Produce Prescription for Type 2 Diabetes in Australia

A literature review and background brief for the Translation Advisory Group Stage 1 Workshop

August 2023





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Context

This document is prepared based on a literature review with the intent to provide the Produce Prescription Translation Advisory Group (TAG) Members with:

- A high-level overview of the governance, funding, and operational structure of produce prescription programs currently operating in the United States,
- An overview of questions related to developing an implementation model for produce prescription in Australia that we will be asking for your input at the upcoming Workshop, and
- An overview of the current proposed design of the Produce Prescription randomized controlled trial for individuals with type 2 diabetes in Australia.

The document has been designed as part of the first produce prescription TAG workshop (August 8th, 2023). By highlighting examples of successful produce prescription programs in the United States, it is hoped the information will support TAG Members to consider the development of a sustainable implementation model of produce prescription in Australia for individuals with type 2 diabetes (e.g. feasible and sustainable funding models and patient referral procedures). Findings from the workshop will also be used to inform and potentially revise the design of the proposed clinical trial to support integration of produce prescription into Australian health pathways.

This brief is prepared by the Produce Prescription Research Team at The George Institute for Global Health, supported by Ms Jenn Madz (Strategic Health Partnership Manager), Diabetes Australia.

Using the document

We ask TAG Members to please review this document prior to the first TAG workshop. If you would like clarification regarding any content, please email us at *ProduceRx@georgeinstitute.org.au*

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Part 1 Introducing Produce Prescription and Case Studies From The Field

Introduction

There is growing recognition that healthcare systems need to address social determinants of health to improve population health and health equity.¹ 'Food is Medicine' characterises a set of social prescribing strategies that seek to integrate nutrition interventions into the structure and funding of healthcare systems for the prevention, management, and treatment of diet-responsive diseases, especially for vulnerable groups.² These interventions are tailored to address specific health conditions, are administered through the healthcare system at no or minimal cost to the patient and are often combined with nutrition education to also address health literacy.

Produce Prescription – a prominent example of the Food is Medicine approach

'Produce prescription' programs have recently been developed whereby health professionals prescribe healthy foods to people with difficulty accessing nutritious foods and/or living with or at risk of chronic diseases. Produce prescription is delivered in the form of monetary incentives (e.g. vouchers or prepaid debit cards for food purchases at retail or program sites), or as subsidised food boxes, either delivered to or picked up by the recipient. Research, mostly from the United States, suggests that produce prescription could have significant health and economic benefits, take pressure off the healthcare system, and contribute to wider food policy and health system reform.^{3, 4, 5, 6, 7}

Overview of Produce Prescription Programs

A summary of the design of typical produce prescription programs in the United States (where most such programs exist) is shown in Figure 1.

Figure 1. A typical produce prescription program in the United States



*Not all produce prescription programs require an education component **Some programs use third party evaluation Source: adapted from the *National Produce Prescription Collaborative* While existing produce prescription programs follow the general blueprint described in Figure 1, differences exist between implementation models to account for local contexts, e.g. participation in produce prescription may range between 6 to 12 months, and healthcare providers may differ in which diet-related chronic diseases are considered eligible for produce prescription.

The United States Context

The number of produce prescription programs across the United States has significantly increased in the last five years (>150 active programs across the country by 2023) driven by a recent influx of healthcare funding. These are outlined below to provide brief context to the case studies that follow.

Under the 2018 Farm Bill, the <u>US Department of Agriculture (USDA) Gus Schumacher</u> <u>Nutrition Incentive Program (GusNIP)</u> is authorised to provide funding opportunities for projects providing incentives to increase the purchase of fruits and vegetables by low-income consumers. There are three types of grants, one of which is the Produce Prescription Grant, that supports grantees to conduct projects to demonstrate and evaluate the impact of produce prescriptions.

In late 2022, the Biden-Harris Administration launched the <u>National Strategy on Hunger,</u> <u>Nutrition and Health</u> that included a commitment to explore using Medicare^A and Medicaid^B funding to enable access to Food is Medicine programs, other nutrition supports and obesity counselling. States like <u>Arkansas</u>, <u>Massachusetts and Oregon</u> have received <u>federally approved</u> <u>waivers</u> to use Medicaid funding to test and evaluate Food is Medicine pilot programs.

