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Title Multi-level factors related to the successful implementation and sustainability of the National Diabetes Prevention Program

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Multi-level factors related to the successful implementation and sustainability of the National Diabetes Prevention Program

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Abstract

Multi-level factors related to the successful implementation and sustainability of the National Diabetes Prevention Program

By Lillian Madrigal

To impact health outcomes at a population level, evidence-based interventions must be adopted, implemented, and scaled by a large number of organizations with sufficient population reach. Since 2012 the National Diabetes Prevention Program (National DPP) lifestyle change program has been scaled across the United States; however, further scaling and program reach are needed to make significant population change. In order to understand how the National DPP might better strategize and mobilize to increase its growth and impact, this dissertation explored the multi-level factors related to the successful implementation and sustainability of the National Diabetes Prevention Program through three aims.

This research focused on the facilitators and constraints both within and outside organizations that impact implementation outcomes. The first aim, used a qualitative construct rating analysis to identify key organization- and structural-level causal factors associated with the implementation within 30 National DPP organizations, particularly as it pertains to reach. The second aim sought to quantitatively test the direct and indirect relationships between the organization- and structural-level causal factors, organizational characteristics, and reach using structural equation modeling. Lastly, the third aim utilized latent profile analysis to identify patterns of sustainability capacity among delivery organizations and their associated organization characteristics. For aims two and three the analysis included 586 respondents from a online survey with National DPP implementers.

All three aims provided valuable information to help guide National DPP implementation efforts. Overall, basic program infrastructure and support, such a staff time, resources, and active leadership engagement were most salient and important to the National DPP implementers. In addition to this, this work also identified organizations working with particular populations (i.e. rural communities, non-white populations, etc.) may need additional or unique resources and assistance. These are very practical and seemly obvious factors that impact implementation, but the more evidence to support and emphasize that staff need sufficient resources, time, and supportive organizational environments to do their work is important.

This work contributes methodologically to the implementation science literature, both in study design and measurement. This dissertation will also directly impact training and technical assistance provided to delivery organizations to continue to support capacity building and its scalability.

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Contents

Preface

The following dissertation proposal explores the multi-level factors related to the successful implementation reach and sustainability of the National Diabetes Prevention Program through three studies. Portions of this work are supported by funding from the Centers for Disease Control and Prevention, Division of Diabetes Translation. The dissertation proposal provides a description of the specific studies of the dissertation, a review of the literature, an account of its expected significance, as well as a description of the methodology for each study.

Study Aims

Public health programs and services are delivered by a variety of organizations that range in characteristics and contexts. The facilitators and constraints from both within and outside an organization can determine how well they are able to implement public health programs. Therefore, understanding the internal and external environments in which organizations operate is a critical piece when assessing their success in delivering public health programs and achieving program objectives (L. J. Damschroder et al., 2009; R. E. Glasgow, Vogt, & Boles, 1999; Meyer, Davis, & Mays, 2012).

Internal factors include organizational-level aspects such as organizational infrastructure, leadership, communication processes, staff dynamics, working culture, etc. While external influences focus on the structural-level "economic, political, and social contexts within which an organization resides" (Damschroder et al., 2009). Both the organization- and structural-level are theorized to be causally related to implementation outcomes (Chaudoir, Dugan, & Barr, 2013). Understanding the relationship between specific internal and external factors and implementation help identify which of these elements are more or less important to overall program success (Hanusaik, Sabiston, Kishchuk, Maximova, & O'Loughlin, 2015; Meyer et al., 2012). Program implementers can use this knowledge when considering organizations to adopt their programs and organization capacity building efforts to improve implementation (Dearing, 2018; LaFond, Brown, & Macintyre, 2002). As public health professionals scale evidence-based interventions (EBIs) in multiple settings, understanding various aspects of the organizational- and structural-level and the impact these causal factors have on implementation and program outcomes is valuable (E. Proctor et al., 2015) is of particular importance.

Dimensions of the internal and external environments of organizations have been studied and measured in many different fields and ways as they relate to program implementation (e.g. organizational capacity, organizational readiness, etc.) (Butterfoss, Kegler, & Francisco, 2008; Miake-Lye, Delevan, Ganz, Mittman, & Finley, 2020; Bryan J Weiner, Amick, & Lee, 2008). Public health implementation science models and

frameworks have also conceptualized these internal and external organizational factors (L. J. Damschroder et al., 2009; Dearing, 2018; Highfield, Hartman, Mullen, & Leerlooijer, 2016; Meyer et al., 2012; Wandersman et al., 2008; Bryan J Weiner et al., 2008). Commonly examined organizational dimensions include staff/human resources, physical infrastructure, leadership, inter-organizational relationships/networks, and organizational culture, among others (L. J. Damschroder et al., 2009; Meyer et al., 2012). The challenge with so many definitions and measures is the lack of standardization, which makes it difficult to decide how to assess these constructs for a specific program.

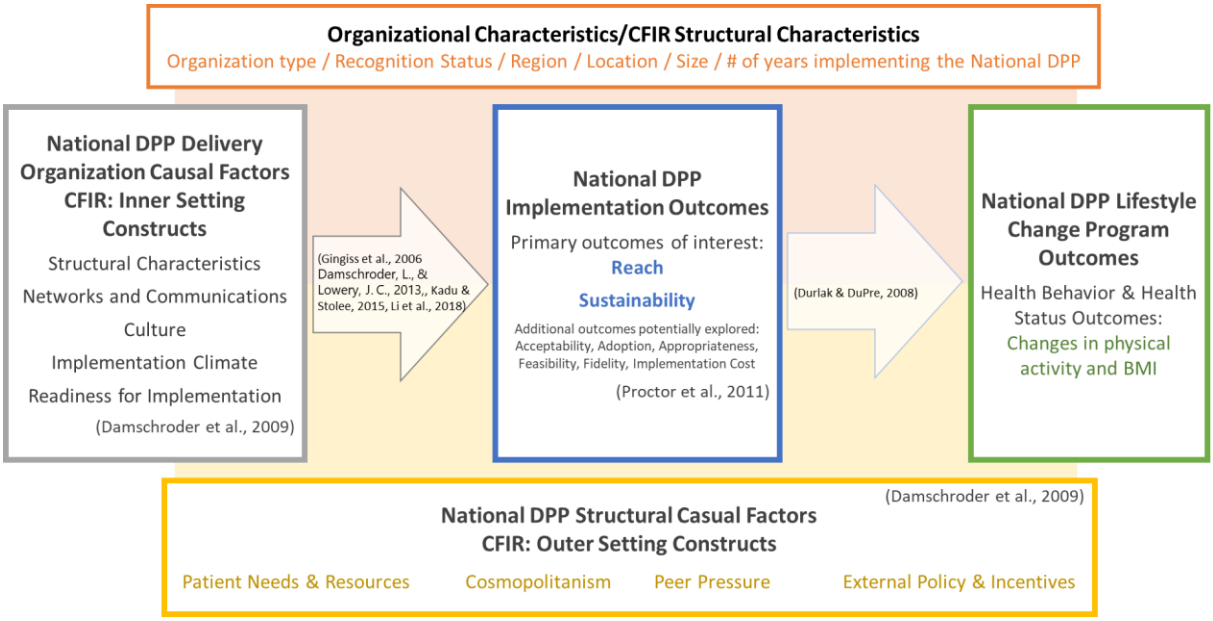
Within public health, the Consolidated Framework for Implementation Research (CFIR) is a meta-theory that has gained popularity in implementation research over the last 10 years since its development (L. J. Damschroder et al., 2009). CFIR is a synthesis of theories or a meta-framework made up of 37 constructs within 5 major domains: inner setting, outer setting, intervention characteristics, characteristics of individuals, and the process of implementation (L. J. Damschroder et al., 2009). CFIR facilitates the identification and understanding of relevant constructs and their application in particular implementation contexts (CFIR Research Team; L. J. Damschroder et al., 2009). The CFIR constructs listed in the inner setting domain aim to capture the complexity within the organization related to implementation. These include constructs such as an organization's structural characteristics, culture, and readiness for implementation. The outer setting constructs provide insight into the greater environments and external context which constrain organizations or facilitate their ability to carry out the intervention. These include constructs such as the cosmopolitanism, peer pressure, and external policies. Therefore, by using the constructs and subconstructs from both the inner and outer settings, various aspects related to organization- and structural-level causal factors can be examined.

The National Diabetes Prevention Program. Using the National DPP as a case study, this project engaged host organizations already implementing the National DPP lifestyle change program to explore, measure, and assess the relationships in the conceptual model. The National DPP lifestyle change program is an

evidence-based, year-long intervention led by lifestyle coaches designed to prevent the progression of diabetes in people with prediabetes (Centers for Disease Control and Prevention, 2018a; Diabetes Prevention Program Research Group, 2015; Knowler et al., 2002). Randomized control trials, efficacy studies and meta-analyses have reported the success of the DPP in impacting type 2 diabetes related health behaviors (physical activity and healthy eating) and outcomes (primarily weight loss and BMI) in program participants across multiple populations (Ali, Echouffo-Tcheugui, & Williamson, 2012; Aziz, Absetz, Oldroyd, Pronk, & Oldenburg, 2015; Ely et al., 2017). With over 2,000 organizations of various types actively delivering this evidence-based program, the National DPP presents a unique opportunity to rigorously study organization- and structural-level causal factors on implementation outcomes.

The CFIR inner and outer setting constructs will be used to operationalize the organization- and structural-level causal factors. The two dimensions of implementation effectiveness examined in this project will be reach (operationalized by the number of participants enrolled in the program) and sustainability capacity (operationalized by the Program Sustainability Assessment Tool scores). Guided by the CFIR meta-theory and the multi-level framework for predicting implementation outcomes by Chaudoir, Dugan, & Barr (2013), this study will address the *central hypothesis* that implementation outcomes (reach and sustainability) are directly influenced primarily by inner setting constructs and these relationships may be directly and/or indirectly influenced (moderated) by the outer setting constructs and organizational characteristics. This is pictured in the conceptual model below (Figure 1). Within the boxes and arrows are key citations of the theory and evidence for these constructs and relationships. This conceptual model is further detailed in the background and significance section under theoretical frameworks.

Figure 1. Conceptual model: organizational factors related to implementation and program outcomes



This study will address critical gaps in the implementation science literature as it will advance the measurement of the CFIR inner and outer setting constructs and test relationships between these constructs and implementation outcomes with a large number of organizations delivering the same evidence-based intervention nation-wide. This work also will advance the mission of the National DPP, by understanding the characteristics and patterns of organization and structural-level factors across delivery organizations. These insights will allow for the CDC, entities providing technical assistance to delivery organizations, and program implementers at delivery organizations themselves to build capacity and plan strategically to increase the impact of the National DPP.

The objective of this dissertation is to further understand of the multi-level factors related to the successful program implementation. This will be accomplished through the following three aims:

Aim 1: Conduct key informant interviews with 30 National DPP organizations to identify the organizational- and structural-level causal factors that most strongly influence implementation reach (measured participant enrollment) using CFIR inner and outer setting constructs.

Aim 2: Quantitatively examine the relationships between CFIR inner and outer setting constructs and the implementation outcome of reach using an online survey with organizations implementing the National DPP lifestyle change program in order to identify which structural- and organizational-level causal factors have the greatest influence on reach.

Aim 3: Explore patterns of sustainability capacity by conducting a latent profile analysis (LPA) with National DPP organizations using the Program Sustainability Assessment Tool (PSAT) in order to understand whether organizations can be categorized into distinct groups based on their sustainability capacity and organizational characteristics.

Chapter 1: Background & Significance

Type 2 diabetes and prediabetes disease burden in the United States

Diabetes is one of the leading causes of death in the country and costs Americans billions in healthcare dollars every year (Centers for Disease Control and Prevention, 2017). According to the latest CDC national diabetes statistics report, approximately 13% of the U.S. adult population are affected by diabetes (Centers for Disease Control and Prevention, 2020). Type 2 diabetes accounts for 90–95% of all diabetes and encompasses individuals who have insulin resistance and usually have relative insulin deficiency (American Diabetes Association, 2004, 2018). One third (34.5%) of adults ages 18 years and older in the United States have prediabetes, a condition that indicates a person is at risk for progressing to type 2 diabetes (Centers for Disease Control and Prevention, 2017, 2020).

Type 2 diabetes is associated with a number of lifestyle-related risk factors primarily physical activity and nutrition that are often influenced by our physical, cultural, and psychological environments (Centers for Disease Control and Prevention, 2017; Rowley, Bezold, Arikan, Byrne, & Krohe, 2017). In fact, type 2 diabetes was previously referred to as “adult-onset diabetes,” due to the appearance in adults typically in middle age as a consequence of these lifestyle behaviors (American Diabetes Association, 2018). However,

recent data revealed that there has been a rise in diabetes risk in younger populations in the U.S., noting that about 1 of 5 adolescents and 1 of 4 young adults have prediabetes (Andes, Cheng, Rolka, Gregg, & Imperatore, 2019). As lifestyle influences impact the health behaviors and outcomes of a growing number of people across the life span it is becoming ever more important to identify interventions that can modify lifestyles and prevent the onset of diabetes.

Preventing type 2 diabetes via behavior change

Before 1990, studies largely focused on diabetes management rather than prevention (Laws, St.George, Rychetnik, & Bauman, 2012). However, as diabetes rates have increased, the focus on prevention has led to the study of many diabetes prevention programs. Lifestyle change/modification interventions in particular have been proven to be an effective means by which to reduce risk of type 2 diabetes and a number of "real world" diabetes prevention trials have been undertaken in a number of countries (Aziz et al., 2015; Dunkley et al., 2014; Johnson et al., 2013; Laws et al., 2012; Mathews et al., 2018; Weber et al., 2016). Lifestyle modification interventions, are those focused on changing individual behaviors (e.g. eating/nutrition and physical activity) related to reducing the progression of type 2 diabetes for people with prediabetes (Balk et al., 2015; Bansal, 2015; Chatterjee, Khunti, & Davies, 2017; Samdal, Eide, Barth, Williams, & Meland, 2017).

Pharmacotherapy is another approach to diabetes prevention; however, there is still a lack of evidence around the long-term effects and benefits of these medications (Bansal, 2015). In fact, what has become known as the original U.S. diabetes prevention program (DPP) lifestyle change curriculum, was born out of a randomized control study to test the efficacy of medication. This study, conducted from 1996-1999, involved more than 3,000 people with prediabetes who were randomized into either a placebo, medication (Metformin, an oral diabetes medicine that helps control blood sugar levels), or lifestyle intervention group (The Diabetes Prevention Program Research Group, 1999).

Researchers found that the lifestyle change intervention significantly reduced the development of type 2 diabetes with greater effect than both the placebo and medication groups (Knowler et al., 2002). Compared to the placebo group, the lifestyle intervention reduced the incidence by 58% (95% CI: 48-66%) and metformin by 31% (95% CI: 17-43%). Furthermore, in a 15-year follow-up study, the lifestyle intervention effects continued to keep type 2 diabetes incidence lower than the no-treatment group (Diabetes Prevention Program Research Group, 2015). The study found that compared with the placebo group diabetes incidence was reduced by 27% in the lifestyle intervention group (hazard ratio 0.73, 95% CI: 0.65–0.83; $p<0.0001$) and by 18% in the medication group (hazard ratio 0.82, 95% CI: 0.72-0.93; $p=0.001$). At year 15, the cumulative incidences of diabetes were 55% in the lifestyle group, 56% in the metformin group, and 62% in the placebo group.

Due to the success of this diabetes prevention program study and several other studies, diabetes prevention lifestyle modification programs have been adapted and translated numerous times, implemented in multiple populations around the world, and are supported by multiple reviews and meta-analyses that continue to report significant positive behavioral and health outcomes (Ali et al., 2012; Aziz et al., 2015; Neamah, Kuhlmann, & Tabak, 2016). In 2015, a systematic-review of 53 studies from around the world including large clinical trials from Finland and China similar to the U.S. DPP study found that programs particularly focused on weight loss and physical activity were effective at reducing diabetes incidence (Balk et al., 2015).

As tracking diabetes incidence is a longer-term indicator, key program outcomes primarily include changes in weight, physical activity, and nutrition (Ali et al., 2012; Ely et al., 2017; Joiner, Nam, & Whittemore, 2017). Studies have also found that program intensity or dosage (e.g. duration of program, number of sessions attended) is associated with program outcomes like weight loss (Aziz et al., 2015; Balk et al., 2015). For example, a meta-analysis of 26 U.S.-based DPP translation studies found a mean weight loss of 4.0% for lifestyle change program participants (Ali et al., 2012). The authors also found that across

programs with every additional lifestyle session attended, weight loss increased by 0.26 percentage point. However, even low intensity interventions have been shown to lead to low or moderate weight loss and can still have considerable impact in lowering diabetes risk in a population (Aziz et al., 2015; Balk et al., 2015).

The DPP curriculum has been adopted and implemented using a variety of cultural adaptation and translational strategies (Neamah et al., 2016). Domestically, scaling the program has typically focused on implementation in specific settings (churches, community centers, etc.) and surface-level cultural adaptations for specific minority or at-risk populations that are not as likely to participate in the program (Rachel G. Tabak et al., 2015). Cultural adaptations aim to increase program fit for the target population to result in greater enrollment, retention, and program outcomes. Adaptations of the program have been made for Alaska Native/American Indians (Jiang et al., 2015), men living in disadvantaged neighborhoods (Gary-Webb et al., 2018; E. A. Walker et al., 2018), the Medicaid population (Kim et al., 2018), and the prison/correctional facility population (Fine, Gallaway, & Dukate, 2019) among others. The CDC also has developed a Spanish-language translation of their curriculum available for programs to use on their website. Successful adaptations and translations of the DPP have also taken place outside the US in India (Mathews et al., 2018; Weber et al., 2016) and South Africa (Catley et al., 2020).

The National DPP Lifestyle Change Program: an evidence-based program to prevent type 2 diabetes through behavior change

In 2010, the CDC established the National DPP to scale and sustain the implementation of an evidence-based, year-long intervention designed for people with prediabetes (Diabetes Prevention Program Research Group, 2015; Knowler et al., 2002). This program, known as the National DPP lifestyle change program, is the most recent evolution of the originally tested lifestyle intervention from the Metformin randomized controlled trial study. The goal of this initiative by the CDC is to create public and private

organization partnerships to deliver evidence-based, cost-effective interventions to prevent type 2 diabetes in communities across the country (Centers for Disease Control and Prevention, 2018b).

This diabetes prevention lifestyle modification program was developed predominantly using constructs from the Social Cognitive Theory (SCT) such as reinforcement, self-efficacy, observational learning, and modeling behavior (Baker, Simpson, Lloyd, Bauman, & Singh, 2011). SCT also targets individual behavior via interpersonal relationships through socio-environmental constructs like collective self-efficacy and social support (Kelder, Hoelscher, & Perry, 2015). In the program, these constructs are mechanized through a group/class-based environment where individuals can create bonds and support with the other participants over time. In addition to SCT, a systematic review of group and individual lifestyle intervention diabetes prevention programs conducted in 2011 found that Transtheoretical Model and Theory of Planned Behavior constructs such as contemplating and preparing for change and goal setting have also been commonly utilized in these types of interventions (Baker et al., 2011).

The current curriculum used in the National DPP is called, “PreventT2”, which mirrors the content of the original DPP lifestyle program and incorporates a number of the health behavior theories mentioned. An organization can choose to use an alternate curriculum, as long as it is reviewed and cleared by CDC and meets all of the key elements of the curriculum used in the DPP research trial. The program is a year-long, with 16 hour-long sessions delivered over 6 months, followed by six additional sessions delivered over the subsequent 6 months (Centers for Disease Control and Prevention, 2021b). Prevent T2 targets a number of health behavior constructs (self-efficacy, attitudes, knowledge, beliefs, social support, etc.) to lead to behavior change. The program’s primary outcome goals for participants include 5%–7% weight loss over 12 months and increased physical activity levels per week.

To assure quality and fidelity of the program the CDC also established the Diabetes Prevention Recognition Program (DPRP). Through the DPRP, the CDC recognizes organizations that successfully deliver the year-

long lifestyle change program consistent with DPRP Standards and Operating Procedures (Centers for Disease Control and Prevention, 2021a). Every three years, the CDC updates its standards based on the scientific literature, analyses of organizational outcome data, and input from public stakeholders, including organizations delivering the program. In addition, the DPRP provides technical assistance to delivery organizations and evaluation reports on organizational outcomes (Nhim et al., 2019). Organizations in the DPRP are designated with a recognition status (preliminary, pending, full, lapsed/inactive) based on their organizational outcomes (participant enrollment, attendance, and outcome goal achievement) and sustainability (length of time delivering the program).

To complement and reinforce the individual-level focused program, in recent years, the CDC has also funded policy, systems, and environmental (PSE) change interventions to address the determinants of lifestyle behaviors at higher levels of the social ecological model to (Honeycutt et al., 2015). For example, implementing new policies in schools and worksites around nutrition guidelines in cafeterias, developing systems in hospitals to more proactively screen patients for chronic disease risk factors, and changing the built environment to reduce barriers and increase access to healthy foods and physical activity opportunities all trickle down to influence the individual and help make "the healthy choice the easy choice" (Bunnell et al., 2012). However, even with many efforts occurring at both the individual and community levels diabetes prevalence continues to rise.

Maximizing population impact

The National DPP was scale-up effort was launched with aspirations to significantly halt the increasing prevalence of type 2 diabetes in the country (Albright, 2012). Maximum public health impact includes reaching a large enough population to influence population-level health outcomes and doing so in the most cost-effective and financially feasible way (Gaziano, Galea, & Reddy, 2007). Unfortunately all too often EBIs are not disseminated quickly enough or at a great enough scale to reach the populations that need them (Milat, Bauman, & Redman, 2015). Barriers to wide-scale implementation are seen at multiple

levels: individual/patient, the provider/staff, organizational, and community and policy levels (Gaglio, Shoup, & Glasgow, 2013). This last step in the translational pipeline requires studying the various adoption, preparation, implementation, and sustainability strategies to successfully scale EBIs (Brown et al., 2017).

Overall, the National DPP has had tremendous success with disseminating the program with over 1,500 organizations actively implementing the National DPP lifestyle change program. A part of this success has been the strong partnerships with the YMCA and other national organizations to adopt the program and federal grants that have mobilized state health departments to focus on scaling and sustaining the program in their jurisdictions (E. C. Chambers et al., 2017; Mensa-Wilmot et al., 2017; Nhim et al., 2019). As of November 2019, there have been 389,125 participants who have ever enrolled in the National DPP.

To date, the CDC has only published one study on the participant results of the National DPP. This study examined the program results of 14,747 enrolled adults from 2012-2016. Overall 35.5% of participants achieved the 5% weight loss goal and 41.8% of participants met the 150 minutes of weekly physical activity goal by the end of the program. In terms of program session attendance, nearly half (48.3%) of participants remained in the program for at least 6 months and 10.4% of eligible participants attended the full 22-session program (Ely et al., 2017). For every additional session attended and every 30 minutes of activity reported, participants lost 0.3% of body weight ($P < 0.0001$). As with earlier DPP studies, intensity of the program was significantly positively associated with the main program outcomes (weight loss).

While the most recent analysis of the National DPP demonstrated statistically significant participant outcomes, only about a third of participants met their weight loss goal and there is an overall desire to improve the enrollment and retention of participants (Ely et al., 2017). In terms of the national impact, only approximately 0.04% of the 86 million adults in the U.S. with prediabetes were reached in the first 4 years of the National DPP implementation (Ely et al., 2017; Ritchie, Kaufmann, & Sauder, 2017). Of the few published evaluations of the National DPP, many report that enrollment (reach) is relatively low

compared to the number of eligible participants identified by host organization referral systems. In an evaluation of one YMCA DPP in Ohio, of the 2200 eligible patients contacted for the program, 351 (16.0%) responded by attending the information session, and 228 enrolled in the YMCA DPP (11.3%) and persisted through at least week 9 (R. Adams, Hebert, McVey, & Williams, 2016). In another evaluation, one CDC-recognized organization in Utah identified and referred 6,862 prediabetes patients to the program, with only 8.4% of patients enrolling (Brunisholz, Kim, et al., 2017).

The Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework proposes five dimensions to assess public health impact of a program (Russell E. Glasgow et al., 2019; R. E. Glasgow, Klesges, Dzewaltowski, Estabrooks, & Vogt, 2006; R. E. Glasgow et al., 1999). The multiplication of the first two dimensions reach and effectiveness yields a composite measure of impact (R. E. Glasgow et al., 2006). While the program continues to achieve effective results, in order to have the national-level population impact desired, it needs to continue to expand its reach. However, currently there is little research within the National DPP focused on examining the various factors beyond the individual participant that impact implementation outcomes. While participants of the program have been carefully studied, the implementing organizations and the organizational- and structural- level causal factors that influence DPP implementation and program outcomes have not been explored in-depth systematically. Now that the program has been scaled up significantly in a diverse range of communities more research should be done in this area to further inform the implementation strategy at a national level.

Theoretical frameworks

Over the last two decades there has been a rise in implementation science frameworks to understand the causal factors and mechanisms at the organizational- and structural-levels associated with implementation outcomes (Nilsen, 2015). Established theories like the Diffusions of Innovations (Rogers, 1962) to newer frameworks like the Consolidated Framework for Implementation Research (CFIR)(L. J. Damschroder et al., 2009) and the Framework for Organizational Assessment (Horton, 2003), to models

like the Practical, Robust Implementation and Sustainability Model (PRISM) (Feldstein & Glasgow, 2008), Model for Improvement (Langley et al., 2009), and the Conceptual Model for Public Health Systems and Services Research (Meyer et al., 2012), have all been used to explore various constructs that influence implementation. Theory is valuable in understanding the internal and external dimensions of organizations and how to bring about organizational change. These theories and frameworks help program implementers understand what their organizations and considerations for successful program delivery and outcomes, including the extent to which the intervention is modifiable to fit with the internal context; the amount of time needed to truly institutionalize a program or change; and to make comparisons between or identify trends among delivery organizations (Batras, Duff, & Smith, 2016).

Beyond public health, other fields and industries have also studied organizations and these dimensions. Psychologist, Kurt Lewin's theories of change are generally noted as the foundation for the field of organizational development (Batras et al., 2016; Butterfoss et al., 2008; Hussain et al., 2018). Lewin's work begins with the understanding that individual behavior is a function of the larger environment, which include characteristics of organizations – both internal (i.e. strategy, management, structure, personnel) and external (i.e. market forces, policy context) (Batras et al., 2016). Historically in public health organization-level theories are not as commonly used compared to classic individual level health behavior theories (Butterfoss et al., 2008). However, organizations are responsible for carrying out many public health programs and services, therefore it is critical to understand their role in individual and population health behavior change.

Organizational studies is an interdisciplinary discipline focusing on administrative, economic, political, psychological, and sociological factors that affect cooperative human systems (Vakola & Petrou, 2018). Theories of organizational change, readiness, culture, development, etc. are applied and used in many different fields. The rise of implementation science in public health emphasizes this need to study and leverage the influence of the organizational-level within health promotion. However, to date most

research in this area has been conceptual or qualitative (Brown et al., 2017). There is much to test and discover in terms of causal relationships between these organizational internal and external factors and implementation outcomes.

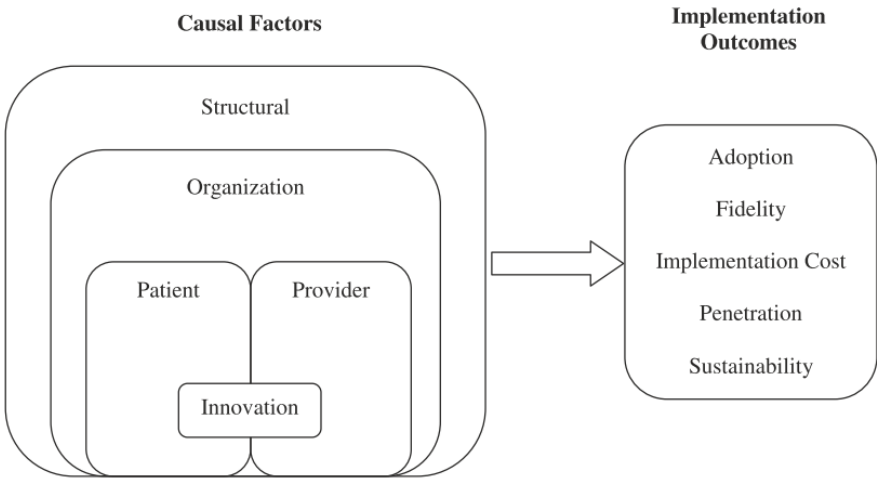
One such implementation science framework developed by Chaudoir; Dugan; & Barr (2013; Figure 2) synthesizes and simplifies the relationship between causal factors and implementation outcomes. The authors identify 5 levels of causal factors: structural-, organizational-, patient-, provider-, and innovation-levels that are hypothesized to cause or predict implementation outcomes. These levels are based on a review by Durlak and DuPre (2008) on implementation factors that affect program outcomes as well as the CFIR framework. This multi-level framework provides a useful broad overview of the causal relationships between the factors at different levels of a public health innovation and implementation environment with implementation outcomes.

In this framework, the structural-level represents the outer setting or external structure of the broader sociocultural context or community in which a specific organization is nested (e.g. political and social climate, public policies, local infrastructure). The organizational-level includes constructs that represent aspects of the organization in which an innovation is being implemented (e.g. leadership effectiveness, innovation climate, culture). The provider-level encompasses aspects of the staff person who is in contact with and implements the innovation with a patient/participant (e.g. provider credentials, staff skills, staff attitudes). The patient-level includes individual characteristics and psychosocial constructs such as health-relevant beliefs, motivation, and personality traits that can impact implementation outcomes. Lastly, the innovation-level focuses on the constructs that represent aspects of the innovation that will be implemented (e.g. relative advantage of the innovation, quality of evidence of intervention efficacy).

The authors note that at all of these levels there is considerable heterogeneity in the operationalization of constructs and measures of interest. To understand the number and validity of existing measures at

each of these levels they conducted a systematic review. They concluded that while there has been some development at each of these levels there are still significant gaps in the availability of valid and reliable measures to demonstrate associations between the causal factors and implementation outcomes (Chaudoir et al., 2013).

Figure 2. A Multi-level Framework Predicting Implementation Outcomes (Chaudoir, Dugan, & Barr, 2003)



Related to implementation outcomes, in 2011, to advance clarity in the language used to describe the different aspects of implementation, a working group of experts convened to develop a taxonomy (Enola Proctor et al., 2011). These experts identified and defined eight implementation outcomes (adoption, penetration, fidelity, cost, and sustainability, acceptability, feasibility, appropriateness) as the desired endpoints of implementation efforts (Table 1). Five of these implementation outcomes are included in the Chaudoir, Dugan, and Barr framework in Figure 2 above.

Table 1. Implementation Outcomes Definitions (Enola Proctor et al., 2011)

Implementation Outcome	Definition
Acceptability	Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.
Adoption	Adoption is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice. Adoption also may be referred to as ‘‘uptake.’’
Appropriateness	Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem.
Feasibility	Feasibility is defined as the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting.

Fidelity	Fidelity is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers.
Implementation Cost	Cost (incremental or implementation cost) is defined as the cost impact of an implementation effort. Implementation costs vary according to three components.
Penetration	Penetration is defined as the integration of a practice within a service setting and its subsystems.
Sustainability	Sustainability is defined as the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations.

Similar to issues with the causal factors, measures for each of the implementation outcomes vary greatly and more standardized measurement tools are still in development. Recently, Weiner et al (2017) conducted a series of exploratory and confirmatory factor analysis studies for measures of acceptability, appropriateness, and feasibility. They produced 5-item scales for each construct with acceptable model fit and high reliability. A predicted validity assessment of the scales is planned and forthcoming (Bryan J. Weiner et al., 2017).

Another commonly used framework to evaluate the implementation of interventions is the RE-AIM model (Gaglio et al., 2013; Russell E. Glasgow et al., 2019; R. E. Glasgow et al., 1999). The RE-AIM domains overlap with many of the implementation outcomes established by Proctor, et al. Similarly, while RE-AIM provides a useful framework for exploring these outcomes individually, like the Proctor, et al. implementation outcomes, it also lacks an in-depth understanding of the inter-relationships and causal links between domains. Glasgow et al. (2019) point this shortcoming out in the 20th anniversary manuscript of the RE-AIM model, noting that, "there have been recent calls to more explicitly describe strategies and context as well as test mediating relationships between implementation strategies and implementation outcomes." The authors also mentioned how other frameworks and models have been working to understand the specific contextual factors from external macro-level factors such as policies, guidelines, and incentives, to more local organizational-level factors (Russell E. Glasgow et al., 2019).

Drawing from both of these frameworks, thi**s dissertation focuses on the structural- and organizational-levels from the Chaudoir, et al. multi-level framework and explores the link between these causal factors with the implementation outcomes of reach and sustainability.** In the RE-AIM framework reach

is defined as the, “absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program” (Russell E. Glasgow et al., 2019). In the implementation outcomes outlined by Proctor, et al. (2011) the authors categorized reach as part of the outcome of “penetration”, which is defined as “the integration of a practice within a service setting and its subsystems.” However the term “penetration” itself is infrequently used in the implementation literature (Enola Proctor et al., 2011). It is far more common to see “reach” measured as an implementation outcome and also a well understood component in the area of process evaluation (Saunders, Evans, & Joshi, 2005). Sustainability, which appears in RE-AIM as the maintenance domain and is defined as, “The extent to which: a) behavior is sustained 6 months or more after treatment or intervention; and b) a program or policy becomes institutionalized or part of the routine organizational practices and policies” (Russell E. Glasgow et al., 2019).

As depicted in the conceptual model for this dissertation (Figure 1), program outcomes (changes in health behavior and health status) are influenced by organizational-level causal factors defined by the five CFIR inner setting constructs, mediated through implementation outcomes, primarily reach and sustainability. Hypothesized to also directly and indirectly influence this series of relationships are the structural-level causal factors, or the external/contextual factors in which an organization operates. These are defined by the CFIR outer setting constructs. Lastly, this model also includes organizational characteristics such as the number of years an organization has been implementing the program and the organization type, which will be examined to see how these characteristics influence these hypothesized causal relationships both directly and indirectly. These also overlap heavily with the CFIR Structural Characteristics construct.

Structural and organizational-level causal factors

While there is no single theory, framework, or model used consistently to study organizational-level causal factors associated with implementation outcomes, in the last few years CFIR has shown great advancement in this area by validating measures and moving toward testing these relationships. CFIR is a

typology of 39 constructs and useful in facilitating the identification and understanding of these constructs within particular implementation contexts (CFIR Research Team; L. J. Damschroder et al., 2009). CFIR is a meta-theory that draws from a number of implementation science and dissemination theories and frameworks and does not specify interrelationships between constructs or hypotheses related to the constructs. The goal of CFIR is that by providing researchers and intervention implementers with a database of constructs this will promote consistent use of constructs and lead to higher quality and rigorous analysis. In a systematic review of 429 studies using CFIR, the authors concluded that the CFIR framework does provide a foundation for being able to generalize and build on findings across studies and contexts (Kirk et al., 2015).

Even at only 10 years old, CFIR has been widely applied to interventions implemented in numerous contexts, settings, and populations (Kirk et al., 2015; Means et al., 2020). Outside of the U.S. and other high-income countries, CFIR constructs have also been found to be compatible with evaluating implementation in low- and middle-income countries (Means et al., 2020). The flexibility and pragmatic nature of CFIR allows researchers to apply it to complex, multi-level interventions through its vast array of constructs (L. J. Damschroder et al., 2009). Another strength of CFIR is the ability to allow for "theory-building" related to a specific intervention and the menu of CFIR constructs allows for a systematic and comprehensive exploration of causal themes and phenomenon within implementation (L. Damschroder & Lowery, 2013).

