

Assessing the Roles of Stakeholders in Medicaid Waivers and
Food Nutrition Services for people with Type II Diabetes

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University of the Sciences in Philadelphia

In Partial Fulfillment
of the Requirements for the
Degree Doctor of Philosophy

By

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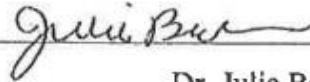
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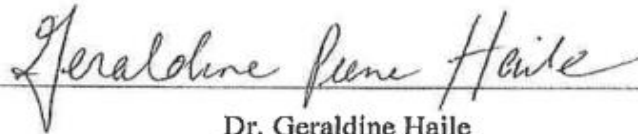
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For my grandmother

To those suffering from chronic illnesses, especially diabetes, may there come a day
when the use of food is the standard of care to reduce the burden of disease and
education is the first line of defense.

I would like to extend my deepest gratitude to my dissertation chair, Dr. Julie Becker, for her unparalleled support, guidance, passion, and commitment to this research. The insights and experiences you provided were invaluable not only to this project, but to life itself. Your thoughtful feedback and unwavering belief in my abilities were instrumental to the success of this dissertation. It has been a true honor to work with you and please know that you have forever changed me. To quote one of your favorite musicals, *“I am young, scrappy, and hungry, and I not throwing away my shot!”*~Hamilton

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To my parents, thank you for all of the encouragement and support, especially through perfectly timed notes in the mail and little presents at each milestone. I am forever grateful for you raising me with a deep love of learning and allowing me to explore all of my curiosities.

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Abstract

Objective: This dissertation examines the roles that stakeholders play in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes.

Research Design and Methods: A mixed-method approach was selected for this research. Two qualitative techniques were deployed, manifest and latent content analysis of Medicaid Home and Community Based Service (HCBS) 1915(c) waivers and semi-structured telephone interviews with stakeholders. The stakeholders selected for this research were: (1) policymakers, (2) Medicaid Insurers, (3) FNS providers, and (4) FNS participants. One quantitative method was deployed to calculate descriptive statistics on healthcare outcomes and costs for FNS participants.

Results: The results of the manifest and latent content analysis suggest that 37 states are using Medicaid HCBS 1915(c) waivers to provide home-delivered meals for specific populations. No states specify that the meals must be medically tailored to a participant's illness. The phrase "Type II Diabetes" was present in 17% of the waivers in this analysis. The results of the stakeholder interviews suggest: 1) politics plays a large role in Medicaid waiver policy; 2) membership within the Food Is Medicine Coalition offers providers with resources and advocacy capacity; 3) FNS participants were divided on the role that FNS played with respect to their Type II Diabetes. The descriptive statistics show reductions in clinical outcomes and healthcare utilization.

Conclusion: The findings offer insight into the role that stakeholders play within Medicaid waiver policies to support FNS. Medicaid HCBS 1915(c) waivers can be used

to provide FNS for beneficiaries, however advocacy is required to specify meals be medically tailored. Stakeholders need to form strong partnerships with natural allies as well as unconventional partners. Data is critical to informing policy decisions, however there is limited access to clinical outcomes and the collection of data lacks rigor in order to assess the efficacy of FNS.

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Chapter 1: Introduction

Since the beginning of the Twentieth Century, primary causes of mortality have transitioned from infectious diseases to chronic diseases. In 2015, worldwide leading causes of death included cardiovascular disease, stroke, lung diseases, and diabetes (World Health Organization, 2016). Global incidence of diabetes nearly quadrupled between 1980 and 2014, from 108 million diagnosed cases to an estimated 422 million; and prevalence almost doubled during the same time frame, from 4.7% to 8.4% (World Health Organization, 2016). The leading cause for this increase is the rise of Type II Diabetes, resulting from the risk factors associated with overweight and obesity (World Health Organization, 2016) .

In the United States, the current prevalence of diabetes is just under 10%, higher than the global prevalence and continues to be one of the leading chronic conditions in this country. Higher rates of diabetes can be observed among different races, ethnicities and geographic areas (Table 1). Since 1999, the prevalence of overweight and obesity in adults and youth has also increased. Overweight and obesity trends map closely to diabetes rates for race, ethnicity and geographic area (Centers for Disease Control and Prevention, 2017). In 2014, the prevalence of overweight and obesity was 87.5% in adults, with over 61% in the obese and severely obese category (Centers for Disease Control and Prevention, 2017). The girth of this nation is causing an increase in morbidity and mortality, reflecting the impact that chronic diseases like diabetes have on health outcomes as a result of overweight and obesity (Centers for Disease Control and Prevention, 2017; World Health Organization, 2016).

In addition to the rise of diabetes, the onset of the medicalization of obesity and the pre-diabetes condition has also increased the need to consider how diabetes and pre-diabetes should be treated. Previously within the medical community, the emphasis has been on diagnosis and treatment, not primary prevention of chronic disease. Moreover, the ideology of the health insurance industry, both federal and private, has been focused on reimbursing pharmaceutical and clinical interventions rather than preventative measures. Existing policies within federal and private insurance reflect these priorities. Yet, policies need to be examined around reimbursement to support other types of interventions, focusing on prevention to address diabetes and other chronic disease related to overweight and obesity.

Table 1. Age-adjusted prevalence of diagnosed and undiagnosed diabetes among adults aged ≥ 18 years, United States, 2011-2014

Characteristic	Diagnosed diabetes Percentage (95% CI)	Undiagnosed diabetes Percentage (95% CI)	Total Percentage (95% CI)
Total	8.7 (8.1–9.4)	2.7 (2.3–3.3)	11.5 (10.7–12.4)
Sex			
Women	8.5 (7.5–9.5)	2.3 (1.8–3.1)	10.8 (9.8–11.9)
Men	9.1 (8.4–9.9)	3.2 (2.4–4.3)	12.3 (11.3–13.4)
Race/Ethnicity			
Asian, non-Hispanic	10.3 (8.6–12.4)	5.7 (4.0–8.2)	16.0 (13.6–18.9)
Black, non-Hispanic	13.4 (12.2–14.6)	4.4 (3.0–6.2)	17.7 (15.8–19.9)
Hispanic	11.9 (10.3–13.7)	4.5 (3.2–6.2)	16.4 (14.1–18.9)
White, non-Hispanic	7.3 (6.6–8.1)	2.0 (1.5–2.6)	9.3 (8.4–10.2)

Characteristic	Diagnosed diabetes Percentage (95% CI)	Undiagnosed diabetes Percentage (95% CI)	Total Percentage (95% CI)
Education			
Less than high school	11.4 (9.9–13.1)	4.1 (3.0–5.6)	15.5 (13.5–17.7)
High school	10.3 (8.8–12.0)	3.2 (2.4–4.2)	13.5 (11.9–15.2)
More than high school	7.4 (6.6–8.4)	2.2 (1.6–3.0)	9.6 (8.6–10.7)
CI = confidence interval. Data source: 2011–2014 National Health and Nutrition Examination Survey.			

Source: Centers for Disease Control and Prevention (2017)

What is Diabetes? Condition and Treatment

Diabetes generally is classified three ways: (1) Type I Diabetes, (2) Type II Diabetes and (3) Gestational Diabetes. Type I Diabetes occurs when the pancreas is no longer able to produce insulin, a hormone that breaks down starch into glucose to be converted into energy (American Diabetes Association, 2016). Type I Diabetes is more common among children, though can occur at later stages in life. Type II Diabetes occurs when the body is no longer using insulin properly, there isn't enough insulin in the blood to break down the glucose at the cellular level, causing excess glucose in the blood stream (American Diabetes Association, 2015). Over time the build-up of glucose in the blood stream can cause severe complications with the nervous system and other vital organs. Gestational Diabetes occurs during pregnancy, when a pregnant woman is unable to make enough or use all of the insulin to convert glucose into energy. If left untreated, gestational diabetes can be harmful to the fetus by increasing its blood sugar levels and causing the fetus' pancreas to produce more insulin (American Diabetes Association, 2016). The extra

production of insulin causes an increased risk for obesity and Type II Diabetes in the fetus, or even death of the fetus (American Diabetes Association, 2016). If an expectant woman has gestational diabetes in her first pregnancy, then she is more likely to have the disease again during a future pregnancy, as well as develop Type II Diabetes as one ages unless she is very vigilant about preventative measures like diet and exercise.

Type II Diabetes is diagnosed using the Hemoglobin A1c (HbA1c) blood test, which measures a patient's blood glucose levels and averages these measurements over an 8-12-week period to determine a percentage. The test is specifically measuring the number of glucose molecules that are attached to a hemoglobin molecule in the blood and is expressed as a percentage of hemoglobin molecules that have glucose attached. If a patient's HbA1c percentage is under 5.6% then they do not have Type II Diabetes; if the percentage is between 5.7% and 6.4% then the person is considered to have pre-diabetes, and any patient with a HbA1c percentage over 6.5% is diagnosed with Type II Diabetes (ADA, 2009; ADA, 2016). The HbA1c blood test does not require the patient to fast, which means it is easier to administer; therefore, more people can be screened and monitored using this test.

A patient's HbA1c percentage will dictate their medication regimen with higher percentages requiring more intensive pharmaceutical remedies such as insulin. There are eight different types of oral medications that can be used to lower blood glucose levels; some facilitate the production of insulin, while others decrease the production of glucose in the liver. In recent years, the pharmaceutical industry has developed injectable blood glucose lowering drugs, called sodium-glucose co-transporter 2 (SGLT2) and glucagon-

like peptide 1(GLP-1), that are used to treat Type II Diabetes by suppressing the amount of glucose the liver creates or slowing down the digestion process to decrease the likelihood of blood sugar rising too quickly after a meal (ADA, 2015). An added bonus of these drugs includes the potential side effect of weight loss, which is often recommended for managing Type II diabetes in overweight and obese patients. Lastly, once the body is no longer responding to its own insulin, a patient is put on an insulin injection regimen. Depending on the physiological needs of the patient, insulin can be categorized into four different types: (1) rapid-acting insulin, works within in 15 minutes, (2) regular insulin or short acting, reaches the bloodstream in 30 minutes, (3) intermediate-acting insulin, reaches the bloodstream in 2-4 hours, and (4) long-acting insulin, reaches the bloodstream several hours after injection (ADA, 2015). Due to the chronic nature of the disease, many patients will be on a combination of different medications and may be able to come off medicine with the addition of exercise, adherence to a Type II Diabetes diet, and weight loss (ADA, 2015; World Health Organization, 2016; Centers for Disease Control and Prevention, 2017).

People with Diabetes (PWD) are instructed to maintain diets that are low in simple carbohydrates, saturated fat, added salt and sugar. A Type II Diabetes diet suggests complex carbohydrates like brown rice and quinoa compared to bread and potatoes, because complex carbohydrates contain more fiber, helping PWD to feel fuller faster and reach satiety, and may help lower cholesterol and glycemic levels. The American Diabetes Association (ADA) recommends PWD fill half of their plates with non-starchy,

fibrous vegetables like green beans, broccoli, cauliflower, and zucchini. These non-starchy vegetables are rich in vitamins and minerals that are essential to health.

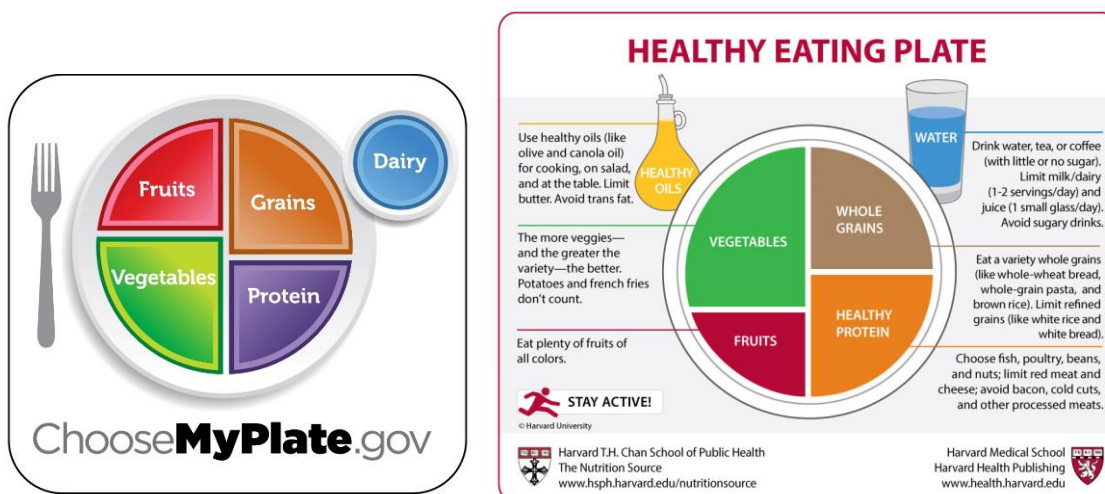
The protein recommendation includes plant-based proteins like black beans and nuts, but also includes fish, poultry, eggs and beef, pork, veal or lamb. Due to the increased risk for cardiovascular complications, the ADA recommends limiting the intake of red meat because it contains higher amounts of saturated fats, contributing to elevated blood lipids. Chronically elevated blood lipids lead to a condition called dyslipidemia. Low-fat dairy products are recommended, such as fat-free milk or Greek yogurt. Fruit is perceived as being a calorie source with mixed benefits: because of the natural sugar, fruit should be eaten in limited quantities and earlier in the day, yet many fruits, for e.g., berries, are often high in fiber. Water is the recommended beverage, however it is understandable that this can become unexciting, so unsweetened coffee, tea, sparkling water, or diet drinks are acceptable.

While there are many ways to measure calorie consumption, many PWD use at least one of these three methods for calculating calorie intake: (1) USDA's plate method (MyPlate); (2) carbohydrate counting; and (3) the Glycemic Index. The USDA's plate method suggests filling half of your plate with $\frac{2}{3}$ vegetables and $\frac{1}{3}$ fruit (USDA, 2018). The other half of the plate is comprised of lean protein that accounts for $\frac{1}{4}$ and the remaining $\frac{3}{4}$'s of the plate is grains, suggesting $\frac{1}{2}$ come from whole grains (USDA, 2018). A single serving of dairy, mainly low-fat and fat-free milk and yogurt should be consumed with each meal (USDA, 2018). This is an effective method to quickly determine if all of the major food groups are being consumed in approximate proportions.

PWD should fill 1/2 of their plate with non-starchy vegetables that are high in fiber to avoid dramatic fluctuations in blood glucose levels (USDA, 2018).

The Harvard Chan School of Public Health has criticized the MyPlate model for its lack of specificity in guiding Americans on what to consume (Harvard T.H. Chan School of Public Health, 2011). To address deficiencies with MyPlate, Harvard created the Healthy Eating Plate to offer more specific recommendations to create a healthy balanced meal. A side-by-side comparison of the models can be found in Figure 1. The Healthy Eating Plate provides examples of macronutrients that are necessary to achieve a healthy diet. The major difference between the two models is that the Healthy Eating Plate advocates drinking water, tea or coffee, whereas MyPlate recommends a serving of dairy. For PWD, the Healthy Eating Plate is more prescriptive and potentially easier to follow compared to MyPlate.

Figure 1. USDA's MyPlate and Harvard School of Public Health's Healthy Eating Plate



Sources: USDA, 2018; Harvard T.H. Chan School of Public Health, 2011

Another method is carbohydrate counting, meaning the PWD counts the number of carbohydrate grams in a meal in order to match to the dose of insulin. The number of carbohydrates a food contains can be found on the nutrition facts label for packaged food. When purchasing fresh fruits and vegetables a PWD can use nutritional information that is displayed at the store, a nutrition application, such as MyFitnessPal, or conduct the research prior to going to the store. A PWD must track blood glucose levels before a meal and two hours after consuming a meal to determine how food affects them. The optimal amount of carbohydrates can vary by person, the National Institutes of Health suggest using the two part formula below to calculate the number of carbohydrate grams based on a daily percentage between 45-65% (NIDDK, 2014).

$$\% \text{ of daily carbohydrate intake} \times \text{caloric intake} = \# \text{ of calories from carbohydrates}$$

$$\# \text{ of calories from carbohydrates} \div 4 = \# \text{ of daily grams of carbohydrates}$$

After the number of calories from carbohydrates is calculated, it is divided by four because one gram of carbohydrate is equal to four calories (NIDDK, 2014). Once the number of daily grams of carbohydrates is established the PWD will need to spread the calories over the day and match the grams of carbohydrates in a meal to the dose of insulin. A patient must be careful not to overcompensate poor eating habits with more insulin because it increases the risk of hypoglycemia. This method can also be used in PWD that are not on insulin to ensure they are consuming an appropriate level of carbohydrates throughout the day.

Lastly, the Glycemic Index ranks foods based on how quickly they raise blood glucose levels compared to glucose or white bread (ADA, 2014). In 2008, researchers assembled a list of 2,480 international foods and their associated indices to enhance the treatment of diabetes and inform clinical practice (Atkinson RD, Foster-Powell RD, & Brand-Miller PhD, 2008). Harvard Medical School compiled a list of 100 common foods that may have more practical application in PWDs' lives (Harvard Medical School, 2015). Foods are grouped into low, medium and high categories. Low glycemic foods receive a ranking of 55 or less and examples include most fruit, non-starchy vegetables and oatmeal. Medium glycemic foods receive a ranking between 56 and 69 and examples include brown rice, couscous and whole wheat bread. High glycemic foods receive a ranking 70 or greater and examples include bagels, pasta and potatoes. Typically, those foods that fall higher on the index tend to be highly processed (ADA, 2014). Those items that are lower on the glycemic index are more favorable for PWD because they will help to keep blood glucose levels stable. All three methods provide quick and relatively easy ways for PWD to assess their diets and develop ways to monitor calorie intake.

