Cost-Effectiveness of a Rural North Carolina Hybrid Prescription Produce Diabetes Self-Management Program

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Abstract

In recent years diabetes has become a prominent issue in healthcare. With diabetes prevalence increasing over the past decades, research into programs that can effectively reduce the symptoms and comorbidities of diabetes has become more popular. Diabetes Management Programs are initiatives that directly work with diagnosed diabetics to improve education on the condition while reducing the impact of it on daily function. Such programs focused on physical activity, medication usage, nutritional education, and prescription all aim to use different methodologies to create this effect. Cost-effectiveness of these programs has been researched through existing literature. The Fresh Start Program is a hybrid 20-week Diabetes Self-Management project created due to the need for sustainable healthy food options in rural areas of Eastern North Carolina. The program aims to educate and provide resources to uninsured individuals in managing diabetes. This paper serves as quantitative evidence of both the cost and cost-effectiveness of participants of the Fresh Start Program. The hybrid Fresh Start Program utilizes approaches of other diabetes management programs and has a comparable cost to each analyzed program type, $528.8 per participant. Participants experience a significant benefit in terms of program benefits including improved diet quality and physical activity, stabilized HBA1c, and decreased weight indicated by a potential cost savings benefit of $2,220.52 per participant. Public health organizers and advocates can utilize the findings of this paper as evidence of the cost-effectiveness of programs similar to Fresh Start.

I. Introduction

Diabetes has become a persistent issue in healthcare. With the prevalence of diagnosed diabetes steadily increasing since 2001, along with estimates of increased prevalence in 2045, the importance of diabetes management has come to the forefront of healthcare.[1,2] Type 2 Diabetes cost the United States an estimated $412.9 billion per year predominantly affecting adults between the ages of 65 and older (29.2% of all diabetics).[3] As a chronic condition that impairs the subject's ability to turn food into sugar for cellular energy, the comorbidities of diabetes also impair regular daily life. Increased risk of vascular disease, stroke, cardiovascular disease, neuropathy (mostly found in the feet), and skin/oral issues are common complications that drive the high healthcare cost for diabetics.[3] Medical costs of managing diabetes are expensive to patients with the condition. On average, in the United States, people with diabetes have annual medical expenditures of $19,736 (2.6 times higher than what would be expected without diabetes) causing many diabetics to worry about finding cost-effective interventions that will reduce their overall healthcare spending.[4]

To further lower A1c levels, many types of diabetes management interventions have been employed including: (1) physical-activity programs that take advantage of the direct correlation between exercise and reduced A1c levels, (2) diabetes medication which directly assists sugar breakdown and intake into the cells, and (3) health/culinary education programs that increase food literacy to offer individualized suggestions for diabetes control.

As of now, there is no other existing literature that compares the cost of these types of diabetes management programs to a program that combines each management type such as the Fresh Start Program and measures the cost savings for each participant post-participation. This study seeks to utilize a comprehensive cost-benefit analysis of the Fresh Start Program to provide further context of the effectiveness of prescription programs on patients with type-2 diabetes. We hope that this analysis will provide evidence for both the effectiveness of the Fresh Start Program along with giving the basis for replication for other organizations.

II. Literature Review

Further analysis of these interventions have shown varying levels of estimated cost savings:

A. Physical Activity Programs

Increasing physical activity is a crucial therapeutic aid in reducing diabetes and its complications. Physical activity can reduce associated stress, heighten one's sense of well-being, and reduce the risk of other chronic conditions along with improving glycemic control.[5] Physical-based diabetes interventions have been growing in popularity as an inverse correlation between the amount of time spent exercising/BMI reductions and healthcare costs have been found. An analysis of responses from the 2000-2010 Medical Expenditure

compared savings from a given percent reduction in individuals within the obesity BMI range and patients with and without diabetes. found that just a 5% reduction in body weight of people with a BMI between 30.0 and 39.9 (the most common BMI range for those diagnosed with diabetes) saved an average of $605.82.[6] When paired with a comprehensive physical activity program researchers found physical activity such as walking or exercising in groups delivered in person, or by phone or mail was more cost-effective than supervised gym-based exercise classes or instructor-led walking programs.[7]