Most researchers agree that the framework is useful and comprehensive, but there are gaps in evidence regarding measurement and testing of the constructs (Fernandez et al., 2018). Qualitative and quantitative methods have been used to operationalize CFIR constructs, these are also well-documented on the CFIR website for all researchers to freely access (CFIR Research Team). However, there are no standardized tools to quantitatively measure CFIR constructs in full. To further advance the use of CFIR and the field of implementation science researchers must continue to develop? accurate and valid

measurement of the constructs. This will allow for constructs to be tested in a consistent way and the possibility for meta-analysis and other analyses to make stronger inferential conclusions (Clinton-McHarg et al., 2016; Fernandez et al., 2018).

The CFIR inner and outer setting domains are most representative of the factors that are related to implementation at the structural- and organizational-levels (levels as defined by the Chaudoir, et al. framework). The CFIR inner setting domain, containing five constructs and nine subconstructs, aims to capture the complexity within the organization related to implementation. The four outer setting constructs provide insight into the greater environments/contexts in which organizations are restricted to or facilitate their ability to carry out the intervention. Definitions of these constructs are presented in Table 2 and detailed descriptions of each construct are also included on the CFIR website (https://cfirguide.org/). The inner and outer setting constructs, will be used to operationalize and test the theorized causal relationship between the National DPP structural- and organizational-level causal factors and implementation outcomes in my studies.

Table 2. CFIR Inner and Outer Setting Constructs and Sub-constructs

Construct	Definition
	Inner Setting
Structural Characteristics	The social architecture, age, maturity, and size of an organization.
Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
Culture	Norms, values, and basic assumptions of a given organization.
Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization. *Sub-constructs: tension for change, compatibility, relative priority, organizational incentives and rewards, goals and feedback, and learning climate*
Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention. *Sub-constructs: leadership engagement, available resources, access to knowledge and information*
	Outer Setting
Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
Cosmopolitanism	The degree to which an organization is networked with other external organizations.

Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.

(Damschroder et al., 2009)

CFIR study designs & measures

To date the majority of the literature exploring these relationships at the structural- and organizational-level have been largely with organizations in the healthcare system. In 2018, a systematic integrative review, attempted to connect the organizational contextual features of healthcare settings and their influence on the implementation of evidence-based practices (Li, Jeffs, Barwick, & Stevens, 2018). Thirty-six studies were included in the final review and qualitatively assessed using the CFIR constructs of organizational culture; leadership; networks and communication; resources; evaluation, monitoring and feedback; and champions. The authors concluded that organizational characteristics did appear to be interrelated and work synergistically to influence implementation outcomes. Organizational culture – defined in this study with a focus on the acceptance of innovations - was most commonly reported to affect implementation. They also found that leadership influenced the other organizational characteristics greatly indicating that it may be a moderator or mediator that enhances or impedes implementation. Since this review was qualitative in nature it was not able to conduct any meta-analysis to support the linkages between characteristics and implementation statistically.

Within the area of chronic disease prevention interventions there are large gaps in the empirical evidence to connect structural and organizational-level causal factors to implementation outcomes. Lifestyle behaviors (tobacco use, physical activity, and healthy eating) are major risk factors for chronic disease and prevention programs often focus on behavioral interventions (Brownson, Haire-Joshu, & Luke, 2006). These interventions not only include individual level knowledge and skill building-type programs, but also those that impact policies, systems, and environmental changes to facilitate the desired healthy behaviors

(Dietz et al., 2016). These behavioral interventions are implemented by a variety of organizations (worksites, schools, community groups, local governments, etc.) however the structural and organizational-level causal factors are not systematically evaluated. A 2019 systematic review by Wolfenden et al. found that of 40 randomized-control trials (RCTs) focused on implementation of non-communicable diseases interventions at the organizational level, the reporting of the study's implementation outcomes (adoption; appropriateness; acceptability; feasibility; cost; and sustainability) was limited. In addition, the majority of the studies had very little focus on the barriers, internal and outer setting causal factors, and their impact on implementation outcomes (L. Wolfenden et al., 2019).

The dissertation's conceptual model (Figure 1) provides references to the strongest examples from the chronic disease intervention literature demonstrating the impact organizational factors have on implementation (Damschroder & Lowery, 2013; Gingiss, Roberts-Gray, & Boerm, 2006; Kadu & Stolee, 2015; Li et al., 2018). For example, Damschroder & Lowery, have used and promoted a rigorous qualitative approach to examining CFIR constructs and their relationship to implementation success. In 2013, Damschorder and Lowery assessed 31 CFIR constructs to examine differences between low versus high implementation effectiveness of a weight management program. They used semi-structured interviews to collect data from key stakeholders with a CFIR focused interview guide and a coding framework.

Interviews were analyzed by CFIR construct and each coded segment was given a rating of valence (positive or negative influence) related to implementation. These segments were aggregated to understand the magnitude (strength of the influence) of that construct on implementation. Using this qualitative methodology, the researchers connected aspects of these constructs against the level of implementation (classified by participation/reach numbers) at each site. For example, for the inner setting construct of "networks and communication", they found that organizations with high quality working relationship across health care providers and services (the networks) were more frequently mentioned in implementation sites with high implementation success (Damschroder & Lowery, 2013).

There are a handful of qualitative studies which have used this construct rating methodology to better understand the magnitude and valence (positive or negative influence) of constructs on implementation. It has been used to assess implementation of colorectal cancer screening at community health centers (Liang et al., 2015); the implementation and outcomes in a community-based cancer prevention intervention (E. S. King et al., 2019); and implementation of alcohol use disorder pharmacotherapy in primary care settings (Hagedorn et al., 2019). However, there is little understanding of how the inner and outer setting constructs interact with each other or how outer setting constructs may moderate relationships between inner setting factors and implementation outcomes (Damschroder & Lowery, 2013; Liang et al., 2015).

On the quantitative side, there has also been a number of studies to explore organizational factors using the CFIR inner and outer setting constructs and their relationship to implementation outcomes. In 2017, Allen et al. conducted a review of implementation studies to identify and describe measures of organizational characteristics using the CFIR inner setting constructs relevant to the adoption and implementation of interventions. In total 83 measures of CFIR constructs were identified, although terminology and definitions of the constructs varied widely (Allen et al., 2017). The two most frequently reported constructs included “readiness for implementation” and “organizational climate.” In the 76 studies reviewed, 46% included psychometric information around organizational measures. Similar to findings from other studies and reviews, one of the main conclusions was that while there are a variety of measures used, robust psychometric properties to measure organization characteristics are lacking (Clinton-McHarg et al., 2016; Dearing, 2018; Kirk et al., 2015; Meyer et al., 2012).

Similarly with regards to outer setting constructs, a recent integrative systematic review examined the external implementation context of 61 evidence-based practices. The review identified eight external context constructs: 1) professional influences, 2) political support, 3) social climate, 4) local infrastructure, 5) policy and legal climate, 6) relational climate, 7) target population, and 8) funding and economic climate

(Watson et al., 2018). These constructs very closely match the CFIR outer setting constructs and provide additional evidence of their impact on the implementation process. However, like the Allen et al. (2017) team, the authors of this review also noted that work needs to be done in operationalization and measurement (Watson et al., 2018).

Recently, there has been some notable development in the measurement of five inner setting constructs (culture, implementation climate, learning climate, leadership engagement, and available resources). In 2018, Fernandez et al. conducted a study with 4 phases, which included identifying relevant CFIR constructs and compiling existing measures, generating and adapting items for scales, pilot testing the scales for each construct, and finally conducting a validation study with the refined measures (Fernandez et al., 2018). They developed two additional sub-construct scales using adapted items from other scales for culture: stress and effort. Cultural stress was defined as perceived strain, stress, and role overload. Culture effort defined as how hard people in organizations work toward achieving goals. The parent construct for culture was defined using the CFIR definition: norms, values, and basic assumptions of a given organization.

Confirmatory factor analysis (CFA) exhibited good model fit for all seven scales. To evaluate internal consistency, Cronbach's alpha was computed for each of the scales. Cronbach's alpha estimates were good ($0.7 \leq \alpha < 0.9$) or excellent ($\alpha \geq 0.9$) for all scales. Discriminant validity was examined by calculating correlation coefficients of each pair of scales using individual-level data and aggregated data by clinic (to represent the clinic-level). Three of the correlations, Culture Overall and Learning Climate, Culture Overall and Leadership Engagement, and Learning Climate and Leadership Engagement had values above 0.80 at both the individual and clinic-levels suggesting there may be some measurement overlap between constructs.

The CFA results found that the scales with the strongest evidence for structural validity were Culture Effort and Available Resources. There was also moderate to strong evidence supporting the structural validity of Culture Overall, Implementation Climate, Learning Climate, and Leadership Engagement. Culture Stress had the weakest evidence for structural validity, the authors suggest this may be due to the limited number of items (4). The highly correlated nature of the constructs not only reflect the expected nature given all of these are different aspects of the inner setting, but also point to the level of influence the constructs may have on one another. These findings provide good support for being able to measure these CFIR constructs with high validity and reliability. In 2019, the authors published another paper using their items to assess the inner setting constructs in a pediatric clinic network implementing HPV programs and continued to find good validity and adequate reliability (T. J. Walker et al., 2019).

While the outer setting measures have not had the same level of development and testing there are many potential measures that could be applied to these constructs. An updated systematic review of the organizational readiness for change assessment was recently published by Miake-Lye et al. (2020), which mapped 1,370 survey items to CFIR constructs. Of those items mapped, 897 were mapped to the inner setting constructs and 80 items to the outer setting constructs (Miake-Lye et al., 2020). While there are limited CFIR-specific tools developed for use, this review identifies items that aim to measure some aspect of these constructs and are potentially appropriate for application in this context.

Implementation outcomes: reach and sustainability

Reach. Program reach is a commonly used metric in public health program evaluation that measures the extent to which a program attracts its intended audience (R. E. Glasgow et al., 1999). Reach is operationalized typically as either the absolute number, proportion, and/or representativeness of individuals who participate or are willing to participate in a given initiative, intervention, or program (Russell E. Glasgow et al., 2019). This can include data sources such as enrollment numbers and attendance records. In addition, process evaluations of programs also explore the characteristics of

participants and any facilitators or barriers to participation (Saunders et al., 2005). As mentioned previously, reach is one of the domains of the widely used RE-AIM framework. In a 2013 review of articles using the RE-AIM framework, of 178 studies reviewed, reach was the most frequently reported dimension (91.5%) (Gaglio et al., 2013).

Reach is also linked to understanding public health impact. Glasgow and colleagues have developed a composite measure for impact by multiplying reach and effectiveness (R. E. Glasgow et al., 2006). The basic calculation includes the participation rate (number participating/eligible and invited to participate) times the effect size on a primary outcome variable. The authors proposed that using reach and effectiveness in this way can assist with decisions between the implementation of different public health interventions. Reach and impact are especially important for chronic disease as the burden of these conditions continue to increase. Chronic diseases prevention and management interventions also tend to be very resource intensive. Therefore, it is critical for public health entities to prioritize the most effective and wide-reaching interventions and strategies to achieve significant impact in the population.

For the National DPP in particular, enrollment (reach) and retention (dose received) remain two key implementation/process outcomes of interest. The CDC and a couple National DPP delivery organizations have used RE-AIM to understand their local implementation outcomes (Brunisholz, Kim, et al., 2017; Nhim et al., 2019). In the Brunisholz et al. (2017) evaluation for a Utah delivery organization, reach was defined as the percentage and characteristics of people receiving the intervention. During the study period, 6,862 were considered eligible for the DPP program, had an in-person office visit with their provider, and had the opportunity to be invited to the program. Of those eligible, 573 (8.4%) patients participated in the DPP. They also found that those who had been diagnosed with prediabetes more recently were more likely to participate in the program. Greater participation was also more likely to be female, older than 70, overweight, diagnosed with depression, and those with a prescription for metformin (Brunisholz, Kim, et al., 2017). This study was conducted at one healthcare facility in Utah during the first year of

implementation. Organizational- and structural-level factors, such as the referral system process in the hospital, staff buy-in for the program, leadership engagement, or patient's needs in the population were not explored.

In 2019, the CDC published a paper which included the findings from an evaluation using RE-AIM with a subset of delivery organizations funded by one of six national partners (Nhim et al., 2019). In this evaluation, reach was defined as the absolute number and diversity of individuals participating in the program. From 2012 to 2016, the number of organizations offering the program increased from 68 to 164, delivering the program across 38 states, and enrolling 14,876 eligible participants (reach). This is an average reach of 91 participants per organization. Characteristics of the organization in relation to reach numbers were not explored. Other National DPP evaluation and research studies, although not explicitly using RE-AIM have reported reach outcomes, using the number of enrolled participants (Brunisholz, Joy, et al., 2017; E. C. Chambers et al., 2017; Ely et al., 2017). However, similar to these studies, organizational characteristics, as well as internal and external organizational factors are not explored or linked to reach numbers.

Sustainability. Another key implementation outcome of interest for evidence-based interventions is sustainability. The field of implementation science defines sustainability as, "the continued use of program components at sufficient intensity for the sustained achievement of desirable program goals and population outcomes." (Shelton, Cooper, & Stirman, 2018, p. 1). In terms of impact, sustainability is also a key factor that must be taken into account as the longer an intervention can be in place, the greater effect and reach it can have (R. E. Glasgow et al., 2006). Sustainability of interventions is particularly critical in the prevention and management of chronic diseases as these are ongoing conditions that developed throughout the life course and that require sustained lifestyle changes. Individuals with and at risk for chronic conditions may need to engage in these programs for the rest of their lives (Hailemariam et al., 2019; Shelton et al., 2018; Tricco et al., 2015; Luke Wolfenden et al., 2019). Furthermore at a population

level, these programs may need to be in place for a number of years before the effect of the program can be maximized. However, while reach is a fairly straight forward metric, sustainability is more complex both conceptually and in measurement.

Programs use a variety of terms to describe sustainability such as routinization, institutionalization, sustainment, durability, maintenance, and long-term follow-up/implementation (Shelton et al., 2018). Conceptual frameworks like the Dynamic Sustainability Framework conceptualize sustainability not as an outcome but as an ongoing and every changing process (D. A. Chambers, Glasgow, & Stange, 2013). Due to the complex nature of sustainability there are a number of frameworks that have been developed in recent years (Shelton et al., 2018; Stirman & Dearing, 2018). Therefore it is important for program implementers to clearly define and operationalize sustainability within the context of their program settings, population, and long-term goals.

There has also been movement in recent years to better define, operationalize, and measure sustainability of public health evidence-based programs (Palinkas et al., 2020; Shelton et al., 2018; Stirman & Dearing, 2018). A few of the more common and tested tools include the following. The Stages of Implementation Completion (SIC), an eight-stage assessment tool observation-based measure that is used to track the time to achievement of key implementation milestones in an EBP being implemented (Chamberlain, Brown, & Saldana, 2011). The Program Sustainability Index includes 53 items reflecting seven sustainability elements (number of items in parentheses): leadership competence (7), effective collaboration (12), understanding the community (9), demonstrating program results (7), strategic funding (5), staff involvement and integration (10), and program responsivity (3) (Mancini & Marek, 2004). The British National Health Service Sustainability Index, is a 10-item measure, which assesses different dimensions of the intervention's outcomes, process, staff, and organization to create a sustainability propensity score (Ford, II, Wise, & Oliver, 2011). The Sustained Implementation Support Scale, is a 40-item measure assessing five categories of common barriers and enablers of sustained program

implementation: program benefits (11 items), program burden (4 items reverse scored), workplace support (9 items), workplace cohesion (8 items), and leadership style (8 items) (Hodge, Turner, Sanders, & Filus, 2017). Therefore, these measures build on a wide variety of subconstructs and domains.

An instrument that has been used largely with chronic disease prevention programs is the Program Sustainability Assessment Tool (PSAT) (E. E. Adams, 2017; D. K. King et al., 2018; Llauradó et al., 2018; Reichert, 2017; Stoll et al., 2015; R. G. Tabak et al., 2016). Published in 2014, the PSAT identifies 8 domains that affect sustainability through a comprehensive review of tools measuring public health program sustainability (Luke, Calhoun, Robichaux, Elliott, & Moreland-Russell, 2014). These domains include environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, public health impacts, and strategic planning. The PSAT has been used primarily to assess capacity and plan for sustainability (Palinkas et al., 2020).

What causal factors are associated with sustainability? A 2005 review and synthesis of 19 empirical studies of American and Canadian health-related programs examined the extent of sustainability achieved and factors contributing to greater sustainability (Scheirer, 2005). This review explored three categories of factors: 1) program design and characteristics, 2) organizational setting, and 3) community and environment. Concerning project design and its characteristics, programs that reported higher % of sites sustained were more likely to have a program that could be modified, access to volunteers or other low-cost ways of program delivery, and a few noted the value of good evaluation data. Concerning aspects of the organizational setting, programs with higher sustainability were more likely to report having strong champions, good program fit with organization mission, and that staff and stakeholders found the program beneficial. Related to aspects of the community environment surrounding the program, successfully sustained programs noted access to additional sources of funding and partners who can supply in-kind resources.

Likewise, in a 2016 scoping study of chronic disease interventions, the authors found that key organizational factors related to sustainability of interventions also included inter-organizational partnerships and environments supportive of comprehensive long-term evaluations (Francis, Dunt, & Cadilhac, 2016). However, while domains and constructs have been identified, the testing of these constructs in relation to actual years of sustainability has yet to be tested. Many researchers have emphasized the need for more rigorous testing in the area of sustainability and are encouraging sustainability studies to use mixed methods designs with multiple time points to assess sustainability outcomes (Francis et al., 2016; Lennox, Maher, & Reed, 2018; Luke Wolfenden et al., 2019).

As far as how sustainability has to date been studied in the National DPP, in the 2019 Nhim et al. published a study with 165 CDC-recognized organizations delivering the National DPP lifestyle change program. The evaluation defined sustainability using the RE-AIM domain of maintenance, defined as, "the extent to which programs had potential for sustainability, measured by the number of delivery sites achieving full CDC recognition, the number of sites continuing to deliver the program without cooperative agreement funding, and organizational and financial support or program reimbursement from private or public payers" pg. 3 (Nhim et al., 2019). To achieve full recognition, organizations need data from at least one cohort. They found that in 4 years (2012-2016), 132 sites had at least 12 months of participant data, and that 33 (25%) of these 132 achieved full CDC recognition. As the National DPP lifestyle change program takes a year to complete, 12-months of data is a short-term indicator of sustainability. In addition, no characteristics of organizations or organizational factors were explored or assessed in relation to this outcome.

Innovation

This work is in part funded by the CDC Division of Diabetes Translation's Innovations to Grow Enrollment and Retention (InGEAR) project. The goal of InGEAR is to explore innovative strategies to increase

enrollment and retention of participants in the National DPP. As previously mentioned, the National DPP wants to increase its impact on a national level. Currently only approximately 0.04% of the 86 million adults in the U.S. with prediabetes were reached in the first 4 years of the National DPP implementation (Ely et al., 2017; Ritchie et al., 2017). In understanding how to improve program enrollment and retention there should be increased knowledge of how organization characteristics (type, size, location, etc.) and the organizational- and structural-level causal factors influence the delivery and sustainability of programs. To date, there is yet to be an in-depth and rigorous examination of the organizational- and structural-level causal factors that impact the implementation success of the National DPP.

With over 1500 organizations across the country participating in the DPRP, the program has now reached a level of dissemination that can provide strong statistical power to the analysis of factors at the organizational-level. The Diabetes Training and Technical Assistance Center (DTTAC) at Emory University is in the perfect position to carry out this work. In the past seven years, DTTAC has directly trained over 3,600 Lifestyle Coaches and 139 Master Trainers (those who train individuals to become lifestyle coaches) representing over 1,300 organizations across 48 states, including Washington DC and Puerto Rico. This represents organizations nationwide of various types, including healthcare systems, state/local departments of health, and for profit, non-profit, faith-based, and community-based organizations. To our knowledge, DTTAC has trained the largest and most diverse network of Lifestyle Coaches and Master Trainers nationwide, which provides a rich data source for exploring the factors related to implementation from those on the ground delivering the program within host organizations.

Studies evaluating the National DPP to date have focused on participant outcomes and organizational attainment of recognition status based on participant enrollment and program outcomes (E. C. Chambers et al., 2017; Ely et al., 2017; Nhim et al., 2019). **This dissertation will fill the gaps in the current knowledge of the program through exploring ways in which organization characteristics (type, size, location, etc.)**

and the organizational- and structural-level causal factors are related to the implementation outcomes of reach (enrollment) and sustainability (sustainability capacity).

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Chapter 2: Aim 1

Title: Inner and outer setting factors that influence the implementation of the National Diabetes Prevention Program (National DPP) using the Consolidated Framework for Implementation Research (CFIR): A Qualitative Study

Abstract

Background: Scaling evidence-based interventions is key to impacting population health. The National DPP lifestyle change program is one such intervention that has been scaled across the United States over the past 20 years, however enrollment is an ongoing challenge. Furthermore, little is known about which organizations are most successful with program delivery, enrollment, and scaling. This study aims to understand more about the internal and external organization factors that impact program implementation and reach.

Methods: Between August 2020 and January 2021, data were collected through semi-structured key informant interviews with 30 National DPP delivery organization implementers. This study uses a qualitative cross-case construct rating methodology to assess which Consolidated Framework for Implementation Research (CFIR) *Inner* and *Outer Setting* constructs contributed (both in valence and magnitude) to the organization's current level of implementation reach (measured by average participant enrollment per year). A construct by case matrix was created with ratings for each CFIR construct by interviewee and grouped by implementation reach level.

Results: Across the 16 inner and outer setting constructs and subconstructs, the interviewees in the higher reach group provided stronger (+2) and more positive examples related to implementation and enrollment of the program, while the lower reach groups reported stronger (-2) and more negative examples across rated constructs. Four inner setting constructs/subconstructs (structural characteristics, compatibility, goals & feedback, and leadership engagement) were identified as "distinguishing" based on

the difference between groups by average rating (+.5 difference between levels), the examination of the number of extreme (+2 or -2) ratings within levels, and the thematic analysis of the content discussed.

No outer setting constructs were distinguishing. Four constructs/subconstructs (incentives & rewards, learning climate, access to knowledge & information, and patient needs & resources) were not discussed in relation to implementation reach sufficiently for the rating analysis.

Conclusions: Our study identified a number of influential CFIR constructs and their impact on National DPP implementation reach. These findings can be leveraged to improve efforts in recruiting and assisting delivery organizations to increase the reach and scale of the National DPP as well as other evidence-based interventions.

Background

According to 2020 data, the Centers for Disease Control and Prevention (CDC) has reported that 96 million adults (38% of the adult population) in the U.S. have prediabetes, a condition that indicates a high risk, and progression to, type 2 diabetes (Centers for Disease Control and Prevention, 2022c). The National DPP lifestyle change program is an evidence-based, year-long intervention with 22 sessions led by lifestyle coaches designed to prevent the progression to diabetes in people with prediabetes (Albright & Gregg, 2013; Centers for Disease Control and Prevention, 2021b; Knowler et al., 2002). Since its inception in 2010 the National DPP has made great strides in raising awareness for and accessibility to its evidence-based lifestyle change program for people with prediabetes including establishing the program as a covered benefit for Medicare and Medicaid beneficiaries (Centers for Disease Control and Prevention, 2021b; Gruss et al., 2019). However, program reach, the number or proportion of individuals participating in program, is lower than hoped. Approximately 2,000 organizations of various types, sizes, and settings currently deliver the program across all 50 states and US territories (Ronald T. Ackermann, 2017; Centers for Disease Control and Prevention, 2022a), but in 2017, the CDC reported that only 0.04% of the U.S. adults with prediabetes had been reached in the first 4 years of the National DPP implementation (Ely et al., 2017; Ritchie et al., 2017). When efficacious programs (like the National DPP) can reach a large number of individuals, population impact occurs (Cheadle et al., 2013; Russell E. Glasgow et al., 2019; Russell E Glasgow, McKay, Piette, & Reynolds, 2001; Wandersman et al., 2008). However, while organizations are adopting the program and expanding financial coverage for participants, enrollment or reach remains a challenge and a key focus for stakeholders (Ronald T. Ackermann & O'Brien, 2020; Burd et al., 2020; Harris Meyer, 2021).

Understanding factors related to adoption, implementation, and reach of the National DPP at the organizational level is critical to scaling the program. To date, research and evaluation of the National DPP has largely focused on participant level outcomes (Ely et al., 2017; Gruss et al., 2019; Nhim et al., 2019).

These show the vast majority of participants are female (around 80%), 45 years or older, and with a prediabetes status determined by blood-based test (Brunisholz, Kim, et al., 2017; Ely et al., 2017). Other studies of program participants identified increasing prediabetes risk perception, health care professional referral and communication, and insurance coverage as potential key focal areas to grow participant enrollment (Mohammed K. Ali et al., 2019). Organization level evaluations have explored specific implementation strategies (referrals, partner networks, adaptation of materials, etc.) and have shown that use of incentives and healthcare provider-based referrals are promising practices to increase enrollment and participation (Mosst, DeFosset, Gase, Baetscher, & Kuo, 2017; Nhim et al., 2019). However, these studies focus on limited organizational characteristics, such as type and location (e.g. state), in their analyses.

In addition to intervention characteristics and program participants, other critical contextual factors internal and external to organizations may impact implementation outcomes. Chaudoir, Dugan, and Barr refer to these as organization (internal) and structural (external) level causal factors in their "Multi-Level Framework Predicting Implementation Outcomes" (Chaudoir et al., 2013). Further, an understanding of organization characteristics (type, size, location, etc.) and factors within and surrounding an organization that influence the delivery of programs may be useful in developing strategies for recruiting new organizations and supporting current delivery. Thus, there is a need for in-depth and rigorous examination of organization- and structural-level causal factors and the ways they impact the implementation success of the National DPP.

This study aims to fill this gap by applying the Consolidated Framework for Implementation Research (CFIR) to examine the possible role these causal factors impact implementation. Over the past 12 years, CFIR, a metatheory comprised of constructs associated with implementation, has been increasingly utilized in public health research to understand diverse aspects of implementation processes and outcomes (L. J. Damschroder et al., 2009; L. J. Damschroder, Reardon, & Lowery, 2020; Kirk et al., 2015).

Within diabetes prevention and management, researchers most commonly have used CFIR to examine facilitators and barriers to program implementation (Bastos De Carvalho et al., 2021; Kowalski, Veeser, & Heisler, 2018; VanDerBrink et al., 2020). For example, Wilcox et al. (2020) used CFIR to identify predictive constructs with implementation outcomes for a cultural adaptation of the National DPP for African-American Churches in the South (Wilcox et al., 2021). To our knowledge, CFIR has not been used to examine the National DPP across organizations.

CFIR contains five domains with 39 constructs and subconstructs related to implementation (L. J. Damschroder et al., 2009). Two of the five domains, the *Inner Setting* and *Outer Setting,* focus on internal organization-level and external structural-level factors. The CFIR constructs listed in the *Inner Setting* domain aim to capture the complexity within the organization related to implementation. These include constructs such as an organization's structural characteristics, culture, and readiness for implementation. The *Outer Setting* constructs provide insight into the greater environments and external context which constrain organizations or facilitate their ability to carry out the intervention. These include constructs such as cosmopolitanism, peer pressure, and external policies and incentives.

To contribute to the current knowledge of the National DPP, this study will explore the organizational- and structural-level factors (operationalized through the CFIR *Inner* and *Outer Setting* constructs) to understand relationships between these constructs and program implementation and enrollment (reach). Insights gained can inform strategies to expand the capacity of delivery organizations to increase engagement in the program and scale the program up and out nationally (Ronald T. Ackermann & O'Brien, 2020; Gruss et al., 2019; Harris Meyer, 2021).

Methods

In 2019, Emory Center's Diabetes Technical Assistance and Training Center (DTTAC) was funded to study the role of Lifestyle Coaches in the implementation of the National DPP through the CDC's Division of

Diabetes Translation's Innovations to Grow Enrollment and Retention (InGEAR) project. Over the last 10 years, DTTAC has directly trained over 5,000 lifestyle coaches representing over 2000 organizations across all 50 states. The National DPP implementers included in this study participated in Emory's DTTAC Lifestyle Coach and/or Master Trainer Select training programs and/or subscribed to the center's resources.

This study uses a qualitative cross-case construct rating methodology to assess which CFIR constructs contributed both in valence (positive or negative influence) and magnitude (combined influence) to the organization's current level of implementation reach (measured by average participant enrollment per year). Between August 2020 and January 2021, data were collected through semi-structured key informant interviews with 30 National DPP delivery organization implementers (see sampling for selection criteria and procedures). This study was reviewed and determined to be exempt by the Emory University Institutional Review Board (STUDY00000658).

Sampling. DTTAC provided a list of National DPP implementers (n=239) and their basic organization characteristics (organization type, location, level of implementation, etc.) that was generated from a call for study participation via the DTTAC mailing list and newsletter. Potential participants were stratified into groups of higher (>85 program participants), medium (26-85 program participants), and lower ($\leq$ 25 program participants) reach organizations based on total enrollment to date. Participant enrollment data from the CDC and DTTAC's records were used to create the higher, medium, and lower tertile ranges.

We purposively selected participants to reflect the diversity of implementers by organization type, length of program delivery, urbanicity, populations served, and size (Table 2). Due to variation in these organization characteristics, we planned to interview at least 30 participants. Thirty-nine National DPP implementers across the three organization implementation levels were selected; nine either did not respond to the invitation or declined to participate. The final sample included 30 National DPP organization key informants located in 24 states and territories. During analysis we found that after

conducting the 30 interviews we had reached saturation, or the point at which no new information relating to the CFIR constructs was identified in each of the groups. Organization staff reported a range of 5 to 600 enrolled participants to date. In the analysis, to control for length of delivery, enrollment numbers were divided by years of delivery to produce the average enrollment per year for each organization. The interviewees were re-stratified by enrolled participants per year into high (36-150), medium (17-35), and low (5-16) reach levels (Table 2).

Instruments. We developed a semi-structured interview guide with questions adapted from the CFIR guide (CFIR Research Team) and studies using similar methods (L. Damschroder & Lowery, 2013; Liang, Kegler, Cotter, et al., 2015). Open-ended question topics included interviewee training and background, program implementation success in terms of reach and sustainability, and 16 questions with suggested probes for each of the inner and outer setting CFIR constructs and sub-constructs (see Additional Table 1 for interview guide). Questions were posed in a way to encourage discussion about ***how*** each construct or subconstruct has positively or negatively impacted program implementation, particularly related to the outcome of reach (enrollment numbers). For example, the culture construct question asked, "In what ways do you think your organization's culture (general beliefs, values, assumptions that people embrace) affect the implementation of the National DPP?" The probe following asked, "How does the organization's culture impact enrollment of participants in particular?"

Data Collection. Interviewees were invited to participate in a 60-minute interview using Emory's secure Zoom videoconferencing account; verbal consent and permission to audio-record were obtained prior to initiating the interview. Interviews were conducted from August 2020 to January 2021. *A*ll recordings were transcribed by a third party, quality checked, deidentified, and uploaded into MAXQDA 2020 (VERBI Software, 2019) for coding and analysis.

Interviewee Descriptive Statistics. Interviewee organizations were categorized into one of five organization types: healthcare/hospitals, community-based healthcare (community health centers, federally qualified health centers, Indian Health Service, etc.) community-based organizations (YMCAs, local nonprofits, etc.), government agencies (state/local health departments), and other (health plans, insurers, worksite wellness programs, universities, private businesses). Descriptive statistics were run on organization characteristics including years delivering the National DPP, size based on the approximate number of people served across the entire organization annually, CDC Diabetes Prevention Recognition Program (DPRP) status [1] for the National DPP (Full vs Pending/Preliminary status), location of the organization by US region, and race/ethnicity of the National DPP participant population at the organization (Table 2).

Coding Interviews. A deductive codebook of CFIR constructs and interview questions was developed; in vivo (inductive) codes were added as relevant topics were identified during initial coding. The codebook was tested for clarity and relevancy and refined prior to coding. Coders (LM and OM) independently coded each transcript and conducted intercoder agreement, discussing and reaching consensus where there were discrepancies in coding. Double coding and intercoder agreement was performed on one third of the transcripts (n=10) to ensure intercoder reliability (Hennink, Hutter, & Bailey, 2010; Malterud, 2001).

Construct Rating. We used a qualitative construct rating analysis approach from Damschroder and Lowery (2013) to rate CFIR constructs related to implementation outcomes (L. Damschroder & Lowery, 2013). Applying this methodology, we identified distinguishing constructs among organizations with different levels of implementation reach and identified themes within those constructs that contribute to those differences.

[1] The DPRP provides national quality standards to ensure organizations are delivering the program with fidelity. These standards and procedures are updated every three years based on new dietary, physical activity, self-efficacy, delivery modality, and other type 2 diabetes prevention evidence. CDC-recognized organizations work toward progressing from pending to preliminary to full recognition status.

Coded segments for each CFIR construct were exported, sorted by organization, grouped by implementation reach level, and reviewed independently by both analysts (LM and OM). All segments were assessed by construct for valence (positive or negative influence on implementation) using construct rating criteria (Table 1). Segments were scored with a -2 to +2, a 5-point bi-polar scale; where there was more than one segment for an interview, the analysts discussed each segment and assigned an average score. Interviews that had positive statements about a construct's influence on implementation were scored with a 1 or 2 depending on the level of detail and impact on enrollment. Likewise, interviews with negative examples were scored with a -1 or -2. An equal mix of positive and negative influences received a score of zero.

Coders met weekly to discuss ratings and consensual validation was achieved through a process of deliberation and consensus. Since our sample had only one interviewee per organization, we adapted Damschroder and Lowery's methods to remove the synthesis of findings among multiple interviewees at the organization level. Once all transcripts were rated across all 16 CFIR constructs and subconstructs (a case-oriented approach, because ratings were applied within each case), both coders examined them across cases by construct (the variable-oriented approach, since each construct is compared across cases).

Table 1. Rating Criteria

Rating	Criteria
-2	Participant describes with detail how the construct is a negative/impeding influence on implementation related particularly to participant enrollment
-1	Participant makes statements about the construct as a negative influence/impeding influence on implementation generally
0	Mixed – participant describes both positive and negative statements about the construct in regards to general implementation and/or enrollment
1	Participant makes statements about the construct as a positive influence/facilitating influence on implementation generally
2	Participant describes with detail how the construct is a positive influence/facilitating influence on implementation related particularly to participant enrollment
X	Purely descriptive, no impact upon implementation or enrollment was described
M	Construct was not discussed during the interview

Analysis and Interpretation. A construct by case matrix was created that listed the ratings for each CFIR construct by interviewee and grouped by implementation reach level (figure 1). This stage of the analysis focused on discerning patterns across the high, medium, and low implementation reach groups. Average rating scores were calculated for each construct by reach level to identify patterns. Interviewees within each reach level were also sorted by organization type and given a summative average rating across all of the constructs to more easily identify rating differences.

Positive and negative extremes were discussed across all constructs and interviewees at every level. Four of the constructs/subconstructs were identified as *distinguishing* based on the difference between groups by average rating (generally if the difference was over $\pm$.5 between levels), the examination of the number of extreme (+2 or -2) ratings within levels, and through thematic analysis based on the content discussed.

Results

Organization Characteristics. Program staff from 30 unique implementing organizations were interviewed. CDC-recognized National DPP organizations designate Program Coordinators who supervise daily operations of the program, provide guidance and support to lifestyle coaches, and monitor and submit all program data to the CDC. Of these, all but one were Program Coordinators and 26 served in a combination of roles as Program Coordinators, Lifestyle Coaches, and/or Master Trainers for the National DPP.

