have suggested positive impacts of produce prescriptions on glycemic control, blood pressure, and BMI (17 and Hager et al., unpublished observations). The first is that our study was affected by the unprecedented national disruptions in clinical care and economic and public safety instability during 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. Nutritional education was cancelled, and patients received vouchers through the mail instead of in-person pickup at the clinic. During spring and summer 2020, some participants likely experienced disruptions in work and/or 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 summer 2020, 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

Table 1—Characteristics of produce prescription participants and control participants

Characteristic	Treatment (*n* = 252)	Control (*n* = 534)	Standardized mean difference	Weighted Treatment (*n* = 252)	Weighted Control (*n* = 534)	Weighted Standardized mean difference
Mean (SD) age at enrollment, years	61 (13.6)	58.4 (14.2)	0.19	60.4 (10)	60.4 (7.2)	0.0
Female sex	164 (65.1)	293 (54.9)	0.21	164 (61.7)	293 (61.7)	0.0
Race/ethnicity						
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						
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						
Never	121 (48.0)	260 (48.7)	−0.01	121 (47.2)	260 (47.2)	0.0
Former	95 (37.7)	183 (34.3)	0.07	95 (36.7)	183 (36.7)	0.0
Current	36 (14.3)	91 (17.0)	−0.08	36 (16.1)	91 (16.1)	0.0
Comorbidities						
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
Mean (SD) cardiometabolic markers at enrollment						
HbA_{1c}, %	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/m^2	32.6 (7.0)	33.1 (8.4)	−0.05	32.5 (5.1)	32.5 (3.9)	0.0
Mean (SD) health care use 6 months before enrollment						
n of emergency department visits	0.01 (0.08)	0.01 (0.07)	0.05	0.00 (0.04)	0.00 (0.03)	0.0
n of inpatient hospitalizations	0.01 (0.10)	0.05 (0.26)	−0.19	0.02 (0.09)	0.02 (0.07)	0.0
n of outpatient office visits	0.8 (1.6)	0.7 (1.7)	0.08	0.8 (1.1)	0.8 (0.7)	0.0
n of outpatient hospital visits	1.8 (0.4)	1.5 (0.5)	0.24	3.3 (2.4)	3.3 (1.6)	0.0
n of clinical consults	2.2 (2.6)	1.7 (2.4)	0.19	2.0 (1.7)	2.0 (1.2)	0.0

Data are presented as *n* (%) unless otherwise indicated.

context of this instability, it simply may be that $60 per month for F&V was not enough to affect 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 and 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 resulting from climate change, another pandemic, or economic downturns.

The high overall redemption rate (90%) shows strong voucher use and suggests this population had a high unmet need for additional resources to purchase F&V. The redemption rate dropped from 98% before COVID-19 to 85% after the COVID-19 pandemic began. This highlights the adverse effects of COVID-19 on program engagement, although an 85% redemption rate is still higher than those in previous produce prescription reports (Hager et al., unpublished observations).

In other prescription produce programs with a median voucher amount of $43 per month (interquartile range 31–60), HbA_{1c} was significantly reduced among patients with diabetes, but this study lacked external controls (Hager et al., unpublished observations). The USDA estimates that an individual would need to spend $63–78 per month to meet their recommended daily F&V intake (32). Thus, the $60 monthly voucher could have provided reasonable financial support for an individual to increase F&V intake. On the other hand, the household size among participants ranged from one to six (median two), and the relative impact of the voucher on F&V intake could decrease with higher household size if F&V were shared among household members. Exploratory analyses did not suggest a differential association between program participation and glycemic control when stratified by household size.

There is wide variation in produce prescription programs in published research (19,34). For example, some programs increased benefits for additional household members (ours did not), and research suggests diminishing returns

Table 2—Change in HbA_{1c}, blood pressure, and BMI between treatment and control groups

	6 months			9 months		
Outcome	Change in treatment	Change in control	Between-group difference	Change in treatment	Change in control	Between-group difference
HbA_{1c}, %	−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)

Data are presented as mean (SE). N = 252 in treatment group, and n = 534 in control group. Results are from longitudinal GEE 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. The produce prescription program lasted 6 months for each participant.

on F&V intake within larger households when the incentive value is not scaled by household size (35). Other components that may affect success include the frequency, intensity, and quality of nutritional education and which retail or farmers market 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 nutritional education (19,21,36); in our study, most participants (86%) did not attend the nutritional education event or grocery store tours. 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 nutritional education on participant health outcomes.

Our study included a sufficiently large sample size, used 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 that did not incorporate control participants were influenced by regression to the mean rather than a causal effect of the intervention (17). However, in pre-/postanalysis in the present patient cohort (i.e., omitting the control group), we did not observe improvements in clinical biomarkers, suggesting that this population and/or time during COVID-19 may be relatively unique. Our findings suggest that future programs may require more touch points with participants, higher incentive values (perhaps scaled by household size), longer duration, and/or more intensive nutritional education to have an impact on health outcomes.