Regardless of the method for calculating calorie intake, diet is only one part of the equation; the other component is exercise. The ADA recommends that PWD exercise because it increases their bodies' sensitivity to its own insulin. There are many additional benefits of exercising such as reductions in HbA1c and, in turn, the dosage and administration of diabetes medications, thereby decreasing the need for healthcare. Exercise has been shown to reduce co-morbidity among PWD for such chronic conditions such as hypertension, high cholesterol and heart disease. Exercise may help to

relieve stress and promote sleep. Both aerobic and anaerobic exercises are important, with 30 minutes of aerobic exercise like walking, running, and bike riding five days per week and anaerobic exercise, such as working with weight-lifting machines or resistance bands, two times per week are recommended by the ADA. If a PWD is able to adhere to their diet, exercise and medication regimen, they are likely to decrease their risk of complications from diabetes.

Diabetes Co-morbidities and Costs

A Type II Diabetes diagnosis automatically increases a patient's risk of developing co-morbidities, like cardiovascular disease, hypertension, nephropathy, neuropathy, stroke and retinopathy (World Health Organization, 2016; Centers for Disease Control and Prevention, 2017). People living with Type II Diabetes have a 50% increased risk of having a heart attack or stroke (World Health Organization, 2016). Type II Diabetes can damage the kidneys, causing the inability to filter waste from the body or nephropathy. If diagnosed early, this condition may be reversed; however if it is diagnosed later, nephropathy will lead to end-stage renal disease, requiring a kidney transplant or dialysis (World Health Organization, 2016). Some PWD develop neuropathy, which is when the small blood vessels become damaged causing pain, numbness, or weakness in the extremities (ADA, 2015). This can lead to wounds that do not heal and potentially to amputation. Lastly, retinopathy is a condition in which the blood vessels in the eye become blocked, leading to blindness (ADA, 2015). Type II Diabetes diagnosis has serious consequences that are not only health related, but may also generate a barrier to

compliance, as with each increasing complication and medication the cost of treatment increases.

In 2012, the estimated national cost of diabetes was \$245 billion, of which \$176 billion were direct health expenditures (ADA, 2013). The remaining \$69 billion represents lost productivity from work related to absenteeism, reduced productivity at work and home, unemployment from chronic disability and premature death (ADA, 2013). People diagnosed with diabetes are shown to have health care expenditures 2.3 times higher than someone that is not diagnosed with diabetes (ADA, 2013).

The national expenditure for hospital inpatient care was projected to be \$475 billion dollars in 2012, of which \$124 billion—over 25%—would be consumed by people diagnosed with diabetes (ADA, 2013). Within that \$124 billion dollars, \$76 billion can be attributed to the direct treatment of diabetes (ADA, 2013). Emergency room visits expenditures were predicted to cost \$119 billion, of which \$14 billion is attributable to people diagnosed with diabetes (ADA, 2013). Within that \$14 billion, \$6.6 billion will go for direct treatment of diabetes (ADA, 2013).

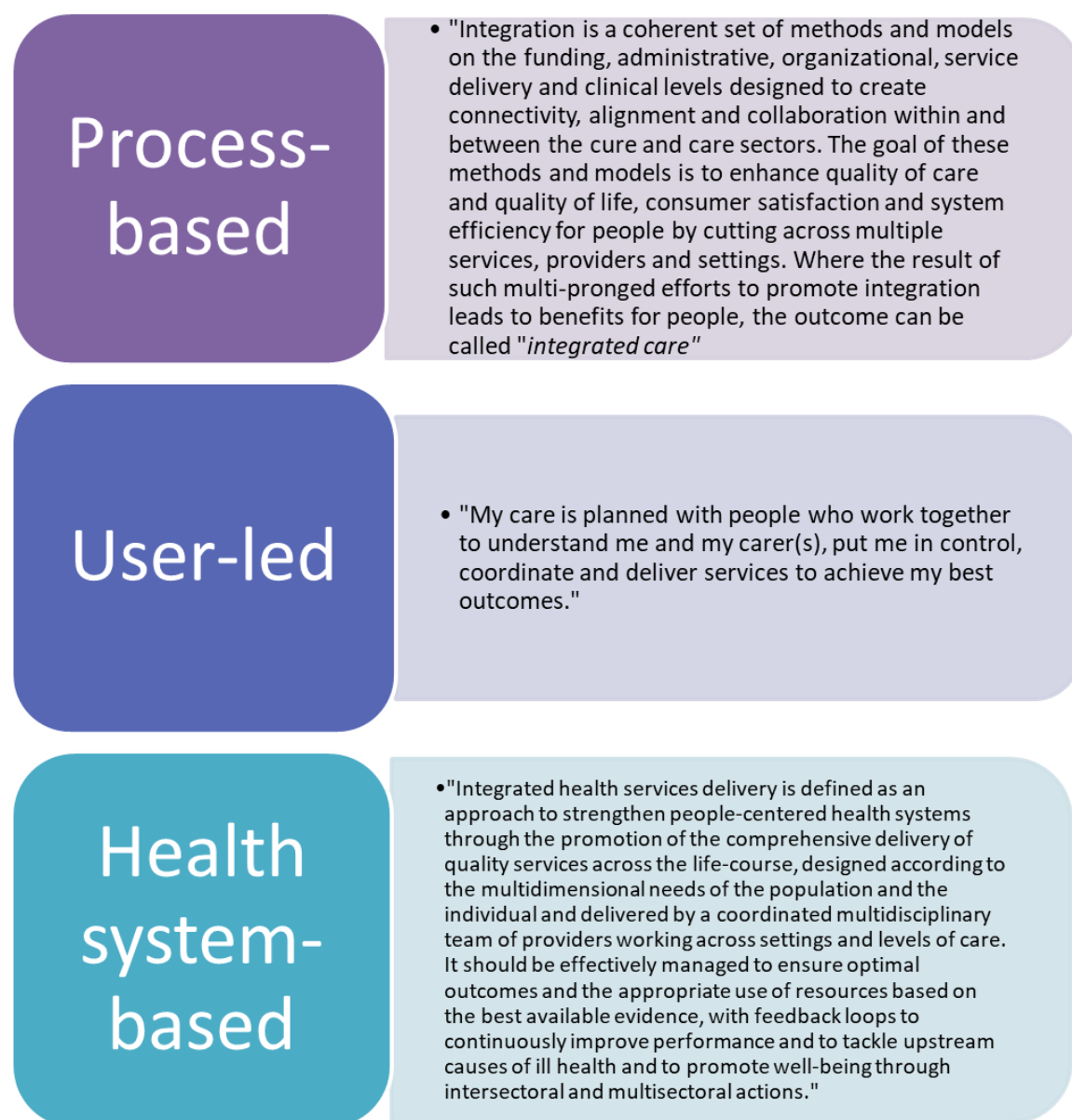
Medications for PWD, including prescription drugs, insulin, and other anti-diabetic agents, represented 28% of all health care expenditures in 2012 (ADA, 2013). By 2017 the percentage of healthcare expenditures on medications increased to 36% (American Diabetes Association, 2018). As discussed earlier, PWD, whose bodies no longer respond to their own insulin, are prescribed insulin injections in order to convert glucose into energy; however, the average price of insulin has increased nearly three times from 2002 to 2013 (Hua, Carvalho, & Tew, 2016). These increases make financing life-saving

medications more difficult for those on limited incomes. In 2012, medication expenditure was anticipated to be \$286 billion dollars, of which \$77 billion dollars can be attributed to people diagnosed with diabetes (ADA, 2013). The direct estimated cost of medication for treating diabetes is \$50 billion dollars (ADA, 2013). As of 2017, the estimated medication expenditure for treating diabetes was \$71.2 billion dollars (American Diabetes Association, 2018). Reducing the cost of treating diabetes is a priority for both the federal and private insurance companies; for that reason, disease-management approaches that include primary prevention models that decrease the need for treatment as well as reduce primary risk factors like obesity and overweight should be encouraged.

Integrated Healthcare and Chronic Care Models

Since the United States does not have a universal healthcare system, care is often fragmented and episodic, leaving most to create different integrated chronic care models to ease the burden of chronic disease. Several definitions exist for integrated healthcare systems. To assess and evaluate these definitions, the World Health Organization (WHO) conducted an extensive literature review to further refine definitions of an integrated healthcare system. The results show that definitions of integrated healthcare systems can be summarized into three types: (1) process-based integrated healthcare, (2) user-led integrated healthcare, and (3) health system-based integrated healthcare that can be found in Figure 2.

Figure 2. Integrated Models of Care Definition



Source: World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health (2016)

Process-based integrated healthcare is defined as a set of methods or models that incorporates all aspects of healthcare from financing to administration to clinical delivery. The use of a method or set of methods by a healthcare system increases the

likelihood of care coordination as well as accountability among stakeholders. This definition eliminates a critical component that is necessary to chronic disease treatment compliance, the patient. A healthcare system may be integrated, but if it does not include the patient it may reduce the probability of success in chronic disease care.

User-led integrated healthcare is the opposite of process-based integrated care, in that the patient is the center of the model. Under this definition, a patient is encouraged to control their chronic condition and directly coordinate their healthcare to achieve optimal health outcomes. This definition was created by the people of England during a consultation with National Voices, a patient representative group, and is now the national standard. While this definition is patient focused, it does not address financial, organization, or administrative concerns. Since this definition grew out of England's universal healthcare system, these concerns may not be relevant for patients in that country.

Lastly, health system-based integrated healthcare is a combination of the process-based and user-led integrated healthcare coupled with a system delivery approach. By incorporating system delivery concepts, evidence and feedback loops are part of the processes to foster continual improvement of the healthcare system. This definition addresses prevention by promoting comprehensive care across the life span and in a variety of settings through interdisciplinary teams at all levels of care (World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health, 2016). The focus on evidence-based system delivery offers a built-in framework for assessing the healthcare system. The U.S. healthcare system currently

operates very similarly to the process-based integrated definition; to adequately address burden of chronic diseases, however, a transition toward a health system-based integrated approach is necessary. To bridge this gap between what we have and what we need, independent healthcare systems must use or develop integrated models of care to reduce the burden of chronic diseases like diabetes.

Integrated models of care in the U.S. can be divided into three types: (1) individual-based, (2) group and disease-specific based, and (3) population-based. Individual based models of care include case-management, individual care plans, patient-centered medical home, and personal health budgets. Group and disease-specific based models are the Wagner Chronic Care Model (CCM), the Innovated Care for Chronic Conditions Model (ICCC) and PRISMA. The population-based model is the Kaiser Permanente model. Each model has its key components, advantages and disadvantages that can be found in Table 2.

Table 2. Integrated Models of Care in the United States

Individual Models of Integrated Care			
Model	Key Components	Advantages	Disadvantages
Case-management	1. Define and select patients that are appropriate for case management 2. Plan and assess individual care 3. Monitor patients 4. Adjust care plans if necessary	• Reduce the number of hospital (re)admissions	• Ongoing debate over cost savings
Individual care plans	1. Use in patients with multiple morbidity factors	• Adjust care plans during treatment	• Increase the cost to create individual plans

Individual Models of Integrated Care			
Model	Key Components	Advantages	Disadvantages
	and chronic conditions. 2. Provide more personalized and targeted care that utilizes shared care plans among providers 3. Articulate roles of providers and patients explicitly 4. Serve as a retrospective and prospective narrative of the patients care		• Increase the number of employees needed to carry out the model
Patient-centered medical home	Physician-directed group practice that provides care that is: 1. Accessible 2. Continuous 3. Comprehensive 4. Coordinated 5. Delivered in a family/community context	• 20% reduction in hospital admissions • 12% reduction in (re)admissions	• Decrease in efficiency of model in fragmented healthcare systems because model is designed around coordinated communication
Personal Health Budgets	1. Decide which health care services to purchase 2. Spend within personal budget to meet health needs	• Increase higher levels of patient satisfaction • Increase in efficiency in the delivery of care • Reduction of duplication of services	• Place administrative burden on the patient • Require the patient to coordinate among all providers and information may not always be up to date

Group- and disease-specific models			
Model	Key Components	Advantages	Disadvantages
Chronic Care Model	CCM has six domains: 1. Community Resources and Policy 2. Health System 3. Self-management Support 4. Delivery System Design 5. Decision Support 6. Clinical Information Systems	• Improve patient outcomes compared to traditional treatment model • Increase patient satisfaction	• Cost savings could take many years to achieve
Innovative Care for Chronic Conditions	ICCC has six domains: 1. Evidence-based decision making 2. Population focus 3. Prevention focus 4. Quality focus 5. Integration 6. Flexibility/adaptability	• Reduce in deaths • Save money and healthcare resources • Increase patient's self-management abilities • Improve quality of life • Improve processes of care	• Establish validity of the entire model, though components have been proven validated
PRISMA	1. Single point of entry system into health care 2. Coordinated services across a network of providers 3. Establish a governing board of health and social care who defines the strategy for specific groups and allocate the resources to the networks and manage the provider groups	• Sustain the functional ability of individuals • Decrease the extent of unmet needs • Reduce burden placed on caregivers • Decrease hospital admissions	• Increase administrative costs • Increase the number of employees needed to carry out the model

Group- and disease-specific models			
Model	Key Components	Advantages	Disadvantages
Population-based models			
Kaiser Permanente	1. Emphasis on prevention and promotion of health 2. Self-management support 3. Disease management 4. Case management for persons with multiple chronic conditions	• Assign accountability to providers for patient outcomes and experience • Link provider incentives to quality of care and patient satisfaction • Use EMR for asymmetry of information	• Ongoing debate over cost savings • Replication is difficult in rural settings

Individual-based models of care have decreased hospital admissions and re-admissions as well as reported higher levels of patient satisfaction and efficiency in the delivery of care by reducing duplication of services (World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health, 2016). Frequently, these models are more costly and labor intensive, requiring coordination by the healthcare system and patient involvement, leading to fragmentation if more than one system is involved or if medical specialists provide care. Intensive individual models are especially good for initially motivating patients with chronic diseases, which—unlike acute disease—frequently requires maintenance care over time. These individual models are not sustainable because of their intensity of care and coordination unless a highly motivated patient is educated and becomes a partner in their care to avoid complications and episodic problems.

Group and disease-specific models also promote healthcare cost reductions and decreases in hospital admissions (World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health, 2016). The additional benefit is that group and disease-specific models can better allocate healthcare resources by establishing coordinated teams of healthcare providers to address acute and chronic disease issues. Furthermore, patients report increases in their self-management abilities and measurable improvements in their quality of life while reducing burden on their caregivers. The return on investment for these models is over time, requiring people to stay with the same healthcare system and not switch plans because of cost or availability. In a market-driven healthcare system, continuity of care within the same plan often faces hurdles; therefore, a long-term return on investment in these types of programs may be problematic.

With the Kaiser Permanente population-based model, providers are held accountable for patient outcomes and their overall experience. The combination of provider accountability and improved patient outcomes and experiences has been shown to lead to a higher quality of care and patient satisfaction. The cost savings of this model are controversial because if the model tries too hard to control patient choice there may be an upswing in visits at higher levels of care (Abelson, 2013). Replication of this model is nearly impossible in rural settings because care is based on the ability to stratify the population to provide services that they need. In the rural setting, then, cost savings may never be realized because of the larger numbers of patients needed for stratification; more often than not, rural settings do not have these numbers.

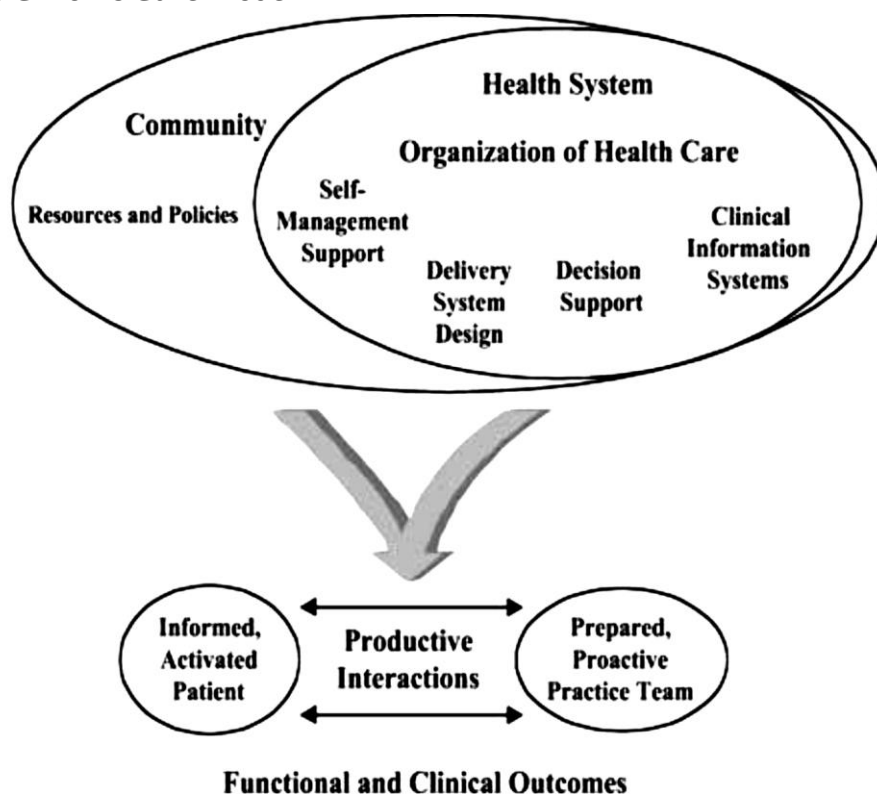
Based upon these three models, it's clear that no one type of model fits all aspects of the U.S. healthcare system. But what is apparent is when patients participate actively in the management of their chronic disease, they have better health outcomes, increase healthcare cost savings, decrease hospital admissions, and the potential for reducing morbidity. The question remains, however, *how should healthcare systems utilize integrated care models to address chronic diseases and achieve the best patient outcomes while improving cost savings?*

One of the most common integrated models of care used for diabetes treatment in the U.S. is the Wagner Chronic Care Model (CCM). This model was chosen because it was proven effective at improving patient outcomes and quality of care. Additionally, when only some components of the model were implemented it resulted in reductions of HbA1c percentages and the risk of heart disease. All the components of the CCM have been validated, while other models have some of their factors tested. An in-depth discussion of additional integrated models will be included in Chapter 2. Furthermore, the Wagner CCM is based upon the Western Medicine's philosophy of treating disease, not prevention, thereby making it easier to convince healthcare systems to adopt this model compared with other models. Time has demonstrated this model to be efficacious, since it has been utilized for nearly two decades and evaluated quite extensively.