About one third (9) of interviewees were from healthcare or hospital settings, followed by a near equal number from community-based healthcare (5, 17%), and other types of organizations (6, 20%) (Table 2). The majority of organizations were in the initial (13, 43%) or intermediate (13, 43%) phases of delivery and held Pending/Preliminary CDC DPRP status (20, 67%). There was consistent representation across the organization size categories and geographic regions. The vast majority have National DPP participants from White (80%), Black (70%), and Hispanic/Latino (63%) racial and ethnic backgrounds. Fewer organizations reported serving Alaska Native/Native American (27%) and Asian/Pacific Islander (27%)

participants in their programs. These racial and ethnic demographics reflect national-level participant data, where White, Black and Hispanic participants make up the majority of enrollees (Ely et al., 2017).

Representation across levels of implementation reach by organization type was also fairly consistent. In terms of years delivering the program, those in the higher reach group had delivered the program for the longest number of years, while the medium and lower reach groups included many organizations in the initial delivery phase (0-2 years). The higher reach group also tended to include those from larger organizations and more often with full DPRP recognition status.

Table 2. Interviewee Organization Characteristics by Implementation Reach

	Implementation Reach			
Implementation level based on reach calculated as the average number of participants enrolled per year.	Low *5-16/yr*	Med *17-35/yr*	High *36-150/yr*	Total (%)
Number of Interviewees	9	10	11	30
Organization Type (n)				
Healthcare/Hospitals	3	4	2	9 (30%)
Community-based healthcare	2	1	2	5 (17%)
Community-based organizations	-	2	3	5 (17%)
Government agencies	3	1	1	5 (17%)
Other: Health insurers, Employers, Academia	1	2	2	6 (20%)
Years Delivering the National DPP (n)				
0-2 Years: Initial Delivery Phase	6	5	2	13 (43%)
3-4 Years: Intermediate Delivery Phase	2	5	6	13 (43%)
5+ Years: Long-term Delivery Phase	1	-	3	4 (13%)
Organization Size (n)				
0-1,000 people served annually across all services & programs	1	3	1	5 (17%)
1,001 – 10,000 people	4	5	2	11 (37%)
10,001 – 100,000 people	4	1	2	7 (23%)
Over 100,000 people	-	1	5	6 (20%)
missing			1	1 (3%)
CDC DPRP Recognition Status[a] (n)				
Pending/Preliminary	7	8	5	20 (67%)
Fully Recognized	2	2	6	10 (33%)
Geographic Region in US (n)				
Northeast	3	1	2	6 (20%)

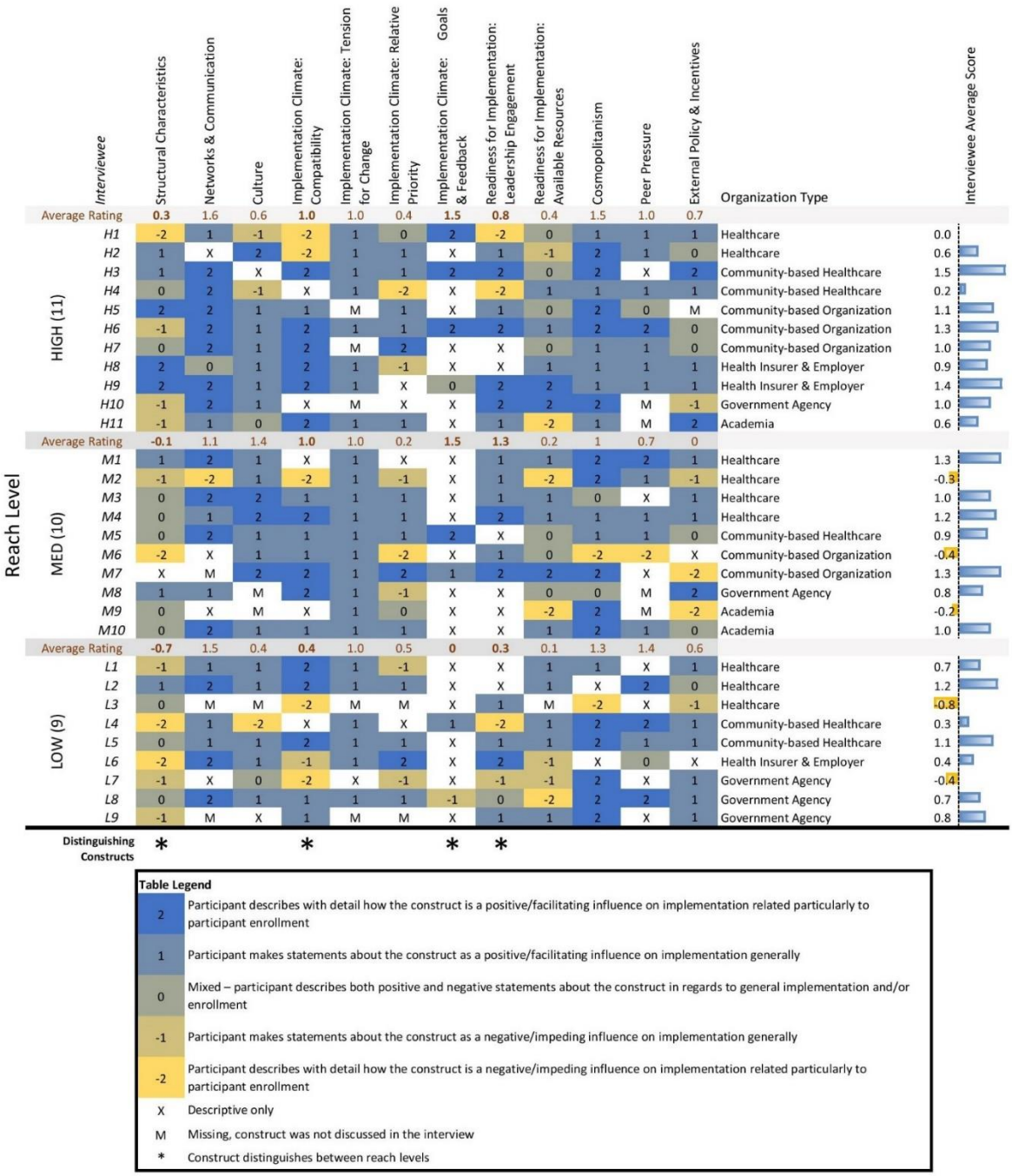
Southeast	3	4	3	10 (33%)
Midwest	-	1	3	4 (13%)
Southwest	3	2	1	6 (20%)
West	-	1	2	3 (10%)
Other (US Territories)	-	1	-	1 (3%)
Populations Served (n)				
White/Caucasian	7	8	9	24 (80%)
Black/African-American	7	5	9	21 (70%)
Hispanic/Latino	7	4	8	19 (63%)
Alaska Native/American Indian	3	-	5	8 (27%)
Pacific Islander/Asian	2	2	4	8 (27%)

[a]*For more details on CDC's DPRP recognition status requirements see – https://www.cdc.gov/diabetes/prevention/requirements-recognition.htm*

CFIR Construct Findings

The Construct Rating Matrix provides the CFIR ratings for each inner and outer setting construct by organization interviewee grouped by implementation reach level (Figure 1). Overall, the majority of interviewees were net positive in terms of their implementation examples across all of the constructs (Figure 1 Interviewee Average Score). However, the interviewees in the higher reach group provided stronger (+2) and more instances of positive examples across all constructs related to implementation and enrollment, while the low reach group stronger (-2) and more instances of negative examples across all rated constructs. Four constructs/subconstructs (incentives & rewards, learning climate, access to knowledge & information, and patient needs & resources) were not discussed in relation to implementation reach sufficiently in the interviews to conduct the construct rating and were omitted from the matrix. The following four *inner setting* constructs/subconstructs were identified as distinguishing: structural characteristics, compatibility, goals & feedback, leadership engagement. No *outer setting* constructs were distinguishing. The following results will highlight these constructs with discussion of the thematic analysis of the coded segments and supporting quotes.

Figure 1. Construct Rating Matrix



Reach Level	Interviewee	Structural Characteristics	Networks & Communication	Culture	Implementation Climate: Compatibility	Implementation Climate: Tension for Change	Implementation Climate: Relative Priority	Implementation Climate: Goals & Feedback	Readiness for Implementation: Leadership Engagement	Readiness for Implementation: Available Resources	Cosmopolitanism	Peer Pressure	External Policy & Incentives	Organization Type	Interviewee Average Score
	Average Rating	**0.3**	1.6	0.6	**1.0**	1.0	0.4	**1.5**	**0.8**	0.4	1.5	1.0	0.7		
HIGH (11)	H1	-2	1	-1	-2	1	0	2	-2	0	1	1	1	Healthcare	0.0
	H2	1	X	2	-2	1	1	X	1	-1	2	1	0	Healthcare	0.6
	H3	1	2	X	2	1	1	2	2	0	2	X	2	Community-based Healthcare	1.5
	H4	0	2	-1	X	1	-2	X	-2	1	1	1	1	Community-based Healthcare	0.2
	H5	2	2	1	1	M	1	X	1	0	2	0	M	Community-based Organization	1.1
	H6	-1	2	1	2	1	1	2	2	1	2	2	0	Community-based Organization	1.3
	H7	0	2	1	2	M	2	X	X	0	1	1	0	Community-based Organization	1.0
	H8	2	0	1	2	1	-1	X	X	1	1	1	1	Health Insurer & Employer	0.9
	H9	2	2	1	2	1	X	0	2	2	1	1	1	Health Insurer & Employer	1.4
	H10	-1	2	1	X	M	X	X	2	2	2	M	-1	Government Agency	1.0
	H11	-1	1	0	2	1	1	X	1	-2	1	M	2	Academia	0.6
	Average Rating	**-0.1**	1.1	1.4	**1.0**	1.0	0.2	**1.5**	**1.3**	0.2	1	0.7	0		
MED (10)	M1	1	2	1	X	1	X	X	1	1	2	2	1	Healthcare	1.3
	M2	-1	-2	1	-2	1	-1	X	1	-2	2	1	-1	Healthcare	-0.3
	M3	0	2	2	1	1	1	X	1	1	0	X	1	Healthcare	1.0
	M4	0	1	2	2	1	1	X	2	1	1	1	1	Healthcare	1.2
	M5	0	2	1	1	1	1	2	X	0	1	1	0	Community-based Healthcare	0.9
	M6	-2	X	1	1	1	-2	X	1	0	-2	-2	X	Community-based Organization	-0.4
	M7	X	M	2	2	1	2	1	2	2	2	X	-2	Community-based Organization	1.3
	M8	1	1	M	2	1	-1	X	X	0	0	M	2	Government Agency	0.8
	M9	0	X	M	X	1	0	X	X	-2	2	M	-2	Academia	-0.2
	M10	0	2	1	1	1	1	X	X	1	2	1	0	Academia	1.0
	Average Rating	**-0.7**	1.5	0.4	**0.4**	1.0	0.5	**0**	**0.3**	0.1	1.3	1.4	0.6		
LOW (9)	L1	-1	1	1	2	1	-1	X	X	1	1	X	1	Healthcare	0.7
	L2	1	2	1	2	1	1	X	X	1	X	2	0	Healthcare	1.2
	L3	0	M	M	-2	M	M	X	1	M	-2	X	-1	Healthcare	-0.8
	L4	-2	1	-2	X	1	X	1	-2	1	2	2	1	Community-based Healthcare	0.3
	L5	0	1	1	2	1	1	X	1	1	2	1	1	Community-based Healthcare	1.1
	L6	-2	2	1	-1	1	2	X	2	-1	X	0	X	Health Insurer & Employer	0.4
	L7	-1	X	0	-2	X	-1	X	-1	-1	2	X	1	Government Agency	-0.4
	L8	0	2	1	1	1	1	-1	0	-2	2	2	1	Government Agency	0.7
	L9	-1	M	X	1	M	M	X	1	1	2	X	1	Government Agency	0.8
	Distinguishing Constructs	*			*			*	*						

Table Legend

2	Participant describes with detail how the construct is a positive/facilitating influence on implementation related particularly to participant enrollment
1	Participant makes statements about the construct as a positive/facilitating influence on implementation generally
0	Mixed – participant describes both positive and negative statements about the construct in regards to general implementation and/or enrollment
-1	Participant makes statements about the construct as a negative/impeding influence on implementation generally
-2	Participant describes with detail how the construct is a negative/impeding influence on implementation related particularly to participant enrollment
X	Descriptive only
M	Missing, construct was not discussed in the interview
*	Construct distinguishes between reach levels

The Structural Characteristics *construct is comprised of many traditional measures of context and organization characteristics (organization size, type, location, etc.).* Among the interviewees, *Structural Characteristics* often involved discussions of organization infrastructure for the program (physical space,

staff size, etc.). As this construct contains a multitude of dimensions, interviewees frequently described both positive and negative examples, resulting in many mixed ratings. This construct appears to distinguish the high and medium reach level organizations from the low reach group. In the medium and high reach levels, interviewees often discussed both the benefits and challenges of implementation related to structural characteristics. For example, this interviewee highlights how the size of the organization can both help and hinder National DPP implementation:

> "So, we're a pretty big organization. […] There are pros and cons to everything. I think our size is a pro just because we have a large population, like a patient population, in which to draw from. […] One thing that can make it a barrier, though, as far as trying to get referrals and spread the word is when it's a huge organization and there's a lot going on, sometimes it is hard to get the message across when there's just so much other stuff going on." Interviewee M2, Medium Reach, Healthcare

However, among the low reach group, the vast majority of the coded *Structural Characteristics* segments were rated negatively. These interviewees reported difficulties with limited infrastructure for the program, lack of staff and staff time, challenges with developing referral systems, and administrative/bureaucratic hurdles due to their organization type. For example, this interviewee from a local government agency shared the challenges involved with applying for and implementing grants for the program:

> "[…] for us to start applying for a grant, we somewhere in our process have to involve the city council. And in addition to that process once the city council okays on us applying for the grant, we receive the grant. Now we have to implement that grant into the city's budget. So that becomes really tedious and becomes a really huge pain as opposed to a nonprofit." Interviewee L9, Low Reach, Government Agency

Across all cases, the most salient dimension of the *Structural Characteristics* construct was organization type and how it impacted their reach to populations, available infrastructure/resources, administrative processes, and reputation in the community.

Compatibility is *a subconstruct of Implementation Climate and relates to how the intervention fits within the organization and its existing workflows, systems, and services.* High and medium reach groups more often yielded strong positive examples of *Compatibility* impacting implementation, compared to those in the low reach group. Interviewees describing positive examples of the influence of *Compatibility* on implementation often mentioned that their organization offered complementary programs to the National DPP (e.g., diabetes self-management, nutrition education, fitness classes, etc.). This allowed them to more easily adopt and implement the National DPP. As described by one high reach organization interviewee (Interviewee H8, High Reach, Health Insurer & Employer), "it's a nice complement and it nicely rounds out the services that we offer."

In the strongest positive examples, interviewees shared how other programs within their organization referred program participants to the National DPP and vice versa. They also gave positive examples of how the National DPP was embedded in their workflows and systems via the electronic health records (EHR) or other referral processes, all of which supported enrollment efforts. Two high reach group interviewees described challenges introducing the National DPP into their organization systems, but by taking time to educate key leaders and staff about the program, they were able to overcome those *Compatibility* challenges and succeed with implementation.

Conversely, in strong negative examples of *Compatibility*, interviewees struggling to implement the National DPP described how it was different from the typical services and programs provided by their organization and was not embedded into their current systems.

> "We have to force it to fit. Do I feel like it -- I feel like it needs to be a part of the entire process, like if someone's coming in for one particular service they should be screened for being at risk of having Type 2 Diabetes. And we've done it, but it's only been during specific times and then it goes away. […] So I would love to see it more integrated into all of the programs. " – Interviewee L7, Low Reach, Government Agency

Across all reach levels there were some additional themes related to *Compatibility.* A commonly voiced complaint was how time consuming and burdensome the data reporting to the CDC DPRP is compared to other evidence-based interventions implemented at their organizations. Lastly, in a few cases, interviewees shared that their organization had a large number of chronic disease programs and this created challenges for staff to remember to refer to the National DPP. While complementary programs was a strength for some, it was also possible for the National DPP to get buried and forgotten when so many programs were available.

Goals & Feedback *is a subconstruct of Implementation Climate and refers to the degree to which goals are clearly communicated, acted upon, and fed back to staff, as well as the alignment of that feedback with goals.* We asked interviewees to discuss how enrollment goals (target number of participants to recruit each year) set by them or leaders at their organization impacted their implementation efforts. This construct was distinguishing among reach groups by the presence and communication of enrollment goals. The majority of the high implementation organizations (n=9, 82%) had formal enrollment goals set by organization leadership or the program coordinator. In comparison, only four (40%) of the medium and three (33%) low reach interviewees reported having enrollment goals.

Overall, interviewees did not provide many details on how enrollment goals impact implementation, but when they did it was very clear how goals facilitate enrollment. One high reach group interviewee described how goals motivate the staff to increase their referrals and enrollment,

> "[…] we always have a goal, an enrollment goal. So we always reach the goal and we have a waiting list. There's always a waiting list and as I said, that's something that we're very proud of. […] it's nice to have the number, I like numbers. Tell me what you want, I'll go for that number."– Interviewee H3, High Reach, Community-Based Healthcare

For organizations that did not have formal enrollment goals, interviewees mentioned other goals such as achieving CDC DPRP recognition status, billing Centers for Medicare & Medicaid Services (CMS)/becoming a Medicare DPP supplier, training their staff to implement the program, general diabetes prevention in their communities, or focusing on the retention of their current cohorts first before attempting to enroll more participants. One interviewee from a medium reach organization said because their focus is on establishing a process for billing CMS, they are not concerned about enrollment and prefer a small cohort at the moment.

Multiple interviewees that currently did not have enrollment goals said they were interested in setting formal enrollment goals. In some cases, interviewees had their own personal enrollment goals, not set by their leadership or organization. While the interviews focused on pre-COVID-19 implementation, a few interviewees mentioned how COVID-19 had disrupted their implementation and therefore currently enrollment goals were not a priority.

Leadership Engagement is *a subconstruct of Readiness for Implementation and refers to the commitment, involvement, and accountability of leaders and managers with the implementation of the program.* This construct appeared numerous times throughout most interviews. While the majority of interviewees simply said they have "support" from their leadership, when asked to describe this support in terms of *Leadership Engagement* their examples varied greatly. Examples of *Leadership Engagement* included: leadership being aware of all program activities and events, making presentations to promote the program, connecting with other organization leaders/partners for the program, facilitating internal

organization processes (e.g. board approvals, system establishment) for the program, obtaining resources including adequate staffing for the program, and providing the program for free to organization employees.

Leadership Engagement was a distinguishing construct as high and medium reach cases had more strong positive examples of *Leadership Engagement* compared to the low reach cases. High and medium reach interviewees also more often connected *Leadership Engagement* with positive examples of successful enrollment efforts and growing the infrastructure for the program.

> "Our leadership has been great […] I'll just give an example when we were going to be Medicare suppliers or applying for Medicare reimbursement. […] And because we had physicians on our board and people that knew about the program, they knew about the process even with Medicare we really had buy-in there because they were able to explain it […] So they really came together and got everybody on board and we were able to get those numbers and submit the application." – Interviewee H6, High Reach, Community-Based Organization

Low reach groups had more mixed experiences with this construct. Leadership was described as not being engaged enough; not doing enough to understand the program, and taking a "hands off" approach. One interviewee described this as a gap in leadership knowledge about the National DPP:

> "[…] I think leadership -- just to actually sit down and know -- understand the program a little bit better and understanding the goals that are attached to it and understanding the work that's needed to get done. That's it. I think that's where the gap comes in."– Interviewee 8, Low Reach, Government Agency

The key message from all interviewees across reach levels was that *Leadership Engagement* is highly desired and appreciated when available. Leadership support and knowledge of the program was discussed as a strong facilitator in implementing and scaling the program.

Discussion

This study applied CFIR to examine the internal and external organization factors influencing National DPP implementation. The four distinguishing constructs from the inner setting (structural characteristics, compatibility, goals & feedback, and leadership engagement) indicate that there are multiple factors internal to the organization that can impact implementation and enrollment success. Our findings are consistent with other studies that have found that some of these same constructs influence successful implementation – particularly within the inner setting domains such as leadership engagement and the implementation climate subconstructs (L. Damschroder & Lowery, 2013; Liang, Kegler, Cotter, et al., 2015; Piat et al., 2021; Shade et al., 2019).

Similar to previous research, positive *Leadership Engagement* on implementation involved going beyond surface level support of the program and was highlighted by taking an active role in understanding the program, attending program events, promoting the program, and providing resources (L. Damschroder & Lowery, 2013; Liang, Kegler, Cotter, et al., 2015; Piat et al., 2021). The distinguishing implementation climate subconstructs of *Compatibility, Relative Priority,* and *Goals and Feedback* indicated that for organizations at higher reach levels, the National DPP fit better with existing services, health promotion programs, and systems, was prioritized by the organization leadership, and had formal enrollment goals outlined.

To date, there is a lack of evaluation of the National DPP using CFIR constructs; however, other lifestyle change programs also focused on physical activity and nourishment behaviors to achieve weight loss have been studied using CFIR (Batsis et al., 2020; L. Damschroder & Lowery, 2013; L. J. Damschroder et al.,

2016; Makama, Skouteris, Moran, & Lim, 2021). These studies have also found a heavy emphasis on the inner setting when exploring program implementation successes and challenges. Related the outer setting, their results described challenges with billing and program reimbursement/financing policies. Our study did not find any outer setting constructs distinguishing between reach levels; however, there were notable themes that emerged from the data around the importance of external partnerships, understanding participant needs, benefits of learning from and competing with other National DPP delivery organizations, and challenges with reimbursement programs (like Medicare DPP). Likewise, the constructs that were not rated (incentives & rewards, learning climate, access to knowledge & information, and patient needs & resources), also provided other insights into the program, such as examples of program participant barriers and challenges, however they did not talk in enough detail about these influences on implementation and enrollment to be included in this analysis.

The findings of this study have the potential to facilitate implementation of the National DPP. While the National DPP provides guidance on the standard infrastructure needed for organizations to deliver the program (*Structural Characteristics*) and the importance of partnerships (*Cosmopolitanism*), previously there has been less of a conversation about organization compatibility, priorities, goal setting and feedback, and active leadership engagement which we identified as important in this study (Centers for Disease Control and Prevention, 2021a; Vojta, Koehler, Longjohn, Lever, & Caputo, 2013). The CDC should consider inclusion of CFIR-related constructs such as leadership engagement in the CDC DPRP Organizational Capacity Assessment, a suggested tool that delivery organizations use at the time of adoption. The assessment is primarily focused on the minimum requirements to deliver the program (e.g. classroom space, equipment, staff requirements) but does not help identify which organization characteristics may be particularly suited to reach a large number of participants and successfully scale. The current version does include about many of the CFIR constructs including the ones identified as distinguishing in our study. For example, there is no discussion of how well the program “fits” within an

organization's current programs and services or how the program would be prioritized if implemented. Inclusion of these constructs could assist with identifying key gaps in organization adoption readiness, enrollment, and scalability (Bryan J. Weiner, 2009; Bryan J Weiner et al., 2008).

To support low reach delivery organizations, the CDC and other National DPP technical assistance providers should consider guidance and resources to increase program compatibility, prioritization, goal setting, and leadership engagement. However, the main program implementers may not have control over these conditions. For example, a frequently mentioned challenge in the relative priority construct was limited staff and staff time dedicated to the program. Organizations may require more assistance and resources from the CDC and others to ensure adequate staff are not only hired and properly trained, but that their time is dedicated sufficiently to the National DPP. These considerations may also be applicable to other evidence-based programs as well.

Future Research. More research is required to understand how internal and external organization factors influence implementation in order to continue to scale the National DPP. While this study did not identify any outer setting constructs as distinguishing, the outer setting *c*onstruct, *Cosmopolitanism,* has appeared in National DPP studies focused on referrals from providers, health systems, and other community partners (Mosst et al., 2017; Nhim et al., 2019; Vojta et al., 2013). Organizations with strong external partnerships were able to leverage this into increased referrals to their programs. Our study may not have found outer setting constructs as distinguishing because the interviewees focused more heavily on the inner setting constructs and interviewees reported mostly neutral and positive experiences regardless of reach level (Figure 1). Additional research may be warranted to explore how the outer setting may affect the National DPP or other chronic disease programs. Likewise, future research should also include exploration of the other CFIR domains (intervention characteristics, process, and characteristics of individuals) to provide a holistic perspective on factors related to reach.

It is challenging to compare the National DPP to other programs using CFIR, as researchers have focused on different dimensions of CFIR constructs, often times based on relevant factors for the specific program. For example in the Cannon et al. 2019 study, the *Culture* construct was operationalized as implementation staff turnover (Cannon et al., 2019), whereas in our study we focused on an organization's general beliefs, values, assumptions. This is a shortcoming of CFIR itself which has been criticized as very complex and multi-dimensional, and requiring more nuanced detail (I. Ilott, Gerrish, Booth, & Field, 2013). The developers of CFIR have announced a second version of the framework with the goal of addressing this criticism and other gaps that may be helpful to use in subsequent studies (Laura Damschroder & Smith, 2021).

Measuring CFIR constructs quantitatively is a growing area that has great potential to assist with understanding the relationship between implementation factors and outcomes (Miake-Lye et al., 2020; Bryan J. Weiner et al., 2020). Implementation science researchers have started testing quantitative measures for CFIR constructs, however more work is needed in this area to fully understand the validity and reliability of these constructs, how they are operationalized in practice, and their associations with implementation outcomes (Dorsey, Mettert, Puspitasari, Damschroder, & Lewis, 2021; Fernandez et al., 2018; McHugh et al., 2020; Tinc et al., 2020; Wilcox et al., 2020). CFIR quantitative measures have typically examined relationships between constructs and shorter term implementation (e.g. adoption) rather than later-term outcomes like sustainability (Chaudoir et al., 2013). Using CFIR measures across the continuum of implementation will be critical to assess differences in key factors related to outcomes in the pre-adoption, early adoption, and maintenance phases (L. J. Damschroder, Reardon, Opra Widerquist, & Lowery, 2022).

Strengths & Limitations. Strengths of this study include *a priori* use of CFIR constructs and instruments, highly trained qualitative researchers and coders, rigorous double coding and analysis of data, and the application of the construct rating methods employed by other researchers. However, this study had

several limitations that should be considered. First, there are 2,000+ organizations delivering this program nation-wide, and our study included only 30 in our sample, therefore results may be limited. In addition, we recruited from Emory's DTTAC contact list and while this population is very large and diverse, there may be implementation differences between this group and the larger National DPP population of implementers because of the training and technical assistance they receive from Emory.

Second, only one interview was conducted per organization. Other papers using this construct rating method typically include 2-3 interviewees per organization (L. Damschroder & Lowery, 2013; Liang, Kegler, Cotter, et al., 2015). However, we were able to talk with 30 different organizations which is a higher number of unique organizations than is typical for this analysis. Instead of depth within organizations, we focused on breadth across a diverse range of organizations and focused on the best possible informant to answer our questions (the Program Coordinator). In order to capture the diversity in National DPP implementation, we did not limit organizations based on a specific number of years of delivery for recruitment. Instead we operationalized reach using the average enrollment per year of delivery. Reach numbers were self-reported by the interviewee and we did not have access to the programmatic data to confirm or examine changes in enrollment over the years of delivery. While imperfect, using the average enrollment per year helps compare implementation success across organizations.

For this study we only focused on the inner and outer setting constructs of CFIR and decidedly focused on the organization-level perspective, which limits our understanding of the other dimensions of implementation (intervention characteristics, process, and characteristics of individuals). Lastly, in early 2020 the COVID-19 pandemic disrupted the National DPP, a largely in-person program, greatly. We did try to limit our interview discussions to pre-COVID implementation, but this was an unignorable outer setting/external factor. It is hard to say how much of the discussion of these topics was impacted by implementers who found themselves in a "survival/adaptation mode" at the time of the interview.

Conclusions

This study found that there are a number of CFIR inner setting constructs that impact implementation reach of the National DPP. This understanding can be leveraged to improve efforts in recruiting and assisting delivery organizations to increase the reach and scale of the program. This is one of only a few studies of the National DPP at the organization level and to use the CFIR construct rating qualitative methodology to explore the national implementation of this program. More focused attention to program compatibility, prioritization, setting program goals, and leadership engagement has the potential to improve program implementation. Furthermore, these results have broader application to understand how best to assist organizations to adopt, deliver, and scale evidence-based programs.

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Supplemental Table

Supplemental Table: *Interview Guide Questions*

Topic/Construct	Example questions
Background	Can you tell us a little about your organization's history with the National DPP lifestyle change program? [Learn about adoption of the intervention]

Outcomes - Reach	How would you define success when it comes to your organization's implementation of the National DPP? How successful do you think your organization has been based on your definition of success?
Outcome - Sustainability	How would you define sustainability for your organizations as it pertains to delivering the National DPP?
Inner Setting	
Structural Characteristics	CFIR Guide Question: How will the infrastructure of your organization (social architecture, age, maturity, size, or physical layout) affect the implementation of the intervention? Adapted Question: How do you think aspects of infrastructure (size, physical space, staff size, age of the organization, type of organization, etc.) impact your ability to implement the National DPP lifestyle change program at your organization?
Networks & Communications	CFIR Guide Questions: Can you describe your working relationships with your colleagues? Do you meet (formally or informally) with a team of people? Are meetings, such as staff meetings, held regularly? Adapted Question: Describe the internal communication processes within your organization that facilitate the implementation of the National DPP lifestyle change program?
Culture	CFIR Guide Question: How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention? Adapted Question: In what ways do you think your organization's culture (general beliefs, values, assumptions that people embrace) affect the implementation of the National DPP? Can you describe an example that highlights this?
Implementation Climate - Compatibility	CFIR Guide Question: How well does the intervention fit with existing work processes and practices in your setting? Adapted Question: How well does the National DPP fit with existing work processes and practices in your setting?
Implementation Climate - Tension for Change	CFIR Guide Question: Is there a strong need for this intervention? Adapted Question: Would you say there is a strong need for the National DPP at your organization? Why/Why not
Implementation Climate - Relative Priority	CFIR Guide Questions: What kinds of high-priority initiatives or activities are already happening in your setting? What is the priority of getting the intervention implemented relative to other initiatives that are happening now? Adapted Questions: What would you say are the key priority programs/activities at your organization currently? Where is the National DPP/diabetes prevention at on the priority list?
Implementation Climate - Organizational incentives & rewards	CFIR Guide Question: What kinds of incentives are there to help ensure that the implementation of the intervention is successful?

	Adapted Question: What kinds of incentives are in place at your organization to help ensure that the implementation of the National DPP is successful?
Implementation Climate - Goals and Feedback	CFIR Guide Question: Have you/your unit/your organization set goals related to the implementation of the intervention? Adapted Question: Can you tell me about any goals you, your team, or your organization have set related to the implementation of the National DPP?
Implementation Climate - Learning Climate	CFIR Guide Question: To what extent do you feel like you can try new things to improve your work processes? Adapted Question: To what extent do you feel you have the power to try new methods/processes as they relate to implementing the National DPP?
Readiness for Implementation - Leadership Engagement	CFIR Guide Question: What level of involvement has leadership at your organization had so far with the intervention? Adapted Question: In what ways has leadership at your organization been involved with the implementation of the National DPP lifestyle change program?
Readiness for Implementation - Available Resources	CFIR Guide Question: Do you expect to have sufficient resources to implement and administer the intervention? Adapted Question: In your experience, what are the key resources your organization needs to implement the National DPP successfully?
Readiness for Implementation - Access to Knowledge & Information	CFIR Guide Question: What kind of training is planned for you? For colleagues? Adapted Question: Beyond lifestyle coach training, what other kinds of preparation or resources do staff working on the National DPP at your organization receive, if any, to support your ability to implement the lifestyle change program?
Outer Setting	
Patient Needs & Resources	CFIR Guide Question: To what extent were the needs and preferences of the individuals served by your organization considered when deciding to implement the intervention? Adapted Question: Generally, what has been the response of your participants to the National DPP? How well do you think the National DPP meets the needs of the individuals served by your organization?
Cosmopolitanism	CFIR Guide Question: What kind of information exchange do you have with others outside your setting, either related to the intervention, or more generally about your profession? Adapted Question: What kind of information exchange do you have with others outside of your organization about the National DPP?
Peer Pressure	CFIR Guide Question: Can you tell me what you know about any other organizations that have implemented the intervention or other similar programs?

	Adapted Question: What do you know about other organizations in your region/state that provide the National DPP lifestyle change program or other similar programs?
External Policy & Incentives	CFIR Guide Question: What kind of local, state, or national performance measures, policies, regulations, or guidelines influenced the decision to implement the intervention? Adapted Question: What kind of local, state, or national policies or initiatives influenced how your organization decided to implement the National DPP?

Chapter 3: Aim 2

Title: A Structural Equation Model of CFIR Inner and Outer Setting Constructs, Organization Characteristics, and National DPP Enrollment

Abstract

Background: The National Diabetes Prevention Program (DPP) has made great strides in raising awareness for and accessibility to its year-long, evidence-based lifestyle change program. Although around 3,000 organizations have delivered the program, there is limited implementation research to understand organization-level factors and characteristics associated with program implementation and reach (enrollment). The Consolidated Framework for Implementation Research (CFIR) *Inner Setting* and *Outer Setting* constructs focus on internal and external influences on organizations related to program implementation and are useful to understanding predictors of implementation outcomes. The purpose of this study was to quantitatively examine the relationships between CFIR *Inner* and *Outer Setting* constructs and the implementation outcome of reach.

Methods: This study analyzed data from a 2021 cross-sectional online survey with 586 National DPP Staff (lifestyle coaches, master trainers, program coordinators) with information about their organization, implementation outcomes, and responses to quantitative CFIR *Inner Setting* and *Outer Setting* construct items. Structural equation modeling was used to test a hypothesized path model with three *Inner Setting* and *Outer Setting* latent variables and organizational characteristics to explore direct and indirect pathways to enrollment.

Results: The CFIR items had good internal consistency and indicated areas of implementation strength and weakness. The latent CFIR construct variables were not significantly related to enrollment numbers directly or indirectly. However, nine variables included as part of the CFIR structural characteristics has significant direct relationships with enrollment. The length of delivery, number of lifestyle coaches, number of full-time staff, large organization size, and organizations delivering in rural, suburban, and/or

urban settings all had positive significant direct relationships with enrollment. While academic organizations and organizations with only non-White participants enrolled in their National DPP lifestyle change programs had a negative association with enrollment.

Conclusions: Participant reach (enrollment) is an important implementation outcome for the National DPP and vital to making population-level decreases in diabetes incidence in the U.S. Our findings suggest that to facilitate enrollment, program implementers should focus on providing adequate staffing, expanding the program in multiple locations (rural, suburban, and urban), and improving recruitment of non-white participants. Strengths of this study include the use of adapted and newly developed quantitative CFIR measures and structural equation modeling to understand relationships between organization-level factors and implementation outcomes. This work builds upon the CFIR literature and provides new understanding of implementation science measures. Health prevention programs can use the methods and findings from this study to further understand and inform the impact of organization factors on implementation outcomes.

Background

Currently, 96 million (38%) U.S. adults have prediabetes, a condition where blood glucose levels are higher than normal, but not high enough to be diagnosed with type 2 diabetes (Centers for Disease Control and Prevention, 2022b). To address prediabetes, the CDC's National Diabetes Prevention Program (DPP) has made great strides in raising awareness for and accessibility to its year-long, evidence-based lifestyle change program (Ely et al., 2017; Harris Meyer, 2021; Ritchie, Baucom, & Sauder, 2020). The goal of this initiative is to create public and private organization partnerships to deliver program in communities across the country (Centers for Disease Control and Prevention, 2022a).

