Implementation Context of Food Insecurity Screening Initiatives in Primary Care:

A Multiple Case Study

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THESIS

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Naoko Muramatsu, Chair and Advisor Angela Odoms-Young, Applied Health Sciences, Co-Chair Nadine Peacock, Associate Professor of Community Health Sciences Michael Fagen, Northwestern University Feinberg School of Medicine Courtney Suh, Loyola University Medical Center This thesis is dedicated to my loving daughter, Naima, who gives me purpose and strength every day. I could never have accomplished this without her asking me *every single day*, "Are ya done yet?" Thank you, Naima, for your unwavering support and for pushing me to complete my life's work.

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| CHAPTER | PAGE |
|--|---------|
| | <u></u> |
| I. INTRODUCTION | 1 |
| | |
| II. BACKGROUND | |
| A. Prevalence of Food Insecurity in the United | |
| B. Underuse of Food Assistance Programs C. Primary Care Clinics as Connectors to Food | |
| D. Application of Implementation Science Res | |
| E. Statement of the Problem | |
| F. Specific Aims | |
| G. Significance of This Study | |
| H. Summary | |
| | |
| III. METHODS | |
| A. Design Overview | |
| B. Adapted Consolidated Framework for Imple | |
| C. Setting | |
| D. Selection of Two Cases | |
| E. Selection of Key Informants that Provided D | |
| F. Qualitative Data | |
| G. Human Subjects Protection | |
| H. Data Management and Analysis I. Methods to Enhance Rigor | |
| | |
| IV. RESULTS OF PRORGRAM A | 35 |
| A. Overview | |
| B. Results of Theoretical Sampling of Key Info | |
| C. Background of Program A | |
| D. Overview of Program A | |
| E. Implementation Factors for Program A | 43 |
| | |
| V. RESULTS OF PRORGRAM B | |
| A. Overview | |
| B. Results of Theoretical Sampling of Key Info | |
| C. Background of Program B | |
| D. Overview of Program B | |
| E. Implementation Factors for Program B | 01 |

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

| CHAPTER | PAGE |
|--|----------|
| VI. CROSS CASE ANALYSIS A. Overview B. Cross-Case Implementation Themes C. Unique Implementation Themes | 70 70 |
| D. Cyclical Implementation Process | |
| VII. DISCUSSION A. Overview | |
| VIII. CONCLUSION | 91 |
| CITED LITERATURE | 93 |
| APPENDICES Appendix A Appendix B | 97 |
| VITA | 113 |

LIST OF TABLES

| TABLE | PAGE |
|---|------|
| I. STUDY CASES | 26 |
| II. PROGRAM A: STUDY CLINICS | 38 |
| III. PROGRAM A: INTENDED SCREENING AND FOOD DISTRIBUTION PROCESSI | ES41 |
| IV. PROGRAM A: IMPLEMENTATION THEMES (FACILITATORS/BARRIERS) | 44 |
| V. PROGRAM B: STUDY CLINICS | 54 |
| VI. PROGRAM B: INTENDED SCREENING AND FOOD DISTRIBUTION PROCESS | ES59 |
| VII. PROGRAM B: IMPLEMENTATION THEMES (FACILITATORS/BARRIERS) | 62 |

LIST OF FIGURES

| FIGURE | | PAGE |
|---|--|--------------|
| 1. Clinical food security screening and | d referral algorithm | 10 |
| 2. Consolidated Framework for Imple | mentation Research (CFIR) | 17 |
| 3. Multiple case study design and tim | eline | 22 |
| 4. Adapted Consolidated Framework | for Implementation Research | 23 |
| 5. Theoretical sampling approach | | 27 |
| 6. Methods crosswalk | | 31 |
| 7. Data interpretation framework | | 32 |
| 8. Healthcare organization hierarchy | of key informants: Program A | 37 |
| 9. Stage 1 recruitment process: Prog | ram A | 37 |
| 10. Stage 2 recruitment process: Pro | gram A | |
| 11. Intended screening through referr | ral pathway: Program A | 42 |
| 12. Healthcare organization hierarchy | / of key informants: Program B | 53 |
| 13. Stage 1 recruitment process: Prog | gram B | 53 |
| 14. Stage 2 recruitment process: Prog | gram B | 54 |
| 15. Intended screening through referm | ral pathway: Program B | 61 |
| 16. Conceptual model for implementa | ation of screening initiatives in primary care | e practice77 |

LIST OF ABBREVIATIONS

| AHE | Illinois Public Health Institute Alliance for Health Equity |
|-------|---|
| CFIR | Consolidated Framework for Implementation Research |
| СМ | Clinic Manager |
| EHR | Electronic Health Records |
| EMR | Electronic Medical Records |
| FI | Food Insecurity/Food Insecure |
| MD | Physician |
| MSW | Medical Social Worker |
| ΡΑ | Physician Assistant |
| PD | Policy Director |
| РМ | Program Manager |
| RD | Registered Dietitian |
| SIREN | Social Interventions Research and Evaluation Network |
| SNAP | Supplemental Nutrition Assistance Program |
| SDOH | Social Determinants of Health |
| SW | Social Worker |
| T2D | Type 2 Diabetes Mellitus |
| USDA | United States Department of Agriculture |

SUMMARY

Food insecurity (hereafter, FI) is an economic condition where access to nutritious food prevents individuals from leading active and healthy lives. Food insecurity is associated with poor nutrition, diet-related health conditions and adverse health outcomes. The cost to treat FI related health conditions is roughly \$160 billion dollars a year. Federal, state and local food assistance programs remain underutilized because at-risk patients cannot gain access to them. Emerging research points to the unique and critical role primary care providers can play to help FI patients navigate participation barriers.

What has evolved are food insecurity screening and referral initiatives in clinical settings where primary care providers act as connecters to food assistance programs. Together, a healthcare organization and food assistance program form a clinical-community partnership to address FI in low-income patient populations. Providers screen for food insecurity during routine patient visits and refer patients to their food assistance partner program that provides immediate and long-term access to food, as well as wrap-around services (e.g. enrollment in federal benefits such as the Supplemental Nutrition Assistance Program (SNAP).

The high demand for these programs has resulted in partnership programs that have developed rapidly and organically across different healthcare settings. Even though the major components for these programs have been identified (i.e. screening, referral to food assistance programs and enrollment in SNAP benefits) standard practices for how these components are implemented have yet to be developed. This limits program upscale and the ability to measure program effectiveness.

With the knowledge that the healthcare organization drives program implementation, this study explored implementation factors at multiple levels within the healthcare organization and the surrounding community.

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SUMMARY (Continued)

The key take away from this study is that because healthcare organizations have limited resources to dedicate to food insecurity screening initiatives, primary care practices need to be supported in their ability to implement programs in a feasible way. In this study, the high level of adaptability and testability of food insecurity screening initiatives allowed each case to implement their program using existing financial and human capital, as well as structural support. All of which was enhanced by each unique context.

One program facilitated ongoing adaptation by leveraging existing cross-sector collaborations, which enhanced financial resources, physical space and program expertise. The other program's culture of clinic-level autonomy allowed program leaders to implement the intervention in a way that maximized existing staff capacity, physical space and patient needs. Both factors enhanced existing program resources and strengthened the adaptability and testability of program activities. Future studies may continue to build on and refine the proposed conceptual model, which is formative in nature and sets the stage for development of standard program practices.

As the U.S. healthcare system continues its transition to a value-based model of care, public health researchers, healthcare practitioners and policy makers need to consider how primary care focused FI initiatives can effectively connect patients to food assistance programs.

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I. INTRODUCTION

Food insecurity (hereafter FI) is an economic condition where access to nutritious food prevents individuals from leading active and healthy lives (United States Department of Agriculture Economic Research Services, 2016a). Some of the highest rates of food insecurity in the United States can be found in the South and West side communities of Chicago and nearby suburban Cook County where up to 85 percent of residents are at risk (*Healthy Chicago 2.0 Partnering to Improve Health Equity 2016-2020.*2016a). Food insecurity is associated with poor nutrition, diet-related health disparities (Seligman & Schillinger, 2010b).

Although federal benefits programs (e.g. Supplemental Nutrition Assistance Program) and local food assistance programs have been proven to reduce household food insecurity, these programs remain underutilized by those communities most in need (United States Department of Agriculture Economic Research Services, 2016a). To address this problem, healthcare organizations have started partnering with local emergency food access programs (Barnidge, Stenmark, & Seligman, 2017). Among healthcare providers, primary care providers demonstrate the most potential to act as connecters between food insecure patients and food assistance programs because they are likely to encounter chronic food insecurity among patients during their routine primary care visits (Gupta, Boland Jr, & Aron, 2017a). In the food insecurity screening program implemented in a primary are setting, the provider is responsible for identifying food insecure patients with the validated Hunger Vital Signs[™] tool. Positively screened patients are referred to emergency and long-term food access programs provided by one or more food assistance program partner(s) (Lundeen et al., 2017b).

The problem is that due to their rapid and organic evolution, we do not know how food insecurity screening programs are implemented in primary care practice (San Diego Hunger Coalition, personal communication, February 5, 2018; Social Intervention Research and Evaluation Network (SIREN), personal communication, March 3, 2018a).

1

Standard practices have not been developed yet and program activities, actors, implementation processes and program outcomes vary across primary care settings (Lundeen et al., 2017b).

The lack of standard practices ultimately limits program replication on a broader scale. (San Diego Hunger Coalition, personal communication, February 5, 2018; Social Intervention Research and Evaluation Network (SIREN), personal communication, March 3, 2018b). The limited evidence about implementation processes suggests that we need to study how these programs operate in the real-world setting.

This research examined how primary care situated food insecurity screening programs operate within their clinical and community contexts. An embedded, multiple-case study design was used to examine two food insecurity screening programs and implementation factors across five clinics in Chicago and suburban Cook County. Some of the highest rates of food insecurity in the United States can be found in the South and West side communities of Chicago and nearby suburban Cook County where up to 85 percent of residents are at risk (*Healthy Chicago 2.0 Partnering to Improve Health Equity 2016-2020*.2016a). An adapted Consolidated Framework for Implementation Research (Damschroder et al., 2009a) guided the process of organizing and analyzing the data from semi-structured interviews with 19 people who implemented the program. Program activities, implementation actors and the implementation barriers and facilitators were identified in each program. A cross-case analysis identified common themes and unique contextual factors. The results were summarized in a conceptual model.

This study is significant, because its findings and resulting conceptual model can serve as a foundation for developing standard practices. The findings pave the way for future effectiveness trials, program upscale and policy development.

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Study results also contribute to an ongoing effort to address food insecurity, reduce health disparities and improve overall quality of life among diverse patient populations.

II. BACKGROUND

This chapter provides a background of FI the United States and associated health disparities. The chapter describes the underuse of federal and local food assistance programs as a contributing factor to persistent FI and the emergence of clinical food insecurity screening programs in primary care practice to connect patients to these programs. The current literature and knowledge gaps in primary care situated FI screening initiatives are then identified. This chapter concludes with the dissertation research question and specific aims that help to address gaps in research.

A. Prevalence of Food Insecurity in the United States

Food insecurity affects close to 33.5 million Americans (United States Department of Agriculture Economic Research Services, 2016b). It is an economic condition at the household level where access to nutritious, affordable and safe food prevents individuals from leading active and healthy lives (United States Department of Agriculture Economic Research Services, 2016). Food insecurity is characterized by the limited or uncertain availability of nutritionally adequate and safe foods or limited and uncertain ability to acquire acceptable foods in socially acceptable ways. The biggest contributor to FI is unemployment and job loss (United States Department of Agriculture Economic Research Services, 2016c).

U.S. households most affected by FI are low-income, ethnic and minority communities (Gundersen, Engelhard, Crumbaugh, & Seligman, 2017b). Twenty-two percent of Black, non-Hispanic households, 18.5% of Hispanic/Latinx households and 9.8% of white households are affected by FI (United States Department of Agriculture Economic Research Services, 2016d).

Economic factors are associated with FI are: 1) The limited number of full-service grocery stores and farmers markets available in low-income neighborhoods that offer fresh, high-quality fruits, vegetables, whole grains, and low-fat dairy products.

2) The high-cost of healthy, nutritious food; 3) the prevalence of cheaper, less healthy alternatives, such as fast food and convenience store food in low-income neighborhoods; 4) limited education about and preferences for healthier, more nutritious food; 5) the cyclical pattern of FI, which is characterized by frequent highs and lows in the household budget that affect dietary patterns and the quality of food purchased and consumed; 6) other issues common in low-income communities such as neighborhood violence, racism and poor quality housing that may lead to weight gain through stress-induced hormonal and metabolic changes in children and adults; 7) limited access to regular healthcare in low-income communities due to financial constraints or lack of insurance, which prevents the early diagnosis and regular management of poor diet-related health outcomes (Adam & Epel, 2007; Laraia, Vinikoor-Imler, & Siega-Riz, 2015; Leung, Epel, Willett, Rimm, & Laraia, 2015; Liu, Njai, Greenlund, Chapman, & Croft, 2014; McLaughlin et al., 2012; Poole-Di Salvo, Silver, & Stein, 2016; Pooler, Levin, Hoffman, Karva, & Lewin-Zwerdling, 2016a; Seligman et al., 2010a; Seligman & Schillinger, 2010b; Stults-Kolehmainen & Sinha, 2014; Tomiyama et al., 2010; Torres & Nowson, 2007).

Regular consumption of poor quality food contributes to poor dietary health, chronic illness (e.g. obesity, diabetes (T2D), pre-diabetes, hypertension and cardiovascular disease), difficulty with chronic disease management and overall poor quality of life (Seligman, Laraia, & Kushel, 2010; United States Department of Agriculture Economic Research Services, 2016e). Studies show that FI adults have twice the odds (95% CI: 1.1, 4.0) of acquiring T2D compared to their food secure counterparts and 32 percent greater odds (95% CI: 1.17, 1.50) of becoming obese (Pan, Sherry, Njai, & Blanck, 2012; Seligman, Bindman, Vittinghoff, Kanaya, & Kushel, 2007). Food insecure individuals also have 20 percent greater odds (95% CI: 4, 38) of self-reported hypertension (Seligman et al., 2010b). In children, FI is correlated with birth defects, cognitive and behavioral problems, as well as asthma and nutrition deficiencies (such as iron deficiency anemia) (Gundersen & Ziliak, 2015).

It is especially critical to address FI for those individuals currently managing diet-related chronic illnesses. Even periodic disruptions in high quality nutrition can have a negative impact on health outcomes (Pooler et al., 2016b).

B. Underuse of Food Assistance Programs

Emergency and non-emergency food assistance programs have been shown to offer a variety of support services and safety nets that improve food availability within FI communities if used regularly (Browne, 2017a; McSpadden et al., 2016). Yet, many of these programs remain underutilized by those communities most in need.

Research shows the chronic underuse of evidence-based, federal benefits programs such as SNAP, (the largest USDA welfare program (Nestle, 2019a)), the Special Supplemental Nutrition Assistance Program for Women's Infants and Children (WIC) and local emergency food pantries is linked to stigma attached to using welfare programs. Limited awareness about their existence and how to navigate complex enrollment processes also contribute to underuse (Browne, 2017b; Gilbert, Nanda, & Paige, 2014a; Neff, Palmer, McKenzie, & Lawrence, 2009a; United States Department of Agriculture Economic Research Services, 2016f).

Strict eligibility requirements also exclude almost a quarter of food insecure individuals that earn too much from participating in federal benefits programs (often times as little as one to two dollars more per month is making too much) (Browne, 2017c; Gilbert, Nanda, & Paige, 2014b; Neff, Palmer, McKenzie, & Lawrence, 2009b; United States Department of Agriculture Economic Research Services, 2016g).

The current administration's suggested federal cuts to the SNAP budget could also exacerbate this problem. In an effort to motivate underemployed Americans to seek long-term employment, current benefits recipients between the ages of 18-49 years old without dependents will need to provide proof of employment every three-months to continue receiving benefits (Nestle, 2019).

It is highly likely that recipients with disabilities that limit work opportunities or individuals that earn their income through non-traditional employment (e.g. short-term or seasonal work difficult to document) will lose their SNAP benefits entirely. Some may be required to reapply for benefits when they are eligible again, which is already a deterrent to participation.

C. Primary Care Clinics as Connectors to Food Assistance Programs

Emerging research points to the unique and critical role primary care providers can play to help FI patients navigate participation barriers. Doctors can connect at-risk patients to food assistance programs through FI screening and referrals to SNAP, WIC and local food pantries during routine check-ups and regular visits for chronic illnesses. This process may improve dietary health and disease management in FI patients (Barnidge, LaBarge, Krupsky, & Arthur, 2017; Browne, 2017d; Schroeder & Smaldone, 2015; Shih, Holben, & Holcomb, 2004; Tscholl & Holben, 2006).

As the U.S. healthcare system shifts towards a value-based model of care to reduce healthcare utilization and the high cost to treat poorly managed chronic illnesses, the Centers for Medicare and Medicaid Services has increased its pressure on primary care practices to address social determinants of health. It is estimated that it costs the U.S. healthcare systems \$160.7 billion a year to treat FI related health conditions (Cook & Poblacion, 2015b). An additional \$41.07 billion can be attributed to indirect costs related to FI such as loss of job productivity, mental health problems, hospitalizations and special education needs (Cook & Poblacion, 2015c).

A California-based study showed that close to half of all patients that visited safety-net clinics were FI (Seligman, Tschann, & Jacobs, 2012). Low-income communities experience dietary-health disparities similarly across the board and we can assume that these study results are reflective of other safety-net clinics across the U.S.

In recent years primary care safety-net and free community clinics have bypassed Emergency Rooms for basic, free health services in low-income Medicaid and uninsured patient populations (Darnell, 2010). Chronic disease management and Social Determinants of Health (hereafter SDOH), such as FI, are common issues addressed in these settings. And unlike emergency room visits, free clinics serve as a medical home for the uninsured, underserved and the working poor (Gertz, Frank, & Blixen, 2011).

There is an opportunity to address FI specifically during routine visits in these clinics. Food insecurity is typically a hidden condition that lacks physical or laboratory indicators, it is difficult to identify unless asked about directly and frequently (Cutts & Cook, 2017b). Primary care providers that have established trust and a working relationship with their patients are in a unique position to identify patients in need and to talk to them frequently about FI and patient use of food assistance program (Steglitz, Sommers, Talen, Thornton, & Spring, 2015).

Prominent healthcare research and advocacy groups also notice the potential of primary care practice to address FI. Several nationally recognized professional groups support universal food insecurity screening and referral in primary care practice. The American Academy of Pediatrics released a policy statement in 2015 that advocates for food security screening and referral in primary care pediatric settings, the cost of which would be covered by healthcare payers. The American Diabetes Association, the American Academies of Family Physicians and the Institutes of Medicine have followed suit with similar recommendations. (Billioux, Verlander, Anthony, & Alley, 2017; Dubowitz, 2002; Garg, Toy, Tripodis, Silverstein, & Freeman, 2015; Health Leads, 2016; OCHIN, 2016).

Overall, research examining the process of clinical food insecurity programs has been limited.

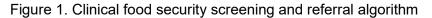
To provide guidance for food insecurity program development and implementation in clinical settings, an algorithm was developed by the Centers for Disease Control and Prevention (CDC)-funded Nutrition and Obesity Policy Research and Evaluation Network (NOPREN). The two major components of the algorithm are circled in Figure 1.