Edward H. Wagner, MD, MPH and his colleagues, responding to the needs to manage and treat people with chronic diseases in Washington State developed The Wagner Chronic Care Model. The CCM has six essential components: (1) Community Resources and Policies, (2) Health Care Organization, (3) Self-management Support, (4)

Delivery System Design, (5) Decision Support, and (6) Clinical Information Systems. While each of these components are designed to build upon each other to improve outcomes for chronically ill patients, case studies have demonstrated improvements in health outcomes by implementing only some components of the model (Bodenheimer MD, Wagner MD, & Grumbach MD, 2002). A diagram of the model can be found in Figure 3.

Figure 3. The Chronic Care Model



Source: Glasgow, Orleans, Wagner, Curry, & Solberg (2001)

The first component of the model is Community Resources and Policies that recommends partnerships be established with community-based organizations; these include exercise programs, patient education classes, or home visiting agencies to offer

continuity of care for the chronically ill patient. This component provides services for people in their community and can help reinforce positive health behaviors for patients with chronic disease. Healthcare organizations are the second component comprised of physician teams who prioritize chronic care over acute care and are reimbursed according to the health outcomes of patients. This reimbursement model incentivizes practitioners to focus on chronic care, patient outcomes and leads in innovation. The third component of the model is self-management support that means the patient is the sole person responsible for the day-to-day management of their disease from diet to exercise to medication compliance. Chronically ill people need to be connected with community resources in the first component to increase the likelihood of controlling their illness.

Delivery System Design, the fourth component of the model, calls for a clear division of labor at the practice level to train non-physician staff to support patient self-management practices, for example through testing blood sugar, foot examinations, and eye care. Within the physician team there also needs to be a clear division of labor in terms of which physician will handle acute issues and which will handle chronic issues. This division of labor will allow the physician team to have a more accurate picture of this person's chronic illness. The fifth component of the model is Decision Support, which relies on evidence-based clinical guidelines that provide standards for optimal care. Healthcare providers should not feel the need to automatically refer a patient to a specialist. Instead, specialists serve as consultants to providers via telephone or electronic communications. Specialists can provide educational sessions to train providers in clinical guidelines to help disseminate disease-specific knowledge to healthcare teams.

Clinical Information Systems are computerized databases that allow chronically ill patients within a practice to be tracked; to illustrate, all bloodwork, blood pressure, and urine screenings can be made accessible from one central location. Clinical Information Systems is the final component of the CCM model. These systems allow for the categorization of patients into risk classes and reminders can be set for key outcomes alerting the physician if tests are not up to date. This is a convenient way for healthcare providers to manage population health and assess deficiencies within the practice to start a course of corrective action.

Even though the Wagner CCM and its components have been proven to be effective, the model takes a very clinical, medical, physician and disease-oriented approach to diagnosis and treatment, despite recognizing that the health outcomes are mostly up to the patient. Additionally, this model focuses on existing outcomes from a disease, focusing on secondary prevention (detecting and treating disease in its early stages), and not on primary prevention (preventing disease). Since the focus of this model is secondary prevention, more emphasis should be placed on the first component, Community Resources and Policies, because local groups may be superior at providing services for some of the risk factors that lead to diabetes, such as food insecurity, poverty or sedentary lifestyle, or co-morbidity like heart disease or neuropathy. Furthermore, changes in healthcare policy could enable more patients to be covered or receive services that may directly affect health outcomes such as a reduction in HbA1c, and decreased risk of comorbidities and death.

Physician training focuses on secondary prevention, using diagnosis and treatment as the key means of dealing with a chronic condition. That focus does not reinforce the importance of community resources and policies as a way to address chronic diseases. Furthermore, community resources and policies as well as prevention services often are not reimbursable through health insurance. Policymakers may lack knowledge and facts about the prevention services that are available within their local communities or states. However, those health care systems that chose to partner with a community organization to provide prevention services often saw improved outcomes in their patients (Glasgow, Orleans, Wagner, Curry, & Solberg, 2001). Community organizations are using novel approaches to address diabetes, including food nutrition services.

Food is Medicine

The model of *Food Is Medicine* challenges the status quo in the treatment of diabetes. Engagement with food is an integral aspect of being human; it provides the nourishment that allows our bodies to operate at optimal levels. But it's more than just nutrition. Food reflects cultural, social, economic, spiritual, and religious significance. With availability of cheap, high calorie foods, large portions, and processed convenience foods, poor food choice has led to the rising rates of overweight, obesity and chronic disease (Crino, Sacks, Vandevijvere, Swinburn, & Neal, 2015). The *Food Is Medicine* model asserts that we can reverse chronic disease and its negative health outcomes through the use of food. The model proposes using medically tailored meals that consider the individual's chronic condition(s), allergies, and personal needs (FIMC, 2018). The theory being if a patient is eating the foods that are nutritionally optimal for their

condition(s), the patient will increase the likelihood of improving their health outcomes. In the case of diabetes, as previously mentioned, diet and exercise are the largest factors associated with lowering blood glucose levels, thus making the implementation of this model highly attractive. Throughout the country, community organizations have applied this model to their clients with resounding success.

The Food Is Medicine Coalition (FIMC) is an association of nonprofit medically tailored Food and Nutrition Service (FNS) providers that operate under the *Food Is Medicine* model. These organizations provide medically tailored meals, designed to address their health conditions and improve their health. In addition to the medically tailored meals, some of these FNS providers also provide medical nutrition therapy, which includes nutritional counseling and support (FIMC, 2018). The central goal of FIMC is to help shift the health care system toward the concept that *Food Is Medicine* to realize better health outcomes, reduced health care costs and improved patient satisfaction.

FIMC organizations have been engaging in research to help show how effective their services can be in improving health outcomes and reducing costs. Project Open Hand in San Francisco, CA, in conjunction the University of California San Francisco, conducted a study in 2014 examining the concept of food as medicine among their clients with Type II Diabetes, HIV, and co-morbid diagnoses. The results of this study demonstrated a 63% reduction in hospitalizations and 58% reduction in client emergency room visits (FIMC, 2018). Moreover, there was a 50% increase in medication adherence among clients (FIMC, 2018).

The Metropolitan Area Neighborhood Nutrition Alliance (MANNA) in Philadelphia, PA, conducted a study examining health care expenditures for MANNA clients compared to a comparison group that did not receive MANNA services. This study revealed that MANNA client's health care expenditures were on average \$12,000 less per month than those in the comparison group (FIMC, 2018) (Gurvey, et al., 2013). MANNA clients were also hospitalized 50% less than the comparison group, and of those that were hospitalized on average their hospital stay was 37% shorter than the comparison group (Gurvey, et al., 2013). Additionally, those clients that were hospitalized were 23% more likely to be released to their homes rather than to a sub-acute care facility (Gurvey, et al., 2013). These two studies suggest the potential effectiveness of FIMC organizations and their mission to demonstrate that *Food Is Medicine*. More studies are currently being conducted to further explore this concept.

By pairing community organizations with research groups, data are collected that further reinforce and better clarify the link between the outcomes and costs of diabetes among the U.S. population. Additionally, supporting evidence is growing to increase Component One (Community Resources and Policies) of the Wagner CCM, where partnerships with FNS providers to “treat” patients with Type II Diabetes using *Food Is Medicine* concepts. As stated previously, prevention services are not typically reimbursed by federal or private health insurance. However, through the use of existing policies, like waivers, FNS services can be reimbursed under Medicaid.

Medicaid Waivers

Medicaid Home and Community Based Service (HCBS) 1915(c), HCBS 1915(i) or 1115 waivers provide policy tools that allows for the reimbursement of services that are not traditionally included in Medicaid benefits. Medicaid waivers are authorized under section 1915(c) of the Social Security Act as a part of the Omnibus Reconciliation Act (OBRA) of 1981. The main goal of a waiver is to provide, for populations whose individuals are at risk of being institutionalized, home and community-based services at a significant cost savings coupled with the potential for better outcomes. Types of services include homemaker and home health aide, personal care services, adult day health, habilitation and respite care, and any other service deemed appropriate by the Secretary of CMS (Shirk, 2006).

Populations that are typically served include senior citizens, people with physical and mental disabilities, people diagnosed with HIV/AIDS, and people suffering from traumatic brain injury. Waivers have been approved for populations with specific chronic diseases, however these programs have developed at a slower rate compared to other populations. Conversely, this does not mean that waivers are not effective at helping to reduce cost and improve outcomes, but rather that as of 2006 there were simply not many states implementing approved waivers for chronic conditions (Shirk, 2006). One reason why states may not have chosen to operate a waiver could be the requirements and monitoring that comes along with waivers.

Medicaid plans must conform to the rule of “statewideness,” meaning comparable services must be provided to all beneficiaries across the state (Shirk, 2006). HCBS

waivers remove that rule allowing states to offer additional services for targeted populations. Income eligibility requirements for Medicaid are typically required; however, the CMS Secretary can alter those requirements in order to serve vulnerable populations. Waivers are initially approved for 3 years, and can be renewed up to an additional five years. States that operate a waiver are required to submit reports to CMS documenting the number of people being served by the waiver and a full accounting of the cost neutrality and financing of the waiver (Shirk, 2006).

Cost neutrality of the waiver is the key to whether a state will be approved initially or renewed and is a statutory requirement. The definition of cost neutrality is:

“The average per capita HCBS waiver costs (including the cost of any other Medicaid state plan services furnished to HCBS waiver participants) must be less than or equal to the service costs for a similar population in an institution (including the cost of any other Medicaid state plan services furnished to institutionalized beneficiaries)...” (Shirk, 2006).

What makes this equation difficult is calculating the estimated cost of services compared with what the state will pay if there is no frame of reference. Additionally, if there isn't a population that is institutionalized it may be hard to project costs as well. Fortunately, there were some rules that were lifted by Congress to help pave the way for the use of waivers.

During the first few years waivers were available there was a policy called the “cold bed” rule that meant in order for a state to be approved for a waiver they had to have an empty or “cold” bed in an institution should the waiver not be effective in maintaining cost neutrality (Shirk, 2006). Once the “cold bed” rule was lifted in 1994, more states began to choose waivers as an option. Additional restrictions were lifted when Congress

passed the Deficit Reduction Act of 2005, allowing states to offer HCBS under their Medicaid states plans without requiring a waiver. The act gave states the freedom to customize HCBS to meet their populations and place their own limits on how many beneficiaries could receive services (Shirk, 2006). Also, states were not required to prove cost neutrality nor apply for waiver renewals. States were not required to add HCBS to their plans, but could still apply for and implement waivers as they see fit. A more in-depth discussion of waivers is included in Chapter 2: Literature Review.

The latitude in the types of programs that can be approved for a waiver suggests that FNS providers using a *Food Is Medicine* model would be waiver eligible. If FNS programs were approved under Medicaid waivers to treat Type II Diabetes, the potential exists for reductions in healthcare expenditures and improved patient outcomes, while decreasing comorbidities. Furthermore, FNS providers would have a stable funding mechanism, often a factor that limits scaling interventions to population levels.

Purpose of This Study

Since the potential to incorporate *Food Is Medicine* into a large, national program like Medicaid through waivers is possible, it is crucial to investigate who would be involved and why. This research will investigate the roles of stakeholders in Medicaid policies to support FNS for people with Type II Diabetes by asking the following research question: ***What are the stakeholder roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?***

The complexity of the healthcare system necessitates many different stakeholders be involved in supporting the Community Resources and Policies component of the Wagner

CCM for treatment; these include doctors, patients, nurses, hospitals, pharmaceutical companies, insurers, FNS providers, and state Medicaid directors and policymakers. Each stakeholder brings their own point of view and experience; however, some stakeholders may have more direct knowledge and expertise than others. For example, hospitals, doctors, nurses and the pharmaceutical industry are not typically involved with the creation and implementation of waivers, thus making them ineligible for this research. Although their perspective could help to inform the *Food Is Medicine* model in the context of the food being a social determinant of health, however that is outside of the scope of this research. This study, then, will focus on four stakeholder groups: (1) policymakers, (2) Medicaid Insurers, (3) FNS providers, and (4) FNS participants.

These four stakeholder groups were chosen because they have knowledge and experiences about their role in supporting—or not supporting—policies for FNS for people with Type II Diabetes. The four stakeholder groups face unique opportunities and challenges and by engaging in this research it may shed light on internal processes at their organization are working and those that could use improvement. Along with the stakeholders, the researcher will gain a macro view of the FNS policy process to learn what is working and where there is room for improvement. Exploring stakeholder roles will provide a blueprint for policy recommendations on how to receive reimbursement under Medicaid for FNS. Lastly, these stakeholders were chosen because of the partnerships and relationships that have been cultivated in order to provide access to the stakeholders. A more in-depth discussion of the stakeholders can be found in Chapter 3: Methods.

In the U.S., diabetes is a key chronic disease, especially as the proportions of the population that are overweight or obese continue to rise. The type of diabetes diagnosis that a patient may receive depends on the hormone insulin, whether the body has none or cannot use what it produces effectively. Diabetes is typically treated with oral and injectable prescription medications that help to either reduce the amount of glucose in the blood stream or supply the body with insulin to convert glucose into energy. These therapies are effective in treating diabetes and improving patient outcomes. Although, prescription drug adherence due to cost may be a barrier for those on a restricted income.

Nationally, the cost of treating this disease will continue to increase and place a greater burden on an already fragmented healthcare system. New and innovative ways of organizing the healthcare system to prevent and treat chronic disease must be explored. The Wagner CCM is a proven framework that can be adapted to have more focus on the Community Resources and Policies component.

The idea that food can be medicine has been demonstrated by FNS providers who are treating patients with chronic diseases, like diabetes and having successes with reductions in cost, hospital admissions and patient outcomes. Since their services are not typically reimbursable, existing policy options need to be explored in order to scale this intervention effectively and provide reimbursement. Using Medicaid waivers to cover the cost of FNS providers programs may help to reduce the severity of diabetes in our communities. In order to move the needle, we must first understand the stakeholders' roles, in particular, policymakers, Medicaid Insurers, FNS providers and Medicaid

beneficiary's roles in Medicaid waiver policies that support FNS for people with Type II Diabetes.

Chapter 2: Literature Review

Introduction

Worldwide increases in the incidence of overweight and obesity has led to escalating rates of chronic disease, primarily Type II Diabetes. As a metabolic condition, Type II Diabetes occurs when the body is no longer able to use the insulin that it produces to provide energy to its cells causing rising blood glucose levels. Over time, uncontrolled high blood glucose levels can lead to many macro and microvascular complications, like cardiovascular disease, stroke, neuropathy, retinopathy, and nephropathy (ADA, 2015). Treatment of Type II Diabetes has been highly medicalized through the use of pharmaceutical interventions, although lifestyle interventions, such as diet, exercise, and education have been proven effective in the management of the disease and the prevention of comorbidities (Avery, Flynn, Van Wersch , Sniehotta, & Trenell, 2012; Baker, Simpson, Lloyd, Bauman, & Fiatarone Singh, 2010; Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014; Coppel, et al., 2010).

To better address these rising rates, a shift towards an integrated primary prevention care model is necessary for those at risk of diabetes or who have been diagnosed with this chronic disease. The focus has been on secondary prevention, specifically diagnosis and treatment of diabetes. To shift this focus from secondary to primary prevention, a different model is needed. The *Food Is Medicine* model can help to make this shift by helping those who have been diagnosed or those who are considered pre-diabetic with medically tailored meals. These meals have shown in small studies improvements in direct health outcomes and reduced healthcare cost (FIMC, 2018) (Gurvey, et al., 2013).

The question arises, how should services that provide medically tailored meals be financially supported? In some places, the use of existing Medicaid Home and Community Based Services (HCBS) 1915(c) waiver policies cover the reimbursement of these services. Precedent has already established the use of Medicaid funds to cover non-traditional service models like medically tailored meals, yet, the pathway for stakeholder reimbursement is less clear (Shirk, 2006). This literature review will: 1) explore the implementation of healthcare models to combat chronic disease, 2) examine pharmaceutical and lifestyle interventions used to treat people with Type II Diabetes, 3) review existing Medicaid waiver policy that could support the *Food Is Medicine* model through reimbursement for medically tailored meals, and 4) propose organizational and institutional theory as a theoretical framework for shaping healthcare policy moving forward.

Chronic Care Models

Throughout the history of the U.S. healthcare system, models of care have been designed and implemented to control rising healthcare expenditures, effect clinical outcomes, and create efficiencies (World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health, 2016). While model types and structures have varied, and some progress has been achieved, it is evident that the U.S. healthcare system is still in search of an effective model that accomplishes all three goals. A potential issue that may hinder progress towards reduced cost, improved outcomes, and efficiencies is the innate reliance on the traditional medical model to treat chronic disease.

Currently the treatment of diabetes follows the traditional medical model of pharmaceutical and surgical interventions to control blood glucose and reduce risks of comorbidities and complications examined in the previous chapter (ADA, 2015). While the medical model is proven to be effective, it is only implemented once a patient is diagnosed and lacks foresight to prevent the diagnosis. The Chronic Care Model (CCM) aims to shift treatment to an integrated model that incorporates physician teams, decision information systems, and community resources to improve health outcomes. This medically based model is more comprehensive than a traditional medical model because it provides additional support to healthcare systems, providers and patients through systems and community involvement. But, the primary emphasis of CCM is medically oriented interventions that diagnose and treat disease through pharmaceutical and surgical means.

CCM has been well studied for outcomes and effectiveness (Baptista, et al., 2016; Chang Ha & Robinson, 2011; Epping-Jordan, Pruitt, Bengoa, & Wagner, 2004; Hroschikoski, et al., 2006). The literature in this review presents a small portion of studies that have implemented the entire model. Continual rising rates of chronic disease is forcing the U.S. healthcare system to identify a model of care that focuses on not only secondary prevention but primary prevention.