Case Studies

Three cases studies are presented below to further illustrate how produce prescription programs currently operate in the United States and highlight similarities and differences between programs. These programs were chosen due to their prominence in the produce prescription space and/or evidence for health benefits and cost-effectiveness of the programs. To help inform and stimulate consideration on how produce prescription could be adopted in the Australian setting, each case study is described by mapping against key implementation framework components:

- *Funding and governance* e.g. What governance structures are in place overall, and who funds these programs?
- *Health System Integrated Pathways* e.g. what are the existing screening tools, eligibility criteria, referral and model of care pathways?
- Produce solutions and delivery e.g. what is the food system intervention design?
- *Maintenance* e.g. What resources exist (services, partnerships, alliances and tools) that could support program implementation and its sustainability?
- *Measures* e.g. What data is being collected and or what measures show success? Are there measures that are most relevant for policy makers?

A Medicare: Federal health insurance for people 65+ and those under 65 with a disability; no income level criteria

B Medicaid: a joint Federal and State program to help cover medical costs for people on low-income, any age. While the Federal government sets general rules for Medicaid, each State runs its own program. This means eligibility requirements and benefits can vary from State to State.

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Case Study 1: DC Greens – Produce Rx

DC Greens is an African American-led, multiracial non-profit organisation that aims to advance equitable food policy, education, and access to build a more just and resilient food system in Washington D.C. They work with residents experiencing food insecurity to influence the production, accessibility, and affordability of nutritious foods. They also work in collaboration with community members, peer organisations and partners in government.

Framework Component	
Funding and governance	Funding: <u>Federal government</u> (USDA GusNIP grant, \$503K 2019-23), <u>State government</u> (DC Health Department), <u>Philanthropic</u> (foundations/trust funds, individual donors, commercial/industry, non-government organisations).
Integration pathway	 Program currently focuses on individuals with the following eligibility criteria: Adults ≥18 years old Diagnosed with hypertension, diabetes, or prediabetes DC Medicaid member Currently enrolled in a partner Medicaid plan at partner primary care clinics (Medicaid enrolment is used as a proxy for food insecurity) Able to shop at a participating grocery store locations Delivered in partnership with a major grocery chain (Giant Food). Health care providers at partner primary care clinics assess program eligibility and issue a prescription, promoting participants to receive the intervention
Produce solutions and delivery	Intervention: Participants receive \$80 per month on a store card that can be spent on eligible fresh or frozen fruits and vegetables at participating stores. Patients can participate in the program for up to 1.5 years. Dollars expire after 3 months and patients renew their prescription through their healthcare provider. Delivery: Participants pick up a Giant Food bonus card in-store. The card is linked with the patient's phone number and features a 'Produce Rx' sticker to identify that it can have produce prescription dollars loaded on it. Patient fills their 'prescription' at a participating Giant pharmacy. Pharmacist loads \$240 (i.e., 3 months of prescription) onto the card. Patients renew their prescription every 3 months and the prescription is sent directly to a Giant pharmacy. Nutrition Education: A dietitian employed by Giant provides free consultations. Participants can also participate in nutrition and cooking classes.
Maintenance	In early 2023, DC Greens partnered with About Fresh (a start-up non-profit in Boston) to scale-up produce prescriptions in Washington D.C. The pilot solution is called <i>Fresh Connect</i> - a Visa debit card designed specifically for produce prescription that integrates healthcare IT infrastructure to streamline program administration and impact measurement. All current DC Greens patients have been transitioned from the Giant Food bonus card to the Fresh Connect Card, enabling them to use their produce prescription dollars in Giant Food as well as participating Walmart and Safeway stores. Fresh Connect was used as part of a produce prescription randomized controlled trial recently completed with Boston Medical Center (data analysis in progress).
Measures	Body-mass index, blood pressure, HbA1c, medical care plan adherence, total health care expenditures, healthcare utilisation costs. Evaluation of program's impact on these measures is ongoing.

Case Study 2: Geisinger Health – Fresh Food Farmacy

Geisinger Health System is an integrated, physician-led health-care delivery system that operates 100 specialty clinics and primary care facilities in Pennsylvania and southern New Jersey. Geisinger is also a health insurance company, offering coverage in conjunction with the Pennsylvania Department of Human Services.