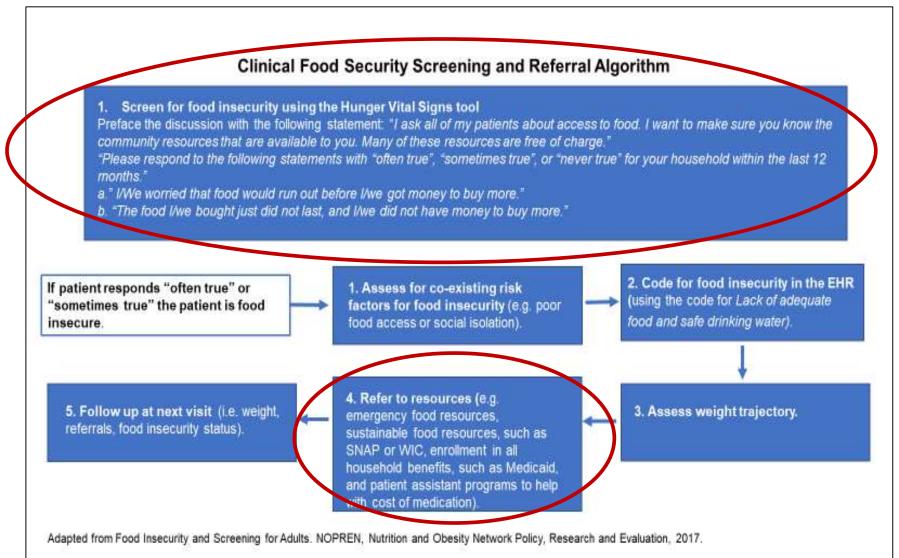
The first recommendation is to screen for food insecurity using the 2-question Hunger Vital Sign[™] tool, developed by Children's HealthWatch, specifically designed for clinical food insecurity screening (Rottapel & Sheward, 2016). This tool is based on the U.S. Department of Agriculture (USDA) Food Security module, which is the gold standard screening instrument for food security screening that has been validated with low-income populations of all ages. (Baer, Scherer, Fleegler, & Hassan, 2015; Gundersen et al., 2017c; Hager et al., 2010).

The screening questions require patients to respond to the following statements: 1) "Within the past 12 months we worried whether our food would run out before we got money to buy more." 2) "Within the past 12 months the food we bought just didn't last and we didn't have money to get more." Responses of, "often true" or "sometimes true" (vs. "never true") are classified as at risk for food insecurity (Rottapel & Sheward, 2016).

The second major recommendation in the algorithm is to refer patients to available food support services, including emergency food resources and enrollment in federal benefits programs. Patient follow-up should occur at subsequent visits to assess food insecurity status and improvements in dietary health and/or disease management.

Grassroots programs comprised of two entities, individual healthcare systems and diverse emergency and/or non-emergency food assistance programs, have emerged onto the healthcare landscape in response to national screening and referral program recommendations. Programs have implemented the screening and referral processes in different ways across healthcare settings and standardized program practices have yet to be identified (De Marchis et al., 2019).





A healthcare system is defined as at least one hospital and at least one group of physicians that provides comprehensive care. These are primary care or other specialty care either at the hospital or associated clinics/hospitals that are all connected through common ownership or joint management (Agency for Healthcare Research and Quality, n.d.).

Emergency food banks collect and supply food to local partner agencies that run food drives, soup kitchens and mobile food distribution or pop-up pantries to meet the immediate food needs of FI patient populations. Non-emergency food assistance partners include urban garden collectives, farmers markets, food retail programs and meal delivery services that provide a longterm supply of healthy food to patients. The food supplied for all food assistance programs is either purchased, donated or part of federal government programs and is collected from farmers, manufacturers, food retailers and wholesalers.

Together, a healthcare organization and food assistance program form a clinical-community partnership to address FI in low-income patient populations. FI screening and referral is the responsibility of the healthcare organization. Access to emergency and non-emergency food assistance is provided by the food partner. One or both entities have been found to refer patients to SNAP enrollment processes. (Lundeen et al., 2017c). Clinical FI initiatives are sometimes supplemented with cooking classes, nutrition education and chronic disease management counseling.

According to A. Shultz, Senior Director of Programs at the San Diego Hunger Coalition and one of the leading experts in the field (personal communication, March 20, 2018), high demand for these programs has resulted in partnership programs that have evolved rapidly and organically across different healthcare settings. Many of these programs apply a range of program strategies and evaluation mechanisms. Even though the major components for these programs have been identified (i.e. screening, referral to food assistance programs and enrollment in SNAP benefits) standard practices for how these components are implemented have yet to be developed. An environmental scan of existing programs across the United States illustrated this point and documented the extent to which programs varied (Lundeen et al., 2017d) The scan identified 22 clinical FI screening programs from geographically diverse areas across the U.S. Programs provided FI screening, referrals to food resources and targeted patients of all ages including seniors. The study used qualitative data in the form of stakeholder interviews with program leaders and document analysis to learn about the different types of initiatives that existed. The study revealed that programs varied by critical program elements including, target patient population and food assistance intervention, as shown below.

Most programs (n = 18) targeted FI patients of all ages. Some programs specifically targeted patients 50 years old and older (n = 7). Close to half the programs addressed FI among children and addressed FI in patients aged 50 years or older (n=10).

The environmental scan found most programs routinely screened for FI (n=14). More than half of all programs focused on chronic disease management (n=13) and more than half partnered with a local food bank (n=12).

The most common type of food intervention was a referral to a list of food resources (n=19).

This program activity was commonly observed alongside other activities, such as a patient navigator to help connect patients to local food resources (n=15) and assistance with federal benefits enrollment (n = 14). Some programs offered patient education and skill building to improve dietary health for disease management in addition to referrals (n = 13). A lesser number of interventions offered direct access to healthy food. In that category, it was common for programs to provide patients with fruit and vegetable vouchers to redeem at farmers markets along with the referral to local resources (n = 8). Standard program practices could not be identified across the 22 interventions.

A wide range of process and program outcomes were used to assess primary care focused food insecurity initiatives.

A systematic review assessed 23 clinical FI intervention studies that were conducted in the U.S. (De Marchis et al., 2019a). Intervention process outcome categories varied among studies with a combination of one or more of the following measurements: Number of patients referred to food assistance or federal food benefits programs (n=6); Number of patients that contacted the referral agency (n=5); Number of patients enrolled in food assistance or federal benefits program (n=6); Use of food assistance programs (n=8); Farmers market revenue (n=1) (De Marchis et al., 2019).

Intervention outcome categories varied among studies with a combination of one or more of the following measurements and not all studies provided program outcomes results. A small number of studies assessed the reduction in FI (n=2); improvement in patient health outcomes (n=5); improvement in patient dietary behavior or self-efficacy for healthy eating (n=4); and/or a reduction in healthcare utilization (n=2) (De Marchis et al., 2019c).

Program outcomes most likely differed because patient needs varied across interventions. Some pediatric interventions targeted caregivers of pediatric patients (n=9), while only one study targeted adolescents themselves.

The majority of those that had a chronic disease management component focused on changes in diabetic patients' blood sugar levels (n=4). One study looked at blood pressure management during pregnancy, while another assessed the change in dietary behavior of adult cancer patients (De Marchis et al., 2019d).

In those cases where outcome categories were similar across different interventions, the metrics differed, as did program effectiveness. For example, two programs addressed prenatal nutrition needs of pregnant women. One intervention, a referral program that targeted pregnant women, evaluated program effectiveness with small, but significant improvements in maternal blood pressure control during pregnancy (Morales, Epstein, Marable, Oo, & Berkowitz, 2016).

The other intervention provided nutrition education, cooking classes and farmers market fruit and vegetable vouchers to pregnant women. Program effectiveness was measured with assessments of maternal dietary health, in addition to mental health with the standard Patient Health Questionnaire, maternal weight gain, breasting feeding at six months after birth and infant development with the use of the standard Ages and Stages Questionnaire. There were no significant effects on infant and maternal health as a result of this intervention (Watt, Appel, Lopez, Flores, & Lawhon, 2015).

The systematic review also revealed that different types of research designs were employed to measure program effectiveness across studies. This included randomized control trials (n=2) cluster randomized control trials (n=1), quasi-experimental studies (n=2), matched cohort studies (n=3), single cohort, pre-/post- studies (n=8); descriptive, mixed methods, or qualitative designs (n=7).

In sum, the emerging literature on primary care focused FI initiatives indicates that program interventions and patient population vary greatly. The evaluation research of this rapidly growing area of practice uses a variety of metrics and outcomes across.

This variation makes it difficult to compare primary care focused FI programs and their outcomes, which limits the development of standard practices for widescale dissemination.

D. Application of Implementation Science

Thus far, the literature on primary care focused FI initiatives is limited in terms of theoretical understanding about how specific clinical FI initiatives have evolved and why they differ so greatly. Clinical FI practices have been largely guided by national screening and referral recommendations or broad principles that have been interpreted in many ways, as demonstrated in the literature.

Theory is "a set of interrelated concepts, definitions, and propositions that present a systematic view of events or situations by specifying relations among variables in order to explain and predict the events or situations," (Glanz, Rimer, & Viswanath, 2008a, p. 26). Intervention designs grounded in theory can yield desirable changes in behavior and health outcomes.

They can be empirically tested in real world contexts to standardize design, implementation and evaluation efforts that can be disseminated on a larger scale. Moreover, program adaptations that accommodate different contexts and settings can be explained by the intervention's theoretical underpinnings (Glanz et al., 2008b).

To address this theoretical gap, I propose implementation science as a useful framework for promoting implementation, scale-up and dissemination of primary care focused FI initiatives. This framework helps us understand that program adaptations are determined by implementation factors found in real-world contexts (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005).

In implementation science, theory derived frameworks are used to study implementation context—specifically how multilevel systemwide factors (e.g. individual level organizational level) and multisector factors (i.e. policies, external partnerships and community needs) interact and determine the quality of implementation outcomes (Damschroder et al., 2009b).

Findings from implementation science studies allow researchers to hypothesize the relationships between implementation factors. These contextual variables can be tested in other settings where program adaptations maybe considered and that lend themselves to widescale dissemination of evidence-based practice (Damschroder et al., 2009c). There is an opportunity to apply implementation science in the context of clinical FI initiatives because exploration of theoretical underpinnings of implementation have not been explored in this way yet.

Implementation science research has been supported in several healthcare research studies, most notably by the National Institutes of Health for a variety of social and behavioral health research, such as tobacco cessation and diabetes prevention. The purpose of these studies was to understand how the complex and interdependent sociocultural, economic and political factors within the implementation context affected the process of program implementation. Ultimately, researchers used findings to determine how to effectively disseminate and adapt these programs into other healthcare settings and contexts (Damschroder et al., 2009d; Glasgow et al., 2012)

The Consolidated Framework for Implementation Research (hereafter CFIR) is an implementation determinants framework comprised of theoretically derived constructs. It has been empirically tested and is widely used in healthcare settings to understand multidimensional, interrelated implementation barriers and facilitators within specific healthcare organizations (Figure 2) (Damschroder, 2020a; Kirk et al., 2016; Li, Jeffs, Barwick, & Stevens, 2018).

The framework is broad with over 30 constructs. When used to map implementation factors, CFIR can help researchers establish a foundation from which theoretically driven semantic relationships between implementation factors can be constructed. Hypothesized relationships between constructs can be used to develop a conceptual model that describes the implementation of a specific intervention.

Conceptual models are used to explain a specific problem within specific settings and contexts with the intent of generalizability (Glanz, Rimer, & Viswanath, 2008). The resulting conceptual model can be tested and refined in follow-up studies (Damschroder, 2020b).

The framework is made up of implementation drivers that are categorized into five domains: 1) The intervention characteristics that point to the quality of the program, compatible design, its cost and adaptability across settings. 2) The inner setting, which directly relates to the physical and cultural setting where daily program processes occur. 3) The outer setting, which refers to any factor external to the program itself, including community needs, influences, local mandates, policies or regulations that affect implementation processes. 4) Characteristics of program staff/individuals, which are their knowledge and beliefs about the program from their own perspective. 5) Implementation processes, which include the steps used in planning, execution and ongoing management of the program (Damschroder et al., 2009e). The clinical FI screening literature lacks a conceptual model that explains why and how the program variations that we see across healthcare settings came to exist is missing. Consequently, program effectiveness is difficult to measure and standard practices are difficult to identify. A conceptual model is needed to highlight the multifaceted and dynamic factors that affect the implementation of these programs. (Aiyer et al., 2019).

An opportunity exists to build on previous research with the use of CFIR to map implementation barriers and facilitators across different primary care settings. Similar implementation themes that emerge maybe used to develop a foundation for a conceptual model that guides implementation in primary care settings. We can assume that the healthcare organization drives program design and implementation processes and therefore needs to be further studied.

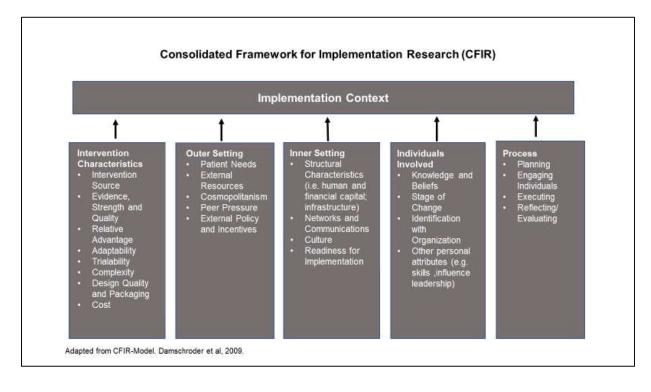


Figure 2. Consolidated Framework for Implementation Research (CFIR)

E. Statement of the Problem

Primary care situated FI initiatives have become increasingly prevalent in low-income communities to link FI patients to food assistance resources. Yet, little is known as to how these programs are implemented in primary care practice. This study addressed this gap of knowledge using a case study of FI screening programs implemented in primary care settings. Findings were used to build a conceptual model that can be used to guide implementation. An overarching research question was: how clinical FI initiatives implemented in primary care settings?

F. Specific Aims

The aims of the study were as follows:

Aim 1: To identify program activities, actors and the process of implementation for these programs. Aim 2: To identify implementation barriers and facilitators.

Aim 3: To conduct a cross-case analysis to identify common themes and unique contextual factors across primary care settings.

Aim 4: To present how implementation themes are related with a conceptual model that can help guide program implementation.

G. Significance of This Study

Primary care focused food insecurity screening initiatives are one way to link under resourced communities to healthy food. It is a part of a larger effort to achieve social justice and health equity. Study findings help us understand how these programs are implemented in primary care practice. The conceptual model proposed in this study establishes a foundation for standard practices that can be built upon, tested and further refined. This study contributes to ongoing policy efforts that look to implement food insecurity screening programs into routine primary care practice

<u>H. Summary</u>

The literature reviewed in this chapter indicates that there remains a gap of knowledge about how to implement FI screening programs in primary care practice. There is a need to develop standard practices that can further program expansion. The purpose of this dissertation research was to understand how implementation of these programs occur across healthcare settings.

III. METHODS

A. Design Overview

This study used an embedded multiple case study design. This design is appropriate for the purpose of examining how the phenomenon of interest functions within different contextual and physical conditions. A case is "a phenomenon of some sort occurring in a bounded context," (Merriam, 1998a, p.27). In this study the phenomenon of interest was primary care situated FI programs. An embedded multiple case study design was used to describe the implementation processes of two programs and to examine how the healthcare and surrounding community context affected implementation processes.

The embedded nature of this study refers to the multiple units of analyses within each case (Yin K., 2018b, p. 52). Previous implementation research of healthcare focused partnership programs illustrated implementation challenges at multiple levels within the program setting that included clinicians at the micro clinic level where implementation actively occurred. Program resources, technology and infrastructure, also identified as implementation barriers, were at the macro, systems level. Therefore, each case in this study is a partnership program and units of analysis are program stakeholders from various levels within the healthcare organization.

Each healthcare organization in the United States is a complex organization with its own governing body, internal politics and funding mechanisms that dictate the culture of care, which patient services are prioritized, and how patient care is delivered. Therefore, specific program components and implementation processes are a result of the people, context or condition bounded within the healthcare organization, its local patient population and neighborhood context.

Preliminary discussions with program leaders prior to this study validated this assertion. Their experiences indicated that the healthcare context drove how their partnership programs were implemented. Food access organization partners were willing to tailor their existing initiatives to the clinical environment, organizational politics and the local patient population. Program leaders also reported that implementation hinged on factors such as: the services that the food organization provided—whether it was home delivered meals, onsite food distribution at the community clinic and cooking demonstrations, nutrition classes, etc. External factors, such as local politics, community needs, neighborhood characteristics or federal mandates (e.g. national healthcare shift to EMR, changes to SNAP eligibility requirements, etc.) also contributed to how program activities were designed and implemented.

The multiple case study was used to explore screening programs situated in primary care practice that had been executed in in Chicago and suburban Cook County. The rationale for the application of this design was to understand how implementation occurred across different program settings that have been effectively implemented within their natural, contemporary settings with no control over the course of events.

Each case's findings is presented intact to illustrate a clear picture of how each program operates within its specific context and organization (Stake, 2006 p. 6a). Results of a cross-case analysis that emphasize the similarities and differences in program process themes were also examined, taking into consideration the complexity and uniqueness of each case to gain a deeper understanding of the phenomenon of interest (Figure 3) (Stake, 2006, p. 6b). The binding program concepts were used to make a final assertion or recommendation for a guiding conceptual model for program implementation.

B. Adapted Consolidated Framework for Implementation Research

This framework was used in this study and adapted to fit the study context. The adapted framework is illustrated in Figure 4. Constructs were added to the a priori codebook that represented CFIR domains and constructs during data collection (Appendix A).

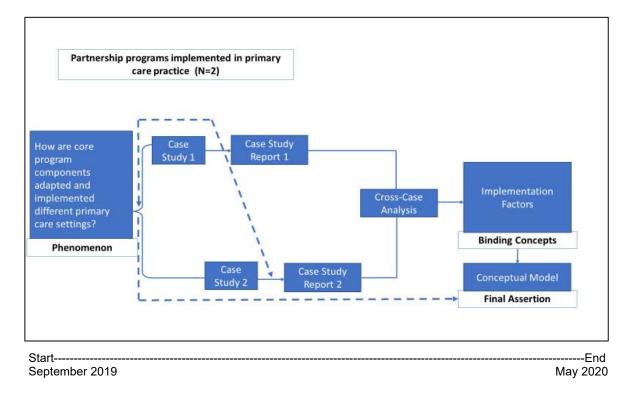


Figure 3. Multiple case study design and study timeline

During coding, it became apparent that "Patient Needs," originally categorized under the construct, "Outer Setting," spanned both the "Outer Setting" and the "Inner Setting," of each program as it related to how the program met patient needs.

For example, this came up during discussions about how the physical space within a clinic affected patient quality of care during program implementation, and how transportation issues prevented patients from using program services.

Therefore, the "Patient Needs" category was placed in a separate domain as its own construct to account for the high frequency and diversity of patient issues that emerged during implementation.

Operational codes that described each program activity that emerged during data collection also needed to be accounted for during the coding process.