The Innovative Care for Chronic Conditions (ICCC) is an integrated care model emphasizing prevention, policies that support chronic care and community resources to reduce the likelihood of diagnosis as well as avert comorbidities and complications among patients diagnosed with chronic disease (Nuno, Coleman, Bengoa, & Sauto, 2012;

Epping-Jordan, Pruitt, Bengoa, & Wagner, 2004). This model takes a broader view of chronic disease to put policies in place at a national level to maximize the impact. The use of food nutrition services, like the *Food Is Medicine* Coalition (FIMC) organizations, addresses all three components of the ICCC: (1) they utilize the concept of *Food Is Medicine* to deliver medically tailored meals that prevent comorbidities and complications in chronically ill patients; (2) they advocate for policies that support the *Food Is Medicine* movement at the local, state and federal level; and (3) FIMC organizations work within their communities as a resource for food, frequently including nutritional counseling to improve the health of the community (Nuno, Coleman, Bengoa, & Sauto, 2012; World Health Organization: Health Services Delivery Programme Division of Health Systems and Public Health, 2016).

A combination of the ICCC and the *Food Is Medicine* movement has the potential to reduce costs and improve the lives of chronically ill patients within their own community (World Health Organization, 2002; FIMC, 2018). This section of the literature review will present evidence to support the transition from a medically based model to a prevention focused model to treat diabetes.

The structure of the United State healthcare system dramatically evolved over the last two centuries, from a home visit by a doctor when a patient was ill to a complex multifaceted industry. From its early inception the healthcare system was designed to treat people's acute or episodic needs, many relating to communicable disease, otherwise people did not go to the doctor. Escalating rates of chronic disease have forced a shift in healthcare systems from acute or episodic care to chronic care. Chronic disease requires a

different model of care due to the nature of disease that requires patients to engage with the healthcare system more frequently than a non-diseased person.

Once a chronic condition is diagnosed, many Americans do not receive adequate healthcare. The ramifications of improper care requires a patient to cope and manage the effects of their condition on their own, leading to a reduction in their quality of life (Nuno, Coleman, Bengoa, & Sauto, 2012). Diabetes presents specific challenges for healthcare systems that do not adopt a chronic care model because diabetes requires an integrated approach between the physicians, patients, and the community to reduce the likelihood of complications and adverse events. As discussed in the previous chapter diabetes self-management requires pharmaceutical medication and routine blood glucose monitoring by the patient and doctors to reduce the risk of complications and death (Bodenheimer MD, Wagner MD, & Grumbach MD, 2002). In addition to blood glucose monitoring PWD must also follow a strict Type II Diabetes diet and exercise regimen as well as perform routine examinations of their feet and eyes. This requires patients to be committed and dedicated to their self-care routines. To aid in compliance with treatment physicians and care teams can play a critical role for PWD as evidenced by integrated models of care.

The Chronic Care Model (CCM) discussed in the last chapter is an integrated model that focuses on six components to improve care for chronic conditions. The CCM components include: (1) Community Resources and Policies, (2) Health Care Organization, (3) Self-management Support, (4) Delivery System Design, (5) Decision Support, and (6) Clinical Information Systems (Baptista, et al., 2016; Stellefson,

Dipnarine, & Stopka, 2013). The literature includes studies where the entire model was investigated as well as others where only some of the components were reviewed for different types of chronic diseases (hypertension, hyperlipidemia, and heart disease). This section of the literature review will focus on studies where the CCM was implemented with diabetes patients. Baptista, et al. conducted a systematic literature review for randomized control trials that implemented any components of the CCM in the treatment of Type II Diabetes. The findings revealed the use of community resource integration was not found in any of the 12 studies under review (Baptista, et al., 2016). Half of the studies did not see any improvements in the clinical outcomes of mortality and HbA1c (Baptista, et al., 2016). The individual components of the CCM were implemented in varying degrees, yet changes in clinical decision support, clinical information systems and design of the service delivery system were observed in all included studies. The conclusion drawn from this review suggests that better health outcomes may be realized with the inclusion of all six CCM components.

Stellefson, et al. performed a literature review to examine the CCM and diabetes management in U.S. primary care. After inclusion and exclusion criteria were applied sixteen studies remained with a mixture of study designs, specifically, randomized control trials, prospective cohort, cross-sectional, qualitative and natural experiments. Six of the sixteen studies implemented each of the six components of the CCM (Stellefson, Dipnarine, & Stopka, 2013). This review did not assess whether those studies that implemented the entire model had overall improved clinical outcomes compared to other studies. The community resources and policies component was specified in seven of the

sixteen studies, a meta-analysis reported that few studies utilize this component, in spite of its ability to provide additional human and financial resources (Stellefson, Dipnarine, & Stopka, 2013; Tsai, Morton, Mangione, & Keeler, 2005). The authors suggest that more partnerships need to be developed between physicians and the community organizations in order to eliminate or reduce any barriers to care for PWD.

The outcomes of these two literature reviews highlight when more components of the CCM are implemented than it increases the likelihood of improved outcomes. While this is a notable finding, the fact remains that community resources and partnership component remains underutilized. This next section will explore studies where randomized control trials (RCT) were implemented to analyze the health outcomes within the CCM framework. Piatt et al., devised a multi-level, non-blinded, cluster study with a pre-cross-sectional chart review, RTC intervention and post cross-sectional chart review (Piatt, et al., 2006). The pre-cross-sectional chart review was conducted to determine patient eligibility for the study and patterns of care patients received. The RCT intervention randomized participants into three separate groups: (1) CCM, (2) provider education, and (3) usual care. The authors hypothesized that they would see reductions in HbA1c, non-HDL cholesterol, and blood pressure readings among patients in the CCM group compared to the other groups. They also postulated that there would be improvements in quality of life, diabetes knowledge, and empowerment in self-monitoring blood glucose among the CCM group compared to the other groups. This study examined all six components of the CCM within the CCM group, but community

resources and policies, decision support, clinical information systems and organizational support were examined for all groups (Piatt, et al., 2006).

The results of the study showed that the CCM group had statistically significant reductions in HbA1c ($p= 0.008$) while no change was observed in the other groups (Piatt, et al., 2006). Even after taking into account the cluster design within the practices and adjusting for factors like age, HbA1c, and insulin use the effect of CCM was still strong ($p= 0.001$) (Piatt, et al., 2006). The secondary outcomes of psychological, psychosocial, and behavioral outcomes showed no improvement between any of the groups, even using adjusted data (Piatt, et al., 2006). The results of this study provide evidence of the effectiveness of the CCM in diabetes care. The long-term sustainability of these outcomes is not addressed, with only a one-year follow up.

To address the concerns of the long-term sustainability of the outcomes Piatt et al., expanded on their original study to include a longitudinal component by following original research participants for three years after the RCT ended (Piatt, et al., 2010). The clinical, behavioral and psychosocial outcomes being examined were the same as the original study. For the clinical outcomes, HbA1c improvements were sustained in 66% of the CCM group; where the other groups observed no significant improvements at twelve month follow up (Piatt, et al., 2010). These results remained consistent at the three year follow up point. Both non-HDL cholesterol levels and blood pressure readings improved over time for all groups (Piatt, et al., 2010). The psychosocial and behavioral outcomes remained consistent at the three year follow up for all groups (Piatt, et al., 2010). While the study results show sustainability over time, the full effect of the intervention may not

have been observed because the sample sizes were small in both the original RCT and the follow-up. In both studies, the authors were constrained in their ability to recruit the participants, potentially affecting sample size (Piatt, et al., 2006; Piatt, et al., 2010). Despite the small sample size this study lays the foundation for additional research for the CCM and diabetes, specifically looking at which type of diabetic patients may fare better in a CCM intervention.

In order to improve clinical outcomes of PWD (HbA1c, blood pressure, cholesterol) Piatt et al., examined patient factors that might lead to improvements in HbA1c, blood pressure and cholesterol based on the original RCT study. Older age, higher baseline HbA1c, higher well-being scores and being in the CCM intervention group were independently associated with improved blood glucose control (Piatt, et al., 2011). Patients using insulin and those without retinopathy saw improvements in their systolic blood pressure readings (Piatt, et al., 2011). For older age patients, those with longer diabetes duration and those with lower empowerment scores saw improvements in diastolic blood pressure readings (Piatt, et al., 2011). Higher baseline non-HDL cholesterol readings saw the largest improvement in non-HDL levels (Piatt, et al., 2011). The research conducted by Piatt and colleagues is seminal to the literature because it is the only one to date to have a follow-up period over 18 months.

Similar to the RCT that Piatt and colleagues conducted, Nutting et al., evaluated the CCM in small primary care practices in the U.S., specifically to analyze clinician-reported use of CCM components against diabetes care outcomes in 2007. The recruiting effort yielded 30 participating practices and patients were recruited after a confirmation

of their diabetes diagnosis was obtained; and 886 patients (74.6%) agreed to participate in the study (Nutting, et al., 2007). To measure the use of the CCM components the authors developed and tested the Use of Chronic Care Model Elements Survey that was administered to all clinical care staff at enrolled practices. A respondent's use of individual CCM components were rated on a five-point scale (never, rarely, occasionally, usually, and always). A mean score was calculated for each of the six CCM components for an overall mean score of 3.24 (SD= 0.70) (Nutting, et al., 2007).

Due to inconsistencies in the medical record formats, the process of care was assessed through the Diabetes Physician Recognition Program (PRP) measures put forth by the National Committee for Quality Assurance (NCQA) and the American Diabetes Association (ADA). The PRP measure uses six-month intervals (within last 6 months, 7-12 months ago, 13-18 months ago) to determine when a physician either performed or ordered HbA1c, blood pressure, lipids, microalbumin, foot examination, and dilated eye exam. A composite clinical score was created based on patient reports for a mean score of 3.0 (SD= 0.95) of the 7 CCM components of the clinical care composite score (Nutting, et al., 2007). Additionally, behavioral outcomes, such as receiving support from practice, nutrition education, and encouragement from the practice to monitor blood glucose were compiled into a composite score. Patients cited receiving 2.1 (SD= 0.95) of 3 CCM behavioral components (Nutting, et al., 2007). These results show increases in both the clinical and behavior composite scores when more components of the CCM are implemented. Statistical significance was achieved for the behavioral composite score ($p= 0.001$), and is approaching statistical significance for the clinical care composite

score ($p= 0.07$) (Nutting, et al., 2007). Physician integration of CCM components into their practices is positively associated with reductions in HbA1c and cholesterol (Nutting, et al., 2007).

While this study does not prove causality, it suggests that any integration of the CCM into small primary care practices may produce better clinical and behavioral outcomes among patients. Regardless of promising results, this research did not specifically address the community resources and policies component in its clinician composite score. The measure that was used was “Refer patients to someone outside your practice for education about their diabetes,” which is far too narrow and undermines other types of support besides education that diabetic patients can receive in their community (Nutting, et al., 2007). Thus far, the studies reviewed have taken place within the primary healthcare setting. The CCM has been proven effective within the community healthcare setting.

Stroebe et al., conducted a study examining the implementation of the CCM in patients with multiple chronic conditions that had no health insurance and received treatment at Salvation Army Free Clinics in Rochester, Minnesota. The study design was a prospective cohort that collected clinical data after a minimum of 100 days, because less than may not have shown any improvement (Stroebe, et al., 2005). Participants were followed for a period of up to 22 months from the baseline. The primary outcome for researchers was to show a significant improvement in at least one chronic disease after the CCM was applied. More specifically, the researchers wanted to measure clinical outcomes with a one-stage reduction in blood pressure, at least a 1% reduction in HbA1c,

and a reduction in risk group for low-density-lipoprotein (LDL) cholesterol (Stroebe, et al., 2005). The population examined in this study was racially and ethnically diverse as well as included a large percentage of migrant workers. The free clinic operated two nights per week to offer access for working patients and was staffed mainly by two internists, one endocrinologist, one dietitian, and two diabetes educators.

This study incorporated all six components of the CCM into their intervention. The clinicians created a chronic disease registry to track patients and highlight when follow-up tests and appointments were required. Algorithms based on clinical guidelines were used to aid nurses in caring for patients at the primary level, and if the case was more complicated or medication needed to be adjusted the patient would meet with the internist or specialist. Over the study period patients had an average of 9.5 encounters (virtual or in-person) with nurses and 1.8 encounters with the internists (Stroebe, et al., 2005). The endocrinologist was only seen by nine patients for one encounter and one patient had two encounters (Stroebe, et al., 2005). All staff were provided with decision support by an endocrinologist and diabetes educators. The CCM component of self-management support was achieved through goal setting sessions with patients and follow-up by nurses on agreed upon goals. The community resources and policies components were addressed due to the fact that the Salvation Army is a community organization; and the building and staff were all community volunteers. The executive leadership at the Salvation Army was fundamental to the success of the community partnership.

A total of 149 patients were enrolled in the study, with 117 diagnosed with hypertension, 91 with diabetes and 51 with hyperlipidemia (Stroebe, et al., 2005). The

loss to follow up was marginal given the population: some were lost due to acquiring health insurance (17), moving out of the area (13), or un-locatable (10) (Stroebe, et al., 2005). The primary study outcome was achieved because overall 53% of the enrolled patients improved at least one chronic disease (Stroebe, et al., 2005). For those patients that completed the study (22M follow-up) 72.5% improved. All of the secondary outcomes saw improvements: hypertension (64%; $p= 0.001$), diabetes (53%; $p= 0.001$), and hyperlipidemia (58%; $p= 0.001$) (Stroebe, et al., 2005). Based upon the authors definition of program effectiveness by improving at least one chronic disease in half of the patients the results show that the CCM was effective in reducing at least one chronic disease for 53% of enrolled patients. This study has limitations of not being a randomized control trial, conversely the authors felt it was important to show that the CCM model can be effective in a free clinic setting. Additional challenges included volunteer staff, financial resources, and patient barriers to access such as transportation to the clinic or childcare (Stroebe, et al., 2005). Notwithstanding the challenges, the CCM model was proven effective and the health of participants was improved, while putting the community resources and policies component at the forefront.

A key criticism of the CCM is that the model does not provide detailed instructions for implementation. Hrosakoski et al. conducted a qualitative study to describe a medical group's implementation of the CCM using semi-structured interviews with all different levels of staff and observations in the clinics (Hrosakoski, et al., 2006). The study evaluated the entire CCM model eighteen months after the overall CCM implementation and then again after the prepared proactive teams were executed in all of the clinics. The

interviews were conducted with all level of staff from organizational leaders to nurses. The interview questions focused on patient care changes, the change process, perceived change facilitator and barriers. The interviews were scored for a level of implementation using a three-point scale based on presence of each component ranging from none (0) to some (1), to substantial (2). The overall mean score was 12 out of a possible 46, meaning the practices had an implementation percentage of 26% (Hroscikoski, et al., 2006). Delivery system and self-management support scored highest with 5.6 and 2.4 respectively (Hroscikoski, et al., 2006).

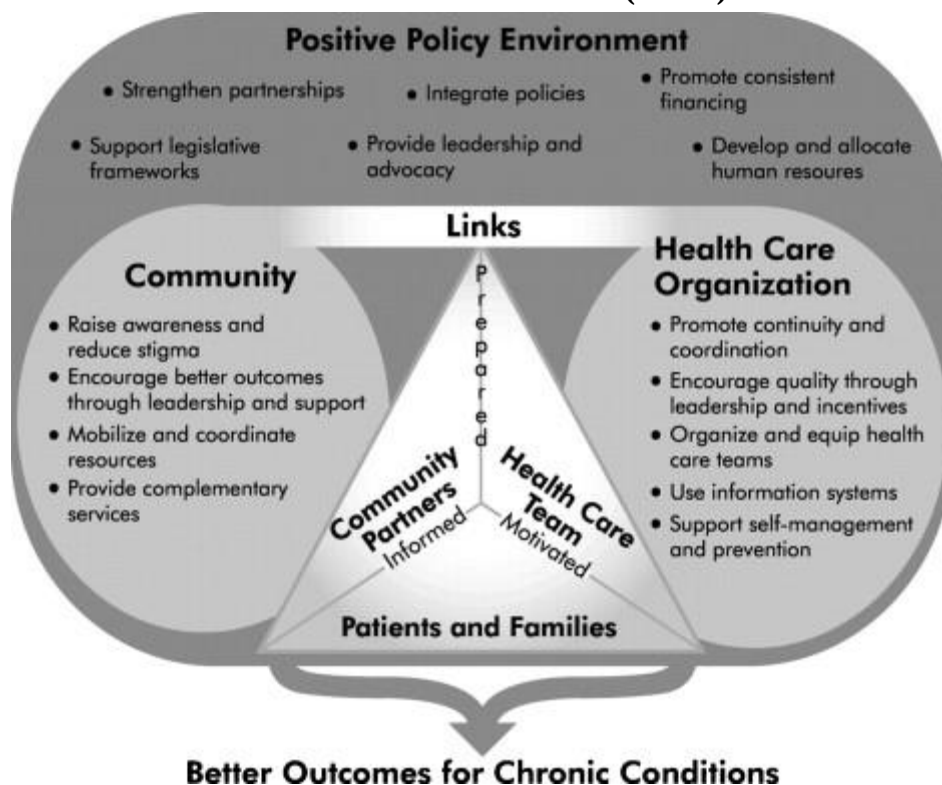
Participants cited that key leaders must be on board with any change activities and provide specific instructions otherwise each clinic would implement the model the way they see fit. Without corporate or managerial buy-in, replication is nearly impossible within in a medical group, never mind an entire healthcare system (Hroscikoski, et al., 2006). A large consideration for making the practice teams effective is the physical space of the office to ensure that team members are seeing each other to foster communication. Physicians need to be engaged in the process as a member of the practice team. Within this study, doctors did not view themselves as an integral or driving force (Hroscikoski, et al., 2006). In summary, the authors learned that change takes time, understanding that change is difficult, unexpected events will happen and cannot be anticipated, and buy-in from all levels of staff is critical.