The programmatic structures of produce prescriptions will be critical to understand as health care policy continues to show a strong interest in produce prescriptions. Increasingly, states are leveraging flexibility in Medicaid through Section 1115 waivers and 1915 waivers in lieu of service options to cover produce prescriptions, and Medicare Advantage plans can provide optional benefits to cover produce prescriptions (37). The USDA is currently providing $5 million per year in competitive grants for produce prescription implementation in health care settings (27) and recently announced a major expansion of this program (38). 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 study with a comparison group to evaluate the impacts of a produce prescription on glycemic control and possibly the first produce prescription evaluation to assess impacts on health care use. The analysis used biomarker data from electronic medical records that were measured by clinical staff, removing concerns of biases related to self-reported health

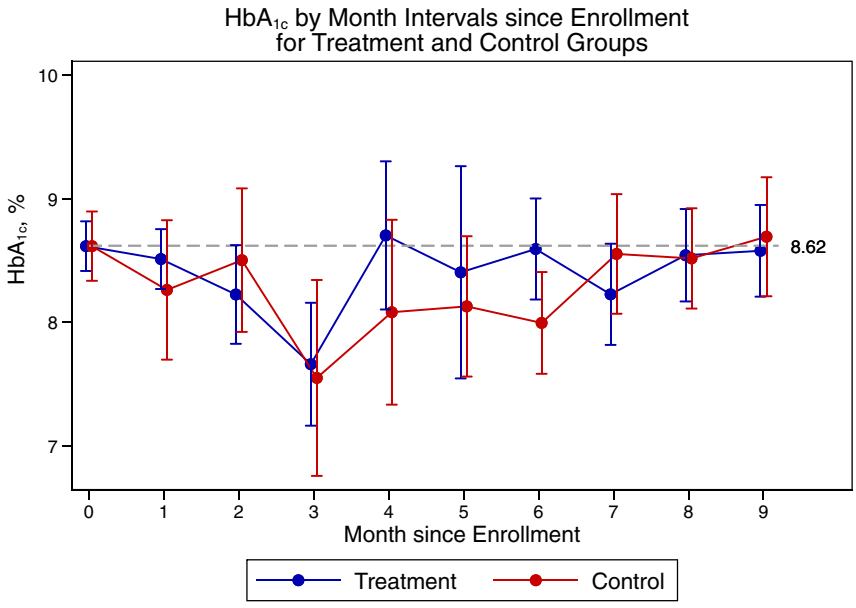

Figure 1—HbA_{1c} (%) by month intervals since enrollment for treatment and control groups. Results are from longitudinal GEE model using overlap weights created from propensity scores that predict probability of treatment. Each dot represents mean HbA_{1c} in treatment (blue) or control (red) group within a monthly interval (e.g., baseline, within first month, within second month, and so on). Bars represent 95% CIs. With overlap weights applied, the mean Hba_{1c} at baseline is equivalent for treatment and control groups. CIs are smallest at baseline because every participant in the treatment and control groups has a baseline measurement.

Table 3—Incidence rates of inpatient hospitalizations and emergency department admissions associated with program participation at 6 and 9 months after enrollment

	Treatment		Control		
Time interval	Count	Incidence rate (SE)	Count	Incidence rate (SE)	Incidence rate ratio (95% CI)
Inpatient hospitalizations					
6 months	3	0.01 (0.01)	14	0.02 (0.01)	0.54 (0.14, 1.95)
9 months	5	0.02 (0.01)	24	0.03 (0.01)	0.54 (0.20, 1.50)
Emergency department admissions					
6 months	1	0.01 (0.01)	4	0.01 (0.00)	0.53 (0.06, 4.72)
9 months	3	0.01 (0.01)	5	0.01 (0.00)	1.27 (0.30, 5.32)

N = 252 in treatment group, and *n* = 534 in control group. Results are from negative binomial GEE models using overlap weights created from propensity scores. Models describe the incidence rate ratio (i.e., relative risk) of hospitalizations 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 before enrollment is equivalent for treatment and control groups. The produce prescription program lasted 6 months for each participant.

measures. We collected data 1 year before program enrollment and up to 1 year after program enrollment, capturing more baseline and end point measurements, minimizing missing data, and extending sensitivity analyses to 9 months postenrollment. We used weighted longitudinal models to assess trends over time between treatment and control groups, incorporating all available measurements to increase statistical precision. Overlap weights improved internal validity by accounting for confounding while overcoming limitations 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. Finally, because repeat clinic visits were required for both treatment and control participants for study inclusion, differential bias resulting from the frequency of clinic visits was less likely, and the internal validity of the study was likely preserved, although findings may be most applicable to patients visiting their provider at least twice per year.

There are several limitations in our study. The health care, societal, financial, and nutritional disruptions of COVID-19 are the largest. Hartford Healthcare reduced its clinic operations from March to June 2020 and relied heavily on telehealth, resulting in fewer laboratory measurements during this period, leading to lower statistical precision. However, sensitivity analyses expanded our time horizon to 9 months postenrollment, allowing the capture of additional end point data. Hartford Healthcare observed that emergency department admissions declined after March 2020, suggesting avoidance or fear of contracting COVID-19 (a trend seen nationwide) (39) and potentially underpowering the health care use analyses. The timing of laboratory 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 control participants to have a laboratory measurement on their enrollment date. This could have contributed to differences in timing and frequency of outcome measures between the two groups and subsequently biased results in unpredictable directions. The program did not assess F&V consumption directly; however, redemption rates were recorded and averaged 90% over the course of the study. Because participants spent most of their allotted produce prescription of $60 per month, F&V consumption likely increased, although we cannot confirm this occurred. This was not a randomized controlled trial and could not determine causality, although our methods aimed to leverage the most robust comparison group available with adequate statistical power.

In summary, this quasiexperimental study found that a 6-month produce prescription program for individuals with diabetes, implemented during the onset of the COVID-19 pandemic, was not associated with a significant change in HbA_{1c}, BMI, blood pressure, or number of inpatient hospitalizations or 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 assess the potential benefits and important programmatic components of produce prescriptions, using strong study designs, including randomized controlled trials, so that successful models can be identified and scaled to improve health equity and quality of care.

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