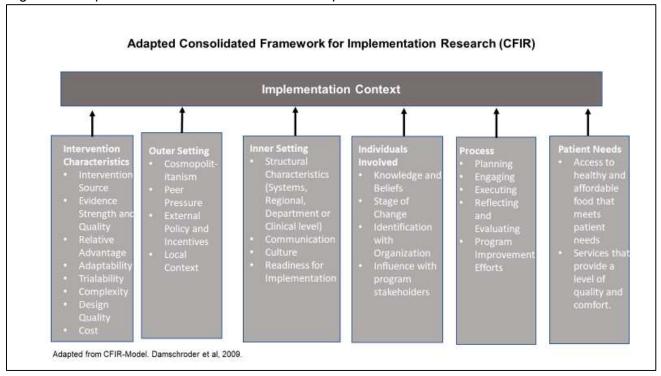


Figure 4. Adapted Consolidated Framework for Implementation Research

Note 1: "Patient needs" was removed as a category from the outer setting and designated as its own construct and theme because it crossed multiple CFIR constructs in Case 1 and Case 2 data. Note 2: Local context was added to the outer setting because of its significance throughout Case 2.

These were added into the "Design" category of the "Intervention Characteristics" domain in the adapted codebook. Food insecurity screening, referral to food distribution program, referral to SNAP enrollment processes, education about local food resources, program promotion and marketing, food distribution processes and program evaluation were added as operational codes.

In addition, the "Inner Setting" domain was broken out into organizational levels during data collection. This included the system level, regional level, department level and/or clinical level to understand how macro, meso and micro levels within each organization affected implementation processes.

Other healthcare studies that applied the CFIR framework for practice-based research similarly divided the inner setting into hierarchical levels to evaluate how factors at each level affected implementation of patient-centered programs (Safaeinili, Brown-Johnson, Shaw, Mahoney, & Winget, n.d.). Based on organizational theory, this process allows researchers to understand the different levels of change that need to occur within a healthcare organization for a new innovation to be implemented effectively (Ferlie & Shortell, 2001).

Specific categories under the "Process" construct and "Execution" construct were also adapted to better fit the data as it emerged. Specifically, clinics experienced challenges to reach program fidelity. Therefore, the "Fidelity" code was created under the "Execution" construct to reflect these statements. Clinics also deviated from the original implementation plan that resulted in improved implementation processes. The "Executing Unplanned" code was created under the same construct to reflect these types of statements.

Statements about implementation were designated as a barrier or facilitator accordingly. These codes were also added to the codebook.

C. Setting

In Chicago and suburban Cook County, nearly one in seven residents is affected by FI, concurrent with national trends. (*Healthy Chicago 2.0 Partnering to Improve Health Equity 2016-2020.*2016b). Eighty-five percent of residents living in the South and West sides of Chicago and neighboring suburbs have the highest risk of experiencing chronic FI. These communities are primarily comprised of low-income, urban black and Hispanic/Latinx populations (*Healthy Chicago 2.0 Partnering to Improve Health Equity 2016-2020.*2016c).

Within Chicago and suburban Cook County exists a complex healthcare and public health community that serves 5.2 million residents with diverse health issues.

Over 37 hospitals, several dozen Federally Qualified Health Centers (hereafter FQHCs), six certified local health departments, and nearly 100 regional and community-based organizations actively work on improving population health through the Illinois Public Health Institute's Alliance for Health Equity (hereafter AHE) (J. Lynch, personal communication, March 26, 2019).

According to J. Lynch, the Program Director (personal communication, March 26, 2019), AHE recognized food insecurity as a region-wide challenge within Cook County and in April, 2018, the first AHE Food Access and Food Security Workgroup (hereafter Workgroup) convened to discuss current FI clinical and community strategies that could lend themselves to policy development. This group consisted of representatives from approximately 50 community-based organizations and healthcare systems actively involved in FI initiatives.

D. Selection of Two Cases

Two programs were identified using criterion sampling from 13 primary care focused programs that were identified from previous AHE environmental scan (TABLE I). This scan identified clinical food insecurity screening and referral programs in Cook County, 13 of which were in primary care. The programs were selected based on differences in location (i.e. suburban and urban) and differences in the type of program model was used to for food assistance. These distinct differences would allow for the exploration of program implementation in different contexts.

Inclusion criteria were based on previous research and national recommendations for clinical FI initiatives. Study cases needed to meet the following criteria: 1) Programs that used the standardized two question Hunger Vital Signs tool to screen for FI; 2) Programs that incorporated a referral system for food assistance; 3) Programs that incorporated a referral system for SNAP enrollment; 4) Programs that had been implemented for a minimum of one year. The last criteria allowed for the examination of programs that had been presumably functioning long enough that initial challenges common to start-up programs had already been addressed. The focus of this study was to explore ongoing issues that hindered implementation outcomes and sustainability.

TABLE I STUDY CASES

| Cases | Characteristic of Healthcare Organization | Program Funding | Food Organization | Location | Initiative | Stage of Implementation |
|--------------|---|-----------------------------|----------------------------|--------------------------------------|---|------------------------------------|
| 1. Program A | Public healthcare System, predominantly urban setting | None | Local Food Bank | Cook County, Chicago | Food security screening, mobile food truck, enrollment/ref erral to benefits program | Full Implementation and beyond) |
| 2. Program B | Private, academic system, predominantly suburban setting | Federal and local grants | Urban Garden Collective | Western Cook County Suburbs | Food security screening, onsite food distribution, enrollment to benefits program | Full Implementation and beyond) |

Through the process of elimination, three programs fit the established study criteria. However, one program voluntarily opted out of the study due to the concern of revealing internal implementation processes and procedures. Program leaders believed the program did not align with national recommendation and wanted to avoid exposure. Their response only strengthened this researcher's resolve to uncover what is still unknown about food insecurity program implementation processes for the advancement of practice-based research.

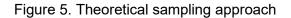
E. Selection of Key Informants that Provided Data for Each Case

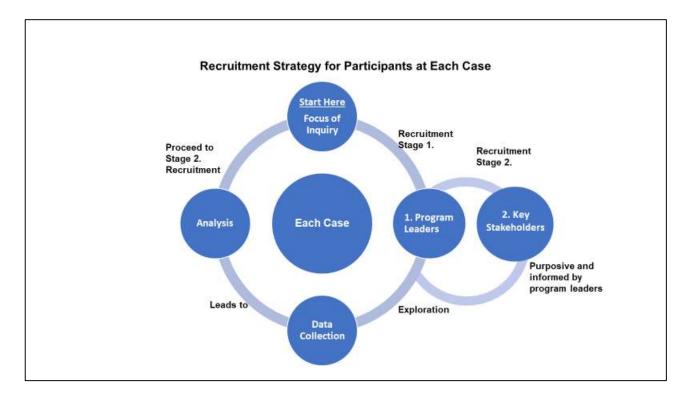
A theoretical sampling approach was used for recruitment for each program (Figure 5).

The individual that led implementation at each case was recruited first to learn more about each program from concept to design and execution. They provided rich data about the implementation context representative of the following CFIR concepts: intervention characteristics, the inner setting, the outer setting, key individuals involved in the program, as well as critical implementation processes (Patton, 1990).

These individuals recommended other individuals throughout the healthcare organization critical to program implementation for recruitment in this study.

This iterative sampling process is concurrent with a constructivist approach for case study methodology where truth is the product of reality (Stake, 1995a).





Qualitative case studies allow us to construct knowledge from different people's experiences that are embedded within a specific context. Data collection and analysis is a dynamic, iterative process that occurs simultaneously as new data sources and ideas are revealed from previous findings until data saturation is achieved (Merriam, 1998b). This process was used in this study to develop a rich understanding of implementation processes for each case until a holistic picture emerged (Stake, 1995b). Data saturation was achieved after 19 interviews with key informants (i.e. 12 interviews for Program A and seven interviews for Program B).

F. Qualitative Data

One way in which case study research is characterized is by the collection of multiple perspectives from people directly involved in the phenomenon to understand the multiple facets that exist (Stake, 1995c). In this study, this provided a holistic understanding about how each program functions (Yazan, 2015a).

Qualitative data were collected from multiple stakeholders within the implementation context. "Context refers to what's going on around the people, groups, organizations, communities, or systems of interest," (Patton, 2015a, p.47). Qualitative data were collected from discussions with key-informants that provided rich and context specific information across each program.

Key informant interviews were conducted with active implementation actors at different levels within each program. This helped to understand multiple perspectives of how each program was implemented and what barriers and facilitators existed.

The interviews were conducted face-to-face onsite at each program site or over the telephone at the study participant's discretion. All interviews were audio recorded for data analysis purposes. Participants recruited for the study were made aware of the audio recording at the beginning of each session and were required to provide verbal consent prior to participation in the study.

The interview guide used for this study (Appendix B) was based on the adapted CFIR constructs that applied to screening programs. The guide was tailored to the role of each implementation actor interviewed.

The researcher took notes in the field that included informal observations about each participant and/or program. These notes were made right after the completion of each interview to document the researcher's immediate thoughts and reactions about participant tone, facial expressions, body language and/or interview setting during each interview that may have effected interview responses.

G. Human Subjects Protection

This study was approved for a claim of exemption with the amendment for the replacement of one of the initial cases (Protocol # 2019-0610) from the UIC Institutional Review Board on August 30, 2019. All interviews took place in a neutral setting that ensured privacy in person or over the telephone. This included conference rooms and private offices where each participant felt comfortable speaking openly about their experiences.

Subjects were required to read and verbally consent to participation prior to the start of the interview. Each participant was made aware that he or she may retain one copy of the consent form for his or her records.

The informed consent included the following information: 1) A statement that the participant was, in fact, participating in a research study, including a statement of the purpose of the research and that each interview would be audio recorded. 2) A statement that all individual level, identifying information would remain confidential for a minimum of five years. All identifying information would be removed prior to data analysis. 3)The risks of participating in this study was minimal, no greater than those encountered in everyday life. 4) The estimated duration of the participant's time for the interview was an average of 45 minutes. 5) A description of any research and training benefits from participation in the research both direct and indirect.

6) A statement that participation was voluntary, and refusal to participate in the research at any time during the interview would involve no penalty or loss of benefits to which the participant was otherwise entitled. This included a clear statement that refusal to participate or decision to withdraw from the study would not affect his/her employment status. 7) An explanation of whom to contact with future questions about the research or the participant's rights, or in the event of a research-related issue. Two contact persons were made available to the subject: The Principal Investigator and the dissertation advisor.

H. Data Management and Analysis

Data were collected, managed and analyzed concurrently over a period of seven months from September 2019 – May 2020 until data saturation was achieved. Audio-recorded data from each case was transcribed using an external transcription service, Rev.com, and uploaded to Atlas.ti v.8 qualitative data analysis software for data management, coding and assistance with analysis. All personal identifying information was removed from the data.

A coding system developed a priori based on the adapted CFIR framework for data interpretation was used during data collection and analysis. Codes were added to this codebook as new ideas and concepts emerged. Two experienced PhD level university students established interrater reliability of the coding process until 80 percent agreement was achieved, and discrepancies in coding were resolved as recommended for reliability in qualitative research (Pluye & Hong, 2014).

As data were collected, a methods cross walk tool was used to guide thematic analysis. Responses to specific research questions were mapped to the CFIR construct(s) that was identified and the related data source (Figure 6).

The Data Interpretation Framework in Figure 7. was used to assist with the organization of themes and codes as they emerged in the data (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

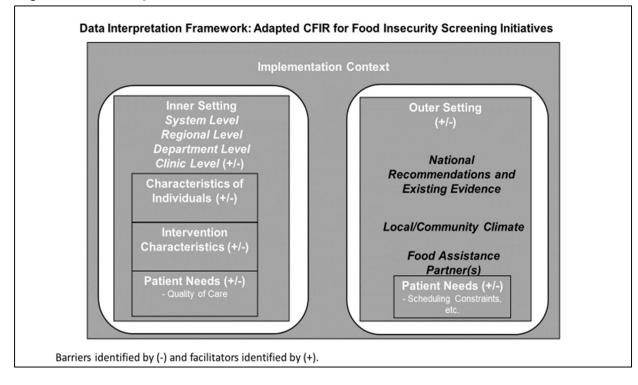
Figure 6. Methods crosswalk

| CFIR Construct | Research Questions | Method | Data Source |
|--|--|--|---|
| Intervention characteristics Inner Setting Outer Setting Implementation Process | 1. How are clinical FI initiatives implemented in primary care settings? | 1. Interviews | Team leaders and other implementation actors identified through theoretical sampling Field notes |
| Inner Setting Outer Setting Implementation Process | 2. What are the major barriers and facilitators that affect the process of program implementation within each setting? | Interviews Data coding and individual case analysis | Team leaders and other implementation actors identified through theoretical sampling Field notes |
| - Implementation Context | 3: How do context specific factors affect overall implementation processes across settings? | 1. Data interpretation during cross-case analysis | Data interpretation framework for N=2 cases. Figure 6. |

The Data Interpretation Framework anchored common concepts and ideas that emerged within each case. Each section functioned as an intellectual "bin" to place the data until further analysis could be done.

For each program major program elements, time of occurrence and implementation actor were defined. Implementation processes were also described as originally designed, as well as unanticipated implementation facilitators and challenges and overall themes that emerged during the within case analysis. During cross-case analysis, the binding themes and unique factors were identified across the two programs to understand how implementation processes may be affected in other settings. The themes and patterns that emerged from each interview were compared to previous interview findings.

Figure 7. Data interpretation framework



This allowed the identification of commonalities or disparities in the data. This iterative process is common in qualitative research and allows for rich understanding of the phenomenon to emerge during data collection and analysis. (Stake, 1995d). These findings were analyzed for each program and across programs.

Code incidence reports were created in Atlas.ti v8 during analysis across all data for each case. This helped during analysis to identify which codes were reflected the most in the data as major themes of barriers or facilitators for program implementation.

The "Co-Occurrence" function in Atlas.ti v8 was also queried to mine data specifically for statements that juxtaposed with each program activity and whether a specific statement had been coded as a facilitator or barrier.

For example, statements with the code, "screening," for Program A were queried with the code "barrier." This query revealed statements that were coded as "Inner setting, clinic level" and "structure" as a "barrier" This statement discussed the limited privacy for screening that resulted in unreliable screening responses. Statements that referenced this implementation barrier were abundant and mentioned by clinic staff across all Program A study sites.

All possible CFIR constructs were queried individually with each program activity and separately for "barrier" and "facilitator." This process allowed for a clearer picture for which program activity yielded the most challenges from the perspective of multilevel stakeholders and from where within the organization those challenges had stemmed. It also revealed program facilitators and successful adaptations. The influence of each factor was examined further to bring clarity to the implementation of each program element. The overlap between constructs helped to establish the semantic relationships between constructs and program activities across both cases.

I. Methods to Enhance Rigor

Several methods were used in this study to enhance rigor throughout the data collection and analysis process. The following methods were used.

Once all themes were identified, preliminary findings for each case as presented to its respective program stakeholders. This strengthened the accuracy and credibility of findings because team leaders input validated the results and helped to refine findings.

During thematic analysis data collected from different stakeholders within each case were triangulated to establish consistency among findings. "Triangulation strengthens a study by combining methods. This can mean using several kinds of methods or data," (Patton, 2015, p.478b). Data provided by different stakeholders or sources within each case were compared to identify discrepancies and to validate findings.

Applying prospective reflexivity this researcher acknowledged that research processes were informed by personal values, past experiences and preconceived notions (Attia & Edge, 2017a).

Rather than the researcher functioning as a potential contamination of the data, prospective reflexivity helps researchers understand how their previous knowledge, feelings, and values help to formulate research questions, and inform data analysis (Attia & Edge, 2017b).

As such, the researcher had engaged in related research with AHE that gave her insight about the variety of FI clinical and community policies and initiatives that existed in Cook County, implementation challenges and what implementation factors still needed exploration. This knowledge informed the development of research questions, as well as study design. Her prior knowledge about FI research, experience working with low-income, urban communities and her deep understanding of clinical practice shaped data collection and the interpretation of findings.

Bi-weekly updates to the dissertation committee chair and monthly check-ins with the rest of the committee were provided during data collection and analysis. This check-in served as an assurance that this study had maintained standards of rigor and that findings were valid. Their research expertise and impartiality to the study findings provided an external audit that assured the interpretation during analysis was supported by the data (Creswell & Poth, 2018).

During data collection and analysis, an ongoing journal was maintained where reflections about data collection, study logistics and ongoing analysis were recorded.

Any major decisions and the rationale about the research process were also noted. This journal served as a guide during data collection and analysis to review the history and evolution of the research and to reflect upon what had influenced the direction of the study. The purpose of doing this was to maintain an active level of self-awareness throughout the research process and to personal cultural and ideological positions in check so as not to overly influence the study processes and outcomes.

IV. RESULTS OF PROGRAM A

A. Overview

This chapter describes detailed findings from Program A that address the following study aims: 1. To identify program activities, actors and implementation processes. 2. To implementation barriers and facilitators.

First, the results of recruitment of key informants are discussed. Next, the background for Program A is described. This provides insight about the program's evolution and setting. Third, intended program elements, activities and actors are described, from the study participants' perspectives. Fourth, implementation barriers and facilitators that affected how implementation occurred are described, also from the perspective of study participants.

B. Results of Theoretical Sampling of Key Informants for Program A

The results of the two-part sampling approach are presented in Figures 8-10.

Program A's healthcare organization's Policy Director was recruited during stage one of the recruitment process. This researcher had already established a working relationship with this individual from previous research projects and agreed to participate in the study.

The Policy Director had worked from the very beginning of program inception to dissemination and evaluation of the partnership program to 12 community health clinics across the Northern and Western Cook County suburbs, as well as the West and South sides of Chicago. This individual was responsible for program design, funding mechanisms and a sustainability plan and was asked to share details about program planning and implementation from their perspective. The policy director was asked to identify other implementation leaders. The Policy Director identified mid-level directors and managers of specific program clinics that could provide additional insight about implementation. The Policy Director identified two Regional Directors that represented the North Central Chicago, South West suburbs and Southside Chicago. During stage two of recruitment, they consented to participate in the study and shared their experiences about program implementation.

The Regional Directors identified Clinic Managers at the three clinics they represented where the program had been implemented effectively. Clinic Managers consented to participate in the study and shared their experiences about program implementation.

Each Clinic Manager identified implementation actors at each of their clinics to share their experiences. This included two physicians, four social workers and one medical assistant. Interviews with all stakeholders gave a holistic picture of how each initiative worked at each clinic site within the critical implementation context that can affect program processes and outcomes.

Stakeholders helped to identify the three clinics for this study (TABLE II). Each clinic represented a different geographic neighborhood in Cook County (two urban and one suburban clinic). System level and mid-level managers verified that the three clinics were good representations of the 12 clinics that implemented the program within the healthcare organization. The target patient populations across clinics are low-income non-Hispanic Black and Hispanic/Latinx patients between the ages of 18-64 years old. Program participation hovered between 120-200 patients a month.

C. Background of Program A

The organizational report indicated that the healthcare organization is one of the largest public healthcare systems in the United States that serves over 500,000 diverse patients across urban and suburban Cook County.