As of March 2022 there were over 600,000 participants reached by the National DPP since February 2012 (Centers for Disease Control and Prevention, 2022a). Even with this success, others have estimated that

in order to have population-level impact the initiative should aim to enroll 12 million people with prediabetes (Ackermann, 2017). Additional efforts are needed to scale and sustain National DPP delivery across the country to this level. While there have been around 3,000 organizations who have delivered the program (Ritchie et al., 2020), very little implementation research has been done to understand organization-level factors and characteristics associated with program implementation and reach (enrollment).

The Consolidated Framework for Implementation Research (CFIR) is a metatheory comprised of constructs that have been associated with effective implementation (L. J. Damschroder et al., 2009). CFIR constructs have been useful in understanding implementation in a wide range of interventions, settings, and research designs (Laura J. Damschroder, Reardon, Opra Widerquist, & Lowery, 2022; Kirk et al., 2015; Means et al., 2020). In particular the *Inner Setting* and *Outer Setting,* focus on internal and external influences on organizations related to program implementation. The *Inner Setting* domain constructs aim to capture the complexity within the organization related to implementation. These include constructs such as an organization's *structural characteristics, culture,* and *implementation climate*. The *Outer Setting* constructs provide insight into the greater environments and external context which constrain organizations or facilitate their ability to carry out the intervention. These include constructs such as *cosmopolitanism, patient needs and resources*, and *external policies and incentives* (see Table 1 for construct definitions). As part of a mixed methods study to evaluate the National DPP implementation, we applied CFIR's *inner and outer setting* constructs to describe these internal and external organization influences on enrollment.

The CFIR *Inner and Outer Setting* constructs have been found to be important factors for outcomes like program delivery and scaling across different health promotion topics and settings. In 2018, a systematic integrative review, identified influential organizational contextual features of healthcare settings on the implementation of evidence-based practices (Li, Jeffs, Barwick, & Stevens, 2018). Organizational

characteristics and *Inner Setting* constructs*, Culture* and *Leadership Engagement* were often interrelated and worked synergistically to influence implementation outcomes (adoption, integration, and intervention use) across the 36 studies included in the review. *Inner Setting* constructs, *Leadership Engagement, Tension for Change,* and *Access to Information and Knowledge* were also found to be influential in an evaluation of the implementation of breast and colorectal cancer screening across a number of evidence-based practice delivery sites (Liang et al., 2015). In a mixed-methods analysis of facilitators and barriers to scaling up tobacco control programs, CFIR *Inner Setting* constructs identified the importance of leadership engagement at multiple levels, compatibility/program fit, and adequate training/skills of staff (Thompson et al., 2019).

The *Outer Setting* is also of particular importance when implementing prevention programs nationally like the National DPP, as these initiatives rely on partnerships between multiple agencies, leaders, funders, and policy makers, across national, state, and local levels (McHugh et al., 2020). In a systematic review of influential CFIR constructs on the implementation of e-health interventions, many studies included *Inner* and *Outer Setting* constructs (Ross, Stevenson, Lau, & Murray, 2016). Within the *Outer Setting*, *External Policy and Incentives* was most frequently identified as impacting implementation of e-health interventions due to effects of legislation, policies, and liability concerns on intervention delivery and the incentives by the government to facilitate intervention adoption (Ross et al., 2016). While there are examples of how these constructs impact implementation outcomes, there is little in the literature around the relationship between the CFIR *Inner and Outer Setting* constructs and any relationships they have with each other.

In a 2022 update of the CFIR, the originators provide implementation outcome definitions categorized into anticipated (adoptability, implementability, sustainability) and actual outcomes (adoption, implementation, sustainment) (Laura J. Damschroder et al., 2022). In this paper, the authors also note that many applications of CFIR have been combined with other implementation frameworks that include

implementation outcomes, like the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) (R. F. Glasgow, Vogt, & Boles, 1999) and the Implementation Outcomes Framework (Proctor et al., 2011). The new CFIR outcomes encompass many of the specific implementation outcomes previously identified in the literature (e.g. acceptability, adoption, fidelity, penetration, etc.).

While past CFIR research has been largely qualitative and focused on implementation at the time of adoption (Kirk et al., 2015), more recent work used quantitative methods to understand the range of implementation outcomes. Quantitative measures have been used to understand the implementation and scale up of tobacco control programs, a mobile health platform, a telemedicine-delivered healthy lifestyle program, and colorectal cancer screening practices (Batsis et al., 2020; El Joueidi et al., 2021; Fernandez et al., 2018; Thompson et al., 2019; Trevena et al., 2021). In 2018, Fernandez and colleagues, published items for five *Inner Setting* constructs (culture, implementation climate, learning climate, leadership engagement, and available resources). These items were found to have good psychometric properties and have been used by others, including to evaluate implementation barriers and facilitators of a telemedicine-delivered healthy lifestyle program (Batsis et al., 2020). For the *Outer Setting,* a recent systematic review has identified 20 measures for the various constructs, however the majority of scales and subscales did not have psychometric information available (McHugh et al., 2020).

Within the broad diabetes prevention program literature, a few studies have been published on CFIR to evaluate program implementation. In 2015, CFIR was used to systematically assess contextual factors that influence adoption and implementation an adaptation of the DPP for U.S. Veterans (Laura J. Damschroder et al., 2017). The study identified a number of facilitators and barriers associated with CFIR *Outer* and *Inner Setting* domains, however they are not described in depth. More recently, two diabetes preventions programs in Canada were evaluated qualitatively using CFIR (Dineen, Bean, & Jung, 2022). Related to the *Outer Setting,* two constructs, *Peer Pressure and Cosmopolitanism* were heavily discussed, emphasizing the benefits of the competitive edge the program gives organizations and strong partnerships. Almost all

constructs within *Inner Setting* were salient in the data, examples of important constructs included *Implementation Climate-Compatibility* which focused on fit within the organization and staff capacity, as well as Readiness for Implementation, which discussed the importance of *Leadership Engagement, Available Resources,* and staff *Access to Knowledge and Information*. To our knowledge there are no National DPP specific studies that have used quantitative CFIR measures or evaluated these concepts across a large sample of delivery organizations.

The purpose of the study reported here was to quantitatively examine the relationships between CFIR *Inner* and *Outer Setting* constructs and the implementation outcome of reach (Figure 1). Using online survey data from National DPP implementers, our main research questions were: how do the *Inner* and *Outer Setting* impact reach (participant enrollment) for organizations implementing the National DPP lifestyle change program? and in what ways do organizational characteristics such as organization type, size, location, etc. influence reach and these pathways directly or indirectly?

In addition, instead of simply understanding the link between CFIR constructs and implementation outcomes, we also aimed to explore the relationship between the *Inner* and *Outer Setting* constructs. Particularly we have emphasized the implementation focused constructs within the *Inner Setting: Implementation Climate* and *Readiness for Implementation* as key mediators. While the other three *Inner Setting* constructs (*Structural Characteristics*; *Networks and Communication*; and *Culture*) represent general organizational internal context, the two implementation focused ones are more focused on the internal context related to implementing the specific intervention. We think that the state of these first *Inner Setting* constructs may facilitate or hinder the implementation focused ones. Likewise, the *Outer Setting* and organizational characteristics may impact the *Inner Setting* and implementation outcomes at multiple points in the model.

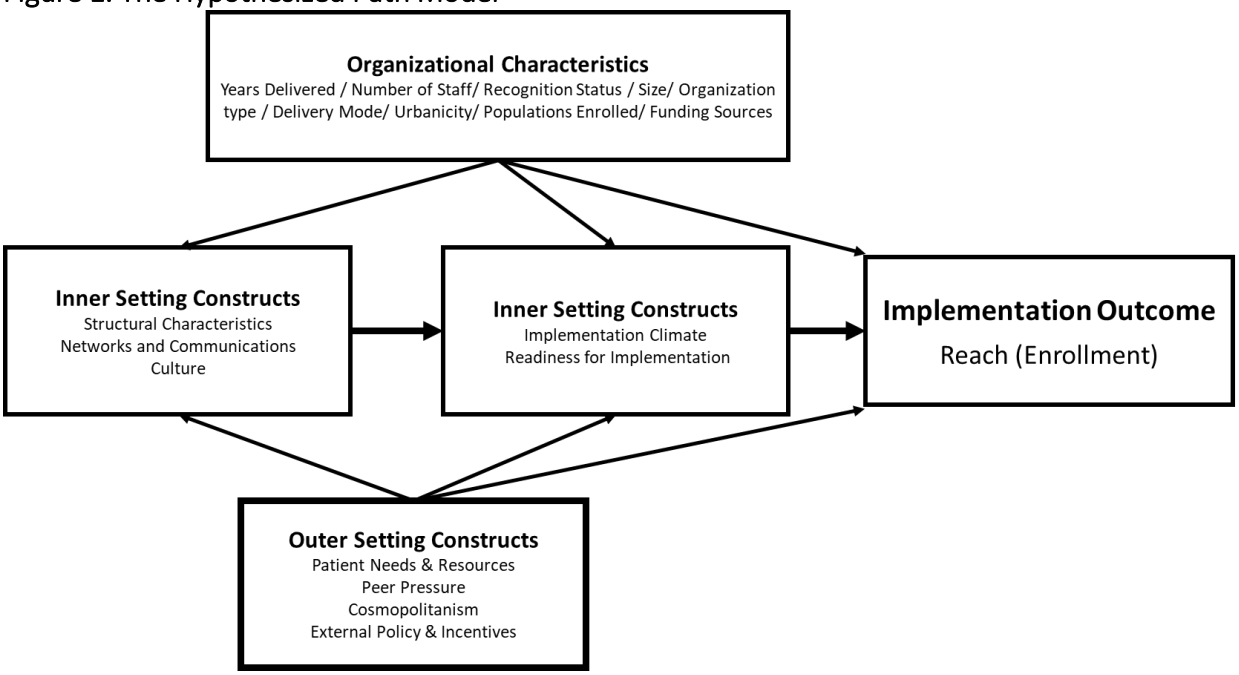
This rationale has led us to our three main hypotheses:

H1. *Inner Setting* constructs (*Structural Characteristics*; *Networks and Communication*; *Culture*) have an indirect relationship with the implementation outcome of reach mediated through *implementation climate* and *readiness for implementation*.

H2. *Outer Setting* constructs (*Patient Needs and Resources; Cosmopolitanism; Peer Pressure; External Policy and Incentives)* may have direct and/or indirect relationships with the implementation outcome of *reach* as well as the *Inner Setting* constructs along the focal pathway.

H3. Organizational characteristics (organization type, number of years implementing the program, region, urban/rural location, size, and recognition status) may have direct and/or indirect relationships with the implementation outcome of *reach* as well as the inner setting constructs along the focal pathway.

Figure 1. The Hypothesized Path Model



Methods

This study was a part of a sequential, mixed-methods evaluation and involved a cross-sectional online survey (Qualtrics) conducted in August-September 2021 with National DPP staff. The National DPP, a year-long lifestyle change program delivered by National DPP organizations which includes 16 hour-long sessions delivered over 6 months, followed by six additional sessions delivered over the subsequent 6 months (Centers for Disease Control and Prevention, 2022a). The National DPP curriculum targets a number of health behavior constructs (self-efficacy, attitudes, knowledge, beliefs, social support, etc.) to change behavior and achieved the health outcome goals for participants (5%–7% weight loss over 12 months and increased physical activity levels per week). National DPP staff members had one or more of the following roles: Lifestyle Coach, Master Trainer, and Program Coordinator. Lifestyle coaches deliver the program to participants. Master Trainers are lifestyle coaches that train lifestyle coaches within the same delivery organization. Program Coordinators supervise daily operations of the program, provide guidance and support to lifestyle coaches, and monitor and submit all program data to the CDC.

National DPP staff were reached through Emory's Diabetes Training and Technical Assistance Center (DTTAC), a CDC-recognized National DPP lifestyle coach and master trainer training program. This paper focuses on the analysis of the CFIR items, participant enrollment numbers (outcome of interest), and organization characteristics data. This study was reviewed and approved by Emory University's Institutional Review Board (STUDYID00002611).

Sampling & Data Collection. Study participants were recruited from DTTAC's National DPP implementer population. Over the last 10 years, DTTAC has directly trained over 5,000 lifestyle coaches representing over 2000 organizations across all 50 states. Using the most up to date list of DTTAC National DPP contacts, the online survey was distributed to 6,470 email addresses in August 2021 to National DPP implementers who have participated in Emory's DTTAC Lifestyle Coach training; Master Trainer Select training; and/or subscribed to the center's resources. All active National DPP program implementers who are either a lifestyle coach, master trainer, and/or program coordinator were eligible for the survey. Funding allowed for the first 336 respondents to receive a $15 Amazon gift card for their participation. The survey was active for 5 weeks. Weekly email reminders were sent to encourage participation. A total of 681 eligible responses were collected, and after data cleaning for completion 587 responses were included in the analysis.

Instrument Development & Measures. The survey instrument included 101 items: 23 items requesting information about the respondent (their role, demographic info, etc.), their organization characteristics (type, location, length of delivery, etc.), and enrollment level to date; 38 Likert scale items related to the CFIR inner and outer setting constructs; and 40 items of the Program Sustainability Assessment Tool (see Table 1 and supplemental files for full survey instrument). Since there are no standard measures for all CFIR inner and outer setting constructs, items from existing scales and recent studies were examined for relevance and psychometric properties (Escoffery et al., 2018; Fernandez et al., 2018; Helfrich, Li, Sharp, & Sales, 2009). The selection of existing items and development of new items for the survey was heavily

based on the preceding qualitative study examining these inner and outer setting constructs with 30 National DPP organization implementers (Madrigal et al., 2022 Under Review). The preliminary analysis of that qualitative study provided insight into which CFIR constructs and subconstructs were most relevant for this population and program. For example, the subconstructs, *Leadership Engagement* and *Available Resources*, within *Readiness for Implementation* were discussed heavily in the interviews and therefore multiple items were used for each of those constructs. On the other hand, A*ccess to Knowledge and Information* and *Peer Pressure* items were not as emphasized and were removed to reduce the length of the survey.

To reduce the survey length further, the CFIR *Inner Setting* construct *Structural Characteristics* was operationalized using the organization characteristics items instead of Likert scale questions. This use of objective organization variables to measure *Structural Characteristics* has also been used in other CFIR studies (Ditty, Landes, Doyle, & Beidas, 2015; Wilcox et al., 2020). All survey items were discussed and reviewed with the study team and pilot tested by subject matter experts at Emory's DTTAC, who suggested wording changes and possible areas to reduce survey length.

The final survey included 38 CFIR items, 24 were adapted from existing scales and studies that have measured these specific CFIR constructs and subconstructs (Helfrich, Li, Sharp, & Sales, 2009; Fernandez et al., 2018; Escoffery et al. 2018). Adaptation of items primarily focused on tailoring language for the National DPP context, such as inserting the program name and terminology relevant to their implementation. Fourteen items were created based on insight from the qualitative study and subject matter expert input (Table 1).

Table 1. Adapted and Created CFIR Items

CFIR Constructs	**Construct Definition**	**Adapted/Created**
Inner Setting		
Networks & Communications	The nature and quality of webs of social networks and the nature and quality of	4 items adapted from the Organizational readiness for

	formal and informal communications within an organization.	change (Helfrich, Li, Sharp, & Sales, 2009) 1 item created
Culture	Norms, values, and basic assumptions of a given organization.	3 items adapted from Inner Setting Measures for Culture (Fernandez et al., 2018) 1 item created
Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.	4 items adapted from Inner Setting Measures for Implementation Climate (Fernandez et al., 2018) 2 items created
Readiness for Implementation - Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.	5 items Adapted from Inner Setting Measures for Leadership Engagement (Fernandez et al., 2018)
Readiness for Implementation - Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.	4 items Adapted from Inner Setting Measures for Available Resources (Fernandez et al., 2018) 2 created
Outer Setting		
Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.	3 items adapted from Escoffery et al. 2018 2 items created
Cosmopolitanism	The degree to which an organization is networked with other external organizations.	4 created
External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.	1 item adapted from Escoffery et al. 2018 2 items created

Data Analyses. Data was exported from Qualtrics and analyzed using SAS Software Version 9.4. and Mplus Version 8.3. Data were cleaned (screened, diagnosed, and edited for suspected data abnormalities) and missing data reviewed in accordance with standard data cleaning procedures (Van den Broeck, Cunningham, Eeckels, & Herbst, 2005). Descriptive statistics were first performed and all variables of interest were examined for normality and outliers. Upon review of variables, the outcome of interested enrollment was recalculated to remove four outliers above the 99th percentile. These outliers were large

online delivery companies very different from the majority of the National DPP organizations in the sample. These outliers were removed to help normalize the data, in addition, this variable was scaled (divided by 100) to assist with comparison across other variables.

For all CFIR Likert scale items, scales were computed and Cronbach's alpha was used to assess the internal consistency of the scale for each of the CFIR constructs. Correlation matrices and Pearson coefficient were reviewed to understand the degree of overlap between related item constructs. Items within each CFIR construct were averaged to create construct variables: 4 inner setting and 3 outer setting variables. Bi-variates and linear regression models were assessed to examine all CFIR and organization characteristic predictor variables related to the outcome variable (enrollment).

We tested our three hypotheses using structural equation modeling in Mplus. For the *Structural Characteristics,* 25 organizational characteristics variables were included in the model for the following: years of delivery, staffing, DPRP recognition status, organization size, organization type, delivery mode, urbanicity, populations enrolled, and funding sources. To run the structural equation model, all variables were transformed into dichotomous (Yes/No) variables for each category. For example, each organization type, DPRP status level, organization size category was a separate variable. In addition, delivery mode variables were combined into like categories and reduced to "in-person" and "virtual" delivery variables. Populations enrolled also were combined and reduced to compare only organizations with only white participants enrolled and those with only non-white participants enrolled. Other participant categories were not used for this analysis. A total of 25 organization characteristic and 7 CFIR variables were included in the final model (Supplemental Table C2). Enrollment was the outcome of interest. Statistical significance for all tests was determined at the alpha = .05 level. Model fit was evaluated using standard goodness of fit indices criteria (Mueller & Hancock, 2019).

Results

Descriptive Statistics. Of the 586 survey respondents, the majority belonged to National DPP delivery organizations with full recognition in the DPRP (51.9%), while 21.5% of organizations were in the pending or preliminary phases of the program, 8.9% reported their organization not being involved in the program, and 17.7% either did not know their organization's status or did not respond to the question (Table 2). The average length of program delivery was 4.5 years (SD=3.1). Our outcome of interest, enrollment to date, was reported by 357 respondents (61%). The average enrollment was 1,758 participants (SD=26,524; range 0 to 500,000), with the 4 enrollment outliers removed, the average enrollment decreased to 183 participants (SD=359; range 0 to 35,000).

The average number of lifestyle coaches at respondent organizations was 7.1 (SD=12.6), with an average of 1.9 (SD=7.8) National DPP staff in other roles (non-lifestyle coaches), and an average of 1.9 (SD=8.4) National DPP staff dedicated 100% to the program. The most common types of respondent organizations were healthcare/hospitals (30.7%); community-based healthcare (community health centers, federally qualified health centers, Indian Health Service, etc., 22.0%); health insurers; employers, and other (e.g. private businesses; 15.5%); and government agencies (13.7%). About half of the respondents reported their organization was offering the program in an in-person small group format (47.6%); however, as this survey was conducted during the COVID-19 pandemic, the vast majority (75%) also were or exclusively offering programs in some type of virtual mode (distance 55.1%, Online 16.7%, and hybrid 24.2%). There was fairly equal representation of respondents implementing the program in rural (39.8%), suburban (32.4%), and urban (40.4%) locations. Of those who reported their organization size, small (0-1,000 people served annually) and medium (1,000-50,000 people) organizations were equally represented at 27.8% and 10.2% were from larger organizations (50,000+ people).

Respondent organizations enrolled mostly white (61.6%), black (43.9%), and Hispanic/Latino (30.2%) populations, which reflects the most commonly enrolled populations for this program nation-wide. There

were 131 respondents (22.4%) from organizations where only white participants happened to be enrolled and 160 (27.3%) from organizations with only non-white participants enrolled. Respondent organizations were primarily funded/supported by grant funding (33.3%), state or local government funding (19.5%), and/or federal government/CDC funding (19.1%).

When asked "How would you describe your current DPP enrollment level?", 56.1% reported that they are actively working to increase enrollment numbers, 15% said they were comfortable with the current level of enrollment, and 10.6% said they would like to increase their enrollment, however they were limited by capacity at the moment. Respondents also were asked, "To what extent do you agree or disagree that COVID-19 prohibited you from enrolling the desired number of participants into your program at this time?" About half of respondents (49.3%) said they agreed or strongly agreed with this statement, 15.5% neither agreed nor disagreed, 18.6% either disagreed or strongly disagreed, and 16.6% did not respond.

Respondents often had multiple National DPP roles, 91.8% said they were lifestyle coaches, 37% were program coordinators, and 9.6% master trainers. Respondents were mostly women (67.4%), white (45.7%), and fairly equally represented across age groups. Demographic questions were asked at the end and 26% of missing responses were due to not finishing the survey.

Table 2. Organization/respondent characteristics (N=586)

	Total Survey Respondents	
Respondent & Organization Characteristics	**n**	**%**
DPRP Status		
Full Recognition	304	51.9%
Pending/Preliminary	126	21.5%
None	52	8.9%
I do not know/Missing	104	17.7%
	n (%)	**Mean (SD)**
Years Delivered	500 (85.3%)	4.51 (3.06)
Enrollment to Date	357 (60.9%)	1758 (26524.44)
Enrollment Scaled (divided by 100 + outliers removed)	353 (60.2%)	1.83 (3.59)
Lifestyle Coaches at Organization	512 (87.4%)	7.1 (12.58)
Non-Lifestyle Coach DPP Staff	500 (85.3%)	1.94 (7.78)
Number of staff dedicated to National DPP 100%	478 (81.6%)	1.94 (8.39)
Organization Type		
Healthcare/Hospitals	180	30.7%
Community-based healthcare	129	22.0%

Community-based organizations	55	9.4%
Government agencies	80	13.7%
Academic	43	7.3%
Health insurers, Employers, Other	91	15.5%
Missing	8	1.4%
Organization Size (Number of people served annually across all programs and services)		
Small (0-1,000 people)	163	27.8%
Medium (1,000-50,000 people)	163	27.8%
Large (Over 50,000 people)	60	10.2%
I don't know/Missing	200	34.1%
Delivery Mode		
In-person small group (meetings with up to 20 participants)	279	47.6%
In-person large group (meetings with 21 or more participants)	19	3.2%
In-person (small or large group)	279	47.6%
Distance (interacting live with all participants as a group using video and/or audio)	323	55.1%
Online (Using a platform for participants to engage with the content on their own - not a live group meeting)	98	16.7%
Hybrid (combination of modes)	142	24.2%
Virtual (distance, online, hybrid)	447	76.3%
Other	40	6.8%
Location/Urbanicity		
Rural Location	233	39.8%
Suburban Location	190	32.4%
Urban Location	237	40.4%
Populations Enrolled		
White/Caucasian	361	61.6%
Black/African American	257	43.9%
Hispanic/Latino	177	30.2%
American Indian/Alaskan Native	67	11.4%
Asian	56	9.6%
Hawaiian Native/Pacific Islander	14	2.4%
Other	26	4.4%
Missing	65	11.1%
Based on responses above:		
Programs with Only White Participants Enrolled	131	22.4%
Programs with Only Non-White Participants Enrolled	160	27.3%
National DPP Funded/Supported By:		
Federal Government/ CDC Funding	112	19.1%
Medicare and/or Medicaid	68	11.6%
State or Local Government Funding	114	19.5%
State employee coverage benefits	24	4.1%
Grant funding	195	33.3%
Missing	212	36.2%
How would you describe your current DPP enrollment level?		
We need to decrease our enrollment numbers (over capacity)	4	0.7%
We are comfortable at this level of enrollment	88	15.0%
We are actively working to increase our enrollment numbers	329	56.1%
We would like to increase our enrollment, but this is all we have capacity for at the moment	62	10.6%
Missing	103	17.6%
To what extent do you agree or disagree that COVID-19 prohibited you from enrolling the desired number of participants into your program at this time?		
Strongly Disagree	46	7.8%

Disagree	63	10.8%
Neither Agree nor Disagree	91	15.5%
Agree	143	24.4%
Strongly Agree	146	24.9%
Missing	97	16.6%
	n (%)	**Mean (SD)**
Average Score	489 (83.4%)	3.57 (1.29)
Respondent Role (may have more than 1)	**n**	**%**
Lifestyle Coach	538	91.8%
Program Coordinator	222	37.9%
Master Trainer	56	9.6%
Respondent Gender		
Woman	395	67.4%
Man	36	6.1%
Other	2	0.3%
Missing	153	26.1%
Respondent Race/Ethnicity		
White/Caucasian	268	45.7%
Black/African American	76	13.0%
Hispanic/Latino	53	9.0%
American Indian/Alaskan Native	22	3.8%
Asian	16	2.7%
Other	4	0.7%
Hawaiian Native/Pacific Islander	2	0.3%
Missing	157	26.8%
Respondent Age Range		
Under 25 years	13	2.2%
25 – 34 years	89	15.2%
35 – 44 years	101	17.2%
45 – 54 years	94	16.0%
55 – 64 years	99	16.9%
65 years or older	36	6.1%
Missing	154	26.3%

CFIR Items. Each of the 38 CFIR items had between a 60-79% (351-463 responses) response rate (Table 3). Items were rated on a 1-5 bi-polar scale. Higher ratings indicate agreement with positive statements related to the implementation construct and there was a 3.82 average rating across all items. The items with the highest and lowest average ratings were both in the Implementation Climate construct. The highest single item rating, “There is a strong need for this program at our organization” (4.34, SD=0.8), and the lowest being, “Organization National DPP staff receive acknowledgement (i.e. bonus, awards, public acknowledgement, etc.) for implementing the National DPP successfully” (2.94, SD=1.2).

The inner setting construct “culture” had the highest average rating of 4.08, followed by “leadership engagement” and “available resources” (both with average rating of 3.91; Table 4). The outer setting

"cosmopolitanism" and "external policies and incentives" constructs had the lowest average ratings (3.63, 3.64). Cronbach's alpha ranged from 0.69 (external policies and incentives) to 0.93 (leadership engagement).

Table 3. CFIR Inner and Outer Setting Likert-Scale Items and Mean Scores

CFIR Item	Question (Response scale Strongly Disagree 1 to Strongly Agree 5)	N	Mean	Std
Networks and Communication	We have regular project meetings with our organization's National DPP team members/staff	429	3.76	1.2
Networks and Communication	There is regular involvement of staff in National DPP planning and implementation	435	3.78	1.1
Networks and Communication	We provide regular feedback to organization management on progress of program activities and resource needs	434	3.95	1.0
Networks and Communication	We provide regular feedback to organization staff on effects of the National DPP on participant outcomes	428	3.92	1.0
Networks and Communication	We consistently use an internal referral processes (referrals within your organization to the program) for the National DPP	417	3.86	1.1
Culture	People at all levels openly talk about what is and isn't working	448	3.95	1.0
Culture	We regularly take time to reflect on how we do things	452	4.01	0.9
Culture	People in this organization operate as a real team	451	4.03	1.0
Culture	The National DPP aligns well with the mission and/or vision at our organization	463	4.33	0.8
Implementation Climate	Our organization has established National DPP goals that the program staff are expected to help meet (i.e. increase DPP enrollment rates)	421	3.78	1.0
Implementation Climate	Organization National DPP staff have the support they need to implement the National DPP	442	3.83	1.0
Implementation Climate	Organization National DPP staff receive acknowledgement (i.e. bonus, awards, public acknowledgement, etc.) for implementing the National DPP successfully	406	2.94	1.2
Implementation Climate	The National DPP is a top priority of the organization	440	3.30	1.1
Implementation Climate	The National DPP fits well with our organization's existing workflow and systems	442	3.85	0.9
Implementation Climate	There is a strong need for this program at our organization	459	4.34	0.8
Leadership Engagement	Organization leadership makes sure that staff have the time necessary to implement the National DPP	445	3.86	1.0
Leadership Engagement	Organization leadership makes sure that staff have the space (physical for in-person classes and/or a virtual/online platform) necessary to implement the National DPP	448	3.95	0.9
Leadership Engagement	Leadership in this organization create an environment where things can be accomplished for the National DPP	450	3.90	0.9
Leadership Engagement	Organization leadership promotes an environment that is an enjoyable place to work on the National DPP	446	3.95	0.9
Leadership Engagement	Leadership strongly supports the National DPP implementation efforts	450	3.92	1.0
Available Resources	Financial resources to support the implementation of the National DPP	426	3.64	1.1
Available Resources	Number of staff (lifestyle coaches and others) to support the implementation of the National DPP	445	3.71	1.1
Available Resources	Basic staff training to facilitate the implementation of the National DPP	456	4.02	0.9
Available Resources	Equipment/materials to facilitate the implementation of the National DPP	456	4.06	0.9

Available Resources	Facilities/space to host the National DPP in-person	432	3.94	0.9
Available Resources	Virtual/Distance/Online platform to host the National DPP via distance or online delivery	446	4.03	1.0
Patient Needs and Resources	Our organization does a good job of assessing participant needs and barriers to enrolling in the National DPP	440	3.86	0.9
Patient Needs and Resources	Our organization uses data from participants to improve program delivery	423	3.95	0.9
Patient Needs and Resources	Our organization uses data from participants to improve recruitment and enrollment strategies	425	3.87	0.9
Patient Needs and Resources	Our organization has taken steps to reduce barriers to enrollment for participants	433	3.92	0.9
Patient Needs and Resources	There is high demand for the National DPP lifestyle change program in the geographic region our organization serves	432	3.69	1.1
Cosmopolitanism	Our organization/staff engages in inter-organizational networking or partnerships (coalitions, meetings, conferences, group trainings, etc.) related to diabetes, prediabetes, and/or the National DPP	421	3.91	0.9
Cosmopolitanism	Our external/community partners promote our National DPP lifestyle change program	406	3.70	1.0
Cosmopolitanism	Our program has an effective participant referral processes with external organizations (healthcare providers, community partners, other National DPP organizations, etc.) in place	416	3.40	1.1
Cosmopolitanism	Our organization works collaboratively with other organizations who deliver the National DPP (i.e. inter-organization referrals, marketing, resource sharing, etc.)	404	3.50	1.1
External Policies and Incentives	Our organization receives acknowledgement for using an evidence-based program	390	3.73	1.0
External Policies and Incentives	External funding for diabetes prevention supports our organization's implementation of the National DPP	351	3.56	1.2
External Policies and Incentives	The CDC DPRP reporting requirements are helpful for our organization's implementation of the National DPP	402	3.56	1.1

Table 4. CFIR Likert-Scale Construct Scores & Cronbach's Alpha

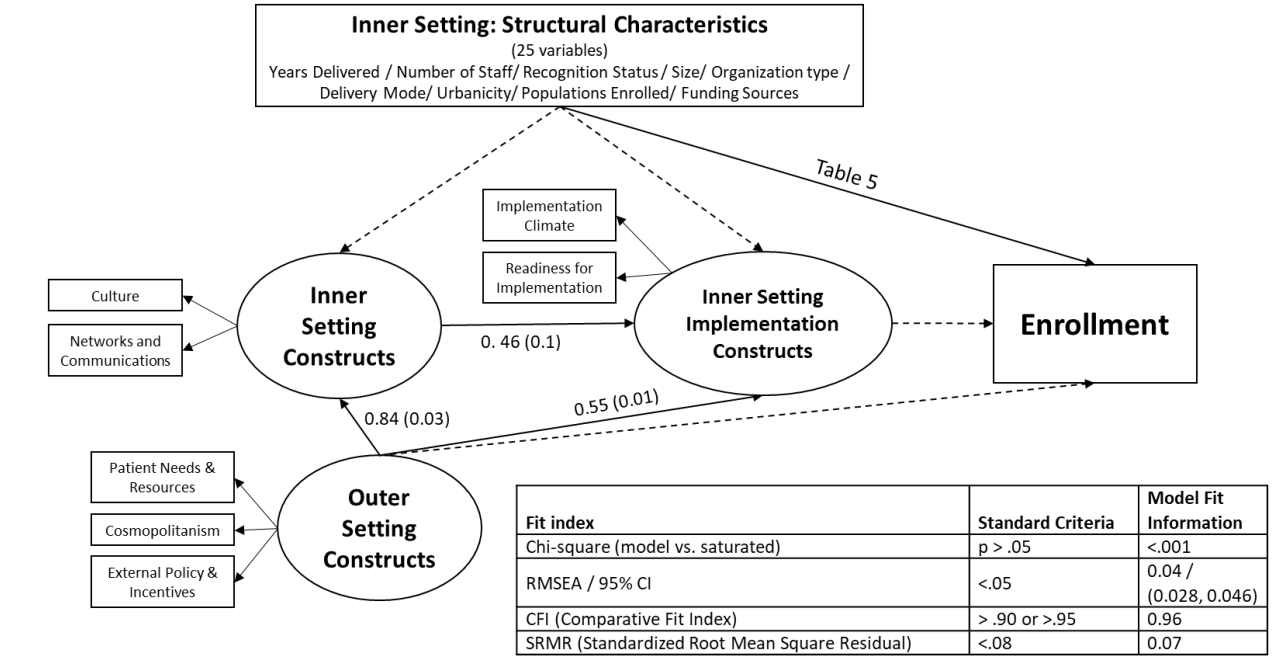
CFIR Construct Aggregated Mean Scores	N	Mean	Std	Number of Items	Cronbach's Alpha
Inner Setting					
Networks and Communication	451	3.85	0.9	5	0.89
Culture	469	4.08	0.8	4	0.86
Implementation Climate	467	3.69	0.8	6	0.84
Leadership Engagement	459	3.91	0.8	5	0.93
Available Resources	463	3.91	0.7	6	0.86
Outer Setting					
Patient Needs and Resources	457	3.87	0.8	5	0.87
Cosmopolitanism	444	3.63	0.8	4	0.81
External Policies and Incentives	433	3.64	0.9	3	0.69

Structural Model. The initial hypothesized model (Figure 1) did not explain the data well (had poor model fit). Due to the high correlation between items, latent variables were created to capture the two-stages of inner setting constructs and the outer setting constructs in our model (Supplemental Table A1). Latent variables explain the variance in its measured indicator variables and induces covariance among them (Mueller & Hancock, 2019). This change in model structure allowed us to remain consistent to our theoretical understanding of the relationships in our operationalized path model. The final model fit the data well (Figure 2).

In the final model, there was a significant direct path from *Inner Setting Constructs* to the *Inner Setting Implementation Construct*, as well as significant direct paths from the *Outer Setting Constructs* to both *Inner Setting* latent variables. None of the latent *Inner* and *Outer Setting* variables were directly or indirectly associated with enrollment. Instead seven of the *Structural Characteristics* variables (length of delivery, number of lifestyle coaches, number of full-time staff, large organization size, and organizations delivering in rural, suburban, and/or urban settings) had significant positive direct relationships with enrollment (Table 5). For example, these parameters can be interpreted as, for every additional lifestyle coach at an organization enrollment increases by 47 participants. While two of the *Structural Characteristics* variables, academic type organizations and organizations with only non-White participants

enrolled in their National DPP lifestyle change programs had significant negative direct relationships with enrollment. Results for all variables included in supplemental Table C.