B. Medication Programs

Medication along with the supervision of a primary care physician can save patients money on healthcare costs. A 2017 study found that when two groups, a DIMM group (Diabetes Intense Medical Management group) and a Primary Care Physician and Pharmaceutical group (which paired both primary care treatment along with pharmaceutical methods to lower A1c) found when physicians and pharmaceuticals are used together patients could save an average of $3,506 per year.[8] Compared to a 2015 experimental study that compared healthcare costs of patients who continuously used a once-a-day Liraglutide versus patients who did not consistently take the medication concluded that patients who did take the medication had a significantly higher drop in A1c levels but had higher healthcare costs. The differing results of medication-based intervention studies are an indication of the need for further studies.[9]

C. Nutrition Education/Culinary Medicine Programs

Culinary medicine is a branch of medicine that focuses on an individual's diet and improving healthy cooking methods for better health outcomes. In literature, the effects of culinary medicine programs have been positive. The Do Well, Be Well with Diabetes Program at Texas A&M is a 5-week education program that promotes lifestyle changes in areas such as nutrition, exercise, and monitoring blood glucose levels type 2 diabetics estimated lifetime health care savings were $96,807 for females and $48,801 for males. Studies have also shown similar positive results. When looking at 317 Hispanic males diagnosed with type 2 diabetes at Mercy Clinic in Laredo, Texas from October 2009 to January 2010, improved culinary education both dropped patients' A1c levels below 7% and found savings that ranged from $10,995 to $33,319 per QALY (Quality-Adjusted Life Year).[10]

D. Diabetes Self-Management Education (DSME) Programs

Diabetes Self-Management programs are programs intended to work with diabetics to better regulate blood glucose levels through better education of diabetes as a chronic condition. DSME Programs look to better patients' health literacy to achieve better outcomes to improve the attitudes and perceived behavioral control of managing diabetes. When studies have been used to verify its effectiveness, DSME programs have been shown to decrease healthcare costs with variable savings. A 2015 retrospective survey of patients within the Behavioral Risk Factor Surveillance System from the Center for Disease Control and Prevention, showed that when diabetics who had partaken in DSME programs were more likely to "receive/perceive care practice than those who did not get DSME" suggesting lower long term comorbidities.[11] DSME patients were also more likely to receive bi-annual HbA1c tests, annual dilated eye exams, comprehensive foot exams, and attend annual doctor visits. When looked at monetarily, DSME programs have similar benefits. An analysis of outcomes of DSME completers found an estimated healthcare savings of $35,900 per 100 DSME completers in West Virginia as they saved money by reducing hospitalization visits and condition management[12]. Although studies can be adjusted when comparing DSME participants to DSME non-participants, studies show that insured patients were more likely to be able to enroll in and complete DSME programs than their uninsured counterparts.[11,13]

Despite having positive results in the ability to improve blood glucose management along with healthcare costs, the influence of DSME programs has been limited to the uninsured, which make up 35.7% of diabetics aged 18-64.[14]

D. Prescription Produce (PRx) Programs

ProduceRx programs (PRx) have been defined as "a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, PRx is designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction."[15] Through the use of these programs, both food insecurity and low fruit/vegetable diets in low-income areas can be addressed while fostering partnerships with participating food markets. The desire to have such programs can be illustrated in literature where providers with patients diagnosed with hypertension were questioned about their feelings about the implementation of PRx programs. Of the responses, 95.5% of physicians would prescribe it to their patients to improve their patient's hypotension and 80.8% would prescribe it to provide their patients with a healthier lifestyle. When looking at patient goals the standard deviation of a serving of fruits improved from 3.4 servings to 4.7 servings a day and also saw 72.3 of 137 patients tried a new recipe while enrolled in this program.[16] Highlighting the effectiveness of such programs further illustrates its aptitude. Results of a 13-week Fresh Prescription Program designed to improve access and consumption of produce to low-income communities found that outcomes such as HgA1c can be significantly lowered through adherence to such programs with a mean of 9.54%, HbA1c being reduced to 8.83% by the end of the program.[17] However, the limitations of these programs have been identified. The same study did not find a significant change in outcomes such as blood pressure and Body Mass Index. Another study found that after distributing