The healthcare organization mission was to provide high quality integrated care to patients regardless of their ability to pay for services. Most patients were African American or Hispanic/Latinx and of these patients, 43 percent were uninsured, and 35 percent were Medicaid recipients.

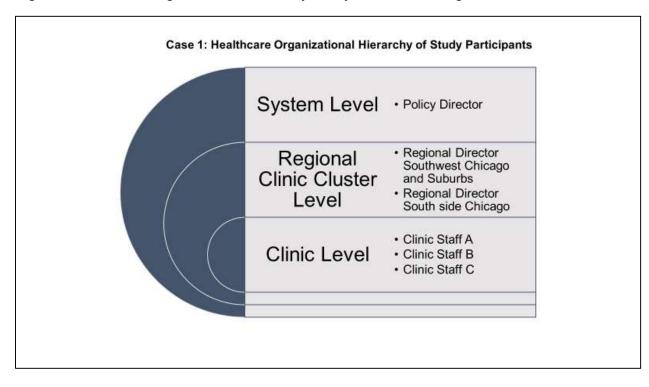
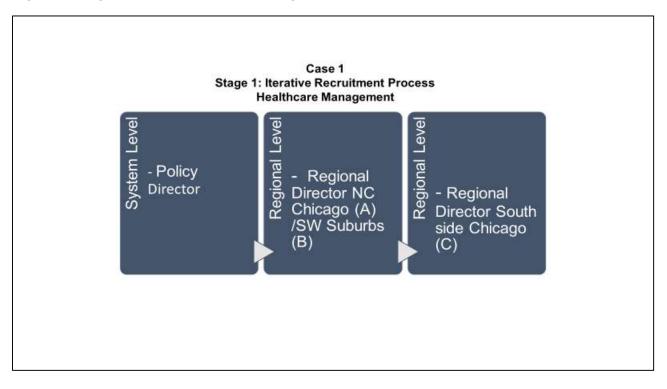


Figure 8. Healthcare organizational hierarchy of key informants: Program A

Figure 9. Stage 1 recruitment process: Program A



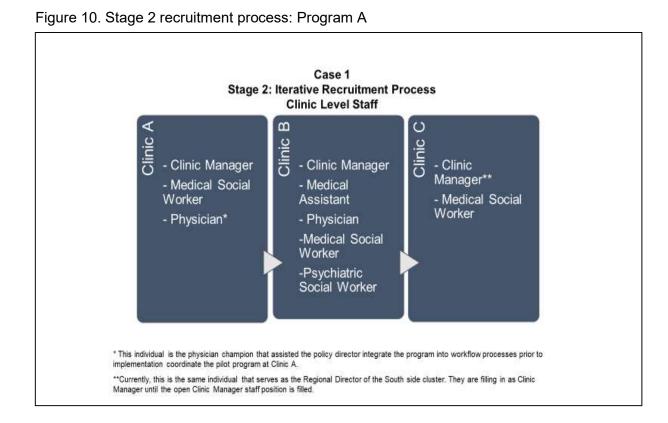


TABLE II PROGRAM A: STUDY CLINICS

| Community Clinic | Location | Patients Served/Year | Patient Demographics | Program Participants/Month |
|---------------------|--------------------------------|-------------------------|---|-------------------------------|
| Clinic A | Northwest Chicago | 16,800 | 18-64 years, Primarily Hispanic/Latinx | 120 |
| Clinic B | Western Cook County Suburbs | 18,000 | 18-64 years, Primarily Hispanic/Latinx | 200 |
| Clinic C | South Chicago | 10,800 | 18-64 years, Primarily Black, Non-Hispanic | 180 |

Through active policy work and community partnerships, this healthcare system worked to create a social safety-net for its vulnerable patient population that supports optimal mental, physical and social well-being.

To that end, a yearly Food as Medicine Summit was convened to discuss outcomes of systemwide food insecurity initiatives and future recommendations. A task force met quarterly to discuss ongoing issues with program implementation. Program A was a result of this Summit.

In 2015, a local food bank presented national and local data to leaders of this healthcare organization. These data illustrated the prevalence of poor dietary health alongside T2D and high blood pression in food insecure populations.

These findings underscored the importance of initiating a FI screening program that also linked patients to affordable, fresh fruits and vegetables—unprecedented for the healthcare organization. These data also motivated the healthcare organization to partner with the food bank to develop Program A.

The healthcare organization's Policy Director (PD), a passionate leader for health equity and food access, was one of the first program champions. They took the helm on the healthcare side, as leader of program design and implementation with the input of a physician champion, a pediatric provider. The PD worked closely with the Director of the food bank to develop and Program A.

Program A's food access organization was a Chicago area food bank in Cook County that works to end hunger in the community. According to the organizational report, the food bank partners with over 700 local agencies to distribute food through school-based programs, adult and senior centers, food pantries, mobile food pantries and veterans' programs. The food bank provided approximately 170,000 meals a day to vulnerable populations at the time of this study and offered job training in kitchen services, as well as information and enrollment in federal benefits programs.

Program A was launched in September 2015 at one clinic in the Northwest part of Chicago. Over the last 5 years, the program has expanded to 12 community clinics within high need communities throughout urban and suburban Cook County.

D. Overview of Program A

TABLE III and Figure 11 list general program activities that participants reported and that are explained in the section below. The table also lists the specific action associated with the program element, time of occurrence and the implementation actor responsible.

Screening: Once a new patient arrived at the clinic, the MA was responsible for intake, therefore the MA was the individual that screened every patient. The FI screening questions came at the very end of the intake process.

Program Referral: If a patient screened positive for FI, the MA referred them to the food truck program and gave them a voucher. The patient was required to bring the voucher with them to the food truck to receive a free bag of fresh fruits and vegetables. The MA then roomed the patient for their doctor's visit.

Referral to Local Resources: During the doctor's visit while the MD assessed patient history, the positive FI should have been flagged in the EMR because it been entered during intake.

The doctor saw this and proceeded to discuss FI and the importance of dietary health for disease management. The MD then discussed local food resources, including food pantries and soup kitchens and provided a list of these resources for the patient to take home with them. The patient was referred to the clinical social worker (MSW) who would enroll the patient in the program.

Enrollment in Federal Benefits: The MSW was responsible for all case management related to SDOH at each clinic, including diet and nutrition, and enrollment in federal benefits. Therefore, the MSW was also responsible for the program enrollment process. The MSW asked the patient if they were interested in the program and if yes, they provided a phone number for promotional and reminder phone calls. The MSW also enrolled patients in SNAP if they were eligible.

| Program Activity | Action & Time of Occurrence | Implementation Actor |
|--------------------------------------|--|---|
| 1. FI Screening | Screen new patients for food insecurity during intake process Follow up screening during yearly visit. | Medical Assistant (MA) |
| 2. Referral to program | Distribute voucher to Food Truck program. | MA |
| 3. Referral to local resources | When patient is roomed and visiting with their doctor, the doctor may discuss with patient food insecurity status, specific food needs and provide resource list about local pantries. Refer to Medical Social Worker for more information. | Doctor |
| 4. Enrollment in Federal Benefits | Enroll patient in SNAP benefits (refer to WIC if WIC clinic) during referral visit with the Medical Social Worker (MSW). Obtain contact information for follow-up and program promotion. | Medical Social Worker (MSW) |
| 5. Program Promotion | One to two weeks prior to the next food distribution, make reminder phone calls to patients that received the voucher. | MSW |
| 6. Food Distribution | Food truck distributes food to patients with vouchers. One day a week/ every two months for a 2.5-hour period. Usually in the morning. Food truck provides recipes and tastings to encourage participation. | MSW in collaboration with community food partner |
| 7. Evaluation | During food distribution, register patients with voucher. After food distribution is completed for the day, count participation rates using food partner provided tools and share with program stakeholders | MSW |

TABLE III PROGRAM A: INTENDED SCREENING AND FOOD DISTRIBUTION PROCESSES

Program Promotion: One to two weeks before the Food Truck Program was scheduled to deliver food at each clinic, the MSW called patients that enrolled in the program. The purpose was to promote the value of the program and remind patients to come back to the clinic with their voucher to pick up their free bag of food. The MSW provided a schedule of the next Food Truck Program distribution.

Food Distribution: The mobile food pantry delivered seasonal produce once every other month at participating clinics.

The delivery window time was a two-and-a-half-hour period in the afternoon. The MSW, and food bank staff managed food distribution. Patients were required to come to the truck that was parked outside of the community clinic to pick up their free bag of food. They needed to sign in and provide their voucher in exchange for food. They then received a voucher for the next distribution.

Program Evaluation: The food partner provided evaluation tools in the form of a paper tracking tool that collected participation rates. The MSW was responsible for the collection of participation rates after each distribution and sharing those numbers with the food partner.

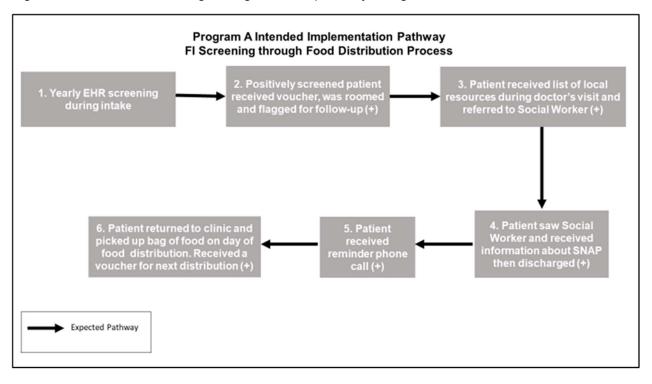


Figure 11. Intended screening through referral pathway: Program A

The major theme that emerged for Program A is that the infrastructure of the healthcare organization drove program design and implementation processes. Nationally recommended screening, food distribution and SNAP enrollment activities were dictated by the current workflow processes and the staff that were a part of the existing clinical workflow. The program resources came from the existing healthcare organization resources, as well as and in-kind donations from the food assistance program.

The food access partner was a local food bank. The model was to use its existing mobile food pantry to deliver fresh fruits and vegetables to each participating clinic.

E. Implementation Factors for Program A

Major barriers and facilitators were identified from study participants, which are described in detail below. These factors were categorized into major themes and constructs (TABLE IV).

Barrier 1: The patient experienced discomfort during screening. Several frontline clinical staff reported that patients appeared uncomfortable when asked about food insecurity during screening.

A part of this barrier was a lack of privacy and trust. Participants reported that this was especially the case when other patients were nearby and could overhear patients' responses to intake questions. They attributed the lack of physical privacy during intake to the way the physical space was designed at each clinic. One participant reported that intake was designed to take place in an open area:

The nurse's station is not that private and there are other patients around; they [patients] don't want them to hear their answers to the screening questions.

| Theme | | | CFIR Construct/Category | |
|--|---|---|---|--|
| Limited Program Resources | Patient experiences discomfort during screening (-) - Lack of Privacy - Overwhelming Intake Process | This barrier refers to the discomfort patients experienced during screening that stakeholders said oftentimes resulted in unreliable responses to screening questions. Stakeholders reported that this was due to lack of privacy during screening because of the layout in the clinic. There was also reference to patients feeling overwhelmed with the intake process when screening questions were asked. | Inner Setting Structure Clinic Level (Physical Space) (-) Systems Level (Workflow Intake) (-) | |
| Value of Individuals Involved | MD unintentionally reveals FI (+) | This facilitator referred to the MD revealing FI status during non-related conversations at the patient visit even if that patient had screened negative for FI—which led to a connection between FI patient with food assistance programs. | Inner Setting Structure Clinic Level Individuals Involved Skills (+) | |
| Limitation of Individuals Involved | Limited staff time for education (MD), enrollment in SNAP(MSW) and patient phone calls (MSW) (-) | This theme refers to limited staff time (i.e. MDs and MSW) to perform their program responsibilities. They reported that they had other responsibilities that were priority as a part of the clinical workflow. | Inner Setting Structure Systems Level Workflow (-) Clinic Level Individuals Involved Capacity (-) | |
| Limited Program Resources | Infrequent food distribution (-) | This theme refers to the overall perspective from stakeholders that food was not distributed often enough to meet patient food needs. Stakeholders said that this was a direct result of a lack of program funding to pay for additional distribution services. | Inner Setting Structure Systems Level Program Funding | |
| Limitation of Individuals Involved | Limited expertise about evaluation (-) | This refers to the limited expertise staff reported about the ability to link program use to health and behavioral outcomes. | Inner Setting Structure Systems Level Skills (-) Individuals Involved Skills (-) | |
| Adaptability and Trialability | Clinic-level autonomy to enhance intervention resources for adaptability and trialability (+) | This refers to the clinic-level autonomy reflected in implementation adaptations that varied across study clinics for referral, promotion and food distribution. Trial and error were reported with the application of different strategies for implementation based on clinic level needs. | Inner Setting Structure Systems Level (+) Culture Intervention Characteristics (+) | |

Another participant validated the lack of privacy during intake:

Unfortunately, it's not very private. And what I mean by that is that it's open to more medical assistants that are sitting at that station and potentially another patient getting vitals next to them. So there is about 15, 20 feet in between the patient's, but that is what is our nursing station. So there's four employees there and then there's two vital stations next to each other. So as they're asking them the questions, there are more people around and it's not very private. Sometimes we do have that inadvertent response of no, no, no I'm fine and then they get inside and they tell the doctor maybe something different.

This could also have been attributed to the stigma and shame associated with FI, as one

frontline provider said about screening:

I think, sometimes, maybe patients don't, may not be answering honestly...I'm saying they might not say they do have the need for whatever reason, they may not want to say yet, maybe they are uncomfortable.

Lack of trust was also reported:

I think that until the patient is fully established within the medical home and they know who their team members are, then that's different. But until they start bonding with their team members, it's hard sometimes really hard to be honest about that stuff.

One participant also pointed out that patients may not want to enroll in Program A, even if

they needed it, because they were embarrassed about their FI:

So not every patient that is identified as food insecure goes to see the social worker necessarily right after the visit. It may be referred to social worker...some are embarrassed and would rather not. It really depends.

Another example of patient discomfort was the intake process. One frontline provider noted

patient fatigue and information overload with the current intake process, and this was validated in

additional conversations with providers:

Intake a so overwhelming. There's so many regulatory pieces...We've tried to do all sorts of screening things in intake from depression to developmental delay in children...I think if you think about that the whole point in flow is overwhelming for patients...it's also just information overload.

Facilitator 1: The MD revealed FI if it was missed during screening. Clinicians agreed that oftentimes in these situations, FI was unintentionally revealed during provider conversations about other SDOH issues, which speaks to their skills and abilities to probe for these types of SDOH issues. One participant said:

Sometimes they [patients] don't open up. They don't open up until they're with the provider a lot of times. So like I'll have a patient, again, I'm a pediatrician, so I'll have a patient who's a new mother and they've already screened negative for food insecurity. But when I get down deep into what is the baby eating, what are we feeding the baby, what is in the house? They really are food insecure.

Barrier 2: Staff had limited time to execute program responsibilities. Participants agreed that

they did not have enough time to execute program responsibilities and that oftentimes patients

would not get connected to services unless they were referred to the MSW.

A part of this was that education about local resources was not regularly provided. Clinicians

reported that the education about local food assistance programs does not frequently occur during

the doctor's visit as intended. This is due to other competing responsibilities and the limited time

allotted for each patient.

One clinician described the experience working with doctors:

What I will say is that the providers that work with this population of patients are working with very chronically ill individuals. And so sometimes, they're tasked with dealing with their pain versus their food insecurity. And that's just the reality of the patient-doctor visit, right? 'What do you need the most today? Or how can we incorporate as much as we can into this visit? But also, we have to see more patients, too...generally speaking, they will refer them over to the social worker because that's what the social workers are tasked with.

Another clinician reported a similar pattern:

Provider discussion with the patient about food insecurity doesn't always happen. It is really up to the provider's discretion to determine what is priority during the visit. If the patient has other immediate health concerns, that is priority for the healthcare provider to treat first before discussing food insecurity.

An additional issue, which, although related, specifally referred to the limited usability of the EMR

software for FI screening:

The [computer] screen is very busy. The questions are in the care coordinator section and I need to scroll down to see the results. If I'm busy treating the patient's other health issues, I am not going to remember to do this.

Clinicians also reported that SNAP enrollment did not occur regularly because they did not

have enough time to manage this cumbersome process.

One reported that the complicated online process was a barrier:

At point when the applications were paper applications. I would do applications all the time, not a big deal. But then, there was that change in which the state of Illinois Department of Human Services started using that Aid Illinois and that complicated everything. Right now, I actually... I stopped doing it because it was so cumbersome, so burdensome. I couldn't do it within a normal scheduled appointment time. It would take too long.

Another participant said that the biggest challenge was incredible amount of time and effort

that was required to follow-up with patients that needed provide the correct documents for the

application:

What is an issue is on their [the patients'] end following up with the [SNAP] application. We talk about the needs and they [patients] have to come back with the documents they need, like proof of address, birth certificates, paycheck stubs, whatever it is that they have access to or have.

Clinicians agreed that the patient phone calls were important to promote the program and to remind voucher holders to come to the food the distribution, but that phone calls were difficult to make. One reported:

I think those reminder calls are very essential when it comes to promoting, reminding, because it's not every week or every month. It's bi-monthly. So sometimes because it's not as consistent as some of the neighborhood food pantries, a patient can forget, or it's just not on their radar, or they work, or whatever the case may be.

However, clinicians also said the process required too much time to perform regularly.

When asked about the need for additional program support one clinician said:

I need help with the reminder phone calls. They're important, but I have trouble getting through all of them. Right now the only time patients get information about the Food Truck is when they ask about it.

This time-consuming nature of the phone calls was verified by another clinician:

About 85% of clinics do this (make patient calls)...One thing that makes it difficult is staff turnover. Vacant posts mean staff are doing more than usual and it makes it difficult to keep the phone call reminders at the top of the priority list.

Barrier 3: Food was distributed infrequently. Participants reported that the frequency of the

food distribution service did not meet patients' food needs. One said:

All of our patients have issues with like where the next meal might come from... we realize that the food truck meeting every other month is not going to answer everything.

Another participant said a challenge to more frequent food distribution was its cost, as well as bad weather, since the lack of clinical space resulted in outside distribution:

The food truck visits at each site are not frequent enough because it requires an incredible amount of [food pantry] capacity to staff to run the truck and we don't have the funds to pay for that. Bad weather, like last year's polar vortex, can deter participants from coming to the distribution...Patients want more frequent distribution.

Barrier 4: Participants reported limited knowledge and expertise about program evaluation.

One participant said that the lack of evaluation experience had negative policy and program

sustainability implications:

We are looking for ways for Medicaid to cover the cost of food. One reason why we can't do that is because we don't know how to increase evaluation knowledge and capacity. Our EMR cannot track redemption yet, so we can't link participation and health data. So we need to increase that. One clinician said that more checks and balances were necessary to assess program

demand:

I would like to see if those patients that we actually are giving the vouchers to actually coming back... Or how many patients that were not given a voucher came back asking for a voucher? Because they might not have had an appointment yet. The month prior or two months prior. So I think, I think doing some kind of evaluation like that would be good.

Another pointed out that this barrier resulted in patients falling through the cracks because

current screening processes could not keep up with the realities of FI:

Well, first of all, the questionnaire is administered once a year. So if they came, say October of 2018 and then something happened either health wise or their family composition changed due to the loss of their breadwinner or they moved or some other tragic thing, they lost their job or something like that. That could have happened four or five months down the line, but we're not going to hear about it in the questionnaire.