Framework Component	
Funding and governance	Funding: Fresh Food Farmacy (FFF) is primarily funded by Geisinger Health revenue streams acquired through its health service and insurance provision i.e. <u>Federal and State</u> government (Medicare, Medicaid), commercial, individual self-pay. FFF is also funded by <u>philanthropic</u> program donations received via the Geisinger Health Foundation.
Integration pathway	 Program currently focuses on individuals with the following eligibility criteria: Adults ≥18 years old Diagnosed with Type 2 diabetes HbA1c levels greater than 8.0% (as assessed by a primary care provider), Geisinger Health patient or have Geisinger Health Plan insurance. Regular primary care provider contact Financial difficulties paying for food Patients are screened and referred by their primary care doctor (Geisinger physician or other) or via contacting the program team.
Produce solutions and delivery	Intervention: Participants receive enough food to prepare meals for their whole family, twice a day for five days (10 meals per week). Food includes wholegrains, fruit and vege- tables (mostly fresh, limited canned/frozen options) lean proteins, low-fat dairy, some other pantry staples. On a case-by-case basis; participants may receive cooking equip- ment to help in food preparation. Program lasts indefinitely; there is no predetermined end date. Delivery: Food is primarily supplied by Central Penn Foodbank and CEO Weinberg Regional Food Bank. Some food is also purchased from wholesale food distribution and retail stores. Participants make bi-weekly food pickups from Geisinger's three FFF sites/ partner satellite location. Nutrition Education: Participants attend a weekly diabetes or chronic disease self-management program and have access to classroom education offered by dietitians and other care team members at no cost. Participants also have access to the FFF mobile app, which includes healthy recipes and nutrition information.
Maintenance	FFF is an example of Geisinger Health's Medical Home Model. This model includes an integrated clinical team of physicians, registered nurses, dietitians, health coaches and/or community associates.
Measures	A <u>randomised controlled trial</u> of Geisinger's Fresh Food Farmacy program is currently underway as the program expands to new sites. Outcomes will include clinical meas- ures (e.g. HbA1c, weight, blood lipids); self-assessed measures (e.g. self-efficacy, patient satisfaction); and healthcare utilisation and healthy behaviour measures (e.g. appointment and preventive care plan adherence) as observed from electronic health records and paid claims data. These will be measured for subjects and their household members.

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<u>Case Study 3: Hispanic Health Council & Wholesome Wave -</u> <u>Fidelity, Equity, and Dignity (FED) in Produce Prescriptions</u>

The FED Program is a collaboration between 1) Hispanic Health Council, a nationally recognised, non-profit organisation, whose mission is to improve the health and social wellbeing of Latinos; and 2) Wholesome Wave, a non-profit based in Connecticut that aims to address diet-related diseases by helping low-income Americans buy and eat healthy fruits and vegetables. It operates nationally through a partnership approach, working with community-based organisations to co-design programs that centre on community fidelity, equity, and dignity.

Framework Component	
Funding and governance	Funding: <u>Federal government</u> (USDA GusNIP project grant \$458K from 2022-25), <u>Commercial</u> (Walmart grant, corporate donors), <u>Philanthropic</u> (individual donors, foundations)
Integration pathway	 Program aims to recruit individuals who meet the following eligibility criteria: Pregnant women in their first trimester served by the Hispanic Health Council Patients registered with Hartford HealthCare's Women's Ambulatory Health Services clinic The program will be implemented at Hartford HealthCare's Women's Ambulatory Health Services clinic.
Produce solutions and delivery	This project will take a highly participatory process with participants to apply the Fidelity, Equity, and Dignity (FED) social justice framework to the implementation and refinement of this program model. Intervention: 10 months of fresh fruit and vegetable prescriptions of \$100/month. Delivery: Prescription is redeemed through Full Cart's food box home delivery program or at a variety of locally owned community markets. Full Cart is a virtual foodbank. Nutrition Education: HHC bilingual registered dietitians will work with patients through participatory planning, goal setting, and culturally-appropriate nutrition education, complemented with supportive text messages.
Maintenance	"Fidelity, Equity, and Dignity (FED) in Produce Prescriptions: Participatory design for social justice and healthy food systems" is a <u>three-year partnership project</u> between Wholesome Wave, Hispanic Health Council, Hartford Health System and Yale- Griffin Prevention Research Centre. Findings will inform updates and refinements to Wholesome Wave's core produce prescription program and build evidence to support scale up of the FED-model to be used by Husky Health, Connecticut's Medicaid program.
Measures	Fruit and vegetable intake (of primary interest), and other outcome measures including HbA1c, body mass index, household food security, gestational weight gain, self-reported health outcomes (e.g., mental health, social cohesion, and dignity) and participant program satisfaction. Evaluation of program's impact on these measures is ongoing.