1,188 vouchers for prescriptions of fruits and vegetables, 72% of participants using such vouchers reported no difference in the consumption and purchasing of fruits and vegetables.[18] Despite the fact that many PRx programs have been geared toward lower-income communities with healthy food insecurity, very few programs have conducted a cost-saving analysis of the program and its outcomes. These programs are typically grant-funded which require in-depth funding requests that highlight the impact of the intervention which newly introduced PRx programs may struggle to provide. Affiliation organizational biases and the economy's status can also be barriers to grant funding.

Although these interventions have shown promising results in managing A1c levels there have been multiple limitations. Interventions such as culinary education and physical activities have not consistently shown that they save participants money in healthcare costs with studies showing differing results. Another limitation is that these interventions are typically held in groups and do not offer individualized goal setting and planning. Other programs such as health coaching and medication have been geared towards individuals but have shown to be more expensive. Not all individuals have adequate access or financial resources to utilize the programs as diabetes disproportionately affects lower-income populations

III. Materials and Methods

Diabetes Overview

The American Diabetes Association has suggested the following ranges of A1c (average blood sugar over the past 2 to 3 months) (Table 1),

Table 1 | American Diabetes Association's Recommended Blood A1C Levels

Category	Range
Normal	<5.7%
Prediabetes	5.7-6.4%
Diabetes	>6.5%

Multiple studies have estimated and/or utilized patient spending records to measure the savings a patient could have through diabetes management (Table 2).

Table 2 | Estimated Diabetes Healthcare Costs per % Reduction

Paper Author(s)	*Cost*	*Measured or Estimated*	*Cost measured*	*Year*
[4]Grabner, M., Abbott,S., Nguyen,M., Chen,Y., & Quimbo,R.	$536 from patients with initial A1c levels >7% to <7% with a 1% A1c reduction	Measured	Medical and pharmacy cost	2013
[20]Lage, M. J., & Boye, K. S.	1% reduction = $429 2% reduction = $736	Estimated	Drug costs, outpatient costs, and acute care costs	2020
[21]Texas A&M AgriLife Extension	$96,807 for females and $48,801 for males (lifetime), reduction the normal range	Measured	Health care and productivity cost	2020
[10]Brown,H. S., Wilson, K. J., Pagán, J.A., Arcari,C.M., Martinez, M., Smith, K., & Reininger, B.	$33,319 Per QALY (Quality-Adjusted Life Year) for those who dropped to A1c level of <7%	Estimated	Medical costs and lifestyle change costs	2012

Fresh Start Program Overview

The Fresh Start program is a hybrid 20-week DSME, physical activity, Culinary medicine, ProduceRx, and counseling program created due to the need for sustainable healthy food options in rural areas of Eastern North Carolina. It works in collaboration with the Department of Nutrition Science at East Carolina University, the North Carolina Association of Free and Charitable Clinics (NCAFCC), the Society of St. Andrews (SoSA), and a local food bank. It differs from other diabetes management programs as it enhances participants' self-efficacy by utilizing different approaches including 1-on-1 behavioral support, group education & physical activity classes to improve knowledge about food literacy along with providing prescriptions.[22,23]Results of the program show improved self-reporting of (1) food literacy (food planning/prepping, budgeting, and nutrition resourcefulness, (2) diet quality (frequency of whole grain, fruit, and vegetable per day), (3) physical activity (minute of physical activity per day, days of physical activity per week, and physical activity confidence), (4) self-efficacy/mental health outcomes (perceived diabetes management and stress), (5) lowered

HBA1c, and (6) decreased blood pressure and weight loss. These results can be attributed to the program's combination of diabetes management approaches at no cost to optimize effectiveness for users.

The Fresh Start Program looks to educate and provide resources to uninsured individuals in managing diabetes. The incidence of diabetes in the adult population of Eastern North Carolina (14%) exceeds both the National (11.6%) and North Carolina average(12.4%)[24]. The program provides (1)fresh produce prescriptions, (2) one-on-one over-the-phone health coaching, counseling, support, and goal setting, and (3) interactive education and physical activity group classes. The free 20-week program utilizes both interns and volunteers for recruitment of participants, packaging and distribution of produce, and facilitation of nine in-person education classes encompassing nutrition education, physical activity, and food preparation/literacy.