Yet another clinician discussed the need to follow up with patients more frequently to better

track program effectiveness. When asked how often this might occur, they said:

Maybe in between [intake] so that we wouldn't have to wait a whole year. Maybe their next visit or it could be, "how's it going?" Something that would indicate that. It could also become like a mandatory thing. Like it is when they do the initial intake could be mandatory maybe like six months in between or something like that.

Facilitator 2: Participants across the three clinic sites demonstrated autonomy, which enhanced program adaptability and trialability to meet patient and clinic staff needs. This was illustrated in the comment from a program leader about how clinics are intended to

implement the program:

It's up to the clinic staff to follow through because we respect the autonomy of each clinic to take responsibility for the program and how it's done.

Another clinician reported that they did things differently from the intended program design

and from other clinics during food distribution to meet patient and staff needs.

This clinician reported:

So we do it different here. It's usually me and another person from the clinic, we process everybody in terms of getting their demographic, their name, their zip code, how many people in their household and if they are patients of the clinic or not. And then we ask them if they want to have information on how to apply for food stamps or not. That's all part of that little questionnaire that we have to go through. So that's what I'm doing, working through the line.

At a different clinic, one provider reported that they did not rely on the positive screening

result to give patients a voucher for the Food Truck Program. They did it differently to facilitate

patient connection to food resources:

Yeah, so anyone can get a voucher that's a patient. How we do it is that even after the nurses give them out, we give vouchers to the clerks and other staff that may run into patients. A patient may come up just to pick up some documentation and be like, Oh, I know the Fresh Food Truck has come in. Can I have a voucher? So we don't have to run and get a nurse. Everyone has access to the vouchers so they can give them out at any time on any day.

And yet another clinician reported that they devised an alternative method to the patient

phone calls and program promotion that worked better for their clinic:

So we have one particular clerk who makes an announcement every so often about the food voucher. And we also have a white board up there that has an announcement when the Food Truck is coming up every month. Yeah. And I believe it works because now patients are like, wait, did I miss the truck? Or can I get a voucher? Or sometimes if they're not here for this one, if they're here for their appointments, they'll make sure they get their voucher for the next time.

V. RESULTS OF PROGRAM B

A. Overview

This chapter describes detailed findings from Program A that address the following study aims: 1. To identify program activities, actors and implementation processes. 2. To implementation barriers and facilitators.

First, the results of recruitment of study participants are discussed. Next, the background for Program B is described. This provides insight about the program's evolution and setting. Third, intended program elements, activities and actors are described, from the study participants' perspectives. Fourth, implementation barriers and facilitators that affected how implementation occurred are described, also from the perspective of study participants.

B. Results of Theoretical Sampling of Key Informants for Program B

The results of the two-part sampling approach are presented in Figures 12-14.

During Stage one of recruitment of Program B, the Medical Director/Physician Champion of the program was recruited first. This individual had been involved with design and implementation from the very start and the researcher already had a working relationship with this person from previous professional work. This individual was also on the researcher's dissertation committee. The Medical Director oversaw the two clinics that participated in the partnership program in the Western Cook County Suburbs. This individual provided insight about the history of the program, implementation challenges, as well as other key informants for recruitment.

The Director of Community and University Partnerships was identified as another key informant. This individual had been working on food justice issues within the community for several years through community partnerships. They helped to establish a connection between the healthcare organization and the food access organization that provided food for the partnership program through an intermediary food justice organization within the community. During Stage two of recruitment, this individual identified the PM of the food insecurity initiative as a key informant. The PM is also an onsite registered dietitian that provided insight about program design, implementation strategies and logistics, as well as funding mechanisms and sustainability.

The physician champion identified practicing physicians to interview for the study. These practicing physicians individuals also held leadership roles within the healthcare organization and were involved in program implementation. They included Chair of the Department of Family Medicine and the Director of Medical Education.

The Clinic Coordinator that managed Program B clinic sites was also identified by the PM to learn more about how implementation functioned within the clinical workflow process.

The PM identified a medical student that assisted with the food distribution aspects of the program that could give insight about active implementation of those program elements. The total number of Program B stakeholders interviewed was seven across two program clinics.

Two clinics participated in Program B, and they were included in the study (TABLE V). The target patient populations across clinics are low-income non-Hispanic Black, non-Hispanic and Hispanic white patients between the ages of 18-64 years old. Program participation ranged between 80-150 repeat patients per month.

C. Background of Program B

Program B was situated in a private, academic healthcare organization. Program B was implemented within two ancillary, primary care clinics that were a part of the Department of Family Medicine on the main campus in the Western Cook County Suburbs.

According to the organizational report, Program B served roughly 10,000 patients a year at the time of this study. The 38 percent of the local population that used these clinics were lowincome and either uninsured or Medicaid recipients. The patient community was primarily non-Hispanic black (i.e. 53 percent), followed by Hispanic/Latinx (i.e. 41 percent).

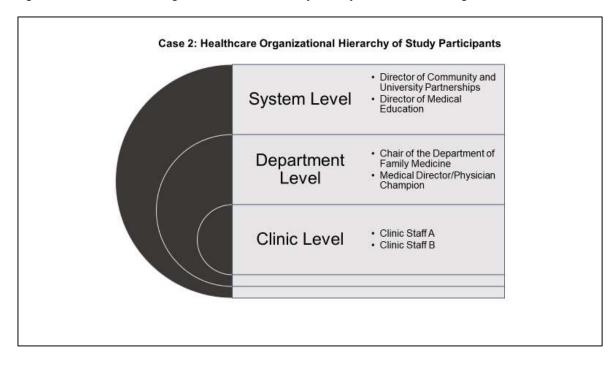
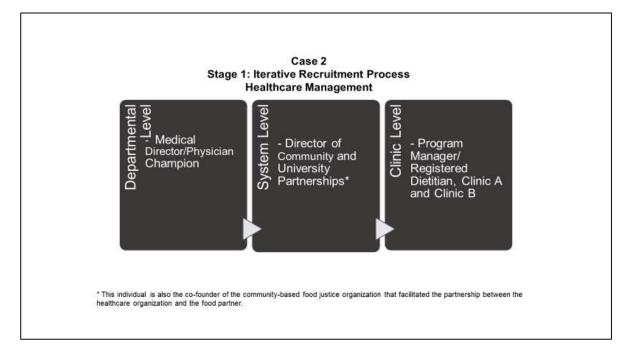


Figure 12. Healthcare organizational hierarchy of key informants: Program B

Figure 13. Stage 1 recruitment process: Program B



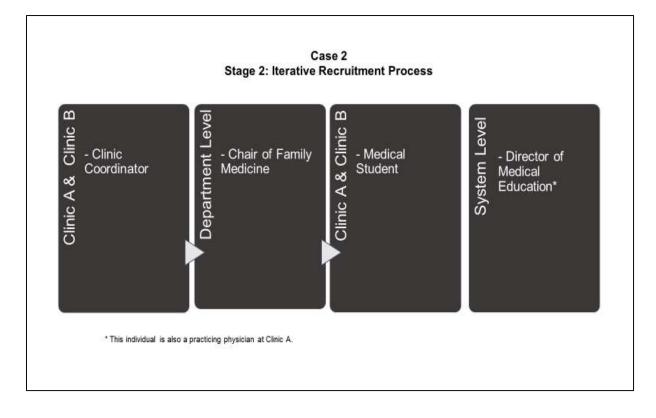


Figure 14. Stage 2 recruitment process: Program B

TABLE V PROGRAM B: STUDY CLINICS

| Community Clinic | Location | Patients Served/Year | Patient Demographics | Program Participants/Month |
|---------------------|--------------------------------|-------------------------|---|-------------------------------|
| Clinic D | Western Cook County Suburbs | 3,775 | 18-64 years, Primarily Black, Non-Hispanic and Hispanic White, | 80 |
| Clinic E | Western Cook County Suburbs | 7,101 | 18-64 years Primarily Black, Non-Hispanic | 150 |

The academic side of the healthcare organization trained future generations of healthcare leaders. At the time of this study, roughly to 520 medical residents and 2,400 medical, allied health and paramedics students of different specialties train at the academic health center every year

The healthcare organization was committed to helping vulnerable and low-income populations. The organizational culture placed a high value on spirituality, social justice and equity for every patient. It manifested these themes through community benefits projects. Priority projects included advocacy for policy that addressed the underlying social and structural determinants of health, as well as multisector partnerships for economic and community revitalization.

The healthcare organization is linked to a local food justice organization (hereafter organization). This organization evolved from evidence-based food access initiatives piloted in the community over the last 16 years with a focus on equitable food access and health equity. This work increased overall awareness about the importance of fostering a healthy food environment in a community characterized by health disparities and limited access to healthy, affordable food. This organization had the vision for Program B and led planning efforts.

The organization and its initiatives were born from partnerships with local food distribution centers, neighborhood businesses, multisector non-profit organizations, and urban garden collectives. It created a demand for a self-sustaining growing infrastructure where local farmers would have the financial support necessary to grow enough food to feed the community.

In 2010, a year-round urban garden was piloted in the community on a small plot of donated land. This growing model demonstrated immediate success with farming-related job opportunities, youth engagement, as well as low-cost fresh produce for the community. Due to its success, this urban garden continued to expand in size and community reach every year, and local food assistance programs utilized this model and infrastructure for support. The climate was primed for the implementation of an innovative healthcare focused FI initiative that could create synergy with existing initiatives and add value to the current food environment.

Local healthcare and food justice leaders became aware of emerging evidence that pointed to the potential for healthcare organizations to reduce the immense costs associated with poor disease management if, among other things, improvements in access to healthy food could be achieved. This was especially the case for low-income communities where health and dietary disparities persisted. The organization wanted the local healthcare system to help fund local farmers to support food as medicine through a sustainable growing model. This initiative would supply the fresh fruits and vegetables for various community food initiatives and fold in the local healthcare organization to expand reach.

An opportunity presented itself to move this agenda forward with the announcement of USDA request for proposals in 2017 that addressed food insecurity in innovative ways, including clinical settings.

In 2017, one of the co-founders and a leader of the food justice organization, brought together other influential leaders to develop Program B. It also happened that the food justice leader held joint appointments as faculty, as well as head of community partnerships within the healthcare organization. This individual was instrumental in bringing together a team of multilevel and multisector stakeholders with considerable expertise and influence in their respective fields to help with program planning and implementation.

This individual oversaw clinical workflow processes at two family medicine clinics within Case 2 and identified as the department's physician champion, with a passion for food justice advocacy work. This individual was instrumental in gaining provider buy-in for the initiative during program planning and implementation with presentations during clinical staff meetings. The Medical Director also provided insight about clinical workflow processes that informed program design.

This individual was responsible for overall management of that department including finances, personnel, resource allocation and academic oversight. This individual was also a practicing physician at Case 2's family medicine clinics and understood the need for a clinical FI

initiative. As a high-level leader in the Department, the Chair supported during internal meetings with clinical staff and healthcare administrators. This individual also knew what internal resources could be allocated towards program costs, including available staff, staff knowledge and skills, financial resources, and EMR accessibility for screening

The onsite Registered Dietitian (RD) at the family medicine clinics was also asked to join the stakeholder team. This individual had served patients at the family medicine clinics for several years and was knowledgeable about the dietary needs of the patient population, as well as community food resources. This individual also functioned as program coordinator for the food justice organization, and managed community and school food initiatives. The RD took on the role of Program Manager (PM) for the FI initiative and was involved in all aspects of program development, planning and implementation due to the incredible amount of related expertise this individual had with the community.

Program B's food organization partner was an urban garden collective. According to the organizational report, the collective managed 15 regional farms and provided 180,000 pounds of fresh produce to local communities in need. At the time of this study, over 500 health centers in the Chicago and the surrounding Cook County suburbs benefited from diet and nutrition education along with free or low-cost produce. The collective also supported the idea of "empowering families to grow their own healthy food." As such the collective had established 60 family-run community garden plots in low-income neighborhoods at the time of this study. It also offered paid, food systems job training to roughly 200 individuals every year.

Program B was implemented in 2018 at Clinic D during the 2018-2019 growing season from June through November. When the growing season ended, Program B rotated to Clinic E for the 2019-2020 growing season.

D. Overview of Program B

TABLE VI and Figure 15 list general program categories that stakeholders reported that are explained in the section below. The table also lists the specific action associated with each program element, time of occurrent and the implementation actor responsible.

Screening: Patient FI would be conducted by either the nurse or MA while they collected other vitals during each patient visit. These questions were already programmed into the current EMR software, Epic, that the healthcare organization used. For every patient that screened positive for FI, the clinic staff made a note in the patient's chart for follow up with their provider. The clinic staff routed the patient information to the onsite RD through Epic for comprehensive follow up later.

Referral to Local Resources: During the doctor's visit, the physician was made aware of the patient's positive FI status as they reviewed the SDOH section in the EMR. The physician then electronically requested a print-out of local food pantries and other related food resources located in the EMR. This list was automatically generated and printed out in the after-visit summary report that each patient received from the front desk staff after their visit.

Referral to Program: Physicians also referred these patients to the produce prescription program that took place at the clinic every week for six months, which included a free bag of seasonal produce, a cooking demonstration that utilized that produce and related nutrition education.

Program Promotion: The PM reviewed EMR patient data and created case files for positively screened patients. The PD contacted those individuals for additional follow-up and program promotion. The PD enrolled patients that were interested in the produce prescription program and provided a schedule of food distribution days.

Food Distribution: Food distribution lasted from June through November, during the food partner's main growing season.

| Program Activities | Action and Time of Occurrence | Implementation Actor |
|--------------------------------------|--|----------------------|
| 1. FI Screening | Frequent EMR FI screening when patient's vitals are collected during doctor's visit. Positive screen is flagged in the EMR | Nurse/MA |
| 2. Referral to Local | When patient is roomed and visiting with their doctor, the doctor provides resource list about local pantries. | Doctor |
| 3. Referral to Program | The doctor also refers the patient to the program | Doctor |
| 4. Program Promotion | Call FI patients that wanted to receive more information. Enroll those that are interested. | PM |
| 5. Food Distribution | The Produce Prescription Program was held weekly during a two-hour window every Thursday evening. Patients were asked to participate in a cooking demonstrate and nutrition education class as well. | РМ |
| 6. Enrollment in Federal Benefits | SNAP eligible patients could enroll in SNAP using an electronic tablet provided by the clinic. | PM |
| 7. Program Evaluation | A weekly patient satisfaction survey distributed to patients after program participation. Questions asked about food preferences, cooking and nutrition lessons. Every fifth session clinical staff distributed a survey to measure change in FI status or improvements in dietary behavior due to program participation. | РМ |

TABLE VI PROGRAM B: INTENDED SCREENING AND FOOD DISTRIBUTION PROCESSES

Food was distributed weekly on a Thursday evening at the clinic during a two-hour window in the late afternoon. On those days, participants were required to sign in prior to program before

participating in the program.

The patient information was entered into the EMR so that program stakeholders could track

improvements in food access status, dietary health and disease management from program

participation. Data entry was entered by a dietetic intern on a separate day.

During the two-hour window of food distribution, participants were invited to participate in a cooking demonstration and tasting, as well as a nutrition education class that utilized the produce distributed that day. These sessions were offered by the PD with assistance from a dietetic intern.

Enrollment in Federal Benefits: Patients interested in enrolling in SNAP could use an electronic tablet that was provided by the PD to look up online enrollment information.

Program Evaluation: After the conclusion of the of the educational programming, participants were given a satisfaction survey to complete. The survey asked questions about how helpful patients found the information provided on that day, how they rated the quality of produce that had been distributed and if they had used the food from the week prior. This information was passed onto the food partner for quality improvement efforts.

Every fifth session, participants were also asked to fill out a paper survey that collected demographic information, food insecurity status and stress levels related to food insecurity. Patient information was entered into their EMR by a dietetic intern after distribution for patient tracking and follow up.

The major theme that emerged for Program B is that the infrastructure of the healthcare organization drove program design and implementation processes. Nationally recommended screening, food distribution and SNAP enrollment activities were dictated by the current workflow processes and available clinical staff. The food assistance partner provided infrastructure for the food intervention component. A multifaceted FI initiative engaged patients through the distribution of a weekly produce prescription box, evidence-based nutrition education and cooking demonstrations. The produce was sourced from an urban garden that promoted a local and sustainable food system.

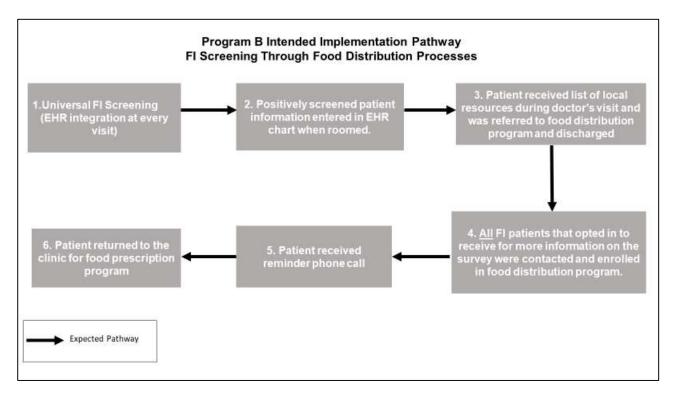


Figure 15. Intended screening through referral pathway: Program B

E. Implementation Factors for Program B

Major barriers and facilitators were identified from study participants, which are described in the section below. These factors were categorized into major themes and associated construct. (TABLE VII).

| Theme | Factor (+/-) | Definition | CFIR Construct & Category |
|--------------------------------------|--|---|---|
| Enhanced Program Resources | Community climate: collaborative networks that provided program model, funding, support and expertise (+) | This refers to the local community environment where a history of multisector collaborations created a climate of continuous work to achieve health equity and food justice in the community. This environment facilitated program support and sustainability through resources, capacity and expertise and created synergy with existing initiatives. | Outer Setting <i>Cosmopolitanism</i> (+) Outer Setting <i>Climate</i> (+) |
| Aligned Implementation Climate | Healthcare setting supported food access initiatives (+) | This refers to the clinical environment that already supported a food as medicine culture prior to the implementation of Program B. Existing food access initiatives at the clinics supported and welcomed the adoption of Program B. | Inner Setting Structure Systems Level (+) Climate |
| Adaptability | Adopt different FI screening process from original plan (+) | This refers to the adaptability of the screening activity that allowed for Program B to use a paper survey mode for delivery when faced with EMR challenges for screening. | Inner Setting Structure <i>Program Level</i> (+) Characteristic of Intervention |
| Limited Program Resources | III-equipped clinic setting to provide evidence-based cooking demos as (-) | This refers to the limited physical space and the lack of kitchen equipment at each clinic that resulted in the inability to provide evidence-based cooking demos as intended. | Inner Setting Structure <i>Clinical Level</i> (-) Physical Space |
| Limited Program Resources | Only SNAP eligible patients could participate in the program (-) | This refers to the USDA funding restrictions. Spending was allocated for SNAP eligible patients only. | Inner Setting Structure <i>Systems Level</i> (-) Funding |
| Limited Program Resources | Intermittent food distribution (-) | The urban garden collective could only provide distribution half the year during the growing season. | Inner Setting Structure <i>Program Level</i> (-) Characteristic of Intervention |
| | | | |

| Theme | Factor (+/-) | Definition | CFIR Construct & Category |
|--|---|---|---|
| Adaptability and Trialability | Cross-Sector Collaborations (+) | This refers to leveraging external resources to supplement current funding streams to expand program reach, frequency of food distribution and program eligibility—this resulted in adaptations to the intervention and subsequent implementation processes. This refers the active outreach stakeholders engaged in with community partners shift the cooking demonstrations from inside the small space of the clinic to the larger community center with a full working kitchen. | Outer Setting Cosmopolitanism (+) Inner Setting System Level (+) Culture Program Level (+) Characteristic of Intervention |
| Adaptability and Trialability | Cross- Departmental Collaboration (+) | This refers the leverage of existing internal assets for program staffing needs through the cross- departmental collaboration with the medical school. The program was adapted to incorporate students as actors. Implementation responsibilities were transitioned to students to increase capacity. | Inner Setting Structure System Level (+) Culture Program Level (+) Characteristic of Intervention |
| Limitation of Individuals Involved | Limited time for doctors and PM to execute program responsibilities (-) | This refers to the limited time the doctors and PM had to execute program responsibilities. | Inner Setting Systems Level (-) Clinical Workflow Individuals Involved Capacity (-) |
| Limitation of Individuals Involved | Limited doctor awareness of program responsibilities (-) | This refers to the limited awareness doctor's reported about their program responsibilities to provide the list of food resources to FI patients. | Inner Setting Systems Level Communication (-) Individuals Involved Knowledge (-) |

Facilitator 1: Program leaders reported the existence of collaborations with external

community organizations and local urban growing models for program support:

We've been close partners with [the urban garden collective], and we wrote the USDA grant together for [Program B]. So, that concept came from them, and it had the pieces like USDA is paying for the food. It's like, we were thinking about it and testing similar pilots, and then they had the grants, opportunity and the growing opportunity in a growing infrastructure. They brought the growing infrastructure, and we brought the community resources of being able to market and partner, and that's a piece they didn't have, and the growing is the part that we don't have... You need all these different players. One, the hospital alone can't do it, [food justice organization] can't do it alone, and [urban garden collective] couldn't do it alone, but when we all came together it was feasible.