The application of the CCM in varied clinical settings led to beneficial outcomes for PWD. This model is still reliant on the traditional medical model. The use of disease registries and clinical decision support do little to help prevent the diagnosis from

occurring. Furthermore, the model is dependent on the individuals proposing the model remain at the institution. If there is staff turnover within the institution, the new staff may not follow through with implementing the model; depending on the stage of implementation (Hroscikoski, et al., 2006). Aside from the reliance on a medical perspective the common theme among the studies reviewed is the underutilization of the community resources and policies component to improve health outcomes of PWD. MANNA provides this community service through medically tailored home delivered meals and has been shown to improve outcomes while reducing health care costs (Gurvey, et al., 2013). The CCM lays the groundwork for medical systems and practices to implement change for chronic care patients. It does not place enough emphasis on community resources and primary prevention.

The Innovative Care for Chronic Conditions (ICCC) framework created by the World Health Organization (WHO) in 2002 is very similar to the CCM, even though community resources, public health, health policies, and prevention have a greater emphasis in the ICCC comparatively (World Health Organization, 2002). A model of the ICCC can be found in Figure 4. The ICCC was developed in response to the perceived gaps in the CCM and to make it more relevant for the international community. The core components of the ICCC are: (1) evidence-based decision making, (2) population health approach, (3) focus on prevention, (4) emphasis on quality of care and systemic quality, (5) flexibility/adaptability, (6) and integration.

Figure 4. The Innovative Care for Chronic Conditions (ICCC) Model



Source: Nuno, Coleman, Bengoa, & Sauto, Integrated care for chronic conditions:

The contribution of the ICCC Framework (2012)

The first core component of evidence-based decision making is critical because it utilizes what is already known about clinical process of care and patient outcomes, as well as highlighting gaps. If no data exists, there is a duty to study disease specific populations to build up the knowledge and evidence to improve healthcare for the chronically ill. Furthermore, evidence based decision making allows for better allocation of healthcare resources, specifically healthcare workers can be strategically placed within the community to better address healthcare needs (World Health Organization, 2002). In the absence of evidence-based decision-making policies could be enacted based on intuition or impulse and have a dramatic effect on a chronically ill population. The

second core component of the model utilizes a population focus that enables better health outcomes because long-term strategies can be developed, and prevention measures implemented for the specific population instead of on a single need basis. Adopting a chronically ill population focus reduces the need for high cost services, like hospital admissions and emergency room visits (World Health Organization, 2002).

The third component of the ICCC is a prevention focus. Its application is based on the shared understanding that most chronic diseases are preventable. If the factors that lead to the development of chronic disease are mitigated; the health of the at-risk population will improve as well as reduce the risk of comorbidities for those already diagnosed (World Health Organization, 2002). The model suggests that a commitment must be made to prevention within all levels of government, healthcare and community. Additionally, the model underscores quality in holding all stakeholders, such as policymakers and insurers accountable for health outcomes, not only clinical staff (World Health Organization, 2002). This focus brings a greater efficiency to healthcare systems as well as better resource allocation.

The most central component of the ICCC that drives change is integration at all levels of the framework: (1) micro—individuals must be activated and engaged in their care, (2) meso—healthcare must be organized so that partnerships can be formed with community organizations, and (3) macro—policy environment must support the common goal of reducing chronic disease burden (World Health Organization, 2002). At the micro—level patients are viewed as an equal partner in the healthcare team in conjunction with doctors and community partners, known as the triad. The model asserts

the notion that positive health outcomes can only be achieved when the entire triad is motivated and working together to prevent or manage chronic disease (World Health Organization, 2002). The meso—level identifies community partnerships as critical because the community is where the chronically ill spend majority of their time. When services are provided through community organizations, for example MANNA, which provides medically tailored meals, this fills a gap that the traditional healthcare system cannot provide while reducing the need for more expensive care (Gurvey, et al., 2013; World Health Organization, 2002). At the macro-level stakeholders need to be identified in order to influence decision makers to put forth policies that aim to reduce the burden of chronic disease at a national level. If new policies do not seem politically feasible, a review of existing policies may yield positive results while reducing redundant legislation. The model also advocates for consistent financing of policies that support innovative approaches to disease management, like the *Food Is Medicine* movement (World Health Organization, 2002). The integration of all levels of the model increases the chances of reducing the burden of chronic disease because it presents the problem through a clear framework that can be customized based on the healthcare system.

While the model is clear it also stresses the importance of flexibility and adaptability of healthcare systems because there could be swift changes in the disease rate, political party, or economic recession that impact the care patients receive (World Health Organization, 2002). To mitigate this, the model advocates for the use of disease surveillance systems to ensure patients are being taken care of during turbulent times. The ICCC model has not been studied as extensively as the CCM, although its focus on

community resources and primary prevention could provide evidence for greater implementation of these components in the CCM within the United States (World Health Organization, 2002).

Anecdotal evidence of the effectiveness of community partnerships can be gleaned from a medication compliance program for tuberculosis patients in Cape Town, South Africa. The compliance service texted patients to take their medication at specific times, as well as provided diet specific recipes and tips to improve their condition. In addition to the texting service patients also had community nurses' available 24-hours per day to help with specific health problems (World Health Organization, 2002). Although this was not a formal evaluation, healthcare workers, patients, and program administrators saw improved outcomes for tuberculosis patients. The cost of administering this program was similar to the cost of regular tuberculosis treatment (World Health Organization, 2002). While a rigorous evaluation was planned for this program, the literature search revealed no publications. In spite of a formal evaluation, this evidence supports the ICCC model and is improving outcomes for chronically ill patients using community-based services.

A Health Policy and Planning journal article details a community based effort in Zambia where HIV/AIDS and tuberculosis patients were provided with home-based care by two community organizations (Nsutebu, Walley, Mataka, & Simon, 2001). Community nurses were responsible for medical, psychosocial, and educational tasks as well as welfare tasks. Community volunteers performed self-management support to both the patient and their caregivers as well as ensured welfare needs were being met, like food and clothing. The results of this case study showed tuberculosis patients involved in

this community effort experienced high TB cure rates and detection of HIV (Nsutebu, Walley, Mataka, & Simon, 2001). Similarly, HIV/AIDS patients were being diagnosed and treated for tuberculosis. Part of the purpose in conducting this case study was to determine the scalability of the program to other parts of the country. What was not assessed was support from the government and other non-government organizations (NGOs) and patient satisfaction. Despite this lack of support from the government and NGOs, the program provides evidence that community partnerships can improve diagnosis and management of chronic illness (Nsutebu, Walley, Mataka, & Simon, 2001).

While the ICCC was intended to focus more internationally, the San Francisco Department of Health established a community based drop-in medication adherence program for HIV positive urban poor in San Francisco, CA. The burden of a chronic disease can be difficult for patients to manage. Adding socioeconomic conditions, like poverty, compounds the patient's situation making treatment compliance less likely (Bamberger, et al., 2000). The program utilized monetary incentives, telephone pagers, and support groups to improve viral suppression. Clients had to visit the center at least one time per week in order to receive the incentive. The telephone pagers that were offered would be used to remind clients to take their medications at specific times. The center offered support groups, including a buddy system to help reinforce healthy behaviors among clients. The program generated a 76% improvement in viral suppression in clients who were prescribed antiretroviral therapy (Bamberger, et al., 2000). The yearly cost of the program was the same as the yearly cost of a single HIV medication

(Bamberger, et al., 2000). Additionally, the authors reported many clients had improved their quality of life.

These studies illustrate both nationally and internationally the effect a public health and community resource forward approach to care can have on the chronically ill (Bamberger, et al., 2000; Baptista, et al., 2016; Hroschikoski, et al., 2006; Nsutebu, Walley, Mataka, & Simon, 2001; Nutting, et al., 2007; Piatt, et al., 2006; Piatt, et al., 2010; Piatt, et al., 2011; Stellefson, Dipnarine, & Stopka, 2013; Stroebel, et al., 2005). The focus on prevention and public health first followed by policies to support public health creates the necessity for community resource partnerships that in turn create a positive feedback loop for public health and policies (World Health Organization, 2002). This model pairs well with the *Food Is Medicine* movement because their main goal is to reduce the burden of chronic disease using a public health approach while advocating for policy changes to support the community resource providers (FIMC, 2018).

The components of ICCC model have not been studied as extensively as the CCM; the model does provide a potential direction that could be adopted in the United States. What may make the ICCC easier to implement in other countries is the structure of the healthcare system, especially those with single payer models. The complex multi-payer healthcare system of the United States has led to slow progress in changing models of care or prioritizing non-pharmaceutical interventions to improve the health for chronic care patients. While the evidence suggests that the U.S. favors a medical model for the treatment of Type II Diabetes, the research literature makes a strong case for lifestyle interventions, such as diet, exercise and education to improve glycemic control or prevent

the disease entirely (Ajala, English, & Pinkney, 2013; Avery, Flynn, Van Wersch, Sniehotta, & Trenell, 2012; Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014; Coppel, et al., 2010; Franz, Boucher, Rutten-Ramos, & VanWormer, 2015; Gaede, Lund-Anderson, Parving, & Pedersen, 2008; Norris, et al., 2005; Orozco, et al., 2008; Thomas, Elliott, & Naughton, 2006).

Pharmaceutical and Lifestyle Interventions in Type II Diabetes

Researchers have been studying diabetes for more than 100 years in an effort to understand the progression of the disease, identify ways to reduce complications and mortality, as well as prevent morbidity in at risk populations (ADA, 2018). The variety and combination of interventions that have been conducted throughout the years can be categorized in to three groups: 1) pharmaceutical, 2) dietary, and 3) physical activity. The efficacy of pharmaceutical interventions to manage Type II Diabetes has been well documented in the literature (Holman, Paul, Bethel, Matthews, & Neil, 2008; NIDDK, 2008; Look AHEAD Research Group, 2007). Many studies use improved glucose control and cardiovascular disease or events as primary outcomes for pharmaceutical interventions because individuals that are diagnosed with Type II Diabetes are at greater risk of cardiac events and disease. There are several studies that analyze blood glucose control interventions and their effect on macro and microvascular complications that are considered seminal to diabetes research (Holman, Paul, Bethel, Matthews, & Neil, 2008; Zoungas, et al., 2009; Skyler, et al., 2009). Chief among them are the United Kingdom Prospective Diabetes Study (UKPDS), Action in Diabetes and Vascular Disease: Preterax and Diamicon MR Controlled Evaluation (ADVANCE), Action to Control

Cardiovascular Risk in Diabetes (ACCORD), and Veterans Affairs Diabetes Trial (VDAT).

The results of these studies concludes tight blood glucose control was associated with reductions in microvascular complications, such as nephropathy, neuropathy and retinopathy; macrovascular events like coronary artery disease, peripheral arterial disease and stroke were mixed (Holman, Paul, Bethel, Matthews, & Neil, 2008; Zoungas, et al., 2009; Skyler, et al., 2009; UKPDS Group, 1998). The UKPDS study determined that an HbA1c of less than 7% would produce a 25% reduction in microvascular complications, but no reductions in macrovascular complications or mortality were observed (UKPDS Group, 1998). The UKPDS spurred researchers in the ADVANCE trial to test whether an HbA1c of 6.5% or less would yield even greater reductions in both macro and microvascular complications. The ADVANCE trial yielded a 10% reduction in macro and microvascular complications with an HbA1c of less than 6.5% (Patel, et al., 2008). The use of blood pressure medication showed reductions in the risk of major vascular events and death (Patel, et al., 2008). Following the same hypothesis of reduced HbA1c in Type II Diabetes improving cardiovascular risk, researchers in the ACCORD trial examined if an HbA1c of less than 6% would reduce rates of cardiovascular events and identify cardiovascular risk factors. This trial did not reach its conclusion because an inverse relationship was established between an HbA1c of less than 6% and cardiovascular events (Gerstein, et al., 2008). Participation in this trial was associated with increased cardiovascular and all-cause mortality (Gerstein, et al., 2008). The intervention participants were noted as having higher rates of hypoglycemia, increased

weight gain and fluid retention compared to control participants. These studies helped to formulate treatment guidelines to produce optimal outcomes, regardless that the majority of these studies do not assess the long-term effects of intense glycemic control.

The UKPDS 10-Year Follow-up was the only study to address long-term effects of intensive glycemic control on macro and microvascular outcomes, with some participants being monitored up to 30 years. Briefly, the UKPDS RCT initial study utilized a three month dietary lead into randomization of patients into three groups: 1) sulfonylurea, 2) metformin, and 3) dietary restriction (UKPDS Group, 1998). The average length of follow up was 10 years for the sulfonylurea group and 10.7 years for the metformin group. Reductions in the relative risk of death from diabetes complications was observed in the sulfonylurea and metformin group only (Holman, Paul, Bethel, Matthews, & Neil, 2008). The sulfonylurea group saw a 25% reduced risk of microvascular disease and a 15% reduction in myocardial infarction (Holman, Paul, Bethel, Matthews, & Neil, 2008). Overall, this group produced a 13% reduced risk of death from any cause with the addition of a sulfonylurea to the treatment plan (Holman, Paul, Bethel, Matthews, & Neil, 2008). Similar results were obtained for the metformin group; 39% reduction in the risk of a myocardial infarction; the reduction in risk of death from any cause was 36% compared to 13% in the sulfonylurea group (Holman, Paul, Bethel, Matthews, & Neil, 2008). The clinical outcomes of this study illuminate the legacy effect that occurs with intensive glycemic control at the outset of diagnosis. These results are further supported by the VDAT trial that examined the effects of intensive and standard glucose control on cardiovascular events. Greater reductions in cardiovascular events were observed when

intensive glucose control was initiated within the first 15 years of diagnosis compared to more long-term diabetes (Duckworth, et al., 2011). While pharmaceutical interventions have shaped the treatment of Type II Diabetes from a clinical point of view, they alone do not represent the entire picture of managing Type II Diabetes. It can be argued that the medicalization of Type II Diabetes has led to an over reliance on medication and less emphasis on lifestyle interventions. The use of lifestyle interventions, like diabetes education, diet, and exercise, has the potential to produce similar effects as medication in people with Type II Diabetes and supports the *Food Is Medicine* movement (Ajala, English, & Pinkney, 2013; Avery, Flynn, Van Wersch, Sniehotta, & Trenell, 2012; Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014; Coppel, et al., 2010).

Interventions that utilize diabetes education, dietary, and physical activity interventions in varying combinations have been well studied through systematic literature reviews and meta-analysis. A review of dietary approaches revealed that diets low in carbohydrates provide superior weight loss, glycemic control, and lipid profile compared to low-fat diets (Ajala, English, & Pinkney, 2013). This finding is in contrast with the traditional dietary advice that recommends consumption of 40-60% of daily calories come from carbohydrates. The Mediterranean diet produced better lipid and glycemic control over the traditional diet through an increase in monounsaturated fatty acids from olive oil, nuts and fish (Ajala, English, & Pinkney, 2013). The improvements in glycemic control for this meta-analysis ranged from 0.12% to 0.5%; and those studies that achieved a 0.5% reduction in HbA1c were statistically significant, and similar to reductions seen with medication (Ajala, English, & Pinkney, 2013).

The Lifestyle Over and Above Drugs in Diabetes (LOADD) study examined the effect of intensive evidence based dietary advice on glycemic control and risk factors for cardiovascular disease in patients with Type II Diabetes that were at high risk for cardiovascular disease and were already taking the maximum dose of prescription drugs. The use of intensive dietary advice produced a 0.4% reduction in HbA1c in participants as well as improvements in anthropometric measurements (Coppell, et al., 2010). There were no improvements in blood pressure and total cholesterol due to the optimization of participant's medication regimen (Coppell, et al., 2010). These results support the notion that glycemic control can be achieved through dietary advice alone. Similar results may be possible to achieve through physical activity alone to provide improvements in glycemic control (Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014).

Exercise is a key component of any Type II Diabetes treatment plan due to the fact that it lowers fasting blood glucose as well as provides cardiovascular benefits. Boulé et al., conducted a review and meta-analysis of the literature to examine the effects of exercise on HbA1c and body mass index in people with Type II Diabetes. The meta-analysis demonstrated a 0.66% reduction in HbA1c through exercise, similar to the results of the UKPDS study (Boule, Haddad, Kenny, Wells, & Sigal, 2001). Within the trials included in the review the authors concluded that exercise does not have to reduce body mass to have a beneficial effect on blood glucose as there was not a significant decrease in body mass index among participants (Boule, Haddad, Kenny, Wells, & Sigal, 2001). In a systematic review conducted by Chen et al., aerobic exercise was associated with greater reduction in HbA1c compared to resistance training. This reduction was not

statistically significant or clinically important (Chen, et al., 2014). Nonetheless, engaging in some physical activity was clinically relevant in reducing HbA1c and other cardiovascular disease risks. Both of these reviews indicated that a combination of diet and exercise may be optimal for achieve glycemic control and reduced risk of cardiovascular disease (Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014).

A systematic review of literature investigating lifestyle interventions that target physical activity and nutrition goals produced weight loss of 2.0% to 8.6% and a 1.2% reduction in HbA1c at the 12 month follow up for those following the Mediterranean diet (Franz, Boucher, Rutten-Ramos, & VanWormer, 2015). Additionally, decreases in medication were observed at the 12 month follow up in 7 out of 11 studies (Franz, Boucher, Rutten-Ramos, & VanWormer, 2015). This review yielded comparable results to Ajala et al., showing reductions in HbA1c when a Mediterranean diet was followed. The Look Action for Health in Diabetes (Look AHEAD) control trial also examined the use of intensive weight loss interventions (diet and exercise) and Diabetes Support and Education (DSE) groups in overweight or obese Type II Diabetes patients to analyze the effects on glycemic control and cardiovascular disease risk. The intensive weight loss interventions in this study produced an average weight loss of 8.6% (SD 6.9%) initial body weight compared to a 0.7% (SD 4.8%) weight loss in the control group (Look AHEAD Research Group, 2007). Participants in the intensive intervention saw a 0.64% reduction in HbA1c compared to a 0.14% reduction for control participants (Look AHEAD Research Group, 2007). The reduction in HbA1c for this study is similar to reductions seen in pharmaceutical medications. This intervention also produced improved

cardiovascular risk factors as well as a 21% improvement in cardiovascular fitness (Look AHEAD Research Group, 2007). At the conclusion of the study 73% of intervention participants met ADA goals of $HbA1c \leq 7\%$ compared to only 43% at baseline (Look AHEAD Research Group, 2007). Additional targets for hypertension and cholesterol were achieved as a result of the intensive intervention. The improvements in glycemic control and cardiovascular disease in diabetic participants in these studies support lifestyle interventions, like the *Food Is Medicine* movement, and offers promise for those that are at risk of developing the disease.