The nine classes consist of healthy eating/healthy living. fruits and vegetables. carbohydrates. cooking/meal planning. shopping/budgeting, stress/mental health, diabetes self-management, heart health and a final review to summarize the course of the program. In addition to classes 1 on 1 telephone-based individualized counseling is utilized to aid in goal setting and offer support to participants. Finally, the program consists of a Produce Prescription (Produce Rx) component which distributes 7-10 lbs/variety produce provided at each of the group classes,

The program seeks to both increase patient's knowledge about diabetes and self-efficacy in the control of symptoms and comorbidities through diet, exercise, and overall self-management. This is accomplished through the training of health navigators who aid in the process through either phone calls or text messages for each participant. The frequency of communication is chosen by the patient. Health navigators are ECU student volunteers who are trained in both written and verbal nutritional and physical education. Initial results of the program showed higher rates of perceived food literacy, diet quality, physical activity, and mental health outcomes along with a reduction in HbA1c. Aggregates of eighty-one 2023 Fresh Start participants a mean reduction of 0.97% of A1c with a maximum reduction of 6.1%.

A. Cost analysis procedure

Cost of Illness

The cost of diabetes utilized came from existing literature, specifically a 2022 analysis of the cost of diagnosed diabetes from the American Diabetes Association[25]. This paper used inflation-adjusted direct and indirect medical costs utilizing both state-level and national-level data from the United States Population.

Cost of Programming

The cost of various diabetes programming was found through the averaging of existing literature outlining the cost to facilitate such programs. Existing literature compiled various costs associated with the management and implementation of different diabetes management programs.

The cost of Fresh Start programming, which combines the fundamental purpose of all of the program types, was calculated using financial records and budget proposals totaling $105,750.67 or $528.80 per participant. Costs included with Fresh Start were divided into direct and indirect program costs. Direct costs are any expense related to the implementation and functionality of the program including staff/intern wages, participant costs for sessions (culinary, exercise, counseling, and health coaching), class-related materials, and transportation

IV. RESULTS

Cost analysis procedure

A. Cost of Illness Analysis: Diabetes

The American Diabetes Association found the average per capita cost of diagnosed diabetes for the average United States is $16,191 including direct medical costs ($12,022)[3] . Direct medical costs included institutional care, outpatient care, and outpatient medication and supplies. Indirect costs included productivity loss, inability to work due to disability, and premature mortality (Table 3).

B. Cost Analysis of Programming

Analysis of multiple types of diabetes management in programming in multiple countries showed varying costs associated with the administration of each program with culinary medicine being the most expensive per participant (Table 5,6,7,8). Fresh Start program costs were calculated using the program's original budget and program cost documents and assuming there are 200 participants in the program (Table 4). Costs were converted to the United States Dollar (USD).

C. Cost Effectiveness

This analysis was done in hopes of providing quantitative evidence of the effectiveness of the Fresh Start Program. With this, additional funding and promotion of the program can be sought after. To access the functionality of the Fresh Start Program as an effective diabetes self-management program that raises participants' self-efficacy while managing the physiological comorbidities of the condition a pre and post-intervention survey/analysis was conducted. Data were collected before the start of the intervention and immediately after the participation of the program. The survey portion asked a total of 65 participants about their perceptions of change in diet quality and the amount of physical activity performed per week. The analysis portion measured the change in HbA1c, blood pressure, and weight loss.

Participants showed a statistically significant ($p<0.05$) increase in consumption of fruit and vegetables and found a

non-statistically significant increase in fruits consumed per day. Post-intervention analysis also showed statistically significant days of physical activity per week and a non-statistically significant increase in minutes of physical activity per week.