Figure 2. Final Structural Equation Model (n=445)



Fit index	Standard Criteria	Model Fit Information
Chi-square (model vs. saturated)	p > .05	<.001
RMSEA / 95% CI	<.05	0.04 / (0.028, 0.046)
CFI (Comparative Fit Index)	> .90 or >.95	0.96
SRMR (Standardized Root Mean Square Residual)	<.08	0.07

Dashed lines indicate non-significant relationships at p<.05

Table 5. Standardized Significant Coefficients (n=445)

Outcome	Structural Characteristics Variable	Coefficient (SE)	P-value
Enrollment (scaled /100)	Years Delivered	0.28 (0.05)	<.001
	Number of Lifestyle Coaches at Organization	0.47 (0.06)	<.001
	Number of Staff Dedicated to National DPP 100%	0.34 (0.12)	0.004
	Organization Size: Large (Over 50,000)	0.14 (0.05)	0.005
	Organization Type: Academic	-0.13 (0.04)	0.001
	Location: Rural	0.21 (0.06)	<.001
	Location: Suburban	0.16 (0.06)	0.009
	Location: Urban	0.16 (0.07)	0.015
	Programs with Only Non-White Participants Enrolled	-0.10 (0.05)	0.030
R-Squared on Enrollment = 0.64			

Discussion

This study aimed to identify CFIR *Inner* and *Outer Setting* measures to explore relationships between internal and external organization factors, organizational characteristics, and participant enrollment. Of our three hypotheses, only the last one (H3), was found to be partially supported; the *Inner Setting Structural Characteristics*, operationalized by organizational characteristics, such as length of delivery, staff size, and participant populations, had significant direct relationships with participant reach.

Our CFIR Likert-scale items had good internal consistency and provide insight into implementation areas of strength and weakness. For example, two *Implementation Climate* items had the lowest average ratings, the first identifies a lack of staff acknowledgements (bonuses, awards, public recognition, etc.) for implementing the program. This aligns with our previous qualitative research in which this *Implementation Climate* sub-construct, *Organizational Incentives and Rewards*, also was absent from the implementation discussion with National DPP staff across all levels of implementation reach (Madrigal et al, 2022 [Under Review]). The second lowest rated CFIR item indicated that the respondents on average are neutral (did not agree or disagree) about if the National DPP is a top priority at their organization. The highest rated items revealed that respondents believed there was a strong need for the program (*Implementation Climate-Relative Priority)* and that the program was aligned well with the organization values and mission (*Culture)*. This reveals that there may be a disconnect between the National DPP staff who completed this survey and their organization leadership, and that perhaps more buy-in from leadership to make this program a higher priority and providing incentives to support staff in their work may be areas for growth.

The length of delivery, number of lifestyle coaches, number of full-time staff, large organization size, and organizations delivering in rural, suburban, and/or urban settings all had positive significant direct relationships with enrollment. Many of these variables (e.g. staff size and organization size) reflect organization capacity which is a critical piece of effective program delivery (Brownson, Fielding, & Green, 2018). Longer length of delivery for example indicates an organization has had the capacity to deliver the program over time and therefore more opportunities to reach more participants. Other variables point to the importance of setting, all locations rural, suburban, and urban were positively related to enrollment. Rural settings had a slightly higher effect size (0.21 vs 0.16 in suburban and urban settings). Which is interesting given the other literature which has found recruitment to be a challenge in rural areas (Ariel-

Donges et al., 2019; AuYoung, Moin, Richardson, & Damschroder, 2019). This may be due to the relatively high representation of respondents delivering the program in rural communities in our sample.

On the other end of our results, academic organizations and organizations with only non-White participants enrolled in their National DPP lifestyle change programs had negative direct relationships with enrollment. Based on other National DPP studies, we know that white participants are more likely to be enrolled in the program, indicating that non-white populations may be harder to reach and recruit (Ely et al., 2017). It is unclear why academic organizations in particular are negatively associated with enrollment. It may be that these institutions run only a few cohorts for their academic community and do not do outreach within the broader community. More examination of organization types and their ability to reach participants should be explored in future work. However, the lack of findings among organization types do support the CDC's National DPP vision that this program can be implemented in various settings (Albright, 2012).

This survey data also supports that reach is an important programmatic goal for National DPP implementers. The majority reported they are actively working to increase enrollment numbers and about the same proportion of respondents also reported that the COVID-19 pandemic has impacted their enrollment negatively. Research on the challenges and adaptations of program delivery during COVID-19 have started to appear in the published literature and reflect similar findings around reach (Spence, Sisson, & Dixon, 2022). Typically, reach literature has focused on participant characteristics and recruitment method predictors to enrollment/participation, not organizational level characteristics (R. E. Glasgow et al., 2019). In 2019, the CDC published findings from an evaluation examining implementation across 164 of National DPP organizations using the RE-AIM framework (Nhim et al., 2019). They identified recruitment strategies associated with higher overall attendance and longer participation duration included using self-referral or word of mouth, providing non-monetary incentives for participation, and using cultural adaptations to address participants' needs. However, they did not report any findings on

any other context-related predictors of enrollment at delivery sites. Disruptive external events like the COVID-19 pandemic, support our research questions focused on understanding how internal and external organizational factors also impact reach and what can be done to support delivery organizations to overcome them and also prepare for future events.

Findings from this study are similar to other evaluation findings and research of the National DPP. For example, regarding staffing, the initiative has promoted building up the DPP workforce in many ways (e.g. standardized training, resource centers, state and federal technical assistance) and been largely successful in scaling the number of delivery sites across the country (Ackermann & O'Brien, 2020). However, evaluations of the program at specific sites often indicate more outreach, involvement, and communication with participants and their referring healthcare providers by National DPP staff would helpful to increase recruitment and retention in the program (Baucom et al., 2021; Nhim et al., 2019). Data from our sample of implementing staff showed that on average organizations have less than 2 staff who are dedicated to working on the National DPP full time. This may not be sufficient for a program as resource intensive as the National DPP. More research should be conducted in this area to understand staff capacity needs that go beyond adequate training, but ask questions about time and resources needed to meet enrollment and other programmatic goals.

Lastly, as described by our findings and other studies, outreach to rural and non-white participants should be considered priority areas for enrollment growth (Ariel-Donges et al., 2019; AuYoung et al., 2019; Batsis et al., 2020; Gruss et al., 2019; Ritchie et al., 2020). In an 2019 published analysis of the National DPP, although diabetes prevention interventions are a high need in rural areas there were significantly fewer rural counties with access to a National DPP site compared with urban counties (14.6% vs. 48.4%, respectively, $p < .001$) (Ariel-Donges et al., 2019). The authors recommended identifying alternative dissemination strategies that address the unique barriers to implementation faced by rural communities to increase program access. Emory's DTTAC has focused heavily on providing National DPP support to

rural areas, which may be why representation among respondents providing the program in rural locations was high (40%) and rural delivery was positively related to enrollment. Adaptations of the DPP in rural communities have been evaluated and encourage use of telehealth/virtual technology to provide the program, as well as partnerships with local, accessible resources (e.g. recreational space at local institutions) to support behavior changes (AuYoung et al., 2019). There have also been a number of adaptations and strategies to address the disparities in reach regarding racial and ethnic minorities and men as well (Ritchie et al., 2020).

Strengths & Limitations. Strengths of this study include the use of adapted and newly developed quantitative CFIR measures, collection of a large number of organizational characteristic variables associated with program reach, and the use of structural equation modeling to understand relationships between these factors and participant enrollment (reach). Our recruitment was limited by Emory's DTTAC contact list and there may be differences between this group and the larger National DPP population of implementers, for example the large representation from organizations delivering in rural communities. However, we still were able to capture data from a relatively large and diverse sample of respondents.

Another limitation was that we had to rely on respondent summitted enrollment data and were not able to verify this with program records. In addition, around 40% of respondents did not know the number of participants they had enrolled to date, which also indicates a lack of awareness of staff on this important metric of program implementation. We were also unable to accurately assess if multiple people from same organization completed the survey due inconsistencies in how organization names were provided by respondents and could not account for this clustering in our analyses. Further research should examine how perspectives on program implementation and CFIR item ratings vary between staff within the same organization.

Our analysis only showed the *Inner Setting Structural Characteristics* to have a direct relationships with enrollment. One reason for this may be due to the fact that many of the variables included in *Structural Characteristics* could also be considered part of other CFIR constructs. For example, the sources of funding/support variables overlap with aspects of the *External Policies and Incentives* construct. This highlights one of the challenges of measuring CFIR constructs quantitatively as their definitions are so multifaceted (Ilott, Gerrish, Booth, & Field, 2012; Kirk et al., 2015). In addition, to reduce participant burden we shortened the length of the survey removing additional CFIR items which may have increased comprehensiveness of these constructs. While our study focuses only on the *Inner* and *Outer Setting* this may have still been too much and future studies may want to focus on specific constructs.

Furthermore CFIR 2.0 is forthcoming and may provide new aspects and/or segmentation of constructs to help address these issues (Laura J. Damschroder et al., 2022). For example, currently the *Outer Setting* does not describe differences in participant populations, but we know from our findings that location setting (rural, suburban, urban) and race/ethnicity are also important factors that are part of the external context in which an intervention is implemented. As CFIR measures are still in development and testing in the field, it will require many more research applications like this to understand the most effective way to capture each of these domains, constructs, and sub-constructs.

Related to our analysis, latent variables usually recommend at least three items per latent construct, however we only had two variable indicators for the first inner setting latent variable and the outer setting latent variable (Mueller & Hancock, 2019). We did find good internal consistency for all of our CFIR constructs and this is also strengthened by our mixed methods study design building off of a previous qualitative study to inform items selection, adaptation, and creation in this quantitative study. We also found good model fit with our latent variables with the divided the *Inner Setting* constructs and found significant paths between all three latent CFIR variables. This is also a new exploration from other applications of CFIR and future research may want to continue to examine relationships among constructs

in addition to CFIR constructs on implementation outcomes. To our knowledge, this is one of the first applications of quantitative CFIR items using structural equation modeling, which we believe helps expand the possibilities of CFIR and implementation science measures and methods.

Conclusions

This study provides valuable insight into the internal and external organizational factors related to National DPP implementation and enrollment. Participant reach (enrollment) is an important implementation outcome for the National DPP and vital to making population-level decreases in diabetes incidence in the US. Our findings suggest that to facilitate enrollment, program implementers should focus on the *Structural Characteristics* such as adequate staffing, expanding the program in multiple locations (rural, suburban, and urban), and improving recruitment of non-white participants. While the CFIR latent variables were not significantly related directly or indirectly to enrollment, the item responses and construct scores provide useful information regarding the implementation strengths and are areas for implementation support. Implementing staff believe that the National DPP is a needed program and aligned with their organization's mission. Those working to scale the National DPP should ensure the program is a priority for organization leadership and all the necessary staff motivators and supports are in place. In addition, other health prevention programs can use the methods and findings from this study to further understand and inform the impact of organization factors on implementation outcomes.

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Supplemental Tables

Tables A1-2. Correlation Matrices

Table A1. CFIR Constructs Correlation Matrix

	Networks and Communication	Culture	Implementation Climate	Leadership Engagement	Available Resources	Patient Needs and Resources	Cosmopolitanism	External Policies and Incentives
Networks and Communication	1	0.68665	0.65683	0.63404	0.54104	0.60149	0.48122	0.4684
		<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
	451	449	446	442	443	437	427	421
Culture	0.68665	1	0.67439	0.71508	0.58656	0.61598	0.44942	0.44884
	<.0001		<.0001	<.0001	<.0001	<.0001	<.0001	<.0001
	449	469	465	457	461	453	443	433
Implementation Climate	0.65683	0.67439	1	0.7552	0.65642	0.66144	0.57902	0.5963
	<.0001	<.0001		<.0001	<.0001	<.0001	<.0001	<.0001
	446	465	467	457	461	454	443	432
Leadership Engagement	0.63404	0.71508	0.7552	1	0.71945	0.624	0.52601	0.53676

	<.0001	<.0001	<.0001		<.0001	<.0001	<.0001	<.0001
	442	457	457	459	457	450	438	430
Available Resources	0.54104	0.58656	0.65642	0.71945	1	0.59105	0.51806	0.54359
	<.0001	<.0001	<.0001	<.0001		<.0001	<.0001	<.0001
	443	461	461	457	463	454	442	432
Patient Needs and Resources	0.60149	0.61598	0.66144	0.624	0.59105	1	0.54124	0.56406
	<.0001	<.0001	<.0001	<.0001	<.0001		<.0001	<.0001
	437	453	454	450	454	457	441	430
Cosmopolitanism	0.48122	0.44942	0.57902	0.52601	0.51806	0.54124	1	0.53702
	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001		<.0001
	427	443	443	438	442	441	444	425
External Policies and Incentives	0.4684	0.44884	0.5963	0.53676	0.54359	0.56406	0.53702	1
	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	
	421	433	432	430	432	430	425	433

Table A2. Organization Variables Correlation Matrix

	DPRP Status	Years of Program Delivery	Number of Lifestyle Coaches	Number of Full Time National DPP Staff	Organization Size	Org Type: Healthcare/Hospitals	Org Type: Community-based healthcare	Org Type: Community-based organizations	Org Type: Government agencies	Org Type: Academic	Org Type: Health insurers, Employers, Other	Delivery Mode: In Person (small or large group)	Delivery Mode: Distance, Online, and/or Hybrid	Rural Location	Suburban Location	Urban Location	White Participants Only	Non-white Participants Only	Funding Source: Federal Government/ CDC Funding	Funding Source: Medicaid and/or Medicare	Funding Source: State or Local Government Funding and/or State	Funding Source: Grant funding
	1.00	0.30	0.11	0.13	0.10	0.13	-0.04	0.08	-0.09	0.00	-0.08	-0.02	0.26	-0.09	0.11	0.02	0.11	-0.16	0.04	0.14	0.04	-0.02
		<.0001	0.03	0.01	0.05	0.01	0.38	0.08	0.04	0.95	0.06	0.73	<.0001	0.06	0.01	0.64	0.02	0.00	0.38	0.00	0.42	0.64
DPRP Status	482	427	439	413	416	482	482	482	482	482	482	482	482	482	482	482	482	482	482	482	482	482
	0.30	1.00	0.17	0.11	0.09	-0.01	0.04	-0.05	0.00	0.04	-0.03	0.03	0.02	0.01	0.03	0.02	0.07	-0.03	0.06	0.09	0.12	0.11
	<.0001		0.00	0.02	0.06	0.91	0.40	0.31	0.93	0.36	0.57	0.44	0.74	0.81	0.52	0.60	0.12	0.45	0.15	0.05	0.01	0.02
Years of Program Delivery	427	500	489	457	466	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500
	0.11	0.17	1.00	0.23	0.14	0.00	-0.06	0.02	-0.06	0.06	0.07	-0.05	0.08	-0.11	0.09	0.15	-0.06	-0.03	0.08	0.05	0.12	0.01
	0.03	0.00		<.0001	0.00	0.95	0.18	0.72	0.21	0.18	0.13	0.30	0.07	0.01	0.04	0.00	0.20	0.51	0.07	0.24	0.01	0.80
Number of Lifestyle Coaches	439	489	512	473	478	512	512	512	512	512	512	512	512	512	512	512	512	512	512	512	512	512
	0.13	0.11	0.23	1.00	0.12	-0.04	-0.05	0.11	-0.08	-0.04	0.14	-0.13	0.08	-0.06	-0.03	0.05	-0.07	0.04	0.13	0.02	0.01	-0.02
	0.01	0.02	<.0001		0.01	0.34	0.24	0.02	0.09	0.33	0.00	0.00	0.08	0.22	0.58	0.29	0.11	0.37	0.00	0.67	0.83	0.68
Number of Full Time National DPP Staff	413	457	473	478	474	478	478	478	478	478	478	478	478	478	478	478	478	478	478	478	478	478
	0.10	0.09	0.14	0.12	1.00	0.04	-0.05	-0.07	0.07	0.07	-0.06	-0.02	-0.02	-0.01	0.06	0.07	-0.01	-0.08	-0.03	-0.05	0.00	-0.03
	0.05	0.06	0.00	0.01		0.33	0.29	0.13	0.14	0.10	0.20	0.59	0.60	0.76	0.20	0.11	0.77	0.10	0.57	0.26	0.95	0.58
Organization Size	416	466	478	474	490	490	490	490	490	490	490	490	490	490	490	490	490	490	490	490	490	490
	0.13	-0.01	0.00	-0.04	0.04	1.00	-0.35	-0.21	-0.26	-0.19	-0.29	0.03	0.02	-0.04	0.04	-0.04	0.17	-0.23	-0.11	0.11	-0.13	-0.09

Org Type: Healthcare/Hospitals	0.01	0.91	0.95	0.34	0.33		<.0001	<.0001	<.0001	<.0001	<.0001	0.44	0.57	0.31	0.38	0.38	<.0001	<.0001	0.01	0.01	0.00	0.04
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Org Type: Community-based healthcare	-0.04	0.04	-0.06	-0.05	-0.05	-0.35	1.00	-0.17	-0.21	-0.15	-0.23	0.05	-0.02	0.15	-0.16	-0.04	-0.14	0.32	0.13	-0.04	-0.03	0.11
	0.38	0.40	0.18	0.24	0.29	<.0001		<.0001	<.0001	0.00	<.0001	0.27	0.57	0.00	0.00	0.40	0.00	<.0001	0.00	0.36	0.44	0.01
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Org Type: Community-based organizations	-0.08	-0.05	0.02	0.11	-0.07	-0.21	-0.17	1.00	-0.13	-0.09	-0.14	0.02	0.01	-0.03	0.06	0.02	0.02	0.10	0.02	0.07	0.03	0.06
	0.08	0.31	0.72	0.02	0.13	<.0001	<.0001		0.00	0.03	0.00	0.61	0.73	0.41	0.12	0.61	0.56	0.01	0.59	0.11	0.50	0.16
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Org Type: Government agencies	-0.09	0.00	-0.06	-0.08	0.07	-0.26	-0.21	-0.13	1.00	-0.11	-0.17	-0.03	-0.04	0.04	0.05	-0.06	-0.02	-0.04	0.03	-0.10	0.26	-0.04
	0.04	0.93	0.21	0.09	0.14	<.0001	<.0001	0.00		0.01	<.0001	0.46	0.39	0.30	0.19	0.12	0.59	0.30	0.41	0.02	<.0001	0.36
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Org Type: Academic	0.00	0.04	0.06	-0.04	0.07	-0.19	-0.15	-0.09	-0.11	1.00	-0.12	0.07	0.08	-0.01	0.01	0.05	0.02	-0.17	-0.02	-0.02	0.06	0.02
	0.95	0.36	0.18	0.33	0.10	<.0001	0.00	0.03	0.01		0.00	0.08	0.05	0.72	0.72	0.24	0.60	<.0001	0.62	0.63	0.17	0.57
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Org Type: Health insurers, Employers, Other	-0.08	-0.03	0.07	0.14	-0.06	-0.29	-0.23	-0.14	-0.17	-0.12	1.00	-0.10	0.03	-0.09	0.05	0.13	-0.05	0.02	-0.03	-0.02	-0.09	-0.01
	0.06	0.57	0.13	0.00	0.20	<.0001	<.0001	0.00	<.0001	0.00		0.02	0.49	0.03	0.27	0.00	0.24	0.58	0.49	0.58	0.03	0.76
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Delivery Mode: In Person (small or large group)	-0.02	0.03	-0.05	-0.13	-0.02	0.03	0.05	0.02	-0.03	0.07	-0.10	1.00	-0.22	0.09	0.02	-0.08	0.11	-0.10	-0.01	0.05	0.02	0.04
	0.73	0.44	0.30	0.00	0.59	0.44	0.27	0.61	0.46	0.08	0.02		<.0001	0.03	0.65	0.07	0.01	0.01	0.78	0.23	0.68	0.28
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Delivery Mode: Distance, Online, and/or Hybrid	0.26	0.02	0.08	0.08	-0.02	0.02	-0.02	0.01	-0.04	0.08	0.03	-0.22	1.00	-0.10	0.08	0.12	-0.06	0.01	0.07	0.09	0.04	0.07
	<.0001	0.74	0.07	0.08	0.60	0.57	0.57	0.73	0.39	0.05	0.49	<.0001		0.02	0.06	0.00	0.17	0.84	0.11	0.03	0.31	0.09
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Rural Location	-0.09	0.01	-0.11	-0.06	-0.01	-0.04	0.15	-0.03	0.04	-0.01	-0.09	0.09	-0.10	1.00	-0.29	-0.43	0.18	0.00	0.09	-0.13	-0.03	0.03
	0.06	0.81	0.01	0.22	0.76	0.31	0.00	0.41	0.30	0.72	0.03	0.03	0.02		<.0001	<.0001	<.0001	0.94	0.02	0.00	0.43	0.54

	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
	-0.11	0.03	0.09	-0.03	0.06	0.04	-0.16	0.06	0.05	0.01	0.05	0.02	0.08	-0.29	1.00	-0.23	0.05	-0.14	0.01	0.08	0.07	0.01
Suburban Location	0.01	0.52	0.04	0.58	0.20	0.38	0.00	0.12	0.19	0.72	0.27	0.65	0.06	<.0001		<.0001	0.24	0.00	0.88	0.06	0.11	0.88
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
	0.02	0.02	0.15	0.05	0.07	-0.04	-0.04	0.02	-0.06	0.05	0.13	-0.08	0.12	-0.43	-0.23	1.00	-0.21	0.10	-0.05	0.10	0.03	0.00
Urban Location	0.64	0.60	0.00	0.29	0.11	0.38	0.40	0.61	0.12	0.24	0.00	0.07	0.00	<.0001	<.0001		<.0001	0.01	0.26	0.01	0.51	0.98
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
	0.11	0.07	-0.06	-0.07	-0.01	0.17	-0.14	0.02	-0.02	0.02	-0.05	0.11	-0.06	0.18	0.05	-0.21	1.00	-0.33	-0.09	0.02	0.03	-0.05
White Participants Only	0.02	0.12	0.20	0.11	0.77	<.0001	0.00	0.56	0.59	0.60	0.24	0.01	0.17	<.0001	0.24	<.0001		<.0001	0.02	0.58	0.42	0.24
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
	-0.16	-0.03	-0.03	0.04	-0.08	-0.23	0.32	0.10	-0.04	-0.17	0.02	-0.10	0.01	0.00	-0.14	0.10	-0.33	1.00	0.10	-0.08	-0.02	0.10
Non-white Participants Only	0.00	0.45	0.51	0.37	0.10	<.0001	<.0001	0.01	0.30	<.0001	0.58	0.01	0.84	0.94	0.00	0.01	<.0001		0.01	0.06	0.66	0.02
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Funding Source: Federal Government / CDC Funding	0.04	0.06	0.08	0.13	-0.03	-0.11	0.13	0.02	0.03	-0.02	-0.03	-0.01	0.07	0.09	0.01	-0.05	-0.09	0.10	1.00	0.03	0.03	-0.12
	0.38	0.15	0.07	0.00	0.57	0.01	0.00	0.59	0.41	0.62	0.49	0.78	0.11	0.02	0.88	0.26	0.02	0.01		0.51	0.52	0.00
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Funding Source: Medicaid and/or Medicare	0.14	0.09	0.05	0.02	-0.05	0.11	-0.04	0.07	-0.10	-0.02	-0.02	0.05	0.09	-0.13	0.08	0.10	0.02	-0.08	0.03	1.00	0.07	0.12
	0.00	0.05	0.24	0.67	0.26	0.01	0.36	0.11	0.02	0.63	0.58	0.23	0.03	0.00	0.06	0.01	0.58	0.06	0.51		0.11	0.00
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
Funding Source: State or Local Government Funding and/or State Employee Benefits	0.04	0.12	0.12	0.01	0.00	-0.13	-0.03	0.03	0.26	0.06	-0.09	0.02	0.04	-0.03	0.07	0.03	0.03	-0.02	0.03	0.07	1.00	-0.04
	0.42	0.01	0.01	0.83	0.95	0.00	0.44	0.50	<.0001	0.17	0.03	0.68	0.31	0.43	0.11	0.51	0.42	0.66	0.52	0.11		0.33
	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586
	-0.02	0.11	0.01	-0.02	-0.03	-0.09	0.11	0.06	-0.04	0.02	-0.01	0.04	0.07	0.03	0.01	0.00	-0.05	0.10	-0.12	0.12	-0.04	1.00
Funding Source:	0.64	0.02	0.80	0.68	0.58	0.04	0.01	0.16	0.36	0.57	0.76	0.28	0.09	0.54	0.88	0.98	0.24	0.02	0.00	0.00	0.33	

Grant funding	482	500	512	478	490	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586	586

Table B. Organization Characteristics & CFIR Item Bi-variates

Bivariates (Outcome = Enrollment)	**Parameter Estimate**	**P-value**
Continuous Variables		
Years Delivered	0.49	<.0001
Lifestyle Coaches at Organization	0.21	<.0001
Non Lifestyle Coach DPP Staff	0.03	0.4358
Number of staff dedicated to National DPP 100%	0.52	<.0001
Dichotomous Variables		
DPRP Status		
Full Recognition	2.12	<.0001
Pending or Preliminary Recognition	-1.34	<.0001
No Status/Not Recognized	-1.46	<.0001
Organization Size		
Small (0-1,000 people)	-1.05	.01
Medium (1,000-50,000)	0.45	0.254
Large (Over 50,000)	1.88	.001
Organization Type		
Healthcare/Hospitals	0.57	0.172
Community-based healthcare	0.08	0.847
Community-based organizations	0.48	0.458
Government agencies	-0.23	0.673
Academic	-0.88	0.266
Health insurers, Employers, Other	0.56	0.197
Delivery Mode		
In-person (large and small)	0.47	0.226
Virtual (distance, online, hybrid)	1.21	0.005
Location/Urbanicity		
Rural Location	0.41	0.284
Suburban Location	1.25	0.002
Urban Location	0.77	0.052
Populations Enrolled		
White-Only	0.17	0.711
Non-White Only	-1.05	0.012
National DPP Funded/Supported By:		
Federal Government/ CDC Funding	1.93	<.0001
Medicare or Medicaid	1.92	0.001
State or Local Government Funding	0.86	0.050
State employee coverage benefits	0.22	0.817
State/Local/State Employee	0.78	0.067
Grant funding	0.93	0.019
CFIR Constructs		
Inner Setting		

Networks and Communication	0.79	0.001
Culture	0.75	0.004
Implementation Climate	0.85	0.001
Leadership Engagement	0.49	0.037
Available Resources	0.62	0.019
Readiness for Implementation	0.64	0.017
Outer Setting		
Patient Needs and Resources	0.75	0.005
Cosmopolitanism	0.80	0.001
External Policies and Incentives	0.76	0.002

Tables C1-3. Structural Equation Model Results

Table C1. R-Square

Observed Variable	**Coefficient (SE)**	**P-value**
Latent Variables		
Inner Setting Implementation	0.96 (0.03)	<.001
Inner Setting	0.77 (0.05)	<.001
Outcome		
Enrollment	0.64 (0.05)	<.001
CFIR Variables		
Readiness for Implementation	0.75 (0.03)	<.001
Implementation Climate	0.76 (0.03)	<.001
Networks and Communication	0.66 (0.04)	<.001
Culture	0.71 (0.03)	<.001
Patient Needs & Resources	0.70 (0.04)	<.001
Cosmopolitanism	0.50 (0.04)	<.001
External Policies & Incentives	0.49 (0.04)	<.001

Table C.2 Direct Effects

Outcome	**Variable**	**Coefficient (SE)**	**P-value**
Latent Variables			
Inner Setting Implementation	Readiness for Implementation	0.87 (0.02)	<.001
	Implementation Climate	0.87 (0.02)	<.001
Inner Setting	Networks and Communication	0.81 (0.02)	<.001
	Culture	0.84 (0.02)	<.001
Outer Setting	Patient Needs & Resources	0.84 (0.02)	<.001
	Cosmopolitanism	0.71 (0.03)	<.001
	External Policies & Incentives	0.70 (0.03)	<.001
CFIR Outcomes			
Inner Setting	**Outer Setting**	**0.84 (0.03)**	**<.001**
	Years Delivered	**-0.09 (0.04)**	**0.04**
	DPRP Status: Full Recognition	**0.23 (0.06)**	**<.001**
	DPRP Status: Pending or Preliminary Recognition	**0.14 (0.06)**	**0.02**
	DPRP Status: No Status/Not Recognized	0.01 (0.05)	0.91

	Lifestyle Coaches at Organization	0.07 (0.04)	0.11
	Number of Staff Dedicated to National DPP 100%	-0.02 (0.04)	0.64
	Organization Size: Small (0-1,000 people)	0.09 (0.05)	0.09
	Organization Size: Medium (1,000-50,000)	0.00 (0.05)	1.00
	Organization Size: Large (Over 50,000)	0.02 (0.05)	0.67
	Organization Type: Community-based healthcare	-0.05 (0.05)	0.33
	Organization Type: Community-based organizations	-0.08 (0.04)	0.06
	Organization Type: Government agencies	-0.06 (0.05)	0.21
	Organization Type: Academic	-0.02 (0.04)	0.56
	Organization Type: Health insurers, Employers, Other	-0.04 (0.04)	0.33
	Delivery Mode: In-person	-0.02 (0.04)	0.70
	Delivery Mode: Virtual	0.00 (0.04)	0.94
	Location: Rural	-0.05 (0.05)	0.38
	Location: Suburban	0.05 (0.05)	0.31
	Location: Urban	-0.05 (0.05)	0.29
	Population Enrolled White Only	-0.05 (0.04)	0.27
	Population Enrolled Non-White Only	0.06 (0.05)	0.18
	Supported By: Federal Government/ CDC Funding	-0.05 (0.04)	0.26
	Supported By: Medicare and/or Medicaid	-0.03 (0.04)	0.53
	Supported By: State or Local Funding	-0.01 (0.04)	0.74
	Supported By: Grant funding	0.06 (0.04)	0.15
Inner Setting Implementation	Inner Setting	0.46 (0.10)	<.001
	Outer Setting	0.55 (0.01)	<.001
	Years Delivered	-0.01 (0.03)	0.88
	DPRP Status: Full Recognition	0.02 (0.05)	0.69
	DPRP Status: Pending or Preliminary Recognition	0.02 (0.05)	0.66
	DPRP Status: No Status/Not Recognized	-0.03 (0.04)	0.39
	Lifestyle Coaches at Organization	-0.05 (0.03)	0.13
	Number of Staff Dedicated to National DPP 100%	0.00 (0.03)	1.00
	Organization Size: Small (0-1,000 people)	-0.02 (0.04)	0.68
	Organization Size: Medium (1,000-50,000)	-0.01 (0.04)	0.84
	Organization Size: Large (Over 50,000)	-0.04 (0.03)	0.25
	Organization Type: Community-based healthcare	0.06 (0.04)	0.12
	Organization Type: Community-based organizations	0.04 (0.03)	0.27
	Organization Type: Government agencies	0.03 (0.03)	0.33
	Organization Type: Academic	0.01 (0.03)	0.82
	Organization Type: Health insurers, Employers, Other	**0.08 (0.03)**	**0.01**
	Delivery Mode: In-person	0.03 (0.03)	0.26
	Delivery Mode: Virtual	0.06 (0.03)	0.06
	Location: Rural	-0.04 (0.04)	0.26
	Location: Suburban	-0.07 (0.04)	0.06
	Location: Urban	-0.07 (0.04)	0.07
	Population Enrolled White Only	0.01 (0.03)	0.80
	Population Enrolled Non-White Only	0.03 (0.03)	0.30
	Supported By: Federal Government/ CDC Funding	-0.01 (0.03)	0.68
	Supported By: Medicare and/or Medicaid	0.00 (0.03)	0.91
	Supported By: State or Local Funding	0.02 (0.03)	0.48
	Supported By: Grant funding	-0.01 (0.03)	0.68
	Inner Setting Implementation	0.29 (0.48)	0.55

Enrollment (scaled /100)	Inner Setting	-0.04 (0.25)	0.86
	Outer Setting	-0.16 (0.29)	0.58
	Years Delivered	**0.28 (0.05)**	**<.001**
	DPRP Status: Full Recognition	0.02 (0.07)	0.82
	DPRP Status: Pending or Preliminary Recognition	-0.02 (0.07)	0.79
	DPRP Status: No Status/Not Recognized	0.01 (0.05)	0.81
	Number of Lifestyle Coaches	**0.47 (0.06)**	**<.001**
	Number of Staff Dedicated to National DPP 100%	**0.34 (0.12)**	**0.004**
	Organization Size: Small (0-1,000 people)	0.03 (0.05)	0.60
	Organization Size: Medium (1,000-50,000)	0.10 (0.05)	0.05
	Organization Size: Large (Over 50,000)	**0.14 (0.05)**	**0.005**
	Organization Type: Community-based healthcare	-0.07 (0.05)	0.22
	Organization Type: Community-based organizations	-0.07 (0.05)	0.11
	Organization Type: Government agencies	-0.05 (0.05)	0.25
	Organization Type: Academic	**-0.13 (0.04)**	**0.001**
	Organization Type: Health insurers, Employers, Other	-0.06 (0.06)	0.33
	Delivery Mode: In-person	0.004 (0.04)	0.92
	Delivery Mode: Virtual	0.03 (0.05)	0.55
	Location: Rural	**0.21 (0.06)**	**<.001**
	Location: Suburban	**0.16 (0.06)**	**0.009**
	Location: Urban	**0.16 (0.07)**	**0.015**
	Population Enrolled White Only	-0.03 (0.04)	0.25
	Population Enrolled Non-White Only	**-0.10 (0.05)**	**0.03**
	Supported By: Federal Government/ CDC Funding	0.07 (0.04)	0.10
	Supported By: Medicare and/or Medicaid	0.02 (0.04)	0.58
	Supported By: State or Local Funding	0.00 (0.04)	0.97
	Supported By: Grant funding	0.05 (0.04)	0.25

Table C3. Indirect Effects

Outcome	**Variable**	**Coefficient (SE)**	**P-value**
Indirect Effects			
Inner Setting Implementation -> Enrollment (Indirect 1)	Inner Setting	0.13 (0.22)	0.55
	Outer Setting	0.16 (.27)	0.55
	Years Delivered	-0.001 (0.01)	0.88
	DPRP Status: Full Recognition	0.01 (0.02)	0.74
	DPRP Status: Pending or Preliminary Recognition	0.01 (0.02)	0.73
	DPRP Status: No Status/Not Recognized	-0.01 (-0.5)	0.62
	Lifestyle Coaches at Organization	-0.01 (0.02)	0.58
	Number of Staff Dedicated to National DPP 100%	0.00 (0.01)	1.00
	Organization Size: Small (0-1,000 people)	-0.01 (0.01)	0.74
	Organization Size: Medium (1,000-50,000)	-0.002 (0.01)	0.85
	Organization Size: Large (Over 50,000)	-0.01 (0.02)	0.60
	Organization Type: Community-based healthcare	0.02 (0.03)	0.57
	Organization Type: Community-based organizations	0.01 (0.02)	0.60
	Organization Type: Government agencies	0.01 (0.02)	0.61
	Organization Type: Academic	0.002 (0.01)	0.83
	Organization Type: Health insurers, Employers, Other	0.02 (0.04)	0.56
	Delivery Mode: In-person	0.01 (0.02)	0.60

	Delivery Mode: Virtual	0.02 (0.03)	0.57
	Location: Rural	-0.01 (0.02)	0.60
	Location: Suburban	-0.02 (0.03)	0.57
	Location: Urban	-0.02 (0.04)	0.57
	Population Enrolled White Only	0.002 (0.01)	0.82
	Population Enrolled Non-White Only	0.01 (0.02)	0.61
	Supported By: Federal Government/ CDC Funding	-0.004 (0.01)	0.73
	Supported By: Medicare and/or Medicaid	0.001 (0.01)	0.91
	Supported By: State or Local Funding	0.01 (0.01)	0.65
	Supported By: Grant funding	-0.004 (0.01)	0.73
Inner Setting -> Enrollment (Indirect 2)	Outer Setting	-0.04 (0.21)	0.86
	Years Delivered	0.004 (0.02)	0.86
	DPRP Status: Full Recognition	-0.01 (0.06)	0.86
	DPRP Status: Pending or Preliminary Recognition	-0.01 (0.04)	0.86
	DPRP Status: No Status/Not Recognized	0.00 (0.003)	0.92
	Lifestyle Coaches at Organization	-0.003 (0.02)	0.86
	Number of Staff Dedicated to National DPP 100%	0.001 (0.01)	0.87
	Organization Size: Small (0-1,000 people)	-0.004 (0.02)	0.86
	Organization Size: Medium (1,000-50,000)	0.00 (0.002)	1.00
	Organization Size: Large (Over 50,000)	-0.001 (0.01)	0.87
	Organization Type: Community-based healthcare	0.002 (0.17)	0.86
	Organization Type: Community-based organizations	0.004 (0.02)	0.86
	Organization Type: Government agencies	0.003 (0.02)	0.86
	Organization Type: Academic	0.001 (0.01)	0.87
	Organization Type: Health insurers, Employers, Other	0.002 (0.01)	0.61
	Delivery Mode: In-person	0.001 (0.004)	0.87
	Delivery Mode: Virtual	0.00 (0.002)	0.94
	Location: Rural	0.002 (0.01)	0.87
	Location: Suburban	-0.002 (0.01)	0.86
	Location: Urban	0.002 (0.01)	0.86
	Population Enrolled White Only	0.002 (0.01)	0.86
	Population Enrolled Non-White Only	-0.003 (0.02)	0.86
	Supported By: Federal Government/ CDC Funding	0.002 (0.01)	0.86
	Supported By: Medicare and/or Medicaid	0.001 (0.01)	0.87
	Supported By: State or Local Funding	0.001 (0.004)	0.88
	Supported By: Grant funding	-0.003 (0.02)	0.86
Inner Setting -> Inner Setting Implementation -> Enrollment (Indirect 3)	Outer Setting	0.11 (0.19)	0.55
	Years Delivered	-0.01 (0.02)	0.57
	DPRP Status: Full Recognition	0.03 (0.05)	0.56
	DPRP Status: Pending or Preliminary Recognition	0.02 (0.03)	0.56
	DPRP Status: No Status/Not Recognized	0.001 (0.05)	0.81
	Lifestyle Coaches at Organization	0.01 (0.02)	0.58
	Number of Staff Dedicated to National DPP 100%	-0.002 (0.01)	0.71
	Organization Size: Small (0-1,000 people)	0.01 (0.05)	0.60
	Organization Size: Medium (1,000-50,000)	0.00 (0.01)	1.00
	Organization Size: Large (Over 50,000)	0.003 (0.01)	0.73
	Organization Type: Community-based healthcare	-0.01 (0.01)	0.61
	Organization Type: Community-based organizations	-0.01 (0.02)	0.57
	Organization Type: Government agencies	-0.01 (0.01)	0.59

	Organization Type: Academic	-0.003 (0.01)	0.68
	Organization Type: Health insurers, Employers, Other	-0.01 (0.01)	0.61
	Delivery Mode: In-person	-0.002 (0.01)	0.74
	Delivery Mode: Virtual	0.00 (0.01)	0.94
	Location: Rural	-0.01 (0.01)	0.62
	Location: Suburban	0.01 (0.01)	0.61
	Location: Urban	-0.01 (0.01)	0.60
	Population Enrolled White Only	-0.01 (0.01)	0.60
	Population Enrolled Non-White Only	0.01 (0.02)	0.58
	Supported By: Federal Government/ CDC Funding	-0.01 (0.01)	0.60
	Supported By: Medicare and/or Medicaid	-0.003 (0.01)	0.66
	Supported By: State or Local Funding	-0.002 (0.01)	0.77
	Supported By: Grant funding	0.01 (0.02)	0.58

Chapter 4: Aim 3

Title: Patterns of Program Sustainability Capacity Among National DPP Delivery Organizations: A Latent Profile Analysis

Abstract

Background: Since the launch of the National Diabetes Prevention Program (DPP) initiative in 2010, there have been over 3,000 organizations who have registered with the CDC to deliver the program, however today only 2000 organizations are registered, indicating challenges with sustainability. Understanding patterns in sustainability capacity across program implementers may be useful in supporting the implementation of the National DPP. This study explores patterns of sustainability capacity of organizations delivering the National DPP using the Program Sustainability Assessment Tool (PSAT) in order to understand whether organizations can be categorized into distinct groups based on dimensions of their sustainability capacity and if those groups are associated with specific organizational characteristics.