The Diabetes Prevention Program (DPP) was a large clinical trial that examined the effects of modest weight loss through dietary changes and increased physical activity compared to treatment with glucose lowering medication to prevent or delay a Type II Diabetes diagnosis in pre-diabetic patients. In this clinical trial, 45% of participants were minorities, which was not typical of most trials, although rates of pre-Diabetes and Type II Diabetes are higher among minorities than non-Hispanic whites (NIDDK, 2008). The results of this trial revealed that millions of Americans can avoid a Type II Diabetes diagnosis through diet and exercise to achieve a healthy weight. Participants under the age of 60 in the diet and exercise group reduced their risk of developing Type II Diabetes by 58% and those over the age of 60 reduced their risk by 71% (NIDDK, 2014). Overall, within the diet and exercise group only 5% of participants developed the disease compared to 11% in the placebo group (NIDDK, 2008). Among those who were given glucose control medication, metformin, delayed the onset of Type II Diabetes. The metformin group saw a 31% reduction in the risk of developing Type II Diabetes; and

7.8% developed diabetes compared to 11% in the placebo group (NIDDK, 2008). The implications of this study show a prevention forward approach through diet and exercise reduces the risk of developing Type II Diabetes, especially within minority populations.

In summary, the literature presents many interventions that have been tested to reduce micro and macrovascular complications, and Type II Diabetes diagnosis through pharmaceutical and lifestyle interventions. Conversely, a gap in the literature exists with respect to utilizing *Food Is Medicine* model to treat Type II Diabetes. Most of the research in this area has focused on healthcare costs and hospitalizations instead of direct health outcomes (Gurvey, et al., 2013). Even though the current research will not provide direct health outcomes of the *Food Is Medicine* movement, it will put forth evidence in support or denial of using a prevention-based model through medically tailored meals to treat Type II Diabetes. The aim of this research is to identify a pathway for stakeholders to be able to test the *Food Is Medicine* model through Medicaid reimbursement.

Medicaid Waiver Policy

Medicaid is the joint federal and state funded insurance plan that covers children, non-elderly adults and persons with disabilities. All beneficiaries are subject to meet specific income eligibility criteria prior to enrolling in the program. As of 2016, children made up nearly 50% of all Medicaid enrollees, with the remaining 50% split evenly between non-elderly adults and people with disabilities (The Henry J Kaiser Family Foundation, 2017). With almost half the Medicaid population made up of children it is increasingly important to prioritize prevention of chronic disease. One study examining the prevalence of Type I and II Diabetes in children and adolescents between 2001 and

2009 and reported a 30.5% increase in the diagnosis of Type II Diabetes among adolescents aged 10 to 19 (Dabelea, et al., 2014). Type II Diabetes is more aggressive in children compared to adults; and many children face serious complications only a few years after diagnosis (Downer, et al., 2015). Increases in the prevalence of Type II Diabetes pose a problem for state Medicaid programs because the length and costs of care for these beneficiaries may become enormously burdensome. Fortunately, since Medicaid is a joint insurance program, there is more flexibility in the eligibility criteria and benefits that a state offers.

States have the ability to set income criteria and plan provisions above the federal criteria, allowing for greater variability in each state's Medicaid program. The healthcare expenditures generated by each state are matched by the federal government to help offset the cost to the state. Every state receives a different federal matching percentage that can range from 50% to 75% in poorer states; and these matched dollars make up the largest portion of revenue in states' budgets (The Henry J Kaiser Family Foundation, 2017). States face formidable challenges in keeping Medicaid expenditures below the federal matched percentage, thus transitioning care from institutions and into the community for the highest need populations may offer financial relief (Eiken, et al., 2014; Eiken, Sredl, Burwell, & Woodward, 2017; Gurvey, et al., 2013).

There are three different ways that community-based services can be reimbursed under Medicaid: (1) Home and Community Based Service (HCBS) 1915(c) waivers, (2) HCBS 1915(i) waivers, and (3) Section 1115 Demonstration waivers. As discussed in the last chapter these waivers were designed to provide services for the most vulnerable

Medicaid beneficiaries. Waiver services are typically the costliest for the Medicaid program. All three approaches allow non-traditional services, like medically tailored meals from Food Nutrition Service (FNS) providers to be reimbursable. However, HCBS 1915(c) waivers contain an additional constraint that beneficiaries covered by the waiver must be at risk of institutionalization, meaning they require hospitalization or nursing home care. Typically, beneficiaries who fall into this category are seniors, people with intellectual or physical disabilities, and those with severe mental illness. Waivers provide flexibility to narrow the scope of the population covered by the waiver to include specific health conditions, for example diabetes (Downer, et al., 2015). States must prove that the non-traditional service is cost neutral, meaning it cannot exceed the cost of institutionalization. HCBS 1915(c) waivers can be administered by an oversight state agency responsible for implementation and reporting of cost neutrality to CMS (LeBlanc, Tonner, & Harrington, 2000; Harrington, LeBlanc, Wood, Satten, & Tonner, 2002). Conversely, some states choose to administer their waivers through the traditional fee-for-service model or under managed care organization (MCO), some states choose a hybrid approach (LeBlanc, Tonner, & Harrington, 2000). Regardless of the administration type, waivers are granted for a period of three to five years with the ability to renew, providing cost neutrality is met. If a community based service is effective in reducing healthcare costs, then states have the ability to alter their benefits plan to include the community service as reimbursable (Downer, et al., 2015).

Medicaid HCBS 1915(i) State Plan Amendments are characterized as a permanent change to the Medicaid plan whereby community-based services are a permanent

reimbursable benefit. This option is less restrictive than the HCBS 1915(c) waiver because it does not require the targeted population to be at risk of institutionalization, therefore potentially allowing more beneficiaries to be covered (Downer, et al., 2015). The legislative language around HCBS 1915(i) waivers was fairly strict until the passage of the Patient Protection and Affordable Care Act (ACA) of 2010 that revised the language to encourage states to use this policy tool. The revision allowed for separate eligibility criteria to be created for those living with chronic illness and additional services, for example medically tailored meals to be reimbursable (Downer, et al., 2015; The Henry J Kaiser Family Foundation, 2015). Furthermore, the ACA expanded eligibility requirements to include low-income, non-elderly adults that reached 138% of the FPL, resulting in a decrease in the uninsured from 16.6% in 2013 to 10% at the beginning of 2016 (The Henry J Kaiser Family Foundation, 2017). HCBS 1915(i) amendments must be renewed every five years when they are for a specified population. These waivers do not have to demonstrate that they are cost neutral, making them a more viable option for states that want to provide additional services. Political climates within state government may dictate whether a state pursues this option.

Lastly, states have the option to use Section 1115 Demonstration Waivers, which test new models of care, expand eligibility and provide non-traditional services. This type of waiver does not include the institutionalization requirement; it is required to be cost neutral (Downer, et al., 2015). The initial waiver period was for five years. As of November 2017, a new rule was issued that 1115 waivers can be renewed for a period of up to five additional years (The Henry J Kaiser Family Foundation, 2015). Home and

Community Based Services are not a full-scale model of care. States could frame the waiver for a specific population, like PWD, in order to provide specific services like medically tailored meals as a standard benefit. Alternatively, an 1115 demonstration waiver could be used to implement the Chronic Care Model, with the specific intention of implementing the community resource and policy component by utilizing FNS for a targeted population like people with diabetes. The waiver could be used to test the efficacy of FNS provider's services to see if there is a reduction in healthcare costs and improved health outcomes and evaluate the CCM.

Each of these options is viable for FNS providers to obtain reimbursement. According to the literature, HCBS 1915(c) waivers offer the best option for reimbursement because they aim to cover the most medically needy beneficiaries and could see greater improvements in health outcomes (Downer, et al., 2015). This option may be more politically attractive than the 1915(i) waivers because it targets a specific population and does not make permanent changes to the state's Medicaid plan. Furthermore, medically tailored home-delivered meals have been covered by 1915(c) waivers, whereas no states have chosen a HCBS 1915(i) or 1115 waiver to cover FNS for its beneficiaries (Downer, et al., 2015). Once a state is approved by CMS to administer a waiver, the state is required to report on cost neutrality and outcomes on a periodic basis, depending on the length of the waiver. State are not required to conduct evaluations of their waivers. The lack of rigorous evaluation has led to a gap within the literature for FNS, specifically medically tailored meals. This research project will provide evidence from stakeholders on utilization of Medicaid waivers for FNS to help eliminate the gap.

While a gap in the literature for FNS exists, the cost of long-term services and supports is well documented since their inception into Medicaid benefits.

According to the Kaiser Family Foundation, Medicaid spent \$310 billion dollars in 2013 on long term services and supports, accounting for 51% of overall Medicaid spending; and specifically \$123 billion was consumed by institutional and community based services (The Henry J Kaiser Family Foundation, 2015). Within the \$123 billion spent on institutional and community based services, spending on Home and Community Based Services (HCBS) specifically accounted for 46% or \$56.6 billion dollars, showing an increase of 32% since 2002 (The Henry J Kaiser Family Foundation, 2015). The increase in spending on HCBS is due to: (1) home health services that are mandatory by the state under federal guidelines, (2) personal care services, such as home health aides for cleaning and cooking, and (3) HCBS 1915(c) waivers. Although there have been increases in spending on HCBS, in 2012 there was a proportional decrease in expenditures for institutional care (Eiken, et al., 2014). This shift from institutional care to HCBS offers evidence of the effectiveness of HCBS services, like medically tailored meals.

In 2011, home health, personal care, or waiver services were received by 3.2 million Medicaid beneficiaries at a cost of \$55.4 billion or \$17,200 per beneficiary (Wiener, et al., 2017; The Henry J Kaiser Family Foundation, 2015). Medicaid spending for HCBS 1915(c) waiver services has remained the largest portion of home and community-based services. HCBS 1915(c) waiver services were received by 1.45 million beneficiaries for a total cost of \$38.9 billion dollars across 291 individual HCBS 1915(c) waiver programs

(The Henry J Kaiser Family Foundation, 2015). Expenditures for waiver services vary greatly by state, for example New Jersey spend 27.4% of its long term services and supports on HCBS; and Oregon spends 78.3% of its long term services and supports on HCBS (Eiken, et al., 2014). The national average holds at 49.5%, with an almost equal division of states that fall above and below the national average of long term services and supports being spent on HCBS (Eiken, et al., 2014). States with the largest increases in HCBS spending include Delaware (10.9%), Massachusetts (10.3%), and New Hampshire (7.8%), suggesting that legislators' efforts to restructure their Medicaid plans are moving in a different direction (Eiken, et al., 2014). Increases in spending on Medicaid long-term services and supports have continued into the second half of the decade.

In 2015, Medicaid long term services and supports expenditures totaled \$158 billion dollars, that represents a 4% increase since 2014 (Eiken, Sredl, Burwell, & Woodward, 2017). Despite the expenditure increase in 2015, the overall Medicaid spending for long term services and supports is stagnant; and the proportion of expenditures that continues to increase is the HCBS while institutional spending remains on a decline. As of 2015, more than half of the states in the country predominately spent the majority of their budget on HCBS; and this is an increase of 5% since 2011 (Eiken, Sredl, Burwell, & Woodward, 2017). Overall spending on HCBS for older adults and people with physical disabilities has increased by 27% since 1995 (Eiken, Sredl, Burwell, & Woodward, 2017). The trend of institutional expenditures decreasing at the same time HCBS is increasing suggests that the services provided by waivers may reach a turning point. At this point there is an even split among older adults being treated in the community and

institutions. Conversely, the literature on the cost savings that can be achieved by HCBS is mixed (Wiener, et al., 2017; Segelman, et al., 2017).

Studies examining the cost effectiveness of HCBS show minimal improvement in nursing home admissions, while another study showed a 3.15% reduction in nursing home admissions (Wiener, et al., 2017). Segelman et al., explored the differences in state's spending on HCBS and risk of long-term nursing home admissions to determine if there was a correlation between the two (Segelman, et al., 2017). Additionally, the researchers examined the characteristics of waiver enrollees to assess their functional and cognitive abilities. The study revealed a correlation between state spending and risk of long-term nursing home admissions. Waiver enrollees in states with higher HCBS expenditures showed a lower risk of a long-term hospital admission and higher functional and cognitive abilities, thus allowing the enrollee to remain within the community (Segelman, et al., 2017). Similarly, Thomas, Keohane and Mor explored the relationship between HCBS spending and nursing home admissions for younger adults. Their study revealed an increase in spending on HCBS at the local level yielded reduced nursing home admission rates among younger Medicaid beneficiaries (Thomas, Keohane, & Mor, 2014). These studies focused on long-term care facilities. The cost savings of HCBS and acute care are limited. One study showed that beneficiaries receiving HCBS were 1% more likely to have a potentially avoidable hospitalization compared to nursing home residents (Wysocki, et al., 2014). Additionally, there was a 40% increased likelihood of having a potentially avoidable hospitalization if beneficiaries were being transferred from their nursing home to the community for HCBS (Wysocki, et al., 2014). Despite the

mixed findings on costs savings for HCBS, the fact remains that rates of Type II Diabetes continue to increase and more research must be conducted to understand the roles of stakeholders to identify a pathway that could lead to changes in Medicaid reimbursement for medically tailored meals for people with Type II Diabetes.

Theoretical Framework

In order for stakeholders to identify a pathway for changes in policy a theoretical framework will be used during the analysis of this research. Based on prior unpublished research about the ability of professional organizations, such as the American Medical Association, to organize and legitimize their profession by encouraging both the concept of individualism and the opportunity to earn more income via membership, Donald Light points to the advantages of using a sociological framework with which to view healthcare (Light, 2004). At the core sociological frameworks provide an understanding of how society operates and how people construct their own reality compared to an economic or psychological approach (Light, 2004). The frameworks of organizational and institutional theories can be used to examine how stakeholders, specifically *Food Is Medicine* Coalition (FIMC) organizations can become institutionalized in order to help shape healthcare policy.

Organizational theory originated with Max Weber, who scientifically examined organizations, specifically looking at the relationships between bureaucracy and modernization (Mitzman, 2018). Weber defined what was necessary for organizations to gain authority: 1) it needed to define an explicit set of rules that has jurisdictional boundaries and 2) a unique division of labor (Mitzman, 2018). These two elements gave

rise to the modern bureaucrat. According to Light, Weber understood the nature of organizations in the pursuit of “quality, prestige, and profits” for their members by forming the organizations to pursue a legal monopoly (Light, 2004). It can be argued that Weber’s insistence on legitimacy as an organizational goal was the precursor to institutional theory (Greenwood & Lawrence, 2005).

The work of Philip Selznick helped to define classical institutional theory as an adaptive process whereby ‘institutionalization’ means to infuse with value beyond the technical requirements of the task at hand (Scott, 1987). Selznick argues that two type of organizations exists, those that are technically devised and disposable and those that have become institutionalized and are only concerned with their own self-maintenance that promotes stability in the structure of the organization over time (Scott, 1987). This framework requires that the researcher must include a historical review of the institution in order to assess it in the present day.

Modern definitions of institutional theory have shifted towards a recognition that social beliefs have become more rationalized, meaning that citizens look to nation-state and professions to dictate social beliefs rather than traditions and customs like elder’s councils (Scott, 1987). This form of institutional theory explores the roles of other actors, like professional organizations, to shape society by pushing their own agenda. It can be argued that these actors are strong enough to impose structural form onto others, either through authority or coercive power. DiMaggio and Powell maintain that organizations exert normative pressures on subordinates to conform, for example, while hospitals are not required to obtain accreditation from professional organizations like the Joint

Commission on Accreditation of Hospitals (JCOAH), it is in the hospital's interest to seek this accreditation because it may help to attract patients to the hospital, meaning more revenue, and thereby can be considered a coercive power (DiMagio & Powell, 1983; Scott, 1987). Organizational and institutional theories provide a lens for the analysis of stakeholders and their role in supporting policies for food nutrition services for people with Type II Diabetes. These perspectives will provide guidance in developing a set of recommendations to stakeholders on how to pursue policy changes to include medically tailored meals for people with Type II Diabetes.

Conclusion

The incidence of Type II Diabetes is nearly 10% among U.S. adults. As many as 1 in 3 new cases of diabetes mellitus are diagnosed in people younger than 18 years old (World Health Organization, 2016; Copeland, et al., 2013). The fragmented U.S. healthcare system does not adequately address the growing need for prevention that serves at risk populations or preventing complications in those diagnosed. Two frameworks were presented, the Chronic Care Model (CCM) and the Innovative Care for Chronic Conditions Framework (ICCC), provide a prevention focus and recognize the importance of providing integrated healthcare services especially through community organizations to improve diabetes health outcomes. Furthermore, policies need to be enacted that support community based services to alleviate the use of more intensive and higher cost services like surgery, hospitalizations and emergency rooms (Downer, et al., 2015). Healthcare systems that have implemented the CCM saw greater improvements in diabetic health outcomes when the entire model was implemented, especially the

community partnerships and resources component (Baptista, et al., 2016; Nutting, et al., 2007; Piatt, et al., 2010; Piatt, et al., 2006; Piatt, et al., 2011; Stellefson, Dipnarine, & Stopka, 2013; Stroebel, et al., 2005). Both models provide a framework for putting the *Food Is Medicine* movement goals into practice to test their ability to improve diabetes health outcomes.