The average HbA1c level reduction was 0.97% (SD= 1.13%) and the maximum A1c decline of 6.10%. Following along with the previous trend the average weight loss and blood pressure decrease was 2.77 kg (~6.1lbs) (SD= 13.70) and 7.0 (SD=21.8) and 3.7 (SD= 13.4) mm HG reduction in SBP and DBP, respectively. The average cost saved was then calculated for every measure using existing literature on the cost-saving per participant who participated in a similar intervention. Costs were then totaled up and divided by the number of participants in the program. Analysis of the programming indicates that on average, each participant saves $2,220.52 in healthcare costs over the course of the intervention with weight loss being the lead factor for cost reduction.

Table 3 | Cost Components of Diabetes[3]

Cost	**Cost included**	**Amount in USD ($)**
Direct Medical	Institutional Care - Hospital Inpatient Days - Nursing/residential Facility days - Hospice Care Days Outpatient Care - Outpatient and ER visits - Office visits to physicians and other health problems - Ambulance, home health, podiatry Outpatient medication and supplies - Insulin and non insulin glucose-lowering medication prescriptions - Other medication prescriptions - Diabetes supplies and other equipment	$12,022
Total		$12,022

Table 4 | Cost of Fresh Start Program				
Cost	**Cost included**	**Amount in USD ($)**	**Number of Participants**	**Cost per participant**
Direct Program	Staff/Intern wages: $78,219.66 Program cost: **Contractual Services:** $6,000 **Software:** 6,600 **IT supplies:** 1,266.67 **Food items:** $666 **Non perishables:** 1,091.67 **Vehicle maintenance cost:** 2,000 **Capital Expenses:** **Vehicle** 9,041.67 **Food supplies** $675 **Group class trip (roundtrip)** $100 Recruitment/enrollment $60		200	
Total		**105,750.67**		**528.80**

Table 5 |Cost of DSME Programs (n=13)				
Paper	**Cost included**	**Amount in USD**	**Number of participants**	**Cost per participant**
Doyle O'Donnell S, Quigley E, et al[26]	Measured in practitioner hours, number of patients, and capacity cost rate	$1,285.23†	10†	$128.53
Molsted S, Tribler J, Poulsen PB, Snorgaard O[27]	Cost were calculated simply by adding "salary and fees for the team, material costs, upkeep of buildings, etc" divided by the number of patients	$529.62⁻»	12	$44.13
Adibe MO, Aguwa CN, Ukwe CV[28]	Costs was the costs of training materials	$0.51⁻»	55	$0.01
Mikhael EM, Ong SC, Hussain SA[29]	Facilities, equipment, furniture, pharmacists costs, salaries cost educational sessions, electricity	$56.55⁻»	30	$1.89
Average		**1,112.65125**		**$45.64**

† - Average of multiple programs
⁻» Adjusted to USD

Table 6 | Cost of Physical Activity Programs (n=6)				
Paper[30]	**Cost included**	**Amount in USD**	**Number of participants**	**Cost per participant**
Cotyle et al	Lifetime membership to a health club and exercise specialist	Combined Exercise = $32445.18 Aerobic exercise = $31797.08 Resistance exercise = $31027.47	251	$126.51
Johnson et al, 2015	Activity time and training of the exercise specialists, administrative support personnel, recreation facilities, supplies, equipment and primary care networks' overhead	$25,775.74	106	$243.17
Sultana et al. 2018	Direct Costs: Medications,. counseling intervention, laboratory testing, hospitalization and outpatient care Direct social costs:value of participants' time, cost of related items (shoes, fitness equipment, etc.), transportation to exercise places and admission to health clubs. - Indirect social costs: time that participants reported as lost from work or usual activities as a result of counseling visits, illness or injury	$2147.60	75	$28.63
Kou et al, 2021	Intervention costs: implementing the interventions by CBT therapists and exercise trainers, passes/memberships to fitness facilities, participant time spent participating in sessions	$1615	34	$47.50
Marios et al. 2012	Intervention costs: included heart rate monitors, exercise test consumables, physician supervision of exercise tests and salary for exercise physiologist	$27,300	26	$1,050
Average		**$21,729.72**		**$299.12**