Part 2 Considerations for Produce Prescription Implementation in Australia

As we begin the process to co-design a sustainable model and framework for implementing produce prescriptions in Australia, we have developed the key questions below that we will be asking for your input at the upcoming Workshop, in relation to key implementation framework components.

Although increasing nutritious produce intake could also be beneficial for other noncommunicable diseases, for the purpose of the Workshop please focus your considerations on developing produce prescription for people with type 2 diabetes.

Workshop Questions

Framework Component	Workshop Questions
Existing Governance Structure	What existing initiatives/schemes/services could this 'prescription' be integrated with to improve its sustainability and success?
Funding	From your perspective, what potential funding models would support implementation of produce prescription programs in NSW and Australia?
Integrated Pathway	From your personal and/or organisational perspective, do produce prescriptions align with your/your organisation's goals or values?a) If yes, whyb) If no, why not?
	Broadly speaking, what do you think are the
	a) potential benefits of implementing produce prescription programs into the Australian healthcare system?
	b) potential challenges of implementing produce prescription programs into the Australian healthcare system?
	What group(s) of individuals with type 2 diabetes should a produce prescription program be designed for? Why?
	How would screening and referral for eligible participants to this type of program be achieved?
	a) Do you think GP or other health professional referrals could work? What considerations go with this?
Program Design	Which organisations are important to have involved in a produce prescription program for Type 2 diabetes?
	a) What do you think each of their roles would be?
	b) How should they work together?
	Considering your district context/location, what would be the best way (i.e. mechanism) to get fresh produce to participants in this type of program?
Measures	From your perspective, what kind of data, measures and outcomes would be important to capture as part of produce prescription programs, to adequately assess the impact of the program on the participants?
Maintenance	Is there anything else that you feel is important to consider for sustainable produce prescription program implementation in NSW/Australia?

Part 3 Proposed Trial Design

The Produce Prescription Randomised Controlled Trial

The produce prescription trial aims to determine the effect of a produce prescription intervention on glycated haemoglobin (HbA1c, %) and other key clinical outcomes in participants with type 2 diabetes and ongoing hyperglycaemia who experience food insecurity.

Figure 2 outlines the current proposed design of the produce prescription randomised controlled trial. Pending information gathered from the Workshop, certain designs of the trial could be revised to incorporate suggestions from TAG members, if within the research team's resource constraints.

Inclusion criteria include: (1) adults (\geq 18 years of age); (2) have had diagnosed T2D for at least 12 months; (3) have persistent significant hyperglycaemia (HbA1c \geq 8% for at least 6 months based on their two most recent clinical assessments); and (4) are food insecure based on a two-item questionnaire, a validated tool that has been used in Australia.

Exclusion criteria include: (1) unable or unwilling to provide informed consent; (2) not staying within their home in the next 6 months; (3) in hospice or palliative care; (4) are living in a facility that provides most of their meals; (5) do not have a refrigerator for storing food; (6) have a medical condition e.g. coeliac disease that requires a specific diet; (7) are pregnant; are (8) participating in other lifestyle modification research projects; or (9) live in a household with someone already participating in the trial.

Intervention: Healthy food boxes will be prescribed to the intervention group and delivered by an industry partner once a week for 6 months. Based on prior research, the boxes will contain healthy foods (fruit, vegetables, grains, and nuts/seeds) with a total retail value of \$30 (for participants with 1-person households), \$45 (2-persons), \$50 (3-persons), and \$75 (4+ persons) per week. Intervention group participants will also have access to 30-minute phone appointments with Accredited Practising Dietitians from immediately after delivery of the first food box, and subsequently at 4 and 10 weeks.

Control: Participants will receive immediately after randomisation a \$50 grocery voucher that can be used at a local food retailer of their choice. They will be provided with another \$50 voucher every 4 weeks and after the final follow-up (total \$400). The goal of providing the vouchers is to achieve ongoing engagement and to maximise the likelihood that full follow-up data are provided. There will be no specific recommendations about how the vouchers are to be spent.

Primary outcome: Glycated haemoglobin (HbA1c)

Secondary outcomes: Blood lipids, blood pressure, body weight, patient reported outcome measures, diet quality, process outcome measures, and cost-effectiveness analysis.





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