Many clinical studies have been conducted using pharmaceutical and lifestyle interventions aimed at improving health outcomes in people with Type II Diabetes. While the effectiveness of pharmaceutical based interventions has been well documented, similar results can be achieved through the use of lifestyle interventions, such as diabetes education, diet, and exercise (Ajala, English, & Pinkney, 2013; Avery, Flynn, Van Wersch, Sniehotta, & Trenell, 2012; Boule, Haddad, Kenny, Wells, & Sigal, 2001; Chen, et al., 2014; Holman, Paul, Bethel, Matthews, & Neil, 2008; NIDDK, 2008; NIDDK, 2014; Norris, et al., 2005; Orozco, et al., 2008; Patel, et al., 2008). The success of lifestyle interventions paves the way for the *Food Is Medicine* movement to prove its efficacy with the use of medically tailored meals. Nevertheless, *Food Is Medicine* Coalition organizations face the challenge of having their services for medically tailored meals reimbursed by public and private insurers. Current Medicaid Home and Community Based Services (HCBS) 1915(c) waiver policy allows for non-traditional services like medically tailored meals to be reimbursed for specific populations like people with Type II Diabetes (Downer, et al., 2015; The Henry J Kaiser Family Foundation, 2015).

The literature revealed mixed results on the cost of HCBS 1915(c) waivers (Eiken, Sredl, Burwell, & Woodward, 2017; Eiken, et al., 2014). The waivers examined were not specifically looking at providing medically tailored meals and cost savings may take longer to achieve as services move from institutions to the community. The roles of stakeholders in supporting policies that favor food nutrition services, like medically tailored meals, is absent from the literature. The theoretical frameworks of organizational and institutional theories will be applied to this research to identify a pathway for stakeholders to pursue policies that support food nutrition services for people with Type II Diabetes.

The proposed research will address the gap identified in the literature by examining existing Medicaid policy to obtain a universal understanding of the Medicaid HCBS 1915(c) and 1115 waivers that have been implemented, specifically identifying those that reimbursed for medically tailored meals. This investigation will quantify states that are and are not utilizing this policy option and analyze waiver language to determine if any themes arise that could help future stakeholder advocacy efforts. Next, this research will explore stakeholders' roles in nutrition policies for people with Type II Diabetes. In-depth interviews with stakeholders will document their unique perspective in their support or non-support of FNS policies, and may identify processes, opportunities, and challenges for advocacy by any stakeholder. Qualitative evidence gathered from FNS participants may bolster the *Food Is Medicine* model further encouraging the transition from institutions to preventive care. The observational research component will investigate the need for additional nutrition support for FNS participants, such as SNAP

or food pantry assistance after cessation of services. Lastly, this research aims to put forth policy recommendations on how to incorporate the *Food Is Medicine* model into the community resources and policies component of the Chronic Care Model.

Chapter 3: Methods

The purpose of this research is to understand stakeholder roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes. This chapter discusses the methodology used to assess the roles of these stakeholders. Through an examination of stakeholders' roles, we plan to develop a series of policy recommendations about FNS as part of both prevention and treatment strategies for diabetes within the context of the Chronic Care Model.

The critical stakeholders selected for this research are: (1) policymakers, (2) Medicaid Insurers, (3) FNS providers, and (4) FNS participants. The four stakeholder groups were chosen for their knowledge, expertise, lived experiences, and characteristics which were discussed in previous chapters. The key question driving this research is: *What are the stakeholder roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?*

To address the stakeholders' roles, a qualitative study is proposed using content analysis, semi-structured in-depth interviews, and potentially photovoice. One component of the Medicaid Insurer and FNS provider's role is the ability to show efficacy of their services aimed at improving health outcomes for people with diabetes (PWD) while reducing healthcare utilization and cost. The opportunity to examine health outcomes, healthcare utilization and costs from stakeholders' roles was not part of the original proposal. Due to diligence and relationship cultivation, the student researcher worked with a Medicaid Insurer to obtain quantitative data to examine outcomes from the funding of FNS, thereby creating the prospect of developing a methodological approach

to consider outcomes of FNS services for Medicaid participants as well as modeling costs for these services. Through the use of quantitative data, we can explore the relationship between medically tailored meals that FNS providers serve and FNS participants as it relates to health outcomes of their diseases. Once a data use agreement was in place the student researcher reached out to the doctoral committee to discuss the impact of this data on the already agreed upon methods from the proposal. This change to the methods was made prior to data collection for all three techniques.

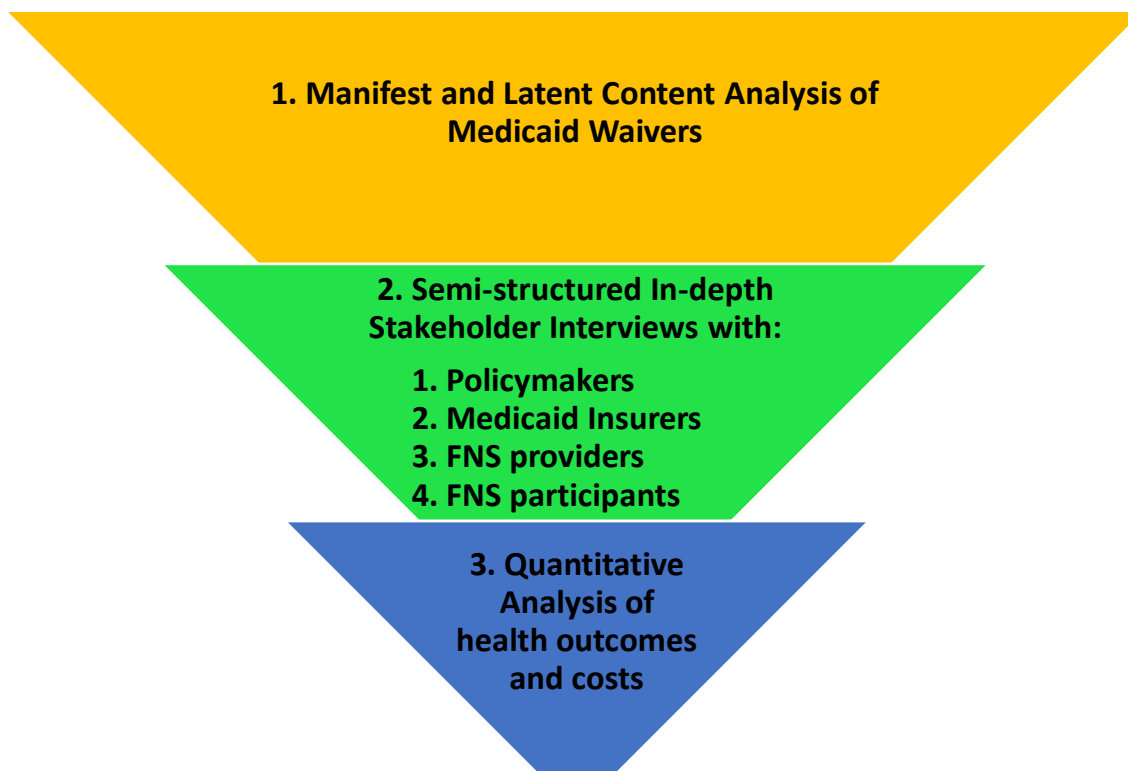
Originally, to identify themes and priorities within and across different stakeholder groups, three qualitative data collection and analysis techniques are proposed: 1) content analysis using manifest and latent analysis for Medicaid Home and Community Based Service (HCBS) 1915(c) waivers; 2) semi-structured in-depth interviews with stakeholders; and 3) photovoice to unobtrusively observe FNS participants in their home settings. Photovoice is encompassed under the Community-Based Participatory Research methodology that requests participants to document visually their lived experiences through photography to identify or represent issues that are important to them (Nykiforuk, Vallianatos, & Nieuwendyk, 2011). In this study, it is proposed that photovoice may be used as a proxy measure to assess the types and quantities of food FNS participants may be consuming at different times of the month, providing indirect evidence of *Food is Medicine*.

Based upon the recommendations and approval by electronic consensus from the doctoral committee, the photovoice component of the proposal has been replaced with the

quantitative analysis of the FNS data from the Medicaid Insurer. The photovoice method is viewed by the student researcher as future research to be conducted at a later date.

The final research design for this dissertation is a mixed methods design to assess stakeholder roles in Medicaid policies for PWD. Two qualitative methods are used: 1) content analysis using manifest and latent analysis for Medicaid HCBS 1915(c) waivers; and 2) semi-structured in-depth interviews with stakeholders. One quantitative method will be used to calculate descriptive statistics for health outcomes, healthcare utilization and costs. Figure 5 below represents the revised, overall structure for the methods of this research, and a methodological reference chart can be found in Appendix A (see Figure 5).

Figure 5. Methods Structure



Included are brief descriptions of each technique with in-depth explanations following.

1. Manifest and Latent Content Analysis of Medicaid Waivers

Content analysis is used in two ways to gain a broad understanding of the Medicaid HCBS 1915(c) waivers that have been implemented through April 2018. First, a manifest content analysis examines the role that politics plays in the Medicaid waiver process by determining and comparing, by political party, the number of waivers applied for from each state. Second, a latent content analysis is used to consider the language within the waivers. The content analysis of the Medicaid waivers was restricted to HCBS 1915(c) waivers (N=831). Content analysis explores the structural underpinnings of words to gain insight into their meaning (Hsieh & Shannon, 2005). Through this exploration of the Medicaid waivers, the strength and meaning of this legislation can be assessed, helping to identify themes for discussion with stakeholders and potentially suggesting future ideas for advocacy work.

2. Semi-structured In-depth Stakeholder Interviews

Semi-structured in-depth interviews with stakeholders illuminates the role that each stakeholder plays in the policymaking process to secure FNS for PWD. This form of interview provides flexibility to adapt the discussion guide in real time so as to receive information that would be almost impossible to collect through a survey instrument or focus group. The sub-questions to be addressed by these stakeholder interviews are outlined in Table 3. Stakeholder Interview Chart.

3. Quantitative Analysis of health outcomes and costs

A Medicaid Insurer partnered with an FNS provider to provide medically tailored meals to beneficiaries with diabetes for 12 weeks to assess the impact on health outcomes and costs. The student researcher is using descriptive statistics to analyze the partnership between the Medicaid Insurer and the FNS provider. Health outcomes of interest for PWD include changes in hemoglobin A1c (HbA1c), total cholesterol, and triglycerides. Healthcare utilization and cost outcomes specifically for emergency room visits (ER), inpatient visits, and total hospital visits are included in this analysis. Paired t-tests are conducted for the entire population to determine significance for each outcome, while odds ratio (OR), and relative risk (RR) are calculated for a sample of the beneficiaries. Testing a methodological approach to analyze this data could inform future partnerships between Medicaid Insurers and FNS providers, promoting future funding opportunities to support the *Food Is Medicine* concept.

Technique 1: Medicaid Waiver Content Analysis

To date, Medicaid's HCBS 1915(c) waivers have not been analyzed to understand their role in providing support for FNS for PWD. While there are many factors that influence a state's decision to submit a HCBS 1915(c) waiver application to Centers for Medicare and Medicaid Services (CMS), politics likely plays a major factor in that decision-making process. To that end, this method will use political party as an analytical lens, by focusing on states where the same party holds both the legislative majority and the Governor's office, which, with some state-to-state variation, often predicts which policies and waivers are passed or implemented.

Medicaid HCBS waivers were first used in 1981 as a policy tool to provide additional services to vulnerable beneficiaries that were at risk of being institutionalized. These waivers allowed states to provide services that fall outside the standard provisions of Medicaid. To date there are limited studies that have examined Medicaid HCBS waivers for FNS for PWD. This research provides an analysis of implemented Medicaid waivers that may contrast specific states providing more services with other states that are providing less services; understanding the details of this contrast may be helpful for policymakers and FNS providers in future reimbursement efforts.

Using both manifest and latent content analysis, this research provides a retrospective cross-sectional snapshot of Medicaid HCBS 1915(c) waivers (N=831) implemented prior to April 2018. A manifest content analysis is proposed to (1) help to determine if a correlation exists between the numbers of waivers implemented and the political parties that draft the waivers, and (2) offer insight into the language used within the waivers to support FNS. The latent content analysis (N= up to 20) explores the *a priori* and emerging themes that could be helpful to other stakeholders seeking reimbursement for FNS under Medicaid.

Content analysis supports the overarching research question by examining the distribution of the number of waivers that were implemented between February 2007 and April 2018. Within that time period there were 831 waivers or amendments to waivers submitted to CMS. The primary goals are to assess the influence that political party plays on waiver implementation and to determine what language and themes were used in order to secure reimbursement under Medicaid. This analysis could be used as a guide for

future waiver applications. Additionally, this analysis could provide insight for FNS providers to strategically plan advocacy efforts in order to create a policy window when that political party is in power within a given state.

The sub-questions addressed through this part of the research are:

1. Is there a relationship between the state Medicaid waivers that support FNS and the political parties that drafted these waivers?
 - a. What is the relative frequency of Medicaid waivers under different political party control of the state waiver process?
2. Within Medicaid waivers, what language supports FNS for people with Type II Diabetes?

The manifest content analysis addresses both sub-questions by (1) developing a frequency table that will show how many HCBS 1915(c) waivers were passed by each political party and (2) developing a frequency table tracking key phrases within a Medicaid waiver such as, “medically-tailored meals,” “home-delivered meals,” and “Type II Diabetes.” Using *a priori* and emerging themes from the latent content analysis of the Medicaid waivers may be helpful to the FNS provider stakeholder groups to inform their advocacy work regarding obtainment of reimbursement for their FNS under Medicaid. Understanding the language used in implemented Medicaid waiver applications by other states may be of use to policymakers currently submitting applications. This information may increase the likelihood of waivers being reimbursed more frequently by CMS if the proper language is used or if the precedent has been set through other language used by states.

The advantages of choosing content analysis as a method are that it is relatively unobtrusive in that the data are words that can be counted and coded by themes (Hsieh & Shannon, 2005). This method does not pose the same risks or burdens to the researcher or participants that interviews or questionnaires may (Berg & Lune, 2012). An additional advantage is that it is a highly cost-effective method when compared to engaging directly with human subjects through interviews or questionnaires. This method also allows for longer retrospective studies; for example, this project will examine Medicaid waivers that have been enacted since 2007 through 2018, which would not be possible using interviews or questionnaires because finding useful informants would be difficult and for identified informants the likelihood of recall bias would be high (Berg & Lune, 2012).

There are two main limitations of content analyses. First, to conduct the analysis, the researcher has to rely on available previously recorded texts, interviews, audio recordings and the like about the topic (Berg & Lune, 2012). This may present a challenge to the researcher in finding useful available material. Second, content analyses do not allow one to establish causal relationships; however, they can reveal the magnitude of a specific word, phrase or theme (Berg & Lune, 2012), which can provide insight into the predominance of a concept within the context of the investigation.

The documentary sample for both the manifest and latent content analysis includes all Medicaid HCBS 1915(c) waivers implemented between 2007 and 2018; this information will be drawn from the Medicaid.gov State and CHIP profiles database, which outlines each state's demonstrations and waivers.

The data for the manifest content analysis will be counted and compared with the *a priori* and emerging themes from the latent content analysis. The units of analysis for the manifest content analysis are the Medicaid HCBS 1915(c) waivers. A latent content analysis will be used to analyze the data to identify a combination of *a priori* and emerging themes. Medicaid HCBS 1915(c) waivers from the Medicaid.gov State and CHIP profiles database will be coded into themes. All data will be examined to create codes that will be collapsed into broader categories.

Due to the number (N=831) and overall length of the waivers, qualitative software is used to help with data reduction, NVivo[®]12, a widely used qualitative data reduction and analysis software package, and Dedoose, an online qualitative software package, are selected for this research. Both qualitative software programs have the ability to analyze mixed method data, and create data visualizations, however there are limitations. Each HCBS 1915(c) waiver is in portable document format (PDF) that includes radial buttons and text boxes that allow states to enter terms and conditions of the waiver. Although both software packages are able to import PDFs, they are unable to properly display the PDF, thus making it impossible to code the waivers. The student researcher constructed a data set from the waivers in Excel v.1912 and will be discussed more in-depth in Results Chapter (Chapter 4).

Technique 2: Semi-structured Telephone Interviews with Stakeholders

Again, the central research question of this dissertation concentrates on the role that stakeholders play to support FNS for PWD. As previously cited in the other chapters, there are four stakeholder groups: (1) policymakers, (2) Medicaid Insurers, (3) FNS

providers, and (4) FNS participants. Each stakeholder group presents a different perspective, but the method for obtaining the evidence is the same, semi-structured, in-depth telephone interviews. For each stakeholder group, little is known about the role that they play in securing FNS services for PWD. Semi-structured in-depth interviews capture each stakeholder's unique perspective through direct testimony about their lived experiences, which would not be accessible through survey or administrative data (Cachia & Millward, 2011). The table below (Table 3) outlines the

Table 3. Stakeholder Interview Chart

Stakeholder Group	Stakeholder Definition (All informants must be over the age of 18 and English-speaking)	Sub-questions	Number of interviews
Policymakers	Any policymaker or legislative aide who has worked on HCBS waivers in their state	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Up to 15

Stakeholder Group	Stakeholder Definition (All informants must be over the age of 18 and English-speaking)	Sub-questions	Number of interviews
Medicaid Insurers	Any Medicaid Insurer in contract with an FNS provider to provide services for up to 18 weeks	What was the decision process for deciding to partner with an FNS provider?	Up to 5
FNS providers	Any FIMC organization policy director or equivalent	What role does FIMC membership play in individual FIMC organizations?	Up to 15

Stakeholder Group	Stakeholder Definition (All informants must be over the age of 18 and English-speaking)	Sub-questions	Number of interviews
FNS participants	Any FNS participants receiving FNS from an FNS provider between 2018-2019 for 6, 12 or 18 weeks with Type II Diabetes as a primary diagnosis	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes? What role do FNS participants perceive their medically tailored home-delivered meals play in their ability to address their Type II Diabetes?	Up to 40

stakeholder groups, sub-questions that will be asked, and the number of interviews per stakeholder that will be conducted. A copy of the scripts that will be utilized can be found in Appendix B.

Policymakers.