Table 7 |Cost of Culinary Medicine Program (n=1)				
Paper	**Cost included**	**Amount in USD**	**Number of participants**	**Cost per participant**
Bonnet JP, Rastorguieva K, Moore MA, Munroe D, Bergquist SH[31]	Costs were then broadly categorized into 1 of 4 areas: program development, course delivery, research, and optional enhancements	$123, 898	40	$3,094.45
Average		**$123, 898**		**$3,094.45**

Table 8 |Cost of Prescription Produce				
Paper	**Cost included**	**Amount in USD**	**Number of participants**	**Cost per participant**
Aiyer JN, Raber M, Bello RS, et al.[32]	Cost of personnel and staffing, food, delivery/inventory, material and supplies including shelf labeling, and other marketing materials	$2,952.4	172	$17.17
Raso D.[33]	Screening and connection to treatment. transportation. capital and material, farmers markets , total nutrition and cooking education general program Cost	$59,152.66	171	$345.92
Newman T.[34]	Food prescriptions,	$13,159	23	$572.13
Average		**$25,088.02**		**$311.74**

management using different approaches. This analysis shows

Table 8 |Benefits of Fresh Start Program				
Benefit	**Number of Participants**	**Savings per participant**	**Source**	**Total costs saved per participant Adjusted to Average Fresh Start Program Change (USD)**
Diet Quality	**1138**	**£695/per participant**	**Gray et al[35]**	**$695**
Physical Activity	**13**	**$492.75/per day on intervention**	**Brun et al[36]**	**$83.66**
HbA1c	**62**	**$56.26/1% reduction**	**Franz et al[37]**	**$56.26**
Blood Pressure	**1,335**	**$188/millimeter of mercury**	**Jacob et al[38]**	**$940**
Weight loss	**70**	**$73/per pound lost**	**Hoch et al[39]**	**$4445.3**
Total Cost Saved per Participant of Fresh Start				**$2,220.52**

V. Discussion

Existing literature has shown evidence of the cost-effectiveness of existing diabetes management programs40. The cost-effectiveness of the Fresh Start Programming compared to existing program types has not been performed compared. Analysis of Fresh Start Programming cost compared to other diabetes management programs indicates that despite being a combination of such programming types, Fresh Start does not differ significantly in cost per participant. Despite having the highest cost to run the program, $105,750.67, with costs coming from staff/intern wages, recruitment, and operational cost; the program is comparable to other management programs including DSME, physical activity, culinary medicine, and prescription produce ($483.16, $229.68, -$2,656.65, and $217.06 respectively). It also shows the potential benefits of the program including improved diet quality and physical activity, stabilized HBA1c, and decreased weight is higher than the direct operation cost of running the program per participant.

The cost-effectiveness of chronic illnesses such as diabetes is crucial in creating successful programming for populations that the condition affects. This paper contextualizes how the low cost of a hybrid diabetes management program aids the enrolled population of uninsured diagnosed type II diabetics to educate and treat the comorbidities of the condition. By utilizing the methodology of pre-existing programs at a low cost, Fresh Start can address the barriers to diabetes that the Fresh Start Program provides the framework for a functional diabetes management program for a vulnerable community. Presentation of such quantitative measures will be used to request additional funding, support, and resources for replication of programming. It serves as a call for increased policy that focuses on medically unserved patient groups.

Limitations

This paper compares the cost of Fresh Start to existing programs. These programs may have not considered several variables that are included in cost measurements. The programs listed contain different participant sample sizes and demographics of participants from various countries using different currencies at varying times of data collection. These variations had an impact on the cost measured per program. We acknowledge that these cost variations could influence the cost measured.

Another limitation of this study is that the cost measured for Fresh Start was taken from proposed budget documents and may not accurately measure the actual cost of facilitating the program.

When measuring the benefits of Fresh Start Programming participants, the average benefits were taken from 65 program participants rather than the 200 regular participants. Although the selection of the 65 participants was completely unbiased, this sample may not accurately represent the effects of participation. Participants were also not asked about other factors that were included in the calculated cost of diabetes such as rate of hospitalization and medication use before and after the program. We hope that future studies will be able to

isolate programs that serve specific subpopulations of diabetics, specifically uninsured type II diabetics when making a cost comparison. We also wish that future studies will be performed as Fresh Start continues to run.

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