Methods: This study includes data from a cross-sectional online survey conducted in August to September 2021 with organizational staff delivering the National DPP. This analysis focuses on the PSAT items and respondent organization characteristics (enrollment, staff size, organization size, delivery modes, location, populations served, funding sources, and organization type). Latent profile analysis (LPA) was used to identify latent subpopulations based on respondent PSAT domain scores into mutually exclusive groups or classes. To estimate associations between derived latent classes and participant characteristics multivariable multinomial logistic regression was conducted using class 1 as the reference group. Lastly, multivariable regression using PSAT score at the outcome was also run to compare to the LPA class regression results. The analysis included 440 respondents with a calculable PSAT score.

Results: The 4-class model included four groups from low to high average domain scores, class 1 was the "low program sustainability" group with 8% of the sample, followed by class 2-the "medium-low program sustainability" group with 22% of the sample, class 3- the "medium-high program sustainability" group with 41.6% of the sample, and class 4-the "high program sustainability" group with 28.4% of the sample. Funding Stability and Partnerships tend to be the lowest domains within all classes across the models, while Program Evaluation and Adaptation have the highest scores. In the regression analyses, compared to the "low program sustainability" group, all of the other classes had on average 5.68 times (95% CI [1.21-27.07]) greater likelihood of having obtained grant funding to support their National DPP efforts. Compared to the reference group, the "medium-low program sustainability" group (class 2) was 4.36 times (95% CI [1.08-17.67]) more likely to be supported by state or local government funding, while class 3 the "medium-high program sustainability" group was less likely to have state employee coverage benefits for the National DPP (0.05, 95%CI [0.003-0.84]). Lastly, the "high program sustainability" group, class 4, was 7.99 times (95% CI [1.07-59.70]) more likely to be a government agency or academic type organization compared to the "low program sustainability" group. In the multivariable analysis with PSAT score at the outcome, virtual delivery mode (0.49) and rural location (-0.48) were significantly associated with PSAT score (t=3.21, p-value=.001; t=-2.92, p-value=.004).

Conclusion: In our sample of National DPP implementers, we found most reported relatively high program sustainability capacity and key indicators associated with sustainability capacity included virtual delivery mode capabilities, location of delivery (rural vs urban), funding sources, and organization type. The results of the LPA also support the internal consistency of the PSAT score and use of the PSAT tool among organizations delivering the national DPP.

Background

In 2020 a reported 96 million adults in the U.S. had prediabetes, a diagnosis that indicates a person is at risk for developing type 2 diabetes (Centers for Disease Control and Prevention, 2022b). For 20 years the

Diabetes Prevention Program (DPP), a lifestyle intervention to delay the onset of diabetes in individuals at high risk for diabetes, has been rigorously tested and adapted in multiple populations and formats (Ackermann et al., 2011; Albright, 2012; Ali, Echouffo-Tcheugui, & Williamson, 2012; Galaviz et al., 2018; Haw et al., 2017; Knowler et al., 2002). In 2010, the CDC launched the National DPP initiative to scale and sustain the intervention to make it widely available to the prediabetes population in the U.S. (Gruss et al., 2019). Today, there are over 2000 registered National DPP organizations implementing the year-long lifestyle change program, a decrease from the over 3000 organizations provided the National DPP between 2012–2019, indicating challenges with sustainability (Centers for Disease Control and Prevention, 2022a; Ritchie, Baucom, & Sauder, 2020).

In order to make a population-level impact, evidence-based interventions need to be scaled *and sustained* (Shelton, Cooper, & Stirman, 2018). The field of implementation science defines sustainability as, "the continued use of program components at sufficient intensity for the sustained achievement of desirable program goals and population outcomes" (Shelton et al., 2018, p. 56). The longer an intervention remains in place, the greater reach and effect it can have (Glasgow, Klesges, Dzewaltowski, Estabrooks, & Vogt, 2006). Factors that are associated with sustainability include the adaptability of a program, support of champions and other key stakeholders, program fit within an organization, perceived impact/benefits of a program, and organization capacity, among others (Scheirer, 2005; Shelton, Chambers, & Glasgow, 2020; Shelton et al., 2018).

While there are many organizations who have been delivering the National DPP for years, there is limited research focused on sustainability. A 2019 study with 165 CDC-recognized organizations delivering the National DPP lifestyle change program defined sustainability using the RE-AIM framework's domain of maintenance ("the extent to which programs had potential for sustainability, measured by the number of delivery sites achieving full CDC recognition, the number of sites continuing to deliver the program without cooperative agreement funding, and organizational and financial support or program

reimbursement from private or public payers") (Nhim et al., 2019, p. 3). To achieve full CDC recognition, organizations need data from at least one cohort meeting specified program outcomes. They found that in 4 years (2012-2016), 132 sites (80%) had at least 12 months of participant data, and that 33 (25%) of these 132 achieved full CDC recognition. However, as the National DPP lifestyle change program takes one year to complete, 12-months of data can only be considered a very short-term indicator of sustainability at most. No other sustainability findings, including factors predicting program sustainability, were reported.

There has been movement in recent years to better define, operationalize, and measure sustainability of public health evidence-based programs (Palinkas et al., 2020; Shelton et al., 2018; Stirman & Dearing, 2018). The Program Sustainability Assessment Tool (PSAT) developed in 2014, identifies 8 domains that affect sustainability capacity through a comprehensive review of tools measuring public health program sustainability (Luke, Calhoun, Robichaux, Elliott, & Moreland-Russell, 2014). The PSAT defines program sustainability capacity as the ability to maintain programming and its benefits over time. The PSAT has been used primarily as a planning tool at one point in time and has not been tested in a predictive capacity (Palinkas et al., 2020).

Understanding patterns in sustainability capacity across program implementers may be useful in understanding the National DPP delivery organization population. Latent profile analysis (LPA) is a statistical method that focuses on identifying latent subpopulations within a population based on a certain set of continuous variables into mutually exclusive groups or class, called "latent profiles" (McCutcheon, 1987; Samuelsen & Dayton, 2019; Spurk, Hirschi, Wang, Valero, & Kauffeld, 2020). The term "latent" is used here to describe the class membership that cannot be directly observed. LPA has been used to understand patterns in patient disease and health behaviors to inform intervention development and use for different patient groups (Cheung et al., 2017; Shen et al., 2020; Vaughan, Ghosh-Dastidar, & Dubowitz, 2018). At the organizational level, LPA has been used to examine patterns in contextual and organizational

factors within community-based programs (Smith, Witherspoon, & Lei, 2021), clinician practice (Becker-Haimes, Lushin, Creed, & Beidas, 2019), and community readiness for programs (De Oliveira Corrêa et al., 2020) to better understand evidence-based program implementation and adoption. However, at the organizational level, there are no studies to our knowledge that have examined sustainability capacity among the National DPP delivery organizations using LPA.

The purpose of this study is to explore patterns of sustainability capacity of organizations delivering the National DPP using the Program Sustainability Assessment Tool (PSAT) in order to understand whether organizations can be categorized into distinct groups based on dimensions of their sustainability capacity and if those groups are associated with specific organizational characteristics. The findings from this research have the potential to support National DPP implementation by providing an understanding of sustainability capacity strengths and weaknesses across different organizations as well as recommendations for capacity building for sustainability within delivery organizations.

Methods

This study includes data from a cross-sectional online survey conducted in August to September 2021 with organizational staff delivering the National DPP. The sample included staff in the following roles: Lifestyle Coaches, Master Trainers, and Program Coordinator[2]. This study was reviewed and determined to be exempt by the Emory University Institutional Review Board (STUDY00002611).

Measures. The survey instrument included 101 items: 23 about the respondent (implementer role, demographics, etc.), their organization characteristics (organization type, location, number of staff, etc.), and enrollment level to date; 38 Likert scale Consolidated Framework for Implementation Research items (Escoffery et al., 2018; Fernandez et al., 2018; Helfrich, Li, Sharp, & Sales, 2009); and 40 items for the

[2] Lifestyle coaches deliver the program to participants. Master Trainers are lifestyle coaches that train lifestyle coaches within the same delivery organization. Program Coordinators supervise daily operations of the program, provide guidance and support to lifestyle coaches, and monitor and submit all program data to the CDC.

Program Sustainability Assessment Tool (See supplemental files for survey instrument). The entire survey took an estimated 20-30 minutes to complete.

This paper focuses on the analysis of the PSAT items and organization characteristics (enrollment, staff size, organization size, delivery modes, location, populations served, funding sources, and organization type). The PSAT explores 8 different sustainability domains: environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, strategic planning (Table 1). Each item participants are asked to assess the extent to which their program has or does the following on a 1- to 7-point Likert scale (1=a little/no extent, 7=to a very great extent). Domain scores are averaged and provide a the PSAT score of 1-7 which indicates the level of sustainability capacity. The higher the score the greater reported sustainability capacity.

The PSAT has been tested for psychometric properties using trainings and evaluations with over 550 individuals and over 250 unique programs at state and local levels (Center for Public Health Systems Science, 2020; Luke et al., 2014). In response to feedback from partners, an updated version (V2) was released in December 2013. The updated version was pilot-tested with 56 state-level chronic disease departments and 2 state-level tobacco control programs with a total of 478 participants. Reliability testing determined a high reliability (domain sub-scales Cronbach's Alpha ranging from 0.79-0.92) (Luke et al., 2014).

Table 1. PSAT Domains and Definitions

Domain	# Items	Definition
Environmental Support	5	Having a supportive internal and external economic and political climate for your program.
Funding Stability	5	Establishing a consistent financial base for your program.
Partnerships	5	Cultivating connections between your program and its stakeholders.
Organizational Capacity	5	Having the internal support and resources needed to effectively manage your program.
Program Evaluation	5	Assessing your program to inform planning and document results.
Program Adaptation	5	Taking actions that adapt your program to ensure its ongoing effectiveness.
Communications	5	Strategic communication with stakeholders and the public about your program.

Strategic Planning	5	Using processes that guide your program's directions, goals, and strategies.

Full descriptions can be found at https://www.sustaintool.org/psat/understand/

Data Collection & Study Sample. Study participants were recruited from Emory University's Diabetes Training and Technical Assistance Center (DTTAC) National DPP implementer population. Over the last 10 years, DTTAC has directly trained over 5,000 lifestyle coaches representing over 2000 organizations across all 50 states. The survey was distributed to an email contact list of 6,470 National DPP implementers who have participated in Emory's DTTAC Lifestyle Coach and/or Master Trainer Select training programs and/or subscribed to the DTTAC newsletter. All active National DPP program implementers who are either a lifestyle coach, master trainer, and/or program coordinator (the key programmatic roles) were eligible to take the survey. The Qualtrics online survey was active for 5 weeks. Weekly email reminders were sent to encourage participation. The first 336 respondents received a $15 Amazon gift card for their participation. A total of 681 eligible responses were collected, after data cleaning for completion 586 responses (9% response rate) were included in the analysis. Of those 586 respondents, 440 (75%) had a calculable PSAT score (based on PSAT instructions averages are totaled excluding non-response items). In other words, excluded respondents had no PSAT item data. Of those who responded to the PSAT questions, on average 35 questions were answered (SD 8.88) and response completion ranged from 1 to 40 items.

Descriptive Analysis. Data were exported from Qualtrics and analyzed using SAS Software Version 9.4. Data were cleaned (screened, diagnosed, and edited for suspected data abnormalities) in accordance with standard data cleaning procedures as outlined through Van den Broeck (Van den Broeck, Cunningham, Eeckels, & Herbst, 2005). We ran standard descriptive statistics (frequencies, distributions, means, etc.) (Table 2). Upon review of the data, enrollment was recalculated to remove four outliers above the 99th percentile. These outliers were large online delivery companies very different from the majority of the National DPP organizations in the sample. In the inferential analyses these outliers were removed to help

normalize the data, in addition, this variable was scaled by 100 to assist with comparison across other variables.

Respondents were compared by those with and without a PSAT score (PSAT scores can be calculated by answering one of more of the items of the assessment) for any significant differences between the groups using chi-square and t-tests. The level of significance was set at the $p<.05$ level for all analyses. These results are included in the supplemental files.

PSAT Item Internal Consistency. The means and standard deviations for all 40 PSAT items were calculated, along with domain averages, and the total PSAT score average (Table 3). Cronbach's alpha was calculated for all domains and total PSAT score, measuring the internal consistency of the items within each of the domain scales and the domains together to form the PSAT score.

Latent Profile Analysis. LPA is a person-centered approach that classifies respondents into mutually exclusive profiles/groups/classes/clusters (Spurk et al., 2020). First the researcher selects a number of groups or classes to assign the participants to. Analyzing all of the participant responses for each PSAT domain score, the participants are assigned a probability of being part of each derived class and classified according to their highest posterior probability (Hancock, Mueller, & Stapleton, 2010; McCutcheon, 1987). The assigned class is treated like an unobserved categorical variable, where its value indicates which profile a respondent belongs to with a certain degree of probability (Spurk et al., 2020).

This LPA included the eight PSAT domain score variables. We ran a succession of eight models using Mplus Version 8.3. Cases with missing items were estimated in Mplus utilizing full-information maximum likelihood (FIML). The selection of the "best" model included reviewing the fit indices and information criteria; latent class proportions and sizes; and the researchers' interpretation and entropy of the latent classes. The entropy indicates the measure of classification uncertainty and ranges from 0 to 1. Values

near one indicate high certainty in classification. Typically, an entropy value of .7 or higher suggests good certainty in classification.

The first step in model selection included comparing the following fit indices and information criteria: the log-likelihood, Akaike Information Criterion (AIC), Bayesian Information Criterion (BIC), Adjusted BIC, and entropy (Supplemental Table 3). The log-likelihood statistic is a form of a chi-squared test that indicates the goodness-of-fit a particular latent class model. These statistics were used to calculate the AIC and BIC, additional goodness-of-fit measures used to compare models to each other. The model with the lowest AIC, BIC, Adjusted BIC values are considered to be the model that "fits" the data best (Hancock et al., 2010). All entropy values in the models run were over .85.

Next, latent class proportions were compared to examine the size of each class within the models. Classes that are "too small" may not represent a meaningful proportion of the population (Hancock et al., 2010). Whereas classes that are too large may not be identifying enough of the diversity of the patterns observed. In the last step of model selection, line graphs were created to visually examine the patterns between the classes and response items. After review of fit indices, class proportions, and the visual profiles of each the 4-class model was selected as the best fit and most meaningful output of class proportions.

To estimate associations between derived latent classes and participant characteristics multivariable multinomial logistic regression was conducted using class 1 as the reference group. Respondent organization characteristics included in the multivariable logistic regression are those presented in Table 2. The final sample for the multivariable logistic regressions included 259 respondents. This is less than our 440 PSAT respondents due to data missing at random.

Bi-variate & Multi-variable Regression. In addition to the LPA, bi-variate and multi-variable regressions were conducted with all key organization characteristic variables with the PSAT score as the outcome to gain a better understanding of relationships between variables and compare to the LPA results

(Supplemental Table 4 and 5). Pearson correlation coefficients were calculated with variables that captured similar dimensions. A number of variables were combined (priority population and delivery modes categories) or eliminated (DPRP status, years of program delivery, non-lifestyle coach staff) based on degree of correlation and theoretical overlap with other variables for the full multivariable regression model. For example, the distance, online, and hybrid delivery modes all include providing the program virtually and therefore combined into the virtual delivery mode variable. The final multi-variable regression model included 21 organization characteristic variables (Table 5).

A review of the patterns of missing data concluded that data was missing at random, i.e. missingness is related only to variables that were collected. Multiple imputations were used to handle data missing at random for the enrollment (30% missing) and organization size (20% missing) variables using SAS Software Version 9.4 (UCLA: Statistical Consulting Group). All 21 independent organization characteristic variables included in the regression model plus four auxiliary organization variables (DPRP status, years of program delivery, non-lifestyle coach staff, and organization type: healthcare-reference group variable) were added to the imputation model. The fully conditional method (FCS) was used in order to handle the continuous, ordinal, and dichotomous variables. A total of ten imputed data sets were created and pooled. These results were compared to the original regression model and the LPA multivariable multinomial logistic regression.

Results

Organizations and Respondent Characteristics. Of the 440 survey respondents with a PSAT score, the majority belonged to National DPP delivery organizations with full recognition in the DPRP[3] (52.5%), the average length of program delivery was 4.6 years (3.1 SD), and average enrollment was 1,991 participants

[3] The DPRP provides national quality standards to ensure organizations are delivering the program with fidelity. These standards and procedures are updated every three years based on new dietary, physical activity, self-efficacy, delivery modality, and other type 2 diabetes prevention evidence. CDC-recognized organizations work toward progressing from pending to preliminary to full recognition status.

enrolled to date (28,325 SD, Table 2). The most common types of respondent organizations were healthcare/hospitals (31.4%); community-based healthcare (community health centers, federally qualified health centers, Indian Health Service, etc.; 23.6%); health insurers, employers, and other (e.g. private businesses; 15.5%); and government agencies (13.4%). The average number of lifestyle coaches at respondent organizations was 7.4 (13.5 SD), with an average of 2.1 (8.2 SD) National DPP staff in other roles (non-lifestyle coaches) and an average of 2.0 (8.7 SD) of National DPP staff dedicated 100% to the program.

As this survey was conducted during the COVID-19 pandemic, the vast majority (78%) were offering programs in some type of virtual mode (distance 57.3%, Online 17.3%, and hybrid 23.9%). There was fairly equal representation of respondents implementing the program in rural (41.1%), suburban (31.1%), and urban (41.4%) locations. Organizations reported mostly enrolling White (67.7%), Black (48.4%), and Hispanic/Latino (33.4%) populations, which reflects the most commonly enrolled populations for this program nationwide. Within our sample, 24.1% of organizations had only White participants, whereas 30.7% had only non-white participants. Respondent organizations were primarily funded/supported by grant funding (41.6%), state or local government funding (23.4%), and/or federal government/CDC funding (22.5%). Respondents often had multiple National DPP roles, 90.7% said they were lifestyle coaches, 41.4% were program coordinators, and 10.9% master trainers.

When comparing the 440 respondents with a PSAT score compared to those who did not answer the PSAT items, one significant difference is that respondents with PSAT scores were significantly more likely to be Program Coordinators and/or Master Trainers for the National DPP. These roles are much more heavily involved with the program at the organizational level and therefore it is not surprising that these individuals were more readily able and willing to complete the PSAT. Almost all (93%) of those that did not complete the PSAT also did not answer the demographic questions which were at the end, which indicate they simply did not complete the full survey. These large amounts of missing data between the

with and without PSAT groups make it difficult to compare significant demographic differences. Of those that completed demographic information, the majority of respondents with PSAT scores identified as women (88%) and white (60%). Respondents were fairly equally represented across age groups.

Table 2. PSAT Respondent & Organization Characteristics (N=440)

Characteristics		
	N(%)	**Mean (SD)**
Years Delivered	419 (95%)	4.6 (3.1) Range 0-20 years
Enrollment to Date	313 (71%)	1991.44 (28325.21)
Enrollment Scaled (divided by 100 + outliers removed)	309 (70%)	1.95 (3.8)
Lifestyle Coaches at Organization	430 (98%)	7.4 (13.5)
Non-Lifestyle Coach DPP Staff	424 (96%)	2.1 (8.2)
Number of staff dedicated to National DPP 100%	425 (97%)	2.0 (8.7)
DPRP Status	**N**	**%**
Full Recognition	231	52.5%
Pending/Preliminary	112	25.5%
None	34	7.7%
I do not know/Missing	61	13.9%
Organization Type		
Healthcare/Hospitals	138	31.4%
Community-based healthcare	104	23.6%
Community-based organizations	40	9.1%
Government agencies	59	13.4%
Academic	30	6.8%
Health insurers, Employers, Other	68	15.5%
missing	7	1.6%
Organization Size		
Small (0-1,000 people)	139	31.6%
Medium (1,000-50,000)	151	34.3%
Large (Over 50,000)	55	12.5%
I don't know/Missing	90	20.5%
Delivery Mode		
In-person small group (meetings with up to 20 participants)	219	49.8%
In-person large group (meetings with 21 or more participants)	14	3.2%
Distance (interacting live with all participants as a group using video and/or audio)	252	57.3%
Online (Using a platform for participants to engage with the content on their own - not a live group meeting)	76	17.3%
Hybrid (combination of modes)	105	23.9%
Virtual (distance, online, hybrid)	343	78.0%
Other	27	6.1%
Location/Urbanicity		
Rural Location	181	41.1%
Suburban Location	137	31.1%

Urban Location	182	41.4%
Populations Enrolled		
White/Caucasian	298	67.7%
Black/African American	213	48.4%
Hispanic/Latino	147	33.4%
American Indian/Alaskan Native	53	12.0%
Asian	44	10.0%
Hawaiian Native/Pacific Islander	9	2.0%
Other	21	4.8%
Missing	7	1.6%
White Only	106	24.1%
Non-White Only	135	30.7%
National DPP Funded/Supported By:		
Grant funding	183	41.6%
State or Local Government Funding	103	23.4%
Federal Government/ CDC Funding	99	22.5%
Medicare or Medicaid	66	15.0%
State employee coverage benefits	24	5.5%
Missing	96	21.8%
Respondent Role (may have more than 1)		
Lifestyle Coach	399	90.7%
Program Coordinator	182	41.4%
Master Trainer	48	10.9%
Respondent Gender		
Woman	387	88.0%
Man	35	8.0%
Other	2	0.5%
Missing	16	3.6%
Respondent Race/Ethnicity		
White/Caucasian	264	60.0%
Black/African American	75	17.0%
Hispanic/Latino	52	11.8%
American Indian/Alaskan Native	22	5.0%
Asian	14	3.2%
Other	3	0.7%
Hawaiian Native/Pacific Islander	1	0.2%
Missing	20	4.5%
Respondent Age Range		
Under 25 years	13	3.0%
25 – 34 years	86	19.5%
35 – 44 years	97	22.0%
45 – 54 years	92	20.9%
55 – 64 years	99	22.5%
65 years or older	36	8.2%
Missing	17	3.9%

PSAT scale. Average scores for individual items in the PSAT instrument ranged from 3.62 (SD=1.9) to 5.6 (SD=1.4) (scale from 1-7, Table 3). All items and domain averages were slightly positively skewed.

Program Evaluation (5.14, SD=1.4) and Adaptation (5.31, SD=1.3) domains were rated the highest, whereas Funding Stability (4.01, SD=1.6) and Partnerships (4.00, SD=1.7) were the lowest. The average PSAT score was 4.64 (SD=1.3).

Table 3. PSAT Item Frequencies and Domain Average Scores (N=440)

PSAT Items (Response 1-7 Likert Scale)	**N**	**Mean**	**Std. Deviation**
Environmental Support *Domain Average*	**428**	**4.61**	**1.5**
1. Champions exist who strongly support our program.	409	4.87	1.7
2. Our program has strong champions with the ability to garner resources.	409	4.49	1.7
3. Our program has leadership support from within the larger organization.	418	4.94	1.6
4. Our program has leadership support from outside of the organization.	384	4.33	1.8
5. Our program has strong public support.	397	4.16	1.7
Funding Stability	**386**	**4.01**	**1.6**
1. Our program exists in a supportive state economic climate.	351	4.24	1.6
2. Our program implements policies to help ensure sustained funding.	348	4.09	1.8
3. Our program is funded through a variety of sources.	346	3.75	2.0
4. Our program has a combination of stable and flexible funding.	340	3.72	1.9
5. Our program has sustained funding.	357	3.83	1.9
Partnerships	**408**	**4.00**	**1.7**
1. Diverse community organizations are invested in the success of our program.	377	3.92	1.8
2. Our program communicates with community leaders.	386	4.37	1.8
3. Community leaders are involved with our program.	374	3.78	1.9
4. Community members are passionately committed to our program.	379	3.97	1.9
5. The community is engaged in the development of our program goals	373	3.62	1.9
Organizational Capacity	**422**	**4.74**	**1.5**
1. Our program is well integrated into the operations of the organization.	407	4.78	1.7
2. Organizational systems are in place to support the various program needs.	411	4.76	1.7
3. Leadership effectively articulates the vision of our program to external partners.	401	4.59	1.8
4. Leadership efficiently manages staff and other resources.	412	4.83	1.7
5. Our program has adequate staff to complete the program's goals.	413	4.81	1.8
Program Evaluation	**412**	**5.14**	**1.4**
1. Our program has the capacity for quality program evaluation.	405	5.28	1.5
2. Our program reports short term and intermediate outcomes.	392	5.21	1.5
3. Evaluation results inform program planning and implementation.	389	5.14	1.5
4. Program evaluation results are used to demonstrate successes to funders and other key stakeholders.	363	5.03	1.7
5. Our program provides strong evidence to the public that the program works.	382	5.04	1.6
Program Adaptation	**409**	**5.31**	**1.3**
1. Our program staff periodically reviews the evidence base.	393	4.98	1.6
2. Our program adapts strategies as needed.	404	5.40	1.4

3. Our program adapts to new science.	389	5.35	1.4
4. Our program proactively adapts to changes in the environment.	404	5.60	1.4
5. Our program makes decisions about which components are ineffective and should not continue.	381	5.23	1.5
Communications	**413**	**4.74**	**1.6**
1. Our program has communication strategies to secure and maintain public support.	384	4.48	1.7
2. Our program staff communicate the need for the program to the public.	386	4.72	1.7
3. Our program is marketed in a way that generates interest.	395	4.62	1.7
4. Our program increase community awareness of the issue (prediabetes/diabetes)	394	4.96	1.6
5. Our program demonstrates its value to the public.	395	4.86	1.7
Strategic Planning	**395**	**4.53**	**1.6**
1. Our program plans for future resource needs.	390	4.96	1.6
2. Our program has a long-term financial plan.	344	4.09	1.8
3. Our program has a sustainability plan.	358	4.26	1.8
4. Our program's goals are understood by all stakeholders.	365	4.45	1.7
5. Our program clearly outlines role and responsibilities for all stakeholders.	359	4.45	1.8
Overall PSAT Score	**440**	**4.64**	**1.3**

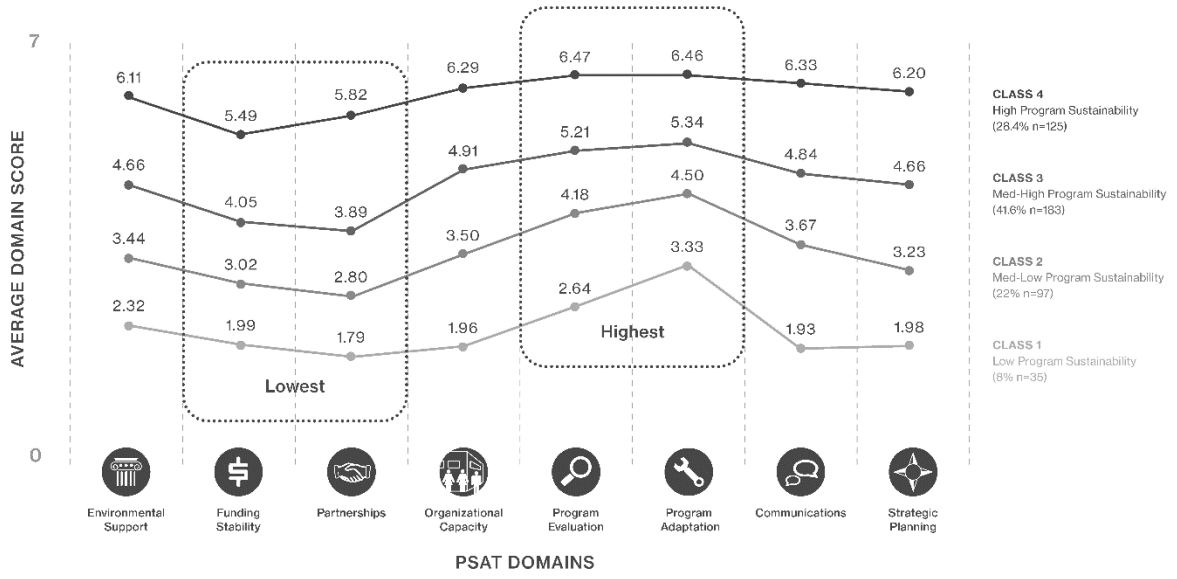
Latent Profile Analysis Results. All participants who had a calculable PSAT score (n=440) were included in the LPA. We began our analysis with a 2-class model, classifying participants into either one of two class/groups based on their PSAT item responses, and continued adding a class to each model until we concluded our exploration with the 8-class model. Fit statistics for all models indicated good model fit, entropy was above the acceptable 0.80 for all models (Supplemental Table 3).

The 2- through 8-class LPA models all resulted in a simple low to high score groupings across all eight PSAT domains. In other words, all eight domains were fairly level (consistently scored) within each class. For example, the 2-class model divided the respondents into a lower domain scores and higher domain score groups. The 3-class model split this up into a low, medium, and high domain score groups. This segmenting of groups continued until the 7-class model. In the 7- and 8- class models we see some deviations in this pattern, with specific groups/classes showing significantly higher or lower scores for particular PSAT domains. However, the class proportions for these divergent groups were very small representing only a handful of respondents (1-3%, 4-13 people) and therefore were not meaningful, but random/ coincidental

patterns. Based on our review of the class proportions, the 4-class model was selected for further analysis between classes (Results from the 2-8 class models are included in the supplemental files).

The 4-class model included four groups from low to high average domain scores, class 1 was the “low program sustainability” group with 8% of the sample, followed by class 2 the “medium-low program sustainability” group with 22% of the sample, class 3 the “medium-high program sustainability” group with 41.6% of the sample, and class 4 the “high program sustainability” group with 28.4% of the sample (Figure 1).

Figure 1. Four Class Model of PSAT Domains



Appearance of no distinct patterns between classes indicate that all eight of these domains are consistently scored across capacity levels, this strengthens the evidence for internal consistency of the PSAT score, which averages the scores of all eight domains. All organizations, despite capacity level, tend to have the same areas of strength and relative weakness. Funding Stability and Partnerships tend to be the lowest domains within all classes across the models, while Program Evaluation and Adaptation have the highest scores. This pattern matches the domain averages seen using the raw PSAT scores (Table 3), further supporting internal consistency of the PSAT score.

Multivariable Multinomial Logistic Regression. To explore possible organizational characteristics predictors of class categorization, the "low program sustainability" group, class 1, was selected as the reference group for the multivariate multinomial logistic regression (n=259). In the regression analyses, compared to the "low program sustainability" group, all of the other classes had on average 5.68 times (95% CI [1.21-27.07]) greater likelihood of having obtained grant funding to support their National DPP efforts (Table 4). Compared to the reference group, the "medium-low program sustainability" group (class

2) was 4.36 times (95% CI [1.08-17.67]) more likely to be supported by state or local government funding, while class 3 the “medium-high program sustainability” group was less likely to have state employee coverage benefits for the National DPP (0.05, 95%CI [0.003-0.84]). Lastly, the “high program sustainability” group, class 4, was 7.99 times (95% CI [1.07-59.70]) more likely to be a government agency or academic type organization compared to the “low program sustainability” group.