This was supported by another report about the larger agenda for food justice through a

sustainable food system:

This is more about the food system than just the public health perspective. So, early on we thought, gosh, if the health system could invest in the farmers, not just buy food as a service, but actually invest in a sustainable contract, so that farmers could have some capital to provide these contracts. Any business needs capital, and if you're black and low income, you're not going to easily get that capital from the economic systems that are available...So, those ideas were with us, and we ... So, over this time, we've been building closer relationships with the hospital, understanding their needs and their values has changed. I don't think they were thinking about growing and food in the way that they are today.

Facilitator 2: Clinicians believed the current food as medicine clinical environment helped

with program adoption. More than one clinician mentioned the onsite farm stand at several clinic

locations within the healthcare organization.

One participant talked about the powerful synergy the clinic had with the farm stand:

I think the strength of having it at the clinic is just the traffic. The traffic of people. So, people walking past the farmstand and seeing the vegetable distribution get naturally brought into the cooking demos... Farmstand is a brilliant move because that Farmstand is sitting there just seamlessly with the distribution [produce prescription program]. And so our nurses were out and physicians were out, everybody was out there buying stuff from the Farmstand. So, it becomes a very collective experience. As a provider in that clinics, and I have clinic on Thursday nights when these are held and just as a provider to be able to see patients coming in with bags of vegetables and have them sitting next to them as I'm talking to them about their hypertension and talking about dietary contributions to hypertension. That was very powerful.

Another clinician reported:

The farm stands are an addition to the eight to 10 pound bag of veggies that they're [patients] getting. At the farm stands, people can use what we call produce perks, which are basically like half off coupons when they use their link card at the farm stand. Or for those that do not have Link or Snap, they can get half off coupons using just cash, credit, debit. The farm stand is from our giving garden and [name of food partner organization]. We also work with the fresh market that has a farm stand, as well.

Facilitator 3: The original screening activity needed to be adapted because the EMR

software could not be used and program leaders said they that they did not have access to best-

practice guidelines. One program leader said:

I know that the other hospitals in the region are, we're all trying to figure out what is the best practice in screening and getting into the EMR. To be honest, I don't really know that answer.

They, however, discussed the paper adaptation and its benefits:

The way we've been doing it is just a paper survey and really just requires everybody kind of knowing what's going on in the clinic. It's very time consuming as you can imagine... Also, after every fifth visit [to the produce prescription program] participants complete a survey about their basic demographics, food insecurity, and then we added a stress screener to see if this [FI] is affecting people's stress levels.

Barrier 1: Food was distributed intermittently.

While program design was greatly facilitated by the urban garden collective, one participant

said they needed to find a way to serve patients year-round due to the limited growing season of

their food partner. Another program leader validated this statement:

People still need to eat fruits and vegetables in the winter. Just because it's not the growing season we still need to find a way we can teach them about seasonality and saving money...

Barrier 2: Program leaders said that the current funding resources limited program

participation and was unsustainable. USDA funding restricted spending for SNAP/Link eligible

patients only, which was a problem that was identified:

We saw that many of our patients who screened positive for food insecurity didn't have SNAP or food insecure people who are interested, didn't qualify because they didn't have the Link card.

Another participant said that funding was also restricted to four years, which jeopardized the longevity of the program:

On that [USDA] grant it's a total of four [years]. I think we'll probably apply, but I think we've also realized that it's not a sustainable solution to food insecurity. We're really trying to think of what else can we do to make this a sustainable food economy here in [neighborhood name]. That's what we're really working on, too.

Barrier 3: Structural resource limitations were also identified. Physical space and lack of

equipment within the clinic also became a challenge during the cooking demos. One clinician said:

When we did it in the summer here at the clinic, space is definitely limited...you can imagine how tight it was. Like we only had the entryway and we had the first-floor clinic. But still, it was literally a waiting room, a small waiting room. And as far as the kitchen goes, we have a break room here that has a refrigerator and a microwave. That's really the extent of our cooking supplies in addition to like bowls and plates and tables and things like that.

Facilitator 4: Program leaders reported on the strength of internal and external

collaborations to leverage their expertise for planning and implementation.

One participant reported:

[Physician Champion Name], a physician, is needed, needed, needed. It doesn't matter how much I do, I'm in the community, I don't have access to the medical records or know about the staff and flow. You need that insider, and I pulled them together individually, got them sold on the idea, and then brought them together.[Program Manager's Name] is the design champion. I'm more of a visionary, like let's bring these folks together and leverage assets and capacity and people. Then, the day-to-day logistics was [Food Partner's Name], [Program Manager's Name] and [Physician Champion's Name]. The Program Manager has a background of working in the clinic, so she knew about workflow.

Another leader talked about collaborations to expand program reach with additional funding

and additional space:

I mean, I'm always looking for grants and partnership opportunities to support and expand our services... we saw that many of our patients didn't qualify. We got some funding through [name of organization] to run [name of another program] We actually had doubled the participation during those couple months in the winter. That led us to expand and look for more funding basically and expand the program to link and non-Link participants.

I worked with the parks department and now we're going to have the gym and full kitchen, so tons of space to expand. And what we're thinking is we will just do the summer distribution at the park district, also. They have a cool, like it's not a gazebo but like a pavilion and we could do as much as we can outside.

Lastly, one program leader spoke positively about the additional funding from partnerships:

[Stakeholder name] took initiative and designed and partnered with the organization and created [program name] for the community that would be for anybody who needs it, not just SNAP recipients.

Facilitator 5: Clinicians talked about the strength of internal, cross-departmental

collaboration that fostered successful program adaptations.

One clinician reported the addition of nontraditional staff to support the program with the use

of healthcare students:

So, starting about two years ago now we surveyed students and found there was a real desire among the students to have a culinary medicine elective. So, to learn more about how to, not only personally themselves learn about aspects of healthy cooking, but to be able to teach that to patients...I really wanted to keep this directed at patients who I have problems accessing services and have food insecurity themselves.

The PM and the medical education leader within the healthcare organization were influential in the development of a culinary medicine elective that trained up to 15 medical students and 15 dietetic students to work together to deliver the patient nutrition education classes and the cooking demonstrations during year two of program implementation. They received course credit in return. The provider also said a significant aspect of the program was the collaborative experience for students:

The other part of the culinary medicine electives that it's not just medical students, they're together with dietetics interns. So we're also creating this interprofessional education opportunity.

A medical student validated this assertion:

We really had the opportunity to work with them [dietetic interns], learn about their training was worth because it, gave me insight into their involvement in the healthcare patients and gave me a better appreciation of what they're involved in.

One clinician said it was incredibly important to give medical students an opportunity to

participate in an unprecedented service-learning experience to engage directly with patients:

So it really took them (students) interacting in a completely community based nonclinical environment and having to apply some of what they learned to normal conversations with people. So I think that is the impact in improving their communication skills with people in the community was pretty big.

In this case, multilevel staff worked cross-departmentally to find solutions for program

staffing challenges. Here is one example of that provided by one clinician:

We don't have any additional funding...I leverage my position to create this. In no way was I mandated to this. But I leverage the capacity I have and also, regulations of creation of elective and giving credit and everything. I have control over that. That, I leveraged in order to make it happen... So simultaneously [the physician champion's] work and working with [the PM] at the screening for the rate of food insecurity at our clinic. That made it all coalesce, that we were going to do an elective. It was going to be about teaching the students about cooking skills that they could share with patients and the focus was on low income populations. Barrier 4: Clinicians agreed that patient visits were not long enough to discuss FI and offer

education when patients presented with other high priority health issues that needed to be

addressed. One clinician indicated that it was a form of self-preservation to avoid FI discussions

entirely:

In general, food insecurity has not been on my radar to be completely honest with you. As you probably know, a primary care visit is completely overwhelming with—'I have to get your foot exam done, you have to get an influenza shot, I've got to draw your A1C.' Food insecurity is a serious conversation that takes time. And until now I haven't had good screening tools and I haven't known what to do with it if I got a positive result. And so if you screen for something and can't do anything with it, it just leaves both parties feeling super helpless. And so that is why it has not been a part of my standard practice.

Another clinician said that frontline staff lacked time to address FI:

We still really don't have time to do all these screens and talk about FI. Our staff just doesn't have time because the PHQ-2 fall risk already takes a lot of time.

Barrier 5: Limited provider awareness was also reported regarding the location of resources

in the EMR. One provider was unsure of where educational resources were in the EMR software:

[The PM] put together some resource that is vaguely familiar to me, I cannot tell you where it is in Epic... [The PM] said that there's some kind of shortcut. I have to go back through my notes, but, and I know [the PM] will come to staff meetings to talk about the program. How regularly does [the PM] do that? Maybe [the PM] might need to come more frequently... I remember [the PM] at least once coming to one of our faculty meetings.

Another provider reported that the list of food resources was in a place they would not

normally access:

It's funny, I just opened Epic, so I'm seeing they've got a 'relationship section' that is new for us. It asks for social connections and asks about intimate partner violence. Got a lifestyle section that asks about physical activity and stress, socioeconomic food insecurity. There's a food insecurity section of this... these are in a totally different section. They're in the history section and all of our other ones are in the assessment section. So under assessments we've got the PHQ-2 fall risks, functional status, hearing, vision, gender, sexuality, health assessment, BMI. Yeah. So it's in the history section. So I would never ever see this.

VI. CROSS-CASE ANALYSIS

A. Overview

The aim of the cross-case analysis was to analyze overall implementation themes across both programs for similar patterns, keeping in mind the unique context of each setting. Salient themes are presented in the proposed conceptual model for program implementation in Figure 16.

B. Cross-Case Implementation Themes

The similar themes that emerged during the cross-case analysis were limited program resources related to human, financial and physical resources. Each program also demonstrated a high-level of adaptability and trialability due to the resource challenges. Both themes are represented in the proposed conceptual model.

One theme observed across cases was limited program resources.

Limited clinic level physical space was a subtheme and associated with the Inner Setting Structure domain. At the clinic level, physical space was an issue for both programs. Screening processes lacked privacy and resulted in patient discomfort for program A. Adequate space with appropriate equipment for the implementation of evidence-based cooking classes could not be provided for Program B. This limited patient participation and quality of programming.

Limitation of workflow processes was also a subtheme—a part of the Inner Setting Structure at the Systems level that affected how the physical space was used. Because screening had to take place during intake, staff capacity and quality of care delivery during daily operations and intervention characteristics and processes at the clinic level.

Capacity limitations of individuals involved was also a subtheme for both cases. Each program had challenges that related to staff time that was a result of the existing workflow processes in both cases.

This was categorized as part of the capacity construct under the Characteristics of Individuals domain, all of which were housed under the system level structure of the Inner Setting domain. Doctors had the same general responsibilities to educate patients about local food assistance resources across programs. Stakeholders reported that competing responsibilities and high-priority health issues prevented doctors from executing this element of the program consistently.

Program A also reported that they lacked research and evaluation expertise that impeded activities related to program evaluation and they struggled to demonstrate a return on investment with their program. They could not connect voucher redemption to patient program use, patient dietary behavior change, health outcomes nor reduction in FI. This limitation is associated with the Inner Setting Structure Systems Level and Individuals Involved domains and Skills construct. Lack of adaptability and the use of external support was also observed in the method for screening.

Limited EMR usability was reported as a subtheme for both Program A and B with respect for the execution of program activities. This was an Inner Setting, systems level structural challenge. Program A had challenges with how EMR was integrated. Stakeholders reported that to use the EMR for screening, the questions needed to be a part of the intake process because that was how the software was designed. Patient discomfort and inability to respond reliably to screening questions was the result of an overwhelming intake process. The lack of privacy from where intake was required to take place exacerbated this problem. Screening frequency was also limited to the intake schedule, where follow-up for SDOH issues, including FI, occurred only once a year.

Program A also reported that the EMR did not provide a flag or reminder to check patients for FI. Stakeholders said a flag in the EMR would help them remember to talk to patients about local food assistance resources, even when if they were busy treating more critical health issues. 71

Program B reported that they had difficulty navigating the EMR to the local food resource list that they were supposed to give to FI patients. Therefore, many FI patients missed out on the resource list. Program B was also forced to use a different mode for screening delivery because the EMR system was not available for use.

Limited funding was a subtheme that affected both programs similarly as it related to frequency of food distribution, program sustainability and reach. This is related to the Inner Setting, systems level domain ant the structure construct. Neither program had enough funding to pay for the cost of food that could be distributed frequently enough to meet patient needs. Program A relied exclusively on in-kind donations from their food partner for food that was too costly to provide more than once every two months.

Program B relied on their food partner program model for food distribution. Unfortunately, the model only allowed for food distribution six months out of the year. This was based on the urban garden collective's growing season (i.e. from June through November), when produce was most abundant. This factor was not only related to the intervention design construct that falls within the inner setting structure. It was a funding issue as well. Program B's USDA funding was not enough to cover the cost of additional distribution during the off-season.

The USDA funding was also limited to a four-year timeframe, which stakeholders said jeopardized program sustainability. The USDA grant also came with spending restrictions. Stakeholders were required to spend the funds on SNAP-eligible patients only. Participants reported that they had to turn away FI patients from the program if they were not SNAP eligible.

The second major theme observed across cases was intervention characteristic in the form of high-Level of adaptability and trialability. The intervention was highly adaptable and testable as seen in Figure 16. Both these constructs are a part of the Intervention Characteristics domain.

Adaptability refers to the degree to which the core program components can be tailored or refined to fit the implementation context, without threat to program fidelity (Damschroder et al., 2009f). Trialability refers to the ability for stakeholders to pilot an intervention on a small scale and to engage in a cyclical process of quality improvement where reflection, experience building and adaptations can be made (Damschroder et al., 2009g).

Both constructs emerged as themes in the context of limited program resources discussed above. It appeared that when program resources were enhanced, it strengthened the adaptability and trialability characteristics of the intervention across both cases. Conversely, the high level of adaptability and trialability of the program allowed for ongoing exploration of alternative and creative methods to enhance resources that improved program implementation processes across cases.

Program A demonstrated adaptability and trialability in the following way. The program was piloted at one clinic before it was expanded to the 12 participating clinics. Participants at each clinic that participated in this study reported that they made minor changes to program activities to meet the needs of their staff and patients after assessing the usability of intended processes. For example, this was reported from how often and to whom vouchers were given to reach more patients. One participant also reported bypassing phone call reminders entirely with a different promotional method that fit better into their daily work schedule.

Program B demonstrated adaptability and trialability in the following way. Program B shifted food distribution activities a community center to take advantage of the larger space and the kitchen equipment. The access to a larger and better equipped space improved the ability to provide the cooking demonstrations and nutrition education as intended, which enhanced patient experiences.

Program B also used a paper screening process instead of the originally intended EMR process.

73

One program leader said that after some trial and error they figured out how to integrate the screening process that avoided any patient discomfort. This process also allowed them to collect and match patient data at multiple points in time and enhanced evaluation activities that included the collection of dietary behavior change as well as reduction in FI.

C. Unique Implementation Themes

A theme demonstrated in Program A was clinic level autonomy, which was not observed in Program B. Each clinic could implement the program based on their patient and staff needs. Clinic level autonomy facilitated the adaptability and trialability of Program A activities.

An example of clinic level autonomy was observed in interviews with clinic managers that demonstrated ownership and passion for the program. They indicated that specific adaptations across clinics fostered connections with their patients. As mentioned above, examples of this came from statements of "we do things differently here," and "the way we do it is..." These kinds of statements referred to referral and voucher activities that one clinic said they changed to suit the needs of their patients. Clinicians said they gave every patient a voucher that asked for one to reach as many FI patients as possible. This was especially so in cases where patients did not want to reveal their FI status during screening.

One clinic adapted the SNAP enrollment process to meet their own capacity and to facilitate the connection between SNAP eligible patients and federal benefits. They did this by engaging patients while they waited in the food truck line instead of at the doctor's visit as intended visit.

Program B demonstrated a theme of community climate and cosmopolitanism as a facilitator, which was not observed in Program A. Program B's healthcare organization was fortunate enough to be a part of a community that had fostered food justice through community collaborations for almost a decade prior to the launch of Program B.

A widely accepted urban growing model promoted local, seasonal and affordable produce. Clinicians said that Program B created synergy with existing community programs, which enhanced program resources, as well as adaptations where necessary.

A subtheme of cosmopolitanism was the expertise of external networks and existing collaborations. A local food justice organization worked with community and regional stakeholders to promote initiatives for economic development, health equity and a sustainable food system for community residents. This organization was a partner with Program B's healthcare organization and facilitated the collaboration with the urban garden collective and other local food growers. Together these organizational entities enhanced program resources with their expertise, staff training and their collective strength.

An example of utilization of existing collaborations was demonstrated in discussions with stakeholders that reported that the food distribution activity was adapted to take place at the community center because of an existing partnership with the parks department. Program leaders also secured additional funding from external partnerships. This allowed Program B to pay for additional food secured from local growers to provide food distribution year-round. Access to additional funding sources also supplemented the existing USDA grant to cover the cost of SNAP ineligible patients to participate in the program.