Within each state's government, policymakers initiate the Medicaid waiver process. Yet, little is known about how policymakers choose to support FNS or the factors that influence their support or non-support of policies for FNS for PWD. Semi-structured, in-

depth telephone interviews will afford policymakers and/or their staff members an opportunity to report about the advocacy work in which they are, or would like to be, engaged to support FNS at the state level. The ability to record this information from policymakers and/or their staff members will give other stakeholders more information on the types of materials or aides that might be helpful to this group when they are engaged in advocacy. The information gathered from those questions could create opportunities for stakeholders to partner with each other to further enhance FNS advocacy.

The purpose of these interviews is to identify factors that either motivate or dissuade policymakers from supporting/non-supporting FNS policies for PWD. Through thematic analysis as a result of these interviews, the emergence of potential factors that influence policymakers may be detected as well as the assessment of the role that politics plays in this process.

Medicaid Insurers.

Medicaid Insurers often are perceived as “middlemen” between CMS and the FNS providers to facilitate FNS for PWD, despite their own corporate agendas. Semi-structured, in-depth telephone interviews address the sub-question by aiming to understand at the organizational level what decision-making process was followed when deciding to form a partnership with an FNS provider. These data will be useful for FNS providers as well as other Medicaid Insurers that may be looking into starting an agreement with an FNS provider. Moreover, these interviews will illuminate the

challenges and opportunities that Medicaid Insurers are presented with when engaging in such agreements with CMS and FNS providers.

Food Is Medicine Coalition (FIMC).

The Food Is Medicine Coalition (FIMC) is an association of nonprofit organizations that encourages advocacy and capacity building to advance the support of food and nutrition services for people suffering from severe and/or chronic disease through public policy. Based on prior unpublished research, professional organizations have exerted major influence over public policy in the United States; for example, the American Medical Association single handedly transformed healthcare by taking control of medical schools and hospitals to ensure that industry remained private and, in turn, could set the fees for services (Reiter, 2016). This question seeks to understand the roles of FIMC organizations as well as the opportunities and challenges they encounter with their advocacy work.

The second sub-question focuses on what the FIMC organization gets from participating in the umbrella group. Often, professional organizations use institutional and organizational theory to further the influence of their professional membership. The goal of this sub question is to assess if that is a possibility through the FIMC umbrella organization.

FNS Participants.

The first sub-question will assess the participants' knowledge about nutrition relative to their Type II Diabetes. This is an important component to assess because consuming a healthy diet is critical to the Type II Diabetes care plan. With this question an FNS

provider may be able to identify gaps in their current nutrition education in order to recreate nutrition education materials so that participants are able to understand directly how nutrition affects their condition. Understanding nutrition from a non-clinical persons' perspective could lead to meaningful insights that generate a better, more informed nutrition education component of the FNS program.

The second sub question examines FNS participants' perceptions about how food can either positively or negatively influence their health and Type II Diabetes. The purpose in asking this question is to explore how participants understand and process the *Food Is Medicine* concept. If participants believe food improves their overall health as well as their Type II Diabetes, then the opportunity may exist to consider food as "medicine." Participants will be asked to compare their health and Type II Diabetes while receiving FNS, and at least three months post services; this will help to reveal whether participants view their medically tailored meals as medicine. A frame of understanding among this group of stakeholders the medically tailored meals are viewed as "medicine" may provide support for the argument that this intervention should properly be covered by Medicaid. The use of an FNS intervention to treat Type II Diabetes has the potential to reduce costs to Medicaid while improving health outcomes for beneficiaries diagnosed with Type II Diabetes.

Advantages of Semi-structured Telephone Interviews

Telephone interviews have two key advantages, i.e., they are cost effective and they reduce the researchers' time in the field, especially when compared to face-to-face in-depth interviews (Cachia & Millward, 2011). Telephone interviews are not confined to a

specific location allowing a more geographically diverse sample of stakeholders; at the same time, the convenience of a telephone interview could increase the likelihood of participants to enroll in the study.

When a participant is interviewed in a face-to-face or focus group setting there may be a level of anxiety and social desirability to their responses; mediation of the communication channel by telephone may diminish this likelihood and provide some “safe” distance that could help the participant to feel more at ease with the discussion (Cachia & Millward, 2011). Also, this method allows for differences in size and organizational structure of stakeholder organizations whose representative may not want to share their processes in a group environment. Moreover, there are studies that suggest people are more willing to be open when being interviewed on the telephone; these studies, however, are not conclusive (Cachia & Millward, 2011). On the other hand, conducting in-depth telephone interviews places added pressure on the researcher to build rapport without personal presence.

Limitations of Semi-structured Telephone Interviews

As noted immediately above, the key limitation of telephone interviews is difficulty in developing a rapport with the participant. The researcher is not able to pick up on any non-verbal or visual cues, although there may be auditory clues such as heavy breathing, sighing, or tone and inflection change. Another limitation is the ability of the participant to suddenly end the interview by hanging up, thus terminating the interview. The researcher must decide if there is enough data from the interview to include in the analysis. If not, the researcher may have to conduct more interviews to reach the point of

saturation. Cachia and Millward also caution that respondents were not willing to give as in-depth answers as researchers would have wanted, so the researcher must be prepared to strike a careful balance between probing and asking questions (Cachia & Millward, 2011).

Sampling

Policymakers, Medicaid Insurers, and FIMC.

A nonprobability snowball sampling technique will be used for policymakers, Medicaid Insurers and FIMC organizations. Although these stakeholders are relatively easy to identify, it can prove challenging to schedule an interview. To increase the likelihood of scheduling an interview, contacts at an FNS provider and FIMC will be utilized to create a snowball sample. This sampling approach is well suited to this research because both an FNS provider and FIMC organizations have established relationships with each of these stakeholders. The number of interviews that will be conducted for each stakeholder can be found in Table 3. Stakeholder Interview Chart.

The inclusion criteria for all stakeholders and/or their representatives is they must be English speaking and over the age of 18. Data on background and experience related to their roles was collected for these stakeholders, but not traditional demographic data. If policymakers are unavailable for an interview, their legislative aide(s) who have knowledge about Medicaid 1915(c) waivers will serve as their proxy. For Medicaid Insurers and FIMC organizations the target sample would be health policy directors that will be able to assess their company's or organization's role in the policymaking process of obtaining coverage for FNS under Medicaid. Additionally, employees of the Medicaid

Insurer that were involved in the decision to partner with an FNS provider will help to address sub-question number one.

Medicaid Beneficiaries using an FNS provider (FNS participants).

The sample for the in-depth interviews was drawn from a list of participants provided by an FNS provider that received services as part of their philanthropic mission. Originally the sample was proposed as interviews with beneficiaries covered by a contract with a Medicaid Insurer in the northeast, however due to the length of time it would take to get access to beneficiary information the philanthropic clients were chosen instead to serve as the sample frame. The sample will include those participants who (1) have Type II Diabetes as their main diagnosis for referral to receive FNS, (2) are over the age of 18, English speaking, (3) received at least six weeks of FNS (which need not be consecutive), and (4) experienced cessation of FNS at least three months prior to the projected interview date. No demographic data was collected during the interviews. Randomization was originally proposed but because there was a drop in the size of the universe, sampling was not appropriate. The criteria listed above was applied and each person that met the criteria was recruited for an in-depth interview.

Recruitment of Stakeholder Groups

Policymakers, Medicaid Insurers and FIMC.

As previously stated, stakeholders are difficult to recruit; therefore, it is crucial to establish collaborative working relationships with individual FIMC organizations to gain cooperation. An email invitation explaining the research study will be drafted and sent from the Director of Policy and Planning at FIMC to additional FIMC organizations.

Choosing to send the email invitation from the director will also serve as an endorsement and, in turn, lend credibility to the research and hopefully increase the likelihood of gaining additional contacts. The email would contain a contact form that organizations could fill out with relevant information for various stakeholders with whom they have established relationships and who would likely be amenable to participation. Then customized emails to the identified stakeholders would be drafted by the student researcher and an IRB-approved consent form would be attached. These follow-on emails would be sent from the contact person at the FIMC organization to further lend credibility to my research. If this protocol does not yield an adequate number of potential participants, then the email invitation approach will, under the principle of adaptive design, be crafted into a calling script for telephone recruitment.

During telephone recruitment, each stakeholder would be given the option to delegate the interview to any staff member who is knowledgeable about the stakeholder's role in FNS for PWD. For policymakers, after one to two months of failed attempts to schedule an interview with the direct policymaker, recruitment would shift to their legislative aides. In an effort to boost cooperation rate, periodically throughout recruitment the FIMC contact person will check in with their Medicaid director, policymaker, legislative aide, Medicaid Insurer and FIMC colleague to advocate the importance of this research.

FNS Participants.

Recruitment first involved a cover letter being mailed to the potential respondents that would outline the purpose of the study, the schedule for the interviews as well as

incentive language. Recruiting materials would include a copy of the consent form text that the participant would be given during the oral consent process at the beginning of the interview. After two weeks of the letter being in the field, telephone recruiting would commence, and the advance cover letter would be transformed into a telephone recruiting script. Copies of the advance letter and consent form would be available upon request by the participant.

Coding and Analysis for All Stakeholder Interviews

All data gathered from these semi-structured in-depth telephone interviews will be professionally transcribed and imported into NVivo[®] 12, a widely used qualitative data reduction and analysis software package. The audio recordings will be compared with the transcripts to ensure accuracy. The codebook will be created *a priori* from the literature and a tertiary review of the transcripts. Up to six transcripts will be double coded and inter-coder reliability will be calculated using inter-coder agreement. Inter-coder agreement takes the total number of coding agreements divided by the total number of coding agreements and disagreements to come up with a percentage. The unit of analysis will be the individual stakeholder. After the data is coded the codes will be collapsed into themes that will be used to examine the stakeholder's perspective of their role in FNS for PWD as well as address the sub-questions.

Additionally, an analysis exploring the opportunities and challenges FIMC organizations are confronted with during advocacy work will be conducted. A comparison of the quantitative results from the annual FIMC survey with these qualitative results will be conducted to see if there are differences between larger and

smaller FIMC organizations both quantitatively and qualitatively. The annual FIMC survey is conducted by the research team at FIMC to assess the capacity of FIMC organizations. This survey specifically analyzes the number of meals served, the type and number of clients served, volunteer and staff hours, programs (home-delivered, pantry, or congregate meals), funding sources, and advocacy efforts. Furthermore, the data will be analyzed to explore the FIMC organization's perspective of their role in policymaking as well as any benefits they derive from membership.

Ethical Considerations

Manifest and Latent Content Analysis of Medicaid Waivers.

While the ethical considerations are minimal, the student researcher still needs to be aware of any inherent biases when collecting data and creating the coding schema.

Policymakers, Medicaid Insurers, FIMC.

The ethical considerations for the policymaker, Medicaid Insurer and FIMC interviews are minimal because the questions that will be asked are within the scope of their job responsibilities. The participants in the research are being asked to provide verbal consent to be part of the study as well as a copy of the consent form will be emailed to the participant in the invitation email. The confidentiality of the respondents will be held consistent with this project's IRB-approved data security protocol. The consent form outlines that only the student researcher and secondary coder will have access to the recordings and notes and will not be shared with other state legislators, CMS, or FIMC. Participant data will be reported in de-identified way using themes gathered from the interviews.

This research requires review by the Institutional Review Board (IRB) of the University of the Sciences in Philadelphia because it involves human subjects and the use of personally identifiable information. From an IRB perspective, this study would require an expedited review because the potential risk, burden, and harm to most of the participants is minimal because many of the questions being asked are under the guise of their professional responsibilities, but the interviews are being recorded and stored eliminating it from being exempt. The student researcher will have personally identifiable information of the participants, despite the results being reported in aggregate. The threat to participants is minimal because they will not be identified, which will eliminate the possibility of their responses causing any criminal or civil liabilities. The questions being asked of the participants are similar in nature to those that would be asked as a part of everyday business practices.

FNS Participants.

The ethical considerations of this qualitative intervention evaluation were minimal because participants discussed their lived experiences in the management of Type II Diabetes. All participants in the sample were recruited for an in-depth interview and were provided with a hard copy of the consent form and were asked for verbal consent prior to the telephone interview. Confidentiality of the respondent's was held to the highest extent and only the student researcher and a secondary coder had access to interview recordings and notes. The participant's data will be reported in a de-identified way using themes gathered from the interviews and any direct quotes will be identified with generic titles.

The proposed research required an IRB review because it involves human subjects. From an IRB perspective, this study required an expedited review because the threat to participants is minimal, but the interviews were recorded and stored eliminating it from being exempt. The student researcher gathered personally identifiable information of the participants, despite the results being reported in aggregate. The threat to participants was minimal because they will not be identified which will eliminate the possibility of their responses causing any criminal or civil liabilities. The questions being asked of the participants are similar in nature to those that would be asked by a primary care doctor or health care professional and mirror everyday life. The biggest potential harm was that the participant might become upset when discussing their Type II Diabetes and their health; however, the student researcher remained sensitive to this possibility.

Technique 3: Quantitative Analysis of Health Outcomes and Healthcare Utilization and Costs

The research literature on the effectiveness of FNS is limited and somewhat out of date (Gurvey, et al., 2013; FIMC, 2018). Even though the results of the studies show promise for the *Food Is Medicine* concept, new studies need to be conducted to provide direct evidence of the potential effectiveness of FNS. There are many factors that can be examined when discussing effectiveness, but arguably the most salient are health outcomes, healthcare utilization and costs especially for PWD. As discussed in previous chapters, individuals with Type II Diabetes typically have comorbidities, higher healthcare utilization and costs compared to their non-diabetic counterparts (ADA, 2013; ADA, 2014; ADA, 2015; World Health Organization, 2016). This study employs a

secondary analysis of de-identified data for Medicaid beneficiaries (N=195) receiving FNS for 12 weeks that will be used to perform descriptive statistics, for example the average change in HbA1c and lipid lab results, healthcare utilization and cost of care. Simply identifying a change in either the HbA1c or lipid lab results does not mean it is statistically significant. The test for statistical significance of this data is a paired t-test. Relative risk and odds ratio will be calculated for specific sub-groups to provide dimensionality to the results of the descriptive statistics.

This quantitative analysis supports the overall research question, regarding fiscal roles, and providing evidence of the efficacy of FNS, which may have policy implications for stakeholders. In 2016, the student researcher began working with an FNS provider and a Medicaid Insurer to be able to gain access to quantitative data on recipients of FNS with regards to health outcomes, healthcare utilization and costs. Under this partnership, FNS is being paid for through Medicaid dollars, although it is not a waiver, it may provide a pathway for other FNS providers to seek arrangements with individual Medicaid Insurers.

The primary objective of this portion of the research is to test a methodological approach on how a study could be designed to measure the effectiveness of FNS. The secondary objective is to provide quantitative evidence to support the use of medically tailored meals to reduce healthcare costs while improving health outcomes for high risk beneficiaries. The tertiary objective is to provide the Medicaid Insurer and FNS provider with quantitative evidence to support the continuation and potential expansion of their partnership.

The sub-questions addressed through this part of research are:

1. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on hemoglobin A1c?
2. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on lipid panels?
 - b. Is there a difference in low-density lipoprotein (LDL) levels after 12 weeks of FNS?
 - c. Is there a difference in high-density lipoprotein (HDL) levels after 12 weeks of FNS?
 - d. Is there a difference in triglyceride levels after 12 weeks of FNS?
3. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on healthcare utilization, specifically emergency room visits, inpatient visits, and total hospital visits?
4. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on healthcare costs, specifically emergency room visit costs, inpatient visit costs, and total healthcare costs?

In late summer of 2018, the student researcher and the Medicaid Insurer reached an agreement to provide quantitative de-identified data to evaluate the partnership between the insurer and the FNS provider. Both parties signed a data use agreement and data was provided in fall of 2018. The data provided was a de-identified file of 195 beneficiaries all diagnosed with diabetes. To address these research questions a pre/post cross sectional

design was used to evaluate the specific health outcomes, healthcare utilization and costs outlined in the questions listed above.

The two health outcomes of interest are HbA1c and lipid panel, pre-and-post FNS for 12 weeks. As discussed in the previous chapters, the results of the HbA1c test determines the presence or absence and severity of Type II Diabetes expressed as a percentage. PWD whose HbA1c is below 7% have lower risk of developing complications compared to those with HbA1c percentages above 7% (ADA, 2015). This study examines HbA1c percentages pre-and-post 12 weeks of FNS to determine if a change occurred. It is important to note that even if a change is observed, it may not be clinically relevant, but could lend support to investigate more weeks of FNS to determine if there is a dose response relationship. While lipid panels do not directly relate to blood sugar levels, they are an indicator for comorbidities like heart disease and stroke (Mayo Clinic, 2019).

Cholesterol is comprised of both high-density lipoprotein (HDL) and low-density lipoprotein (LDL) that is used to create healthy cells within the body. High cholesterol causes fatty deposits in the arteries, and when they become clogged, they can lead to heart disease and stroke (Mayo Clinic, 2019). Triglycerides are fat that circulates in your blood and is typically measured in conjunction with cholesterol and is a predictor of heart disease. This study examines lipid lab results pre-and-post 12 weeks of FNS to determine if there is a change in beneficiaries with Type II Diabetes. Similar to HbA1c, any changes in lipids may not be clinically meaningful, however they may provide evidence to support examining a longer dose response relationship to see if it exists.

Two additional areas of interest are explored in this quantitative analysis: healthcare utilization and costs. Healthcare utilization among high risk beneficiaries is greater than non-high-risk beneficiaries and is well documented in the literature. This research will examine emergency room visits, inpatient visits and total hospital visits to determine if there is a change in the utilization pre-and-post 12 weeks of FNS. Similar to healthcare utilization, costs are typically higher among high-risk beneficiaries and is discussed in previous chapters. The healthcare costs being examined in this analysis are emergency room costs, inpatient visit costs, and total health care costs pre-and-post 12 weeks of FNS. For both healthcare utilization and costs, if a difference is observed it is hard to say that FNS is the sole cause of the reduction, however it can be argued that decreased utilization and costs among high-risk beneficiaries is a step in the right direction.

Advantages of Cross-Sectional Design, Descriptive Statistics, Relative Risk and Odds Ratio

The advantage of a cross-sectional design allows the researcher to measure the pre-