Table 4. Four-Class Model Multivariable Multinomial Logistic Regression: Associations Between Organization Characteristics and Latent Profiles (n=259)

Reference Group: Class 1: Low Domain Scores (class proportion 8.0%)	Class 2: Medium-Low Domain Scores (22.0%)			Class 3: Medium-High domain Scores (41.6%)			Class 4: High Domain Scores (28.4%)		
Variables	**Estimate**	**95% Confidence Limits**	**p-Value**	**Estimate**	**95% Confidence Limits**	**p-Value**	**Estimate**	**95% Confidence Limits**	**p-Value**
Enrollment	1.33	(0.80; 2.23)	0.28	1.27	(0.76; 2.12)	0.36	1.44	(0.86; 2.40)	0.16
Number of Lifestyle Coaches at Organization	1.12	(0.89; 1.42)	0.34	1.14	(0.90; 1.43)	0.28	1.15	(0.91; 1.45)	0.24
Number of staff dedicated to National DPP 100%	0.88	(0.44; 1.76)	0.71	1.30	(0.72; 2.37)	0.38	1.38	(0.75; 2.51)	0.30
Organization Size medium vs small	1.01	(0.31; 3.28)	0.98	1.62	(0.52; 5.05)	0.40	1.11	(0.34; 3.68)	0.86
Organization Size large vs small	0.31	(0.05; 1.81)	0.19	0.66	(0.12; 3.59)	0.63	0.55	(0.10; 3.05)	0.49
In-person (small or large group)	2.44	(0.81; 7.37)	0.11	1.76	(0.62; 5.05)	0.29	1.38	(0.46; 4.18)	0.57
Virtual (distance, online, hybrid)	0.97	(0.29; 3.20)	0.95	1.20	(0.37; 3.85)	0.76	1.53	(0.42; 5.51)	0.52
Rural Location	1.40	(0.15; 12.89)	0.77	0.57	(0.06; 5.16)	0.62	0.35	(0.04; 3.27)	0.35
Suburban Location	2.77	(0.31; 24.68)	0.36	2.42	(0.28; 21.12)	0.42	1.77	(0.20; 15.92)	0.61
Urban Location	3.44	(0.34; 34.83)	0.30	1.80	(0.18; 17.62)	0.62	1.73	(0.17; 17.36)	0.64
Programs with only white participants	2.54	(0.71; 9.15)	0.15	1.96	(0.57; 6.80)	0.29	1.31	(0.35; 4.93)	0.69
Programs with only non-white participants	2.35	(0.60; 9.24)	0.22	1.80	(0.49; 6.53)	0.37	1.90	(0.49; 7.39)	0.35
Grant funding	**7.06**	**(1.84; 27.07)**	**0.004**	**5.30**	**(1.45; 19.45)**	**0.01**	**4.66**	**(1.21; 18.03)**	**0.03**
Federal Government/ CDC Funding	2.66	(0.50; 14.29)	0.25	3.97	(0.82; 19.20)	0.09	3.25	(0.62; 16.95)	0.16
State/Local government funding	**4.36**	**(1.08; 17.67)**	**0.04**	2.99	(0.76; 11.71)	0.12	0.89	(0.20; 3.99)	0.88
State employee coverage benefits	0.43	(0.04; 4.54)	0.48	**0.05**	**(0.003; 0.84)**	**0.04**	0.34	(0.03; 3.39)	0.36
Medicare or Medicaid	0.69	(0.13; 3.76)	0.67	1.20	(0.25; 5.77)	0.82	0.75	(0.14; 4.08)	0.74
Org Type: Community-based healthcare	0.76	(0.19; 3.09)	0.70	1.68	(0.46; 6.16)	0.43	0.92	(0.22; 3.90)	0.91
Org Type: Community-based organizations	0.47	(0.06; 3.50)	0.46	1.04	(0.16; 6.83)	0.97	1.15	(0.16; 8.12)	0.89
Org Type: Government agencies or Academic	2.21	(0.29; 17.00)	0.45	5.46	(0.75; 39.91)	0.09	**7.99**	**(1.07; 59.70)**	**0.04**
Org Type: Health insurers, Employers, Other	1.72	(0.31; 9.53)	0.54	2.56	(0.48; 13.61)	0.27	1.62	(0.28; 9.33)	0.59

Bold: Indicates significant variable, p<.05

***Multi-variable Regression Analysis*.** Since our LPA model demonstrated the internal consistency strength of the PSAT score we also ran a multi-variable regression model using PSAT score as the outcomes with the multiple imputations dataset to compare organizational characteristic predictors (n=440, Table 5). In this analysis, virtual delivery mode (0.49) and rural location (-0.48) were significantly associated with PSAT score (t=3.21, p-value=.001; t=-2.92, p-value=.004). The regression model using the original dataset (n=259) also found virtual delivery mode and rural location to be significantly associated and with similar parameter estimates, these results are included in the supplemental files.

Table 5. Organizational Characteristics Associated with PSAT Scores

N=440 / Estimates from 10 imputations Variables	Estimate	Std Error	95% Confidence Limits	t for H0:	p-value	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Intercept	4.23	0.30	(3.64; 4.83)	13.93	<.0001	9%	0.08	0.99
Enrollment	0.03	0.02	(-0.02; 0.07)	1.16	0.246	13%	0.12	0.99
Lifestyle Coaches at Organization	0.00	0.01	(-0.01; 0.01)	0.47	0.641	6%	0.06	0.99
Number of staff dedicated to National DPP 100%	0.01	0.01	(0.00; 0.03)	1.51	0.131	8%	0.07	0.99
Organization Size	0.01	0.10	(-0.18; 0.20)	0.08	0.938	20%	0.17	0.98
In-person (small or large group)	-0.01	0.13	(-0.26; 0.23)	-0.11	0.910	0%	0.00	1.00
Virtual (distance, online, hybrid)	**0.49**	**0.15**	**(0.19; 0.79)**	**3.21**	**0.001**	**1%**	**0.01**	**1.00**
Rural Location	**-0.48**	**0.16**	**(-0.80; -0.16)**	**-2.92**	**0.004**	**1%**	**0.01**	**1.00**
Suburban Location	-0.12	0.16	(-0.44; 0.20)	-0.74	0.457	1%	0.01	1.00
Urban Location	-0.17	0.16	(-0.49; 0.16)	-1.01	0.311	1%	0.01	1.00
Programs with only white participants	-0.13	0.16	(-0.44; 0.17)	-0.86	0.389	0%	0.00	1.00
Programs with only non-white participants	0.15	0.15	(-0.15; 0.45)	1.00	0.316	0%	0.00	1.00
Grant funding	0.20	0.13	(-0.05; 0.45)	1.54	0.125	1%	0.01	1.00
Federal Government/ CDC Funding	0.26	0.15	(-0.04; 0.56)	1.72	0.086	1%	0.01	1.00
State/Local government funding	-0.11	0.15	(-0.40; 0.19)	-0.69	0.490	0%	0.00	1.00
State employee coverage benefits	-0.14	0.27	(-0.68; 0.40)	-0.51	0.607	1%	0.01	1.00
Medicare or Medicaid	-0.05	0.18	(-0.40; 0.30)	-0.29	0.775	1%	0.01	1.00
Org Type: Community-based healthcare	0.11	0.18	(-0.24; 0.46)	0.62	0.534	0%	0.00	1.00
Org Type: Community-based organizations	0.38	0.23	(-0.08; 0.84)	1.63	0.104	0%	0.00	1.00
Org Type: Government agencies	0.12	0.21	(-0.29; 0.54)	0.59	0.554	0%	0.00	1.00
Org Type: Academic	0.02	0.26	(-0.49; 0.54)	0.09	0.928	1%	0.01	1.00
Org Type: Health insurers, Employers, Other	0.09	0.19	(-0.28; 0.47)	0.49	0.625	0%	0.00	1.00

Discussion

The PSAT has been used by a number of health promotion programs to improve sustainability planning (Adams, 2017; King et al., 2018; Llauradó et al., 2018; Reichert, 2017; Stoll et al., 2015; R. G. Tabak et al., 2016). This is the first study to examine sustainability capacity using the PSAT within a sample of National DPP implementers. The LPA did not identify any distinct patterns among PSAT respondents. Instead National DPP implementers were categorized into a series of classes from low to high PSAT scores. Overall, National DPP implementers reported relatively high program sustainability capacity, as the majority were placed in the high (28.4%) and medium-high program sustainability (41.6%) classes. These results provide evidence to support the reliability of the PSAT score to identify organization sustainability capacity.

Similar to other studies using the PSAT, the funding stability domain had the lowest average score among our sample, while program adaptation and evaluation had the highest scores (Luke et al., 2014; Moreland-Russell, Combs, Polk, & Dexter, 2018; Stoll et al., 2015). In the multivariable multinomial logistic regressions of the 4-class LPA model, we also found that those in the higher program sustainability classes were more likely to have grant funding support for their National DPP efforts. Funding stability is often thought of as one of the most important factors in many sustainability frameworks and can influence other sustainability domains (Bodkin & Hakimi, 2020; Shelton et al., 2020).

While external grant funding was found to be associated with sustainability capacity in our study, the focus of the National DPP in regards to financial sustainability has been on insurance provider (employer, Medicare, Medicaid) reimbursements (Ritchie et al., 2020) and not on funding for program implementation. However, only 15% of our analyzed sample indicated having Medicare and Medicaid supports for their programs. Nationally, there have been a variety of challenges with Medicare and Medicaid funding, namely in that reimbursement rates are low compared to the costs incurred by organizations, which may indicate why this was not significantly associated with sustainability capacity in our study (Harris Meyer, 2021; Ritchie et al., 2020). Future research could examine the extent to which

organizations receive various financial support, the duration of funding, and the impact funding has on sustainability outcomes for DPP and other chronic disease programs.

Program evaluation and adaptation domains had the highest averages in the sample, which may be explained by the robust standards and guidance provided by the CDC DPRP. Many implementers are familiar with collecting and analyzing their program data to submit to the CDC to maintain their recognition status (Centers for Disease Control and Prevention, 2021). Likewise, the CDC has promoted various program adaptations to ensure the lifestyle change program curriculum is effective with the communities and populations they are implemented in. Adaptations have ranged from surface level changes, such as using examples of culturally specific foods, having lifestyle coaches of the same cultural background lead their class, and translating the curriculum into other languages, to more deep structural level adaptations like the "Power Up DPP" designed specifically for men in low-income and minority communities (Gary-Webb et al., 2018; Resnicow, Baranowski, Ahluwalia, & Braithwaite, 1999; Rachel G. Tabak et al., 2015). The National DPP's Customer Service Center also provides technical assistance resources around tailoring program elements for a variety of situations.

In the LPA model, the higher program sustainability capacity classes, also rated the organizational capacity and communications domains highly. Similar findings have been found in other sustainability frameworks and studies (Bodkin & Hakimi, 2020). Organizational capacity refers to having the internal support and resources needed to effectively manage the program, while communications focuses on strategic contact with stakeholders and the public about the program. It is not surprising that organizations with resources/capacity and strong communications can maintain their health promotion programming. Factors related to these dimensions also include things like effective leadership and support from champions, which in the PSAT is captured by the environment support domain, which was also highly rated for the higher program sustainability groups (Durlak & DuPre, 2008).

One way in which organizational capacity strengths can be seen within our population is with the technology and staffing for virtual delivery. While before the COVID-19 pandemic only a small number of organizations were offering the program virtually (121 in 2019), today many more organizations have had to use virtual methods out of necessity (Gruss et al., 2019). Benefits of virtual delivery include lowering cost of delivery, logistical challenges like finding space for the program, and participant barriers to attendance such as transportation or scheduling, while maintaining program outcomes on par with the in-person DPP (Katula et al., 2022). Using the PSAT score as the regression outcome we found that respondents from organizations with any type of virtual delivery modes (online, distance, hybrid) were associated with higher sustainability capacity.

In addition, virtual delivery allows for greater geographical reach of participants. In our research, the programs in rural locations were significantly associated with lower sustainability capacity scores. Virtual delivery may be one solution to improve program delivery in hard to reach populations, however challenges like broadband Internet access create other barriers in rural settings (Hirko et al., 2020). While there are many logistical challenges like this to delivering programs in rural communities it is vitally important to work on overcoming them as these communities also have higher prevalence of chronic diseases like diabetes and less access to health care (Coughlin et al., 2019). One implication of these data is that the National DPP should prioritize improving implementation in rural communities and virtual delivery modalities to enhance their sustainability efforts.

Overall, organization type did not appear to have an influence on sustainability capacity. In our multivariable multinomial logistic regressions of the 4 class LPA model, government and academic type organizations were positively associated with one of the higher capacity classes, which may indicate some benefit of being a government agency or academic institution when considering the long-term delivery/maintenance of the National DPP. Perhaps there may be more opportunities and capabilities of the staff (i.e. grant writing skills) to receive funding at these types of institutions. Government agencies

also receive chronic disease funding and technical assistance which may also impact their sustainability capacity. However, the lack of significant relationships between organization types and sustainability capacity supports the CDC's vision that a wide variety of organizations can deliver the National DPP (Albright, 2012). More research with a larger sample of National DPP organization should be used to examine sustainability outcomes (length of delivery, enrollment growth, maintained participant outcomes, financial self-sustainment, etc.) based on organization type. In fact, previous research from our team have identified qualitatively different facilitators and barriers based on organization type, such as organizational bureaucratic processes, however it is unclear to what extent these influence implementation outcomes (Madrigal et al., 2022 – Dissertation Aim 1).

The National DPP and other chronic disease prevention programs can use the findings of this study to support using the PSAT to assess capacity of their programs and as a first step toward sustainability planning. Future research can build on this work by using the PSAT to assess sustainability capacity at the point of program adoption and how well the measure can predict long-term sustainability outcomes (e.g. length of delivery, sustained health outcomes, program growth, etc.). Implementation technical assistance providers can also use the PSAT as the first step in a sustainability capacity building intervention to help organizations with lower PSAT scores as others have done in the past (Calhoun et al., 2014). Based on what we found related to low funding stability ratings, technical assistance should pay particular attention to this area and help organization secure new funding before current sources expire. Lastly, our study found that the National DPP program coordinator and master trainers were more likely to complete the PSAT assessment. This indicates that the staff in these roles may be most able to complete organization-level assessments and should be engaged in sustainability planning and these types of studies in the future.

Strengths and Limitations. Strengths of this study include the use of the PSAT, a validated measure for sustainability capacity with a large and diverse sample of National DPP implementing organizations.

Although we did have issues with missing data we were able to use multiple imputation methods to account for this and draw meaningful conclusions. Another strength includes the large number of organizational characteristic variables used to study associations with program sustainability capacity scores. One limitation is that we recruited our sample from Emory's DTTAC contact list and there may be differences between this group and the larger National DPP population of implementers because of any resources they may have received from Emory. We were also unable to accurately assess if multiple people from same organization completed the survey due inconsistencies in how organization names were provided by respondents and could not account for this clustering in our analyses. However, since we used a measure based on individual implementer perceptions of their organization's sustainability capacity, we did not believe this was a major concern for our analysis. An opportunity for future research may be to examine differences in sustainability capacity perception from different organization stakeholders (i.e. leadership compared to implementation staff) and how to engage various individuals in sustainability planning.

Conclusion

Using the PSAT tool, our study described the sustainability capacity perceptions of National DPP implementers. Understanding sustainability capacity is important to help program implementers with program planning, delivery, and scaling. Maintaining a program over time allows for growth and evolution within an organization in ways such as increasing program offerings, participant enrollment, and reach to new populations (Shelton et al., 2020). Increased delivery allows for more program impact locally, while understanding sustainability across organizations offers collective learning and best practices to scale-up and scale-out programs in different settings, organizations, and populations (Aarons, Sklar, Mustanski, Benbow, & Brown, 2017). Within our sample of National DPP implementers, we found that although there was a wide range, most implementers reported relatively high program sustainability capacity. Key indicators associated with sustainability capacity included virtual delivery mode capabilities, location of

delivery (rural vs urban), funding sources, and organization type. With the limited resources we have in public health promotion, we must strive to develop plans and interventions to scale and sustain effective evidence-based programs as best we can.

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Supplemental Tables & Figures

Supplemental Table 1. Survey Instrument

Section 1 - Background

This questionnaire consists of a series of questions to understand the implementation of the National DPP Lifestyle Change Program at your organization.

First we'd like to ask you a few background questions about the National DPP delivery organization you work for. If you are affiliated with more than one organization, please think of your primary organization as you answer the following.

#	Variable	Item	Response Categories/Scale
1	Role	What is your role at this organization as it pertains to the Diabetes Prevention Program (DPP)?	[Select All that Apply] Lifestyle Coach Master Trainer Program Coordinator *OR* I do not serve in any of the roles above [*SKIP Pattern – If this is checked then participant is ineligible and survey ends]

2	Organization	What is your National DPP organization name? [If you work for multiple organizations please list your primary one]	[Open text response]
3	DPRP ID/Registration Number	Where possible, we'd like to supplement the information gathered from this survey with the information about your organization in the CDC's Diabetes Prevention Recognition Program (DPRP). If your organization participates in the DPRP are you able to provide us your organization's ID or registration number?	[Multiple Choice] Yes, I can provide this information No, I would prefer not to provide this information I do not know my DPRP ID number Not Applicable [*Skip Pattern for YES responses]
	3a. DPRP ID/Registration Number	What is your organization's DPRP ID/Registration Number? If your organization has multiple please select the one where you see the most participants.	[Number]
4	Recognition Status	For the organization you listed, what is the organization's status in the CDC's Diabetes Prevention Recognition Program (DPRP)?	[Multiple Choice] Pending Preliminary Fully Recognized Lapsed/No longer active in the DPRP Not involved in the DPRP I do not know
5	Delivery Modes	What delivery modes do you currently offer at your organization?	[Select all that apply] In-person small group (meetings with up to 20 participants) In-person large group (meetings with 21 or more participants) Distance delivery (interacting live with all participants as a group using video and/or audio) Online delivery (Using a platform for participants to engage with the content on their own - not a live group meeting) Hybrid/combination of those above Other
6	Organization Type	What is the organization type?	[Multiple Choice] 1. Local or community YMCA 2. University/School 3. State/Local Health Department 4. Hospital/Healthcare System/Medical Group/Physician Practice 5. Community-Based Organization/Community Health Center/Federally Qualified Health Center 6. Pharmacy/Drug Store/Compounding Pharmacy 7. Indian Health Service/Tribal/Urban Indian Health System 8. Business Coalition on Health/Cooperative Extension Site 9. Worksite/Employee Wellness Program 10. Senior/Aging/Elder Center

			11. Health Plan/Insurer 12. Faith-Based Organization/Church 13. For-profit Private Business 14. Other – please specify
7	Region/State	In what state/territory is this organization located?	[Drop down of States & US Territories] Multiple
8	Location/Urbanicity	Would you describe where this organization is located as a rural, suburban, or urban area?	[Select All the Apply] Rural Suburban Urban
9	Number of years implementing the program	How long has this organization implemented the National DPP lifestyle change program? Specify in years, round up.	[Drop down menu - # of years]
10	Population Served Race/Ethnicity	Which racial/ethnic populations are primarily enrolled in your organization's National DPP?	[Select all that apply] American Indian/Alaskan Native Asian Black/African American Hawaiian Native/Pacific Islander Hispanic/Latino White/Caucasian Other – please specify [open text]
11	Cohorts	In a typical year (think pre-COVID if you were implementing before 2020), how many cohorts does your organization host?	[Drop down menu of # of cohorts]
12	Lifestyle Coaches	How many trained lifestyle coaches do you have at your organization?	[Drop down # of LCs]
13	Other Staff	How many staff who are NOT lifestyle coaches work on the National DPP at your organization? (e.g. administrative staff, etc.)	[Drop down # of other staff]
14	Dedicated Staff Time a	What percentage of your work responsibilities is dedicated to the National DPP?	[Enter 0-100%]
15	Dedicated Staff Time b	How many of staff at your organization have roles that are 100% dedicated to the National DPP?	[Drop down menu of numbers]
16	Organization size	Approximately how many people does the entire organization serve across all of their programs and services per year?	[Multiple choice] 0-1,000 people 1001-5,000 people 5,0001-10,000 people 10,001-50,000 people 50,0001-100,000 people Over 100,000 people
17	Outcome – Implementation Reach	How many participants have been enrolled since the beginning of this program (first ever cohort) at this organization? [Total number of enrolled participants to date]	[Multiple Choice with text box for entering #] Exact number [Enter number] Best guess [Enter number] I do not know
18	Current Delivery Level	How would you describe your current DPP enrollment level? Select the response that best fits your current situation.	[Multiple Choice] We need to decrease our enrollment numbers (over capacity) We are comfortable at this level of enrollment

			We are actively working to increase our enrollment numbers We would like to increase our enrollment, but this is all we have capacity for at the moment
19	COVID-19 Question	To what extent do you agree or disagree that COVID-19 prohibited you from enrolling the desired number of participants into your program at this time?	[Multiple Choice] Strongly Disagree Disagree Neither agree nor disagree Agree Strongly Agree
20	External Funding	Is your organization's National DPP supported by any of the following:	[Select All that Apply] Federal Government/ CDC Funding Medicare Medicaid State or Local Government Funding State employee coverage benefits Other grant funding

Section 2 - CFIR items

Thinking about the primary National DPP delivery organization that you work for, please rate how much you agree or disagree with the following statements.

Note: This survey refers to the program as the "National DPP" – however we know that you may have a specific program name for your lifestyle change program or be implementing a specific version of the DPP (i.e. YDPP, etc.). Please answer the questions related to the implementation of the National DPP lifestyle change program at your organization.

#	Construct / New or Adapted	Items	Scale
	Networks & Communications	As National DPP staff in your organization, to what extent do you agree that the following communication processes are in place?	
21	Adapted	We have regular project meetings with our organization's National DPP team members/staff	**SD D N A SA NA I don't know**
22	Adapted	There is regular involvement of staff in National DPP planning and implementation	**SD D N A SA**
23	Adapted	We provide regular feedback to organization management on progress of program activities and resource needs	**SD D N A SA**
24	Adapted	We provide regular feedback to organization staff on effects of the National DPP on participant outcomes	**SD D N A SA**
25	Created	We consistently use an internal referral processes (referrals within your organization to the program) for the National DPP	**SD D N A SA**
	Culture	To what extent do you agree with the following aspects of the working culture at your organization?	
26	Adapted	People at all levels openly talk about what is and isn't working	**SD D N A SA**
27	Adapted	We regularly take time to reflect on how we do things	**SD D N A SA**
28	Adapted	People in this organization operate as a real team	**SD D N A SA**

29	Created	The National DPP aligns well with the mission and/or vision at our organization	**SD D N A SA**
	Implementation Climate	To what extent do you agree with the following aspects as it relates to the implementation the National DPP?	
30	Adapted (Goals & Feedback)	Our organization has established National DPP goals that the program staff are expected to help meet (i.e. increase DPP enrollment rates)	**SD D N A SA**
31	Adapted (Learning Climate)	Organization National DPP staff have the support they need to implement the National DPP	**SD D N A SA**
32	Adapted (Org incentives and rewards)	Organization National DPP staff receive acknowledgement (i.e. bonus, awards, public acknowledgement, etc.) for implementing the National DPP successfully	**SD D N A SA**
33	Adapted (Relative priority)	The National DPP is a top priority of the organization	**SD D N A SA**
34	Created (Compatibility)	The National DPP fits well with our organization's existing workflow and systems	**SD D N A SA**
35	Created (Tension for Change)	There is a strong need for this program at our organization	**SD D N A SA**
	Readiness for Implementation		
	Leadership Engagement	To what extent do you agree with the following statements about the level of leadership engagement? *You may think of leadership at any or all levels of your organization that are relevant to your experience with National DPP.*	
36	Adapted	Organization leadership makes sure that staff have the time necessary to implement the National DPP	**SD D N A SA**
37	Adapted	Organization leadership makes sure that staff have the space (physical for in-person classes and/or a virtual/online platform) necessary to implement the National DPP	**SD D N A SA**
38	Adapted	Leadership in this organization create an environment where things can be accomplished for the National DPP	**SD D N A SA**
39	Adapted	Organization leadership promotes an environment that is an enjoyable place to work on the National DPP	**SD D N A SA**
40	Adapted	Leadership strongly supports the National DPP implementation efforts	**SD D N A SA**
	Available Resources	In general, to what extent do you agree that you have the following resources for program implementation?	
41	Adapted	Financial resources to support the implementation of the National DPP	**SD D N A SA**
42	Adapted	Number of staff (lifestyle coaches and others) to support the implementation of the National DPP	**SD D N A SA**
43	Adapted	Basic staff training to facilitate the implementation of the National DPP	**SD D N A SA**
44	Adapted	Equipment/materials to facilitate the implementation of the National DPP	**SD D N A SA**
45	Created	Facilities/space to host the National DPP in-person	**SD D N A SA**
46	Created	Virtual/Distance/Online platform to host the National DPP via distance or online delivery	**SD D N A SA**
	Outer Setting		
	Patient Needs & Resources	To what extent do you agree with the following?	
47	Adapted	Our organization does a good job of assessing participant needs and barriers to enrolling in the National DPP	**SD D N A SA**

48	Adapted	Our organization uses data from participants to improve program delivery	**SD D N A SA**
49	Adapted	Our organization uses data from participants to improve recruitment and enrollment strategies	**SD D N A SA**
50	Created	Our organization has taken steps to reduce barriers to enrollment for participants	**SD D N A SA**
51	Created	There is high demand for the National DPP lifestyle change program in the geographic region our organization serves	**SD D N A SA**
	Cosmopolitanism	To what extent do you agree with the following?	
52	Created	Our organization/staff engages in inter-organizational networking or partnerships (coalitions, meetings, conferences, group trainings, etc.) related to diabetes, prediabetes, and/or the National DPP	**SD D N A SA**
53	Created	Our external/community partners promote our National DPP lifestyle change program	**SD D N A SA**
54	Created	Our program has an effective participant referral processes with external organizations (healthcare providers, community partners, other National DPP organizations, etc.) in place	**SD D N A SA**
55	Created	Our organization works collaboratively with other organizations who deliver the National DPP (i.e. inter-organization referrals, marketing, resource sharing, etc.)	**SD D N A SA**
	External Policy & Incentives	To what extent do you agree that the following local, state, or national policies or initiatives have facilitated your organization's implementation of the National DPP?	
56	Adapted – Escoffery et al. 2018	Our organization receives acknowledgement for using an evidence-based program	**SD D N A SA**
57	Created	External funding for diabetes prevention supports our organization's implementation of the National DPP	**SD D N A SA**
58	Created	The CDC DPRP reporting requirements are helpful for our organization's implementation of the National DPP	**SD D N A SA**

Section 3 – PSAT

In the following questions, you will rate your organization's National DPP lifestyle change program across a range of specific factors that affect your program's **sustainability**. Please respond to as many items as possible. If you truly feel you are not able to answer an item, you may select "NA."

For each statement, circle the number that best indicates the extent to which your program has or does the following things.

Environmental Support: Having a supportive internal and external climate for your organization's program.

	To little or no extent					To a very great extent		Not able to answer
1. Champions exist who strongly support our program.	1	2	3	4	5	6	7	NA
2. Our program has strong champions with the ability to garner resources.	1	2	3	4	5	6	7	NA
3. Our program has leadership support from within the larger organization.	1	2	3	4	5	6	7	NA
4. Our program has leadership support from outside of the organization.	1	2	3	4	5	6	7	NA
5. Our program has strong public support.	1	2	3	4	5	6	7	NA

Funding Stability: Establishing a consistent financial base for your organization's program.

	To little or no extent					To a very great extent		Not able to answer
1. Our program exists in a supportive state economic climate.	1	2	3	4	5	6	7	NA
2. Our program implements policies to help ensure sustained funding.	1	2	3	4	5	6	7	NA
3. Our program is funded through a variety of sources.	1	2	3	4	5	6	7	NA
4. Our program has a combination of stable and flexible funding.	1	2	3	4	5	6	7	NA
5. Our program has sustained funding.	1	2	3	4	5	6	7	NA

For each statement, circle the number that best indicates the extent to which your program has or does the following things.

Partnerships: Cultivating connections between your organization's program and its stakeholders								
	To little or no extent						To a very great extent	Not able to answer
1. Diverse community organizations are invested in the success of our program.	1	2	3	4	5	6	7	NA
2. Our program communicates with community leaders.	1	2	3	4	5	6	7	NA
3. Community leaders are involved with our program.	1	2	3	4	5	6	7	NA
4. Community members are passionately committed to our program.	1	2	3	4	5	6	7	NA
5. The community is engaged in the development of our program goals	1	2	3	4	5	6	7	NA

Organizational Capacity: Having the internal support and resources needed to effectively manage your organization's program and its activities.								
	To little or no extent						To a very great extent	Not able to answer
1. Our program is well integrated into the operations of the organization.	1	2	3	4	5	6	7	NA
2. Organizational systems are in place to support the various program needs.	1	2	3	4	5	6	7	NA
3. Leadership effectively articulates the vision of our program to external partners.	1	2	3	4	5	6	7	NA
4. Leadership efficiently manages staff and other resources.	1	2	3	4	5	6	7	NA
5. Our program has adequate staff to complete the program's goals.	1	2	3	4	5	6	7	NA

For each statement, circle the number that best indicates the extent to which your program has or does the following things.

Program Evaluation: Assessing your organization's program to inform planning and document results.								
	To little or no extent						To a very great extent	Not able to answer
1. Our program has the capacity for quality program evaluation.	1	2	3	4	5	6	7	NA
2. Our program reports short term and intermediate outcomes.	1	2	3	4	5	6	7	NA
3. Evaluation results inform program planning and implementation.	1	2	3	4	5	6	7	NA
4. Program evaluation results are used to demonstrate successes to funders and other key stakeholders.	1	2	3	4	5	6	7	NA
5. Our program provides strong evidence to the public that the program works.	1	2	3	4	5	6	7	NA

Program Adaptation: Taking actions that adapt your organization's program to ensure its ongoing effectiveness								
	To little or no extent						To a very great extent	Not able to answer
1. Our program staff periodically reviews the evidence base.	1	2	3	4	5	6	7	NA
2. Our program adapts strategies as needed.	1	2	3	4	5	6	7	NA
3. Our program adapts to new science.	1	2	3	4	5	6	7	NA
4. Our program proactively adapts to changes in the environment.	1	2	3	4	5	6	7	NA
5. Our program makes decisions about which components are ineffective and should not continue.	1	2	3	4	5	6	7	NA

For each statement, circle the number that best indicates the extent to which your program has or does the following things.

Communications: Strategic communication with stakeholders and the public about your organization's program								
	To little or no extent						To a very great extent	Not able to answer
1. Our program has communication strategies to secure and maintain public support.	1	2	3	4	5	6	7	NA
2. Our program staff communicate the need for the program to the public.	1	2	3	4	5	6	7	NA
3. Our program is marketed in a way that generates interest.	1	2	3	4	5	6	7	NA
4. Our program increase community awareness of the issue (prediabetes/diabetes)	1	2	3	4	5	6	7	NA
5. Our program demonstrates its value to the public.	1	2	3	4	5	6	7	NA

Strategic Planning: Using processes that guide your organization's program's direction, goals, and strategies								
	To little or no extent						To a very great extent	Not able to answer
1. Our program plans for future resource needs.	1	2	3	4	5	6	7	NA
2. Our program has a long-term financial plan.	1	2	3	4	5	6	7	NA
3. Our program has a sustainability plan.	1	2	3	4	5	6	7	NA
4. Our program's goals are understood by all stakeholders.	1	2	3	4	5	6	7	NA
5. Our program clearly outlines role and responsibilities for all stakeholders.	1	2	3	4	5	6	7	NA

Section 4 - Demographic Questions
Lastly, please take a moment to answer these demographics questions.

99	Demographics – Gender	Which gender do you identify with?	Man Woman Other
100	Demographics – Race/Ethnicity	What is your race/ethnicity?	American Indian/Alaskan Native Asian Black/African American Hawaiian Native/Pacific Islander Hispanic/Latino White/Caucasian Other – please specify [open text]
101	Demographics – Age	What is your age?	[Multiple Choice] Under 25 years 25 – 34 years 35 – 44 years 45 – 54 years 55 – 64 years 65 years or older

Supplemental Table 2. Respondent & Organization Characteristics

	Total Survey Respondents		Respondents with PSAT Score		Respondents without PSAT Score		
Respondent & Organization Characteristics	**N=586**	**%**	**N=440**	**%**	**N=146**	**%**	**P-value**
DPRP Status							
Full Recognition	304	51.9%	231	52.5%	73	50.0%	0.60
Pending/Preliminary	126	21.5%	112	25.5%	14	9.6%	<.0001
None	52	8.9%	34	7.7%	18	12.3%	0.090
I do not know/Missing	104	17.7%	61	13.9%	34	23.3%	0.007
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	
Years Delivered	500 (85.3%)	4.51 (3.06)	419 (95%)	4.6 (3.1)	81 (55%)	4.0 (3.0)	0.079

Enrollment to Date	357 (60.9%)	1758 (26524.44)	313 (71%)	1991.44 (28325.21)	44 (30%)	95.57 (121.47)	0.658
Enrollment Scaled (divided by 100 + outliers removed)	353 (60.2%)	1.83 (3.59)	309 (70%)	1.95 (3.8)	44 (30%)	0.96 (1.21)	0.085
Lifestyle Coaches at Organization	512 (87.4%)	7.1 (12.58)	430 (98%)	7.4 (13.5)	82 (56%)	5.4 (5.5)	0.184
Non-Lifestyle Coach DPP Staff	500 (85.3%)	1.94 (7.78)	424 (96%)	2.1 (8.2)	76 (52%)	1.2 (4.6)	0.395
Number of staff dedicated to National DPP 100%	478 (81.6%)	1.94 (8.39)	425 (97%)	2.0 (8.7)	53 (36%)	1.3 (5.6)	0.546
Organization Type							0.686
Healthcare/Hospitals	180	30.7%	138	31.4%	42	28.8%	
Community-based healthcare	129	22.0%	104	23.6%	25	17.1%	
Community-based organizations	55	9.4%	40	9.1%	15	10.3%	
Government agencies	80	13.7%	59	13.4%	21	14.4%	
Academic	43	7.3%	30	6.8%	13	8.9%	
Health insurers, Employers, Other	91	15.5%	68	15.5%	23	15.8%	
missing	8	1.4%	7	1.6%	1	0.7%	
Organization Size (Number of people served annually across all programs and services)							0.141
Small (0-1,000 people)	163	27.8%	139	31.6%	24	16.4%	
Medium (1,000-50,000)	163	27.8%	151	34.3%	12	8.2%	
Large (Over 50,000)	60	10.2%	55	12.5%	5	3.4%	
I don't know/Missing	200	34.1%	90	20.5%	14	9.6%	
Delivery Mode							
In-person small group (meetings with up to 20 participants)	279	47.6%	219	49.8%	60	41.1%	0.069
In-person large group (meetings with 21 or more participants)	19	3.2%	14	3.2%	5	3.4%	0.886
In-person (small or large group)	279	47.6%					
Distance (interacting live with all participants as a group using video and/or audio)	323	55.1%	252	57.3%	71	48.6%	0.069
Online (Using a platform for participants to engage with the content on their own - not a live group meeting)	98	16.7%	76	17.3%	22	15.1%	0.536
Hybrid (combination of modes)	142	24.2%	105	23.9%	37	25.3%	0.718
Virtual (distance, online, hybrid)	447	76.3%					

Other	40	6.8%	27	6.1%	13	8.9%	0.251
Location/Urbanicity							
Rural Location	233	39.8%	181	41.1%	52	35.6%	0.238
Suburban Location	190	32.4%	137	31.1%	53	36.3%	0.248
Urban Location	237	40.4%	182	41.4%	55	37.7%	0.431
Populations Enrolled							
White/Caucasian	361	61.6%	298	67.7%	63	43.2%	<.0001
Black/African American	257	43.9%	213	48.4%	44	30.1%	0.000
Hispanic/Latino	177	30.2%	147	33.4%	30	20.5%	0.003
American Indian/Alaskan Native	67	11.4%	53	12.0%	14	9.6%	0.419
Asian	56	9.6%	44	10.0%	12	8.2%	0.526
Hawaiian Native/Pacific Islander	14	2.4%	9	2.0%	5	3.4%	0.344
Other	26	4.4%	21	4.8%	5	3.4%	0.493
Missing	65	11.1%	7	1.6%	58	39.7%	<.0001
White Only	131	22.4%	106	24.1%	25	17.12%	0.0799
Non-White Only	160	27.3%	135	30.7%	25	17.12%	0.0014
National DPP Funded/Supported By:							
Federal Government/ CDC Funding	112	19.1%	99	22.5%	13	8.9%	0.0003
Medicare and/or Medicaid	68	11.6%	66	15.0%	2	1.4%	<.0001
State or Local Government Funding	114	19.5%	103	23.4%	11	7.5%	<.0001
State employee coverage benefits	24	4.1%	24	5.5%	0	0.0%	0.004
Grant funding	195	33.3%	183	41.6%	12	8.2%	<.0001
missing	212	36.2%	96	21.8%	116	79.5%	<.0001
Respondent Role (may have more than 1)							
Lifestyle Coach	538	91.8%	399	90.7%	139	95.2%	0.084
Program Coordinator	222	37.9%	182	41.4%	40	27.4%	0.003
Master Trainer	56	9.6%	48	10.9%	8	5.5%	0.053
Respondent Gender							<.0001
Woman	395	67.4%	387	88.0%	8	5.5%	
Man	36	6.1%	35	8.0%	1	0.7%	

Other	2	0.3%	2	0.5%	0	0.0%	
missing	153	26.1%	16	3.6%	137	93.8%	
Respondent Race/Ethnicity							
White/Caucasian	268	45.7%	264	60.0%	4	2.7%	<.0001
Black/African American	76	13.0%	75	17.0%	1	0.7%	<.0001
Hispanic/Latino	53	9.0%	52	11.8%	1	0.7%	<.0001
American Indian/Alaskan Native	22	3.8%	22	5.0%	0	0.0%	0.006
Asian	16	2.7%	14	3.2%	2	1.4%	0.244
Other	4	0.7%	3	0.7%	1	0.7%	0.997
Hawaiian Native/Pacific Islander	2	0.3%	1	0.2%	1	0.7%	0.411
missing	157	26.8%	20	4.5%	137	93.8%	<.0001
Respondent Age Range							0.345
Under 25 years	13	2.2%	13	3.0%	0	0.0%	
25 – 34 years	89	15.2%	86	19.5%	3	2.1%	
35 – 44 years	101	17.2%	97	22.0%	4	2.7%	
45 – 54 years	94	16.0%	92	20.9%	2	1.4%	
55 – 64 years	99	16.9%	99	22.5%	0	0.0%	
65 years or older	36	6.1%	36	8.2%	0	0.0%	
missing	154	26.3%	17	3.9%	137	93.8%	

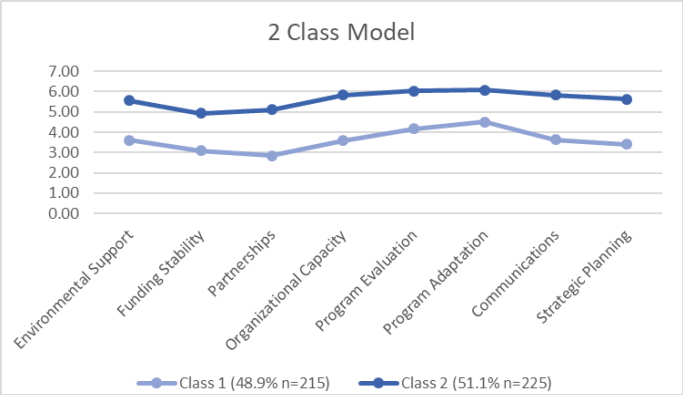
Supplemental Table 3. Latent Class Proportions and Fit Statistics

Classes	N	Para-meters	LogLik	AIC	BIC	Adjusted BIC	Entropy
2	440	25	-5267	10583	10685	10606	0.87
3	440	34	-4931	9931	10070	9962	0.91
4	440	43	-4841	9767	9943	9807	0.88
5	440	52	-4784	9672	9884	9719	0.85
6	440	61	-4739	9601	9850	9657	0.86
7	440	70	-4695	9530	9816	9594	0.87
8	440	79	-4659	9475	9798	9548	0.89

LPA Model Proportions

Model	Class 1	Class 2	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
2-Class	48.7%	51.3%						
3-Class	20.5%	48.9%	30.7%					
4-Class	8.0%	22.0%	41.6%	28.4%				
5-Class	6.6%	17.5%	38.9%	24.3%	12.7%			
6-Class	3.1%	8.1%	18.4%	35.1%	23.1%	12.2%		
7-Class	3.0%	18.0%	3.0%	33.6%	8.2%	23.2%	11.1%	
8-Class	3.0%	8.2%	3.0%	18.4%	0.9%	32.3%	23.0%	11.4%

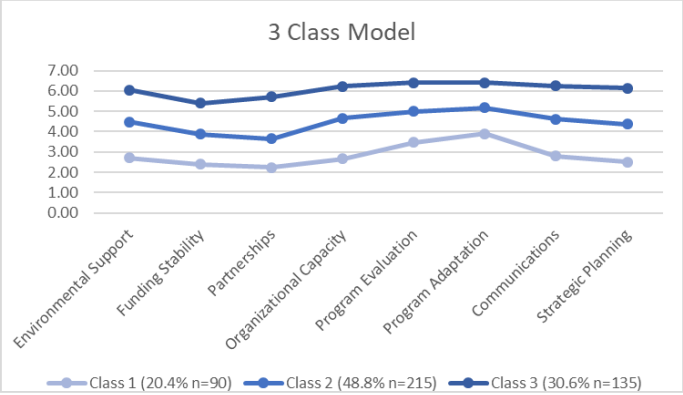
Supplemental Figures. Latent Models 2 – 8



2-Class Model

Class 1 = lower domain scores

Class 2 = high domains scores

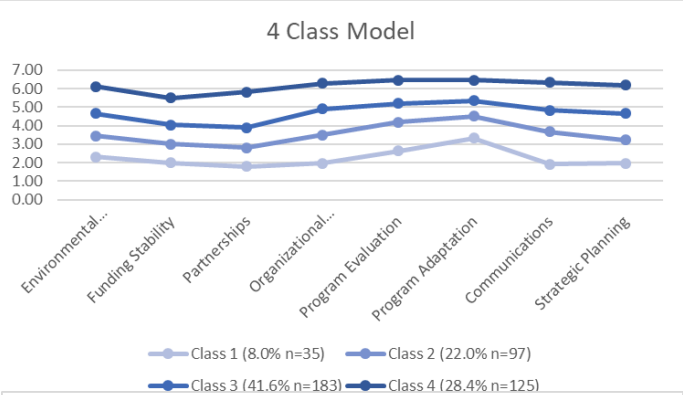


3-Class Model

Class 1 = low domain scores

Class 2 = medium domain scores

Class 3 = high domain scores



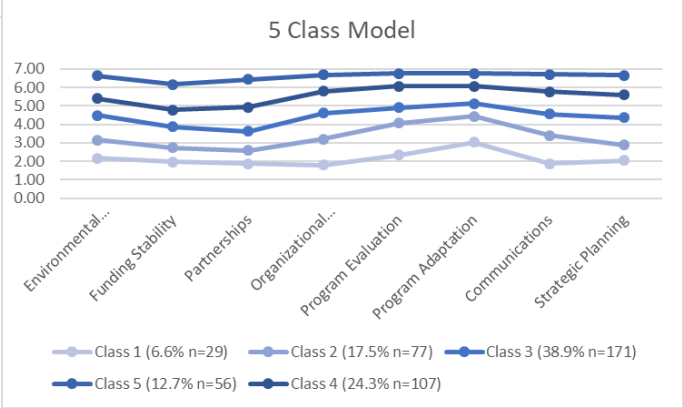
4-Class Model

Class 1 = low domain scores

Class 2 = medium low domain scores

Class 3 = medium high domain scores

Class 4 = high domain scores



5-Class Model

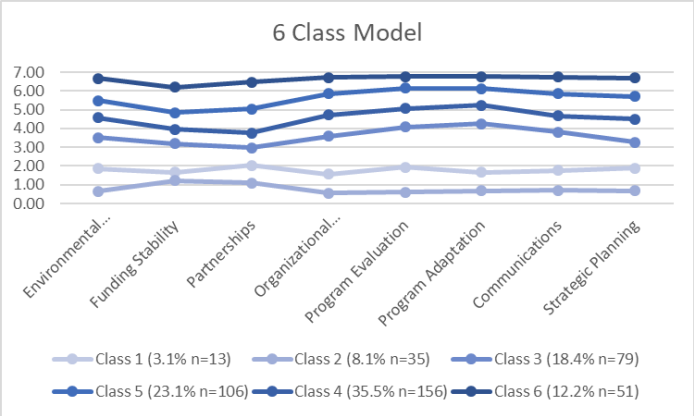
Class 1 = low domain scores

Class 2 = medium low domain scores

Class 3 = medium domain scores

Class 4 = medium high domain scores

Class 5 = high domain scores



6-Class Model

Class 1 = low domain scores

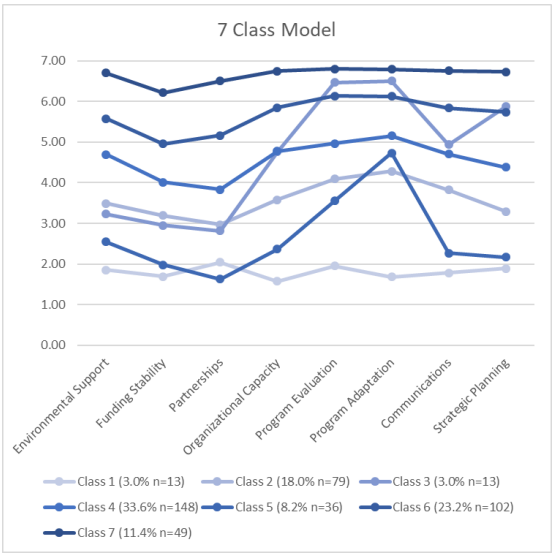
Class 2 = medium low domain scores

Class 3 = medium domain scores

Class 4 = medium high domain scores

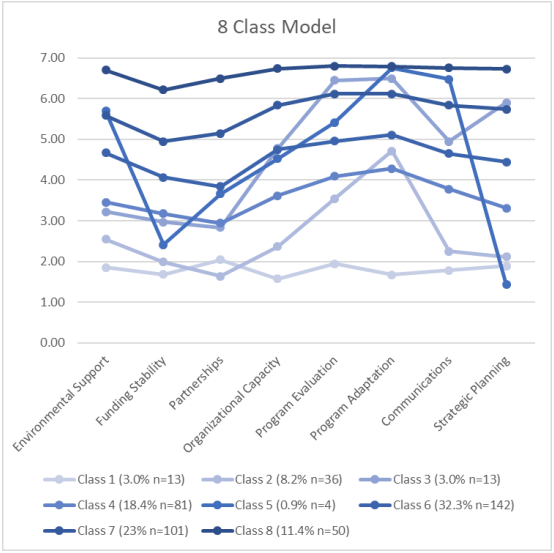
Class 5 = high domain scores

Class 6 = highest domain scores



7-Class Model

Classes 3 and 5 show spikes in the evaluation and adaptation domains indicating these groups have particular strengths in these areas relative to the other domains. Class 3 also has relatively high strategic planning scores.



8 – Class Model – more unique divisions, but very small proportions

Supplemental Table 4. Bi-variate Regression Analysis Results

Outcome = PSAT Score (N=440)	**n**	**Parameter Estimate**	**P-value**
Continuous Variables			
Years Delivered	419	0.02	0.342
Enrollment To Date (scaled by 100)	309	0.06	**0.004**
Lifestyle Coaches at Organization	430	0.01	**0.008**
Non Lifestyle Coach DPP Staff	424	0.01	0.287
Number of Staff Dedicated to the National DPP 100%	425	0.03	**0.000**
Ordinal Variables			
DPRP Status	377	0.47	**<.0001**
Organization Size	345	0.05	0.621
Categorical Variables (Dichotomous)			
Organization Type			
Healthcare/Hospitals	440	-0.24	0.069
Community-based healthcare	440	0.07	0.623
Community-based organizations	440	0.46	**0.031**
Government agencies	440	-0.09	0.603
Academic	440	-0.06	0.815
Health insurers, Employers, Other	440	0.11	0.513
Delivery Mode			
In-person small group	440	-0.24	0.053
In-person large group	440	-0.22	0.527
In-person (large and small combined)	440	-0.237	0.053
Distance	440	0.11	0.376
Online	440	0.35	**0.033**
Hybrid	440	0.49	**0.001**
Virtual (distance, online, hybrid combined)	440	0.64	**<.0001**
Other	440	-0.52	**0.040**
Location/Urbanicity			
Rural Location	440	-0.44	**0.000**
Rural Only	440	-0.37	**0.004**
Suburban Location	440	0.13	0.324
Suburban Only	440	0.20	0.178
Urban Location	440	0.21	0.100
Urban Only	440	0.27	0.041
Populations Enrolled			
White/Caucasian	440	-0.28	**0.032**
Black/African American	440	0.26	**0.034**

Hispanic/Latino	440	0.13	0.307
American Indian/Alaskan Native	440	-0.10	0.581
Asian	440	0.07	0.738
Hawaiian Native/Pacific Islander	440	-0.09	0.835
Other	440	0.31	0.286
White-Only	440	-0.42	**0.004**
Non-white Only	440	0.27	**0.040**
Top 3 Populations (white,black, latino)	440	-0.07	0.710
All Other Populations	440	-0.02	0.865
DPP Minority Pops Only	440	0.04	0.829
National DPP Funded/Supported By:			
Federal Government/ CDC Funding	440	0.36	**0.013**
Medicare	440	0.11	0.560
Medicaid	440	0.29	0.301
Medicare or Medicaid combined	440	0.085	0.621
State or Local Government Funding	440	-0.08	0.594
State employee coverage benefits	440	0.00	0.992
State/Local/State Employee combined	440	-0.103	0.460
Grant funding	440	0.24	0.055
			***Bold = p-value <.05**

Supplemental Table 5. Multi-Variable Regression Analysis Results

Variable (N=259) 59% of PSAT score respondents	**Parameter Estimate**	**Standard Error**	**t value**	**P-value**
Intercept	3.99	0.38	10.37	<.0001
Enrollment	0.02	0.03	0.6	0.55
Lifestyle Coaches at Organization	0.01	0.01	1.13	0.26
Number of Staff Dedicated to National DPP 100%	0.10	0.04	2.47	**0.01**
Organization Size	0.06	0.12	0.53	0.60
In-person (small or large group)	-0.04	0.17	-0.25	0.80
Virtual (distance, online, hybrid)	0.41	0.20	2.09	**0.04**
Rural Location	-0.52	0.23	-2.27	**0.02**
Suburban Location	-0.05	0.24	-0.22	0.83
Urban Location	-0.09	0.23	-0.39	0.70
Programs with Only White Participants	0.03	0.20	0.17	0.86
Programs with Only Non-White Participants	0.09	0.20	0.44	0.66
Grant Funding	0.24	0.17	1.4	0.16
Federal Government/ CDC Funding	0.24	0.22	1.09	0.28
State/Local Government Funding	-0.39	0.20	-1.98	0.05
State Employee Coverage Benefits	0.05	0.38	0.13	0.89
Medicare or Medicaid	-0.03	0.25	-0.1	0.92
Org Type: Community-Based Healthcare	0.09	0.23	0.37	0.71

Org Type: Community-Based Organizations	0.11	0.29	0.38	0.71
Org Type: Government Agencies	0.69	0.28	2.49	**0.01**
Org Type: Academic	-0.08	0.37	-0.2	0.84
Org Type: Health insurers, Employers, Other	0.07	0.27	0.28	0.78
R-squared = 0.18				
				***Bold = p-value <.05**

Chapter 5

Introduction & Summary of Key Findings

To impact health outcomes at a population level, evidence-based interventions must be adopted, implemented, and scaled by a large number of organizations with sufficient population reach. Since 2012 the National DPP lifestyle change program has been scaled across the United States; however, further scaling and program reach are needed to make significant population change (Ackermann, 2017; Albright, 2012; Ritchie, Baucom, & Sauder, 2020). In order to understand how the National DPP might better strategize and mobilize to increase its growth and impact, this dissertation explored the multi-level factors related to the successful implementation and sustainability of the National Diabetes Prevention Program through three aims.

This research focused on the facilitators and constraints both within and outside organizations that impact implementation outcomes. The aims of this project were to: 1) identify qualitatively key organization- and structural-level causal factors associated with the implementation of the National DPP, particularly as it pertains to reach; 2) test the direct and indirect relationships between the organization- and structural-level causal factors, organizational characteristics, and reach; and 3) identify patterns of sustainability capacity among delivery organizations and the associated organization characteristics with these patterns.

First, qualitative data were collected through semi-structured key informant interviews with 30 National DPP delivery organization implementers. A qualitative cross-case construct rating methodology was applied to assess which Consolidated Framework for Implementation Research (CFIR) *Inner* and *Outer Setting* constructs contributed (both in valence and magnitude) to the organization's current level of implementation reach (measured by average participant enrollment per year). This study found that across the 16 inner and outer setting constructs and subconstructs, the organizations in the higher reach

group provided stronger and more positive examples related to implementation and enrollment of the program, while the lower reach groups reported stronger and more negative examples across rated constructs. Four inner setting constructs/subconstructs (structural characteristics, compatibility, goals & feedback, and leadership engagement) were identified as "distinguishing" based on the difference between groups by average rating (±.5 difference between levels), the examination of the number of extreme ratings within levels, and the thematic analysis of the content discussed.

Next, we built on the qualitative analysis by using structural equation modeling to quantitatively examine the relationships between CFIR *Inner* and *Outer Setting* constructs, organizational characteristics, and the implementation reach (operationalized as program enrollment). An online survey was distributed to the DTTAC National DPP implementer population and 586 responses were included in analysis. The CFIR Inner Setting construct *Structural Characteristics* included the variables: the length of delivery, number of lifestyle coaches, number of full-time staff, large organization size, and organizations delivering in rural, suburban, and/or urban settings which all had positive significant direct relationships with enrollment. Academic organizations and organizations with only non-White participants enrolled in their National DPP lifestyle change programs had negative direct relationships with enrollment. In addition, the CFIR items had good internal consistency and provided insight into implementation areas of strength and weakness.

Lastly, the same survey data were used to examine patterns of sustainability capacity among organizations delivering the National DPP. This analysis focuses on the Program Sustainability Assessment Tool (PSAT) items and respondent organization characteristics (enrollment, staff size, organization size, delivery modes, location, populations served, funding sources, and organization type). The PSAT includes 40 items and explores 8 different sustainability domains: environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, strategic planning (Center for Public Health Systems Science, 2020; Luke, Calhoun, Robichaux, Elliott, & Moreland-Russell, 2014). Latent profile analysis (LPA) was used to identify latent subpopulations based on respondent PSAT

domain scores into mutually exclusive groups or classes. A 4-class model was selected as the best model for the data. This included 4 groups, class 1 was the “low program sustainability” group with 8% of the sample, followed by class 2 the “medium-low program sustainability” group with 22% of the sample, class 3 the “medium-high program sustainability” group with 41.6% of the sample, and class 4 the “high program sustainability” group with 28.4% of the sample. Funding Stability and Partnerships tend to be the lowest domains within all classes across the models, while Program Evaluation and Adaptation have the highest scores. In the regression analyses, compared to the “low program sustainability” group, all of the other classes a greater likelihood of having obtained grant funding to support their National DPP efforts. The secondary multivariable analysis with PSAT score as the outcome, found that virtual delivery mode was positive associated and rural location was negatively significantly associated with PSAT score.

Overall Themes

All three aims provided valuable information to help guide National DPP implementation efforts. No single type of organization was consistently associated with any of the implementation outcomes, which supports the CDC’s initiative to scale this program widely in various organizational settings. Overall, basic program infrastructure and support, such a staff time, resources, and active leadership engagement were most salient and important to the National DPP implementers. In addition to this, this work also identified organizations working with particular populations may need additional or unique resources and assistance. These are very practical and seemly obvious factors that impact implementation, but the more evidence to support and emphasize that staff need sufficient resources, time, and supportive organizational environments to do their work is important.

In the qualitative study, staffing and staff time were challenges often discussed within the *Structural Characteristics* construct and the impact this construct had was different among the levels of implementation reach, where organizations with lower reach more often mentioned greater challenges with this compared to higher reach organizations. Providing adequate staffing also was an example in

discussions about leadership support, where once again lower reach organizations struggled more than higher reach ones. In the second study, the structural equation model, found the number of lifestyle coaches and number of staff dedicated full time to the National DPP at organizations to be significantly positively related to organization enrollment. Lastly in the third study, the higher program sustainability capacity classes, rated the organizational capacity PSAT domain (which included items about staffing) highly compared to the lower capacity classes.

There were also a range of discussions on leadership engagement and how the prioritization and recognition of the program by leadership impacts implementation. In the qualitative study *Leadership Engagement* organizations with higher reach described a greater number of strong positive examples of *Leadership Engagement* compared to the low reach group. The higher reach implementers also more often connected *Leadership Engagement* with positive examples of successful enrollment efforts and growing the infrastructure for the program. In the sustainability study, PSAT items around leadership in the Environmental Support and Organizational Capacity domains were on average highly rated compared to the other domains, indicating good sustainability capacity in those areas. At the same time the second study found that on average, staff did not agree nor disagree that the National DPP was a top priority at their organization and they slightly disagreed about the presence of staff acknowledgements (bonuses, awards, public recognition, etc.) provided by leadership. These sentiments were also apparent in the qualitative study interviews. Therefore, while there were indications and examples of strong leadership involvement and support, implementers also noted many ways in which leadership could make this program a higher priority and increase incentives to support staff in their work.

Organizations serving specific populations, like rural populations, and non-white populations – may have specific needs or challenges. Implementation outcomes in rural populations was a theme in aims 2 and 3. In aim 2, our data showed organizations delivering the program in all location types (rural, suburban, and urban) were positively associated with enrollment. However, in aim 3, the organizations delivering in rural

locations were significantly associated with lower sustainability capacity scores. So, while our sample population seems to have good reach in rural populations, it is a perceived challenge for long-term maintenance. In aim 2, organizations delivering the program with only non-white populations had a negative association with enrollment. This indicates some challenges with enrolling these populations compared organizations who serve white populations. Both rural and non-white communities have been a focus for the National DPP to increase enrollment, retention, and program outcomes (AuYoung, Moin, Richardson, & Damschroder, 2019). These findings support those initiatives.

Strengths, Implications, & Future Research

Strengths of this dissertation include the use of existing and established implementation science theories and tools, robust primary data collection from knowledgeable program implementers, strong participation and diversity among respondents, leveraging established partnerships to engage community-level implementers who often do not get an opportunity to provide feedback or share what the work looks like on the ground, and feedback from National DPP experts at DTTAC to ensure the study design and data collection instruments and protocols would work well with the population. This work is useful to the field in a number of ways, namely, 1) this research helps build upon implementation science theory and methodology; and 2) the findings of this research can be applied to improve the training and technical assistance provided to National DPP implementers.

Implementation science is still a relatively new field of practice and with many newly developed frameworks and models that require testing. There are also not many studies that have been able to understand program implementation with the organization as the unit of analysis. Often research is focused on individuals or program participants within one or a few implementation sites. Using the National DPP to explore these research questions with CFIR and the PSAT in hundreds of implementing organizations is rarely done in the literature. It has been exciting to build upon the implementation science

literature and successfully show how CFIR constructs and items, and tools like the PSAT, can be used and provide helpful information to scale and sustain programs.

There are also very few studies of the National DPP that examine implementation at the organizational level and with the number and diversity of implementers we were able to engage. Previous research and evaluations of the National DPP have focused on the intervention components and participant outcomes (Chambers et al., 2017; Ely et al., 2017; Nhim et al., 2019). To our knowledge the research presented in this dissertation is among the first to examine delivery organizations at the organizational- and structural-level causal factors using the CFIR and PSAT.

There are a number of ways in which the findings from this dissertation will also be used to further support National DPP organizations and implementers. DTTAC provides ongoing training and technical assistance to implementers at all levels of delivery – from coaches to State health departments who are working to promote and support these programs across their jurisdictions. For example, DTTAC currently provides a training for State Quality Specialist, a special position at state health departments for the National DPP to be the point person for all National DPP outreach and support in their state. Currently, this training includes an exercise I developed in which participants are asked to use the CDC's organizational capacity assessment to rate potential National DPP organizations using provided scenarios. Using what we know from these studies we can now enhance this exercise to also include many CFIR *Inner* and *Outer Setting* constructs not currently captured in that capacity assessment, such as *Compatibility* and how the National DPP may fit into their organization services and workflows. In this same way, DTTAC will be able to use these findings to enhance the resources, tools, and trainings provided to improve program delivery.

There are many other ways in which this research can be applied in practice related to ongoing training and technical assistance. These findings support the efforts DTTAC and others working on the National DPP have made to focus on program access, enrollment, and retention in rural communities and non-

white populations. Our study 3 findings also point to virtual delivery modes to be linked to sustainability capacity and could also assist with reaching these populations of focus. DTTAC has provided a number of webinars and resources over the course of the pandemic to assist organizations with the transition to virtual delivery. And the participants in this study as well as other research indicate that these delivery modes are desirable for the numerous benefits they provide in terms of increasing access to the program (AuYoung, Damschroder, Kinsinger, Moin, & Richardson, 2017; Cannon, Ng, Lloyd, Reynolds, & Ely, 2022). This research also suggests that TA providers should prompt organizations to have discussions between leadership and staff to understand their similar or differing perspectives on program implementation and outcomes. TA providers can help organizations increase alignment between leadership and staff to ensure the program is prioritized and resourced to achieve programmatic success.

TA for the National DPP also should consider using the PSAT tool. With some additional formative evaluation to assess implementer satisfaction with the tool, the PSAT could be turned into a helpful teaching and planning tool for those who have been implementing the National DPP, particularly those who have completed 1-2 years of delivery and are at or close to full recognition. While the CDC's DPRP standards helps organization maintain their participant level outcomes, this tool can help the organization think through their organizational suitability capacity and how to maintain program delivery. Using this tool with National DPP organizations may be on opportunity to understand both of these aspects of sustainability. Furthermore TA can support organizations in areas of sustainability capacity weakness. Additional research may also test to see how well the PSAT tool can predict actual program sustainability.

More research is required to understand how internal and external organization factors influence implementation in order to continue to scale the National DPP. All three of the aims had a heavier emphasis on the *Inner Setting* compared to the *Outer Setting.* Study 1 did not identify any outer setting constructs as "distinguishing" or different between higher and lower reach organizations. Study 2 also did not find any significant paths between *Outer Setting* variables and enrollment. However, the outer setting

*c*onstruct, *Cosmopolitanism,* has appeared in National DPP studies focused on referrals from providers, health systems, and other community partners (Nhim et al., 2019; Vojta, Koehler, Longjohn, Lever, & Caputo, 2013). Study 2 and 3 did have organizational variables around funding and partnerships that could be considered part of *Outer Setting* constructs. In study 3, Funding Stability was the lowest rated domain on the PSAT and in study 2, availability of funding resources similarly was rated low relative to other items. In addition, in study 3, compared to the "low program sustainability" group, all of the other classes had on average 5.68 times (95% CI [1.21-27.07]) greater likelihood of having obtained grant funding to support their National DPP efforts. External partnerships was also one of the lowest rated PSAT domains and the CFIR items for cosmopolitanism were fairly neutral in their average ratings (indicating a lack of agreement in strength and breadth of partnerships). While in the qualitative study no outer setting constructs were distinguishing, obtaining funding and external partnerships were discussed in *Leadership Engagement* as important ways in which higher reach level organizations said their leadership actively support for the program. Additional research may be warranted to explore how the *Outer Setting* may affect the National DPP or other chronic disease programs. Likewise, future research should also include exploration of the other CFIR domains (intervention characteristics, process, and characteristics of individuals) to provide a holistic perspective on factors related to reach.

Another area of future research is to further refine CFIR measurement. Researchers have focused on different dimensions of CFIR constructs, often times based on relevant factors for the specific program. Related to the *Outer Setting* discussion above, one reason we did not see stronger relationships in our analyses may be due to not measuring the constructs well enough. For example, some of the organizational characteristics around funding sources are within the *External Policies and Incentives* construct. In fact, all of the organizational characteristics variables we collected could represent a number of CFIR constructs. In addition, some CFIR items that would have captured these constructs more robustly were cut to reduce the burden on participants, however this may have caused some of the measurement

limitations found. As CFIR measures are still in development and testing, it will require many more and larger applications like this to understand the most effective way to capture each of these domains, constructs, and sub-constructs. The developers of CFIR have announced a second version of the framework that may be helpful to use in subsequent studies (L. Damschroder, Reardon, Widerquist, & Lowery, 2022).

Additionally, more research needs to be done to define and measure implementation outcomes, especially when collecting data from implementers. My CFIR aims asked staff how constructs impacted "implementation" generally; however, it is not clear what staff believe "implementation" means. With the new CFIR implementation outcomes mapped on to previous outcomes from RE-AIM and the Implementation Outcomes Framework (L. J. Damschroder, Reardon, Opra Widerquist, & Lowery, 2022), future studies may need to more explicitly define the type of implementation outcome these constructs impact. My aims were focused on reach (defined by enrollment) and sustainability, which was often emphasized, but respondents may have also had different ideas of "implementation success", especially based on their length of delivery, which was not explored.

The first study of this dissertation was supported by CDC Division of Diabetes Translation's Innovations to Grow Enrollment and Retention (InGEAR) project. The other parts of that study were an examination of lifestyle coach practices. The interviews from study 1 have also been analyzed using the lifestyle coach codebook and incorporated into the lifestyle coach success model developed by the study team. DTTAC is using the findings from this project to enhance lifestyle coach training and ongoing development, as well as to understand the contextual factors in which program implementers operate. Proposed future work will include collaboration studies with other National DPP training entities like DTTAC to see if this model also applies to their implementer population, as well as research to test the model to see if this coaching model is in fact associated with programmatic success.

Limitations

There were a number of limitations with this body of work. The main limitation is with our recruitment sample. Due to many limitations at the CDC on what kinds of data can be collected and shared from those participating in the DPRP, it was necessary to separate our data collection from the CDC and use the Emory DTTAC network to recruit participants. While the DTTAC population is large and diverse, there may certainly be differences among those who are on the DTTAC contact list compared to the larger National DPP population of implementers. However, when comparing our respondent characteristics to the CDC DPRP data we received in November 2019 on the makeup of delivery organizations, our sample was similar to the national population with regards to average enrollment and the range and proportions of organization types and state locations.

The second limitation was the reliance on self-reported data, especially for our main outcome of interest, enrollment. It still unclear how many respondents had access to program records to provide the most up to date and accurate enrollment numbers. Furthermore, 40% of respondents indicated they did not know this information. Once again due to limitations with CDC data sharing it was not possible to verify numbers with DPRP records. However, even if this data was accessible, organizations only report their data every 6 months so there could have been challenges with alignment between CDC data and most recent organization data. Future studies may consider asking National DPP organizations to share with researchers their most recent CDC DPRP reported data so that if CDC verification can happen the numbers will match. If time and monetary resources were unlimited, I would have spent much more time reaching out to staff to provide program records/data and also complete survey data.

Other limitations included the inability to accurately track if more than one person from the same organization completed the survey. Organizations may have different DPRP registration IDs based on location, so it was not always clear even when the same organization was listed if they belong to the same registered organization. Only a handful of respondents were able to list their DPRP registration ID. This

would be another area where it would be helpful to have had CDC records to confirm information or to reach out to organizations based on their DPRP registration information. However, those data are not accessible based on CDC data user agreements with the registered organizations.

The analyses were also limited by the sample size and missing data. Although I was able to employ multiple imputation methods, it would have been more desirable to have access to complete and direct programmatic information from the DPRP database. It should be noted that all data from this study were from the perspective of implementation staff and therefore may be biased toward identifying these challenges and needs. Organization leadership may have a different perspective or emphasis. Future research may seek to more systematically sample respondents in different roles from the same organization. Regardless of these limitations, the hope is for this work to be a model to CDC and others evaluating this program for future studies that may engage a larger sample and more effective data collection methods.

While overall the CFIR was useful in my work and provided a foundation to explore the many dimensions of internal and external to organizations that impact implementation, it was not without limitations. This work may have been limited by the deductive approach in which CFIR was used to organize all data collected. There may be nuances of constructs or completely new constructs I missed to identify. I could have taken a more inductive approach, where I derived codes and themes from more open-ended interviews with implementers. I could have also used other theories/models to ground this work (e.g. organizational capacity models, etc.). However, there are always tradeoffs in approaches and I believe while imperfect CFIR was a good choice and allowed for comparisons to be made with other findings, given that CFIR is widely used in the public health implementation science field.

Lastly, given the disruption caused by the COVID-19 pandemic, it is hard to truly understand how much implementation and the responses of the participants were impacted. We have seen a largely in-person

program shift to virtual delivery overnight, multiple organizations stop program delivery all together, and new priorities to address the emergency situation overtake/overshadow diabetes prevention. While at the same time these changes have also opened up new opportunities for the National DPP in terms of virtual delivery modes. In both the qualitative and quantitative data collection participants were asked to think about pre and post pandemic implementation, but it is hard to say how well participants were able to compartmentalize those responses. For example, finding that virtual delivery increased sustainability capacity scores may be largely due to implementers feeling the virtual delivery modes have kept their programs afloat during the pandemic and that being able to adapt in these ways has strengthened their program.

Reflexivity

As a researcher I understand my prior and current experience, assumptions, beliefs, and other roles influence the work at hand. Before starting this dissertation, I worked to provide technical assistance to organizations implementing the National DPP in various settings. These experiences, along with the scientific literature, provided me with the context to ask the research questions in this dissertation and informed my hypotheses. While conducting this dissertation research, I have also been involved in providing training and technical assistance for DTTAC for a variety of National DPP stakeholders. To help reduce biases in my methods and interpretations, I conducted my qualitative and quantitative analyses with partners not involved directly with DTTAC and generally unfamiliar with the National DPP. In addition, none of my committee members are a part of DTTAC, and only one is a subject matter expert on the National DPP. This provided grounding and help check any preconceived assumptions or insights. DTTAC team members were involved only during the development of the data collection instruments and recruitment of participants. In addition, I avoided working on DTTAC projects that involved similar topics and refrained from sharing my findings with others at DTTAC until they were sufficiently concluded.

Conclusion

My research sought to identify and understand factors beyond the components of the intervention itself that impact successful delivery and outcomes. Using the National DPP to examine the organization and structural levels, this research was able to explore influences and predictors of two implementation outcomes: reach and sustainability capacity. Reach can help assess the level of impact an intervention may have by how many the intervention touches and sustainability helps us to understand how to best leverage this impact over time. Both of these outcomes must be successful in order for the National DPP to make a true impact on diabetes prevention in this country.

It is clear that National DPP implementers must continue to ask questions around the internal and external environments that lead to successful program delivery and outcomes. This work has found that there are multiple factors that may be influential and provide insight into ways in which implementation training and capacity building must emphasize. It is not enough to know this is an evidence-based intervention that can be successful in any organization type, but implementers need to carefully think through *how* their organization can best adopt, support, and maintain this program. What kinds of organizational systems will need to be in place? How many staff are needed? How should leadership best engage with the program to ensure success? What funding and support are needed from external partners? How will these factors differ based on where and with which populations we delivery the program? How do organizations ensure continued delivery in times of crises? These are essential questions to continue to ask in future research and practice in order to provide new tools, resources, and guidance to support National DPP adoption, organizational capacity building, and organizational sustainability.

This work contributes methodologically to the implementation science literature, both in study design and measurement. This dissertation also provides new insights into the delivery of the National DPP and will directly impact training and technical assistance provided to delivery organizations to continue to support capacity building and its scalability.

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