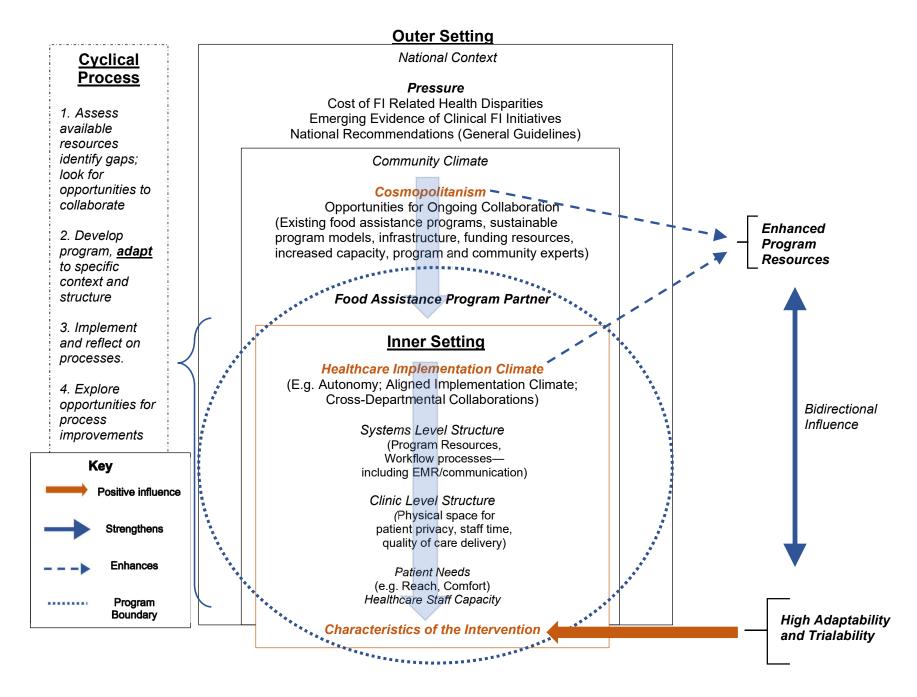
Another subtheme of cosmopolitanism was an aligned implementation climate, part of the Inner Setting Systems Level Domain and the Climate construct. Program B stakeholders reported that farm stands already existed on the healthcare campus and outside each program clinic. One clinician said that implementation climate promoted a food as medicine culture, and it was common to see doctors and patients shopping at the farm stand together. Moreover, patients oftentimes came to their appointments with their shopping bags of produce from the stand. This inner setting climate was well aligned with Program B and was a product of the overall community climate. This is represented by the blue arrow in the middle of the diagram that spans the community context and the inner setting context.

The aligned climate was also observed in the academic side of the healthcare organization. One program leader reported that medical and dietetics students, aware of the importance of food as medicine and existing farm stand interventions, demanded culinary medicine training.

This demand combined with the need for additional staff support for Program B resulted in a cross-departmental collaboration to leverage existing assets. The result was additional staff support in the form of medical and dietetics students for Program B, which, in-turn offered them an experiential learning opportunity and course credit.

D. Cyclical Implementation Process

Implementation is a cyclical process. The conceptual model illustrates the themes that emerged in this study and continual assessment of available assets and gaps in program resources. Program development and implementation relied on the community and clinical context, as well as the ability to reflect on processes that did and did not work. The continuous process of reflection combined with the level of adaptability and trialability of the program to situational constraints facilitated implementation.



VII. DISCUSSION

A. Overview

This multiple case study examined implementation of two different FI screening initiatives in two diverse primary care contexts. One was embedded in urban, safety-net clinics that were part of a publicly funded healthcare organization. The second was embedded in a suburban private, non-profit healthcare system. Both healthcare organizations served predominantly low-income patients with a high prevalence of FI.

Study findings indicate that each site's program activities and implementation processes were driven by the unique culture and context of its healthcare system. In the face of structural, financial and human resource challenges, each program demonstrated a high-level of adaptability and trialability to accommodate the situational context. This is an important finding, considering the resource challenges that are inherent to U.S. hospital and healthcare systems. The ability to test, adapt and refine FI screening programs to various implementation challenges across primary care settings is critical for further research and practice.

This is the first study, to this author's knowledge, that used CFIR to examine context specific, multilevel implementation factors of clinical FI screening initiatives. These empirically tested and theoretically derived concepts guided the development of a conceptual implementation model that may be tested and refined in follow-up studies. The findings are discussed next in the context of the current literature, as well as recommendations and future implications for research and practice based on study findings.

B. Recommendations

Because findings demonstrated that the healthcare organization drove program processes it should not come as a surprise that both programs, situated in their respective healthcare systems, experienced financial, staffing, workflow and EMR challenges. U.S. hospital and healthcare systems are built around rigid compliance and legal regulations intended to maximize delivery of care at minimal cost. Many of these challenges were and will continue to be unavoidable.

Recommendation 1: Allow for adaptability with caution. What is striking is the unique implementation context that fostered program trialability and adaptability. In Program A, clinic-level autonomy fostered by the healthcare organization motivated each clinic to make changes to program activities where warranted. In Program B, cosmopolitanism enhanced program adaptability. In both cases, program activities were tested and refined to meet the needs of implementation context (i.e. paper screening versus EMR screening in Program B, and SNAP enrollment during food distribution instead of during a patient visit in Program A).

While program stakeholders reported that these types of adaptations helped them implement the program more efficiently, from a research perspective, these types of variations may make it difficult to assess overall program effectiveness down the road. Program fidelity, a key factor for the systematic uptake of evidence-based programs, is compromised when program processes of the same intervention change across community-based settings (Breitenstein et al., 2010a). While FI screening programs need to demonstrate a high level of adaptability due to the multiple resource constraints that were identified in this study, adaptations need to be monitored regularly with the use of validated strategies (Breitenstein et al., 2010b). This can ensure that core intervention components, even with adaptations, are implemented consistently and with high-quality, and that program outcomes are a result of the intervention, not confounding factors (Breitenstein et al., 2010c).

For example, Program B implemented alternate paper screening processes that was used consistently across program sites. This helped to reduce the threat to fidelity. It also gave stakeholders the opportunity to evaluate changes in dietary behavior and FI status regularly because of program participation.

79

Conversely, Program A's EMR system required the placement of the FI screening questions at the very end of the intake process that was accessible only once a year. Stakeholders said they could not change these aspects of the screening process because it was a software issue that was out of their hands. This not only resulted in limited frequency of program evaluation, it also resulted in an adaptation that bypassed screening completely--a core program component—to connect patients to the program.

This is an example of the tension that exists between the push of a research or policy agenda and the pull of practice needs and circumstances often times observed in community-based research that can threaten fidelity (Brownson, Fielding, & Green, 2018a). The rush to implement the EMR screening that was recommended by national experts, without having appropriately assessed its usability within the implementation context resulted in limited program fidelity and the inability to tie program outcomes to intervention activities.

Recommendation 2: Consider how or if the context can support intervention activities. Consideration of context during the early stages of planning are just as important as examining the evidence (Brownson et al., 2018b). Stakeholders should assess the value of the evidence of recommended screening practices with respect to their clinical context and search for options that can be consistently implemented and monitored across program settings.

Recommendation 3: Consider external partnerships. Program B stakeholders also shared their experiences working with external organizations to facilitate program implementation, capacity and expansion. These factors facilitated the design and implementation of Program B that had a synergistic effect on existing food access initiatives throughout the community.

However, this recommendation raises its own challenges. Questions may arise, such as how are partnerships formulated? Or, whose responsibility is it to do this? These are factors stakeholders will need to address if established networks do not already exist. The strength of multisector collaborations also assisted with program adaptations that allowed for additional expansion and reach during year two of implementation. Resources to pay for gaps in year-round food distribution and to expand program eligibility requirements was secured by the healthcare organization through outreach with an external entity. An established partnership the healthcare organization had with the parks department provided more resources in the form of physical space to host cooking demonstrations and nutrition education classes.

Implementation science tells us that established partnerships for the purpose of capacity building has been proven effective in the dissemination of evidence-based research across various healthcare settings. Moreover, implementation science recommends capacity-building early during program planning to maximize those relationships (Brownson et al., 2018c).

With respect to the resources challenges many healthcare organizations face, community collaborations can fill resource gaps that may never be solved by the healthcare system alone. Program B' healthcare organization had a connection to the community that had been established prior to the point in time when this study was conducted. It demonstrated how community and clinics can be aligned to address similar health needs from multiple access points and iniatives. "Community food justice" had a strong presence during discussions about implementation and sustainability. From the very beginning, these gaps in resource were identified that stakeholders worked quickly to address.

Conversely, the local community context (e.g. the existing food access programs, policies and organizations) did not have a strong presence during conversations about Program A. In fact, the program seemed to function in a silo. Stakeholders said that they did not receive assistance from programs outside of their own.

However, in a follow-up conversation with a system-level leader, community collaboration was promoted at the clinic level and was intended to strengthen clinic-level autonomy through local support.

This demonstrates that Program A was aware of the potential that cosmopolitanism has to support capacity, expansion and sustainability. Nevertheless, they were limited in staff capacity to forge those partnerships.

Recommendation 4: Consider non-traditional forms of staff support. Another unique feature of Program B was use of medical and dietetics students during year two of program implementation. This was the result of cross-departmental collaboration in the healthcare organization to creatively adapt existing assets for program staffing needs. In turn students engaged in experiential learning, learned how to engage with diverse patient populations about dietary health and received course credit.

This is an opportunity for healthcare organizations to enhance their existing program resources by tapping into human capital available in affiliated academic institutes—A best practice with potential for further exploration.

C. Findings Supported by Previous Research

Findings from this study are consistent with previous research. A limited number of implementation studies exist for clinical FI screening initiatives. Those studies identified implementation challenges of screening and referral at the micro and macro levels within a healthcare setting (Knowles et al., 2018a; Stenmark et al., 2018a). These studies applied various quantitative and qualitative research methods to understand context; however, most do not explicitly apply a framework made up of theoretically derived constructs for data collection and analysis. Many are characterized by the limited application of theory, which used to explore provider-specific factors of implementation that did not consider the larger organizational or community context.

Nevertheless, implementation factors identified in previous studies mirror this paper's findings. Two studies examined implementation processes of screening and referral programs in pediatric settings (Knowles et al., 2018b; Stenmark et al., 2018b).

One of the studies assessed a FI screening and referral program in pediatric clinics during a three-month pilot intervention for caregivers with children younger than five years old. Grounded theory was used to identify implementation barriers and facilitators that emerged in the data.

The other key study examined implementation of a clinical FI screening and referral service in two pediatric clinics. The purpose of the intervention was to reduce FI by connecting positively screened patients to a statewide hunger relief hotline that helped families enroll in SNAP and other federal benefits and provided referrals to local food pantries (Stenmark et al., 2018c).

Patient privacy during screening was a key theme in the Knowles et al. (2018) study. Patients were given a choice between self-reported paper or provider implemented screening methods. Patients preferred the privacy of a self-reported paper survey where interaction with staff was minimal and where they did not have to verbally disclose FI. (Knowles et al., 2018c).

Similar to this study's findings, Knowles et al. (2018) concluded that EMR screening elicited patient discomfort due to the lack of privacy during screening. It also pointed to the stigma and shame of talking about FI.

Knowles et al. (2018) did not report any other barriers to EMR screening, such as the overwhelming intake process that was reported in this study. The issue of the overwhelming intake process with FI screening embedded into it had not been previously identified in the literature as an implementation barrier and should be further studied.

Another similar theme was clinician awareness about FI and availability of Federal benefits programs and local resources. Stenmark, et al. (2018) reported that FI was not always acknowledged by clinicians and that they were unaware about how federal benefits worked. This may be due to the study setting. It was conducted in a non-urban, healthcare organization in Colorado. Providers may not face the same types of multifaceted and chronic FI related issues in Colorado that Cook County providers face. In this study Program A and Program B stakeholders reported that doctors were wellaware of the seriousness of FI and with SNAP and WIC. Study sites were predominantly urban and treated mostly low-income populations that faced many SDOH challenges.

While previous studies provided insight about implementation factors within a unique implementation context, these studies lacked a theoretically driven conceptual model that explains the interaction between implementation factors. This study, in contrast, applied CFIR, a conceptual framework comprised of theoretically driven constructs that had been empirically tested in previous healthcare studies.

Few clinical FI screening studies explicitly applied implementation science frameworks or findings related to salient implementation factors. One study adapted, the Core Implementation Components Framework, to examine provider acceptance, training and execution of ta produce prescription program within three safety-net clinics in (Fixsen, Blase, Naoom, & Wallace, 2009). Provider knowledge, capacity and systems-level support needs were identified using qualitative data from the perspective of implementation actors during the formative research phase.

The findings ultimately informed planning strategies for effective program execution specifically for implementation actors (Joshi et al., 2019). However, Joshi et al. (2019) did not consider factors external to the healthcare system that may have affected the process of program implementation and service delivery. It also missed an opportunity to collect critical, context specific information from multilevel stakeholders within the organization to incorporate their perspectives about implementation factors. This limits our understanding about how these programs are implemented in primary care settings, which multilevel factors affected program implementation and the development of recommendations for further practice and research.

D. Theoretical Contributions

This dissertation research has significant contribution to the current body of clinical FI screening research. In particular, the proposed conceptual model constitutes the foundation for the development of theory-driven standard program practices. The proposed conceptual model is an adaptation of CFIR, a theoretically derived determinants framework. Though formative in nature the model identifies areas of exploration that have not been considered in previous research.

For example, data collected from multi-level stakeholders provided a holistic understanding about implementation context within each healthcare organization. External factors, such as community collaborations and climate were also considered as a part of the implementation context and were integrated into the conceptual model as a part of the implementation process.

The model points to a relationship between the high level of adaptability and trialability of the FI screening intervention, cosmopolitanism, and clinic level autonomy as a part of the inner setting. The hypothesized relationships that were established between constructs in the proposed model may be tested, expanded upon or refined in follow-up studies.

E. Practice and Research Contributions

Study findings also have implications for practice-based research. Stakeholders should consider the exploration of external factors and creative uses of internal assets for program support—especially due to the scarcity of funding for community-based interventions within healthcare organizations that have yet to demonstrate healthcare cost-savings.

Future studies should consider exploring how external collaborations/climate can foster the intervention's high adaptability and trialability. The effect these factors have on enhanced program resources and implementation need to be explored further within the context of each healthcare setting. Practice-based research should also consider adopting Community Based Participatory Research (CBPR), alongside CFIR, to tailor primary care focused FI initiatives to the realities of patient needs. This requires viewing the intervention design and implementation through a community lens (Cacari-Stone, Wallerstein, Garcia, & Minkler, 2014). The findings may provide critical insights about privacy, trust and workflow processes from the patients' perpectives that affected the reliability of screening responses in this and previous studies. This method can also help stakeholders understand the complexities and cyclical nature of household FI. The results may be used to design a clinical FI initiative that enhances patient care, as well as process and program outcomes.

F. Policy Contributions

Study findings have implications for national screening recommendations that support universal clinical FI screening policy. The findings can be used to begin a dialogue between researchers, practitioners and policy makers about how the realities of practice may inform the development of standard practices that can be applied in various healthcare contexts. The implementation factors identified in the proposed conceptual model should be further explored, built on and tested. This model establishes a foundation for the development of standard practices that can be tested for future policy work.

The practice of translating evidence into real world healthcare settings is often a challenge encountered in implementation of programs aimed at serving historically underresoured communities. Theoretically derived models that identify unique implementation contexts, as observed in this study, can help to create standard practices for program upscale and policy development (Baumann & Cabassa, 2020).

G. Study Strengths

The study had several strengths. The multiple case study captured multilevel stakeholder perspectives about program implementation.

The used an embedded multiple case study design with multiple units of analyses. Several perspectives were used to triangulate findings from each case and strengthen the rigor of this study. These data provided rich information and created a narrative that described how each program functioned within a specific implementation context—an area that, prior to this study, had yet to be fully explored in clinical FI screening initiative research.

Moreover, there was an advantage of using the cases from the AHE Workgroup. This researcher had established a previous working relationship with the workgroup, which streamlined recruitment efforts. The specific characteristics of potential study cases were also already known. This helped to inform the study goals, objectives and instrument development.

The study used CFIR to capture context specific variations in implementation. Previous partnership program research rarely applied theory to understand variations in implementation, which hampered the development of standard practices and wide-scale dissemination. In this study, CFIR established a foundation for the development of a hypothesized conceptual model that can be built on.

Additional qualitative research methods were used to enhance the rigor of this study. Ongoing feedback was elicited from research and practice experts during study design, instrument development, data collection and interpretation. Insights were gleaned from key study participants and dissertation committee members. An ongoing reflexive journal of study methodology and findings also served as an audit trail during the research process.

The study design incorporated multiple study sites within each case. This was a strength to the research process because it allowed for comparison of study clinics within each program and overarching conclusions to be made about each program's implementation processes. This served to enhance the external generalizability of study findings (Yazan, 2015b).

Lastly, the study findings build on previous research by exploring how clinical FI screening initiatives were implemented in real-world clinical settings.

The evidence-based research that existed prior to this study did not take into consideration how the complexities of healthcare organizations and the community context affected implementation processes. The lack theory to guide research limited the successful and sustainable execution of clinical FI programs across various healthcare organizations.

This study aimed to begin addressing the evidence to practice gap by conducting a cross-case analysis to understand how implementation occurs across different healthcare settings. Qualitative data from this study provided implementation context for two very different types of healthcare organizations.

Factors that affected program activities, actors and implementation processes were examined from multiple perspectives and multiple levels within the healthcare organization. Findings provide a holistic picture about implementation context and add to the current body of knowledge of clinical FI screening initiatives in primary care.

H. Study Limitations

This multiple case study had several limitations. First, as a study instrument, the researcher was positioned alongside study participants during the process of information discovery during data collection and analysis. As such, this was a subjective process that relied on the time and context of data collection and may have been affected by the researcher's own biases and experiences (Stake, 2006, p. 2c). The researcher disclosed her role in the study in the Methods chapter and utilized source triangulation and member checks to negate the effect of these factors during data analysis and interpretation.

The presence of the researcher during data collection may also have affected participant responses to questions, potentially undermining the reliability of responses. However, the purpose of qualitative studies like this one is to explore practice activities as they occur within specific contexts and to build on previous practice knowledge (Miles, 2015a).

The knowledge about individual experiences that were gained from this study assisted with translating partnership program implementation practices into theoretical assertions. It is these concepts that can be generalized in future research and practice (Miles, 2015b).

Second, there was a disadvantage associated with using the cases from the AHE Workgroup. It may not have been representative of all primary care situated programs in Chicago and Suburban Cook County that were not connected with AHE. The Workgroup was also highly engaged in advocacy and policy development to address FI in their local and/or patient populations. While it is important to include these stakeholders in this study, it is also worth noting that inherent bias came with using a sample primarily comprised of highly motivated and passionate individuals.

Third, while this study incorporated the perspective of multilevel stakeholders representative of the implementation context, the study did not include patients' perspectives. Their experiences would have enriched the findings and strengthened the study by validating and adding to the patient quality of care issues that had been reported. However, the scope of this study was limited to implementation stakeholders because it was not feasible to do more with the time allotted for this study. Future studies should incorporate patient perspectives about program implementation through a CBPR approach.

The fourth limitation was the lack of direct observations of implementation practices. In vivo observations could have offered a real-time representation of implementation processes that would have enhanced study findings through triangulation and, perhaps, additional insight. Again, as with the previous limitation, time restrictions prevented the addition of observations to this multiple case study. Future qualitative studies of partnership programs should consider direct observations to build on current findings.

Finally, this study relied on data that was collected from stakeholders at one point in time. Implementation is a dynamic process.

89

A study that incorporates data collection from the same participants at multiple points in time would allow for the exploration of how implementation processes change. The time restrictions of this research study did not allow for follow-up. Future studies should consider this aspect of implementation and incorporate multiple points in time for data collection.

VIII. CONCLUSION

This study effectively applied implementation science and an embedded multiple case study design to understand how FI initiatives, situated in primary care practice, were implemented. With the knowledge that the healthcare organization drives program implementation, this study used a theoretically derived implementation determinants framework to explore implementation factors at multiple levels within the healthcare organization and the surrounding community.

The key take away from this study is that because healthcare organizations have limited resources to dedicate to food insecurity screening initiatives, primary care practices need to be supported in their ability to adapt and test program activities to what is feasible for their specific context. From this study, this was exhibited through cosmopolitanism and by an inner work culture that supported clinic-level autonomy. Future studies may continue to build on and refine the proposed conceptual model, which is formative in nature and sets the stage for development of standard program practices.

As the U.S. healthcare system continues its transition to a value-based model of care, public health researchers, healthcare practitioners and policy makers need to consider how primary care focused FI initiatives can effectively connect patients to food assistance programs. In doing so, we can begin to improve dietary behavior and disease management. This is only one aspect of social justice and health equity. If we can reduce the burden of health disparities caused by inequitable access to affordable and healthy food, we may be able to simultaneously chip away at the high cost of care, while improving quality of life.

The recent global COVID-19 pandemic only highlights the critical need of clinical FI screening initiatives. An unexpected rise of FI in the U.S. is a result of millions of jobs lost due to COVID-19 and ineffectiveness of current referral processes to food assistance.

Findings from this study offer insight into one possible solution that can combat the rising tide of FI in the U.S.

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APPENDICES

Adapted CFIR Codebook *

*During coding and analysis, each construct and related category was designated as a barrier (-) or facilitator (+) as it related to implementation processes.

| | Construct 1: Intervention Characteristics | | |
|----|---|----------------------------|---|
| | Code | Category | Definition |
| a. | Source | Intervention Source | Definition/Statements Perception of key stakeholders about whether the intervention is externally or internally well-developed. |
| | | | Include statements about the quality of current intervention design. |
| C. | Adaptability | Adaptability | Definition/Statements The degree to which an intervention can be adapted, tailored, refined or reinvented to meet local needs. |
| | | | Include statements about adaptability of the intervention to the specific context of each clinic. |
| d. | Complexity | Complexity | Definition/Statements Perceived difficulty of implementation, |
| | | | Include statements about duration, scope, disruptiveness, number of steps to implement. |
| e. | Design | Design/Program Elements | Definition/Statements Perception about how the intervention is designed. |
| | | | Include statements about intervention design, specific program elements intended program modelhow things are supposed to work. |
| f. | | i. FI screening | Definition/Statements Any mention of the process for food insecurity screening, using validated screening questions. |
| | | (1) Too infrequent | Definition/Statements This code refers to participant discussion about the inability to track and follow up with patients after initial screening due to the infrequency of routine FI screening that was intended by the program design. |
| | | (2) Ineffective | Definition/Statements This code refers to participant discussion of food insecure patients that are not identified as food insecure during the screening process. |
| | | (3) Stigma | Definition/Statements This code refers to any mention of patient discomfort to respond reliably to food insecurity questions during screening. |
| | | (4) Provider effectiveness | Definition/Statements This code refers to any mention of doctor revealing food insecurity in patient that originally screened negative. |

APPENDIX A (Continued)

| | (5) EMR | Definition/Statements This code refers to any mention of using the |
|------|-------------------------|--|
| | | EMR system for FI screening. |
| Code | Category | Definition |
| | (6) Paper | Definition/Statements This code refers to any mention of using a paper format for FI screening. |
| | ii. Referral | Definition/Statements Referral food distribution program. |
| | (1) No Referral | Definition/Statements This code refers to any mention of a food insecure patient that does not receive a referral to the food distribution program due to challenges experienced during the implementation process. |
| | | Include statements about FI patients that were not effectively identified during screening or during conversations with doctor. |
| | iii. Patient Education | Definition/Statements Any type of education/referral/enrollment in other, supporting resources, including local pantries, housing or job security programs. |
| | (1) Lack of time | Definition/Statements This code refers to any mention of doctors' lack of time to talk to patients about food access resource list |
| | (2) Alternative staff | Definition/Statements This code refers to the role SW's, clinic managers and front desk staff take to support providers' role in program implementation. |
| | iv. Enrollment | Enrollment in SNAP and other federal benefits programs. |
| | (1) Lack of time | Definition/Statements This code refers to any mention of the inability to enroll patients in SNAP due lack of staff time. |
| | (2) Lack of training | Definition/Statements This code refers to any mention of the inability of staff to enroll patients in SNAP due to a lack of training to use online enrollment processes effectively. |
| | (3) Patient disinterest | Definition/Statements This code refers to any mention of patients' lack of interest to enroll in SNAP benefits. |
| | v. Program promotion | Definition/Statements Any mention of program promotion or marketing to patients, reminders to increase participation including signage, phone calls, emails, word of mouth. |
| | (1) Lack of time | Definition/Statements This code refers to any mention of the inability of staff to complete phone call reminders for program participation because of the lack of time |

| | | (2) Alternative method | Definition/Statements This code refers to any mention of alternative methods to reach patients to educated them about the program that deviates from the intended method for program promotion/marketing. |
|----|------|----------------------------------|--|
| | | vi. Food distribution | Definition/Statements Any mention of food distribution processes. |
| | Code | Category | Definition |
| | | (1) Lack of Space | Definition/Statements This code refers to any mention of the lack of space inside the clinic to distribute food to patients. |
| | | (2) Too infrequent | Definition/Statements This code refers to any mention of food distribution as a result of the program design that does not occur often enough to meet patient needs. |
| | | (3) Inaccessible | Definition/Statements This code refers to any mention of patient limited access to food distribution due to transportation or scheduling issues. |
| | | (4) Mobile food pantry/truck | Definition/Statements This code refers to any mention of the use of the mobile food truck service provided by the local food bank partner for Program A. |
| | | (5) Produce prescription program | Definition/Statements This code refers to any mention of the produce prescription program service provided by the urban garden collective for Program B. Also included with distribution is a training module for staff to provide nutrition education and cooking demonstrations to FI patients. |
| | | vii. Program evaluation | Definition/Statements Assessment of program outcomes, which includes change or no change observed in health outcomes, behavior change, dietary health, access to healthy food, patient participation rates as a result of patient participation in the screening and the food distribution elements of the program. |
| | | (1) Lack of EMR | Definition/Statements This code refers to participants expressing limited ability to use the EMR system for program evaluation. |
| | | (2) Patient participation rates | Definition/Statements This code refers to mention of ability to collect participation rates for program evaluation. |
| h. | Cost | Program Cost | Definition/Statements Costs of the intervention and costs associated with implementing the intervention. |
| | | | Include statements about program funding to pay for program elements, staff needs and additional resources. |
| | | i. Food distribution cost | Definition/Statements This code refers to any mention of the cost of food distribution to meet program objectives. |

| | Construct 2. Outer Setting Code | Category | Definition |
|----|---------------------------------------|--|---|
| j. | Cosmopolitanism | Cosmopolitanism | Definition/Statements The degree to which an organization is |
| | | | networked or partnered with multisector external organizations that support the intervention through capacity, resources and expertise. |
| | | | Include statements about referrals to organizations that provide local food pantries, job services, housing, etc. that are tied to food insecurity. |
| l. | External Pressure | External Recommendations and Evidence | Definition/Statements External policy, research and recommendations (governmental or other central entity), benchmark reporting or community needs assessment that support the need for the intervention. Include statements that mention the Community Health Needs Assessment (CHNA), Nat'l FI screening and referral policy recommendations or any other needs assessments conducted by external organizations or agencies. |
| | Construct 3: Inner setting | | |
| | Code | Category | Definition, Inclusion Criteria |
| j. | Structural | Structural Characteristics | Definition/StatementsThe structural maturity and size of an organization; infrastructure and physical space to support the intervention.Include statements about the organization's infrastructure to support the intervention, including hours of operation, location, EMR, number of and appropriate type of staff/implementation actors to support the program; frequency of staff turnover/physical space to allow for intervention to run smoothly and consistently. |

| | Code | Category | Definition |
|----|---------------|--------------------------------|--|
| | | i. Systems level | Definition/Statements This code refers to the organizational level where the program lives, which includes EMR infrastructure, funding/resources, culture and climate for program implementation. |
| | | ii. Regional level | Definition/Statements This code refers to the regional cluster of primary care clinics within an organization that is overseen by one Regional Director. |
| | | iii. Department level | Definition/Statements This code refers to departmental clusters of primary care clinics overseen by one Department Chair where program implementation occurs. |
| | | iv. Clinic level | Definition/Statements Each primary clinic within an organization that is overseen by one Clinic Manager or Clinic Coordinator where program implementation occurs. |
| | | v. EMR usability | Definition/Statements This code refers to how well the EMR system fits with intended program design and implementation. |
| k. | Communication | Networks and Communications | Definition/Statements: The nature and quality of formal and informal communications within an organization about program planning, execution reaching implementation goals and progress in meeting those goals; distribution of responsibilities. |
| | | | Include statements about staff communicate with one another about program implementation; roles and responsibilities; how the quality of internal communication affects program implementation. This can include any mention of emails, internal memos, meetings, signs, etc. |
| | | | |

| | Code | Category | Definition |
|----|------------------------------------|--|--|
| | | | |
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| | | | |
| | | | |
| I. | Culture | Culture | Definition/Statements: Norms, values and basic assumptions of a given organization and its staff that reflect the organization mission statement, |
| | | | Include statements about whether the culture of the organization |
| | | | supports the intervention; does the intervention fit into the organization's overall mission for patient care? |
| | | | |
| m. | Climate | Implementation Climate | Definition/Statements: The absorptive capacity for change; relative priority and shared perception of the importance of the intervention within |
| | | | the system Include statements about whether the organization makes space to |
| | | | accept the program as a priority and a part of day-to-day activities. |
| n. | Readiness | Readiness for | Definition/Statements: Tangible and immediate indicators that an |
| | | Implementation | organization has prepared to implement the program; organization access of information and knowledge about program implementation |
| | | | Include statements about assigned staff roles; dedicated time and space |
| | | | for screening, education and food distribution to follow through with the |
| | O a materia t | | program as planned. |
| | Construct 4. Characteristics of | | |
| | Individuals | | |
| | Code | Category | |
| 0. | Knowledge | Knowledge and beliefs about the intervention | Definition/Statements: Individuals' knowledge placed on the intervention as well as familiarity with facts, truths and principles related |
| | | | to the intervention. |
| | | | Include statements about the individuals that implement the program that |
| | | | reflect their knowledge about FI, the patients they serve, implementation processes, goal of the program. |

| | Code | Category | Definition |
|----|----------------|--|---|
| p. | Efficacy | Efficacy | Definition/Statements: Perception of own or staff capabilities to execute courses of action to achieve implementation goals. Include statements individuals make about their own or others' abilities to execute the intervention. Include statements about factors that affect how an individual implements the program, including time-management, training, etc. |
| r. | Identification | Individual Identification with Organization | Definition/Statements: A broad construct related to how individuals perceive or are perceived within the organization and their relationship and degree of commitment to implementation responsibilities. Include statements about individuals' roles within the organization and their responsibility for program implementation; if they feel their main job responsibilities take priority before program responsibilities. Do they feel they are responsible for program implementation or do they believe it is someone else's job? How do others perceive their role in the organization and program implementation? |
| S. | Skills | Skills | Definition/Statements: Intellectual ability, competence, capacity, communication skills, empathy, ability to read patient needs that contribute to implementing the program as planned. Include statements about patient-provider communication (language and cultural understanding) during screening, education and food distribution; ability to enroll in SNAP and WIC, provide additional resources for FI patients; cooking demos, recipes; ability to make patients feel comfortable. |
| | | | |

| | Construct 5. Process | | |
|----|-------------------------|---------------------------------|--|
| | Code | Category | Definition |
| t. | Planning | Planning | Definition/Statements: The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods (including marketing and promotion; planning for unforeseen barriers and challenges). Include statements about the process of program development, education/training for implementation, as well as collaborative approach |
| | | | with food partner. |
| u. | Engaging | Engaging | Definition/Statements: Involving appropriate individuals in the ongoing implementation and problem solving 1. Opinion leaders, 2. formally appointed internal implementation leaders, 3. champions, 4. external change agents and community stakeholders. Include statements about leadership engagement for effective |
| | | | implementation, external businesses and stakeholders for parking |
| V. | Fidelity | Fidelity | Definition/Statements: Carrying out or accomplishing the implementation according to plan. Include statements about program execution as planned. |
| | Executing unplanned | Changes to improve processes | Definition/Statements: Evolving implementation processes that deviate from the original implementation plan that results in improved implementation to meet patient and provider needs. Include statements about lessons learned and improvements made at the clinic level due to unforeseen events or needs. |
| W. | Reflecting | Reflecting | Definition/Statements: Ongoing feedback/process evaluation about the progress and quality of implementation. Include statements regular debriefing about progress and experiences, including process evaluation. |

| Construct 6. Patient needs | Patient Needs | Definition/Statements: The extent to which patient needs are accurately known and prioritized by the organization. |
|-------------------------------|-------------------------|--|
| | | Include statements about whether patient food needs are met through the intervention and whether they have access to specific intervention services frequent enough; if they have reliable transportation; if the food is culturally acceptable; if staff communicate appropriately; patient comfort |
| Code | Category | Definition |
| | i. Program improvements | Definition/Statements: The extent to which the implementation team makes changes to the intended program design and related implementation processes to meet patient needs. Include statements about ongoing efforts to improve implementation processes to meet patient needs. |

APPENDIX B

Interview Guide for Key Program Planners

INTRODUCTION:

In September 2018, the Illinois Public Health Institute Alliance for Healthy Equity sent you a Landscape Scan for more information about current Healthcare and Food Access Partnership programs. The goal of the scan was to learn more about how your programs address food insecurity in Chicago and suburban Cook County.

Now, I'm conducting interviews with key individuals from those organizations that have a focus on screening for food insecurity in primary care settings. I want to learn more about the planning stage, program features, implementation processes, individuals involved in implementation and what barriers and facilitators you have experienced during the stages of program planning and implementation.

The interview will be used to understand how organizations develop partnerships with food access organizations to address food insecurity and the process for program implementation. Your participation in this interview is important because it will inform the development of program guidelines that may be distributed to other healthcare organizations interested in implementing a similar initiative.

Do you have any questions before we begin?

1. How would you define food insecurity or low food security?

2. What is your role or job title in this healthcare organization?

3. What is the name of the initiative we are discussing today and how long has your program been operating?

4. What is your role in implementing the (Program Name)?

5. How were you selected for this role?

Probe: Were you assigned by senior staff, did you volunteer, were you nominated?

Probe: What knowledge or skills does this role require?

6. What role do you think your healthcare organization should play in addressing food insecurity in your patient population?

Program Components—planning, development, implementation procedures,

sustainability

7. Please tell me about the major components of your program and who is responsible for executing each component.

Probe: Screening and which tool is used

Probe: Program Referral

Probe: Program Enrollment

Probe: Program Delivery

8. How did your organization decide to implement these components and who would be responsible for which component?

Probe: How were program partners established?

Organizational Support

9. How are frontline providers trained or educated to execute the program?

Probe: Individuals that oversee and provides training
Probe: Ongoing consultation or technical support
Probe: Pretest/posttest assessment of knowledge and skills
Probe: Performance assessments
Probe: Fidelity assessments—implementing the program as intended

10. What types of systems, policies or procedures have been implemented to support program implementation?

Probe: EHR integration, what software system, who oversees this process, who

provides technical support

Probe: Integration into workflow or caseload management

Probe: Data sharing procedures with external stakeholders

Probe: Problem solving procedures within your organization and with external

stakeholders

Probe: Systems wide communications procedures

11. How does your leadership support program implementation? *Probe:* Culture change and motivation

Probe: Technical support

Probe: Content expertise

Probe: Problem solving strategies

Probe: Funding

Probe: Communication

12. How does your organization measure program outcomes?

13. Overall, how effective do you think the program is? *Probe:* Number of patients screened

Probe: Number of patients that participate in the program or receive services

Probe: Number of patients that change behavior

Probe: Addresses food insecurity

Probe: Disease management

14. What do you consider are the strengths and limitations of the program?

15. What are major barriers to program implementation?

16. What are critical facilitators during program implementation?

17. Is there anything else you wish to share with me today about the program? *Probe:* program procedures, meeting notes discussing implementation processes

Frontline Provider Interview Guide

INTRODUCTION:

In September 2018, the Illinois Public Health Institute Alliance for Healthy Equity sent your organization a Landscape Scan for more information about current Healthcare and Food Access Partnership programs. The goal of the scan was to learn more about how your programs address food insecurity in Chicago and suburban Cook County.

Now, I'm conducting interviews with frontline providers from your organization to learn more about your experience with program implementation. I want to learn more about your role, program procedures, as well as barriers and facilitators you have encountered. The interview will be used to understand your experience with program implementation. Your participation in this interview is important because it will inform the development of program guidelines that may be distributed to other healthcare organizations interested in implementing a similar initiative.

Do you have any questions before we begin?

- 1. How would you define food insecurity or low food security?
- 2. What is your role or job title in this healthcare organization?

3. What is the name of the initiative we are discussing today and how long has your program been operating?

4. What is your role in implementing the (Program Name)?

5. How were you selected for this role?

Probe: Were you assigned be senior staff, did you volunteer, were you nominated? **Probe:** What knowledge or skills does this role require?

110

6. What role do you think your healthcare organization should play in addressing food insecurity in your patient population?

Screening

7. Who is screened for food insecurity? **Probe:** What are the eligibility requirements or is everyone screened for food insecurity?

8. How does screening occur? Walk me through the screening process.

Probe: Where does screening occur?
Probe: What screening tool do you use?
Probe: Is screening integrated into EHR?
Probe: At what point in time during the patient visit does screening occur?
Probe: How long does it take?

9. What do you think of this process?

10. Have you encountered any major barriers to this process? *Probe:* appropriate skills, knowledge, time, technical issues with systems and data

management

11. What has helped support your adoption of screening practice behaviors? *Probe:* Training/knowledge/education, system support, data management processes,

communication with managers

Referral and Enrollment Process

12. How do patients receive information about the food access service and enroll in the program? Walk me through this process.

Probe: onsite or offsite

13. Overall, how effective do you think the program is?

Probe: Number of patients screened

Probe: Number of patients that participate in the program or receive services

Probe: Number of patients that change behavior

Probe: Addresses food insecurity

Probe: Disease management

14. Is there anything else you want to share with me about the program?

Probe: program screening and referral sheets, procedural guidelines, meeting notes and communication notes or email

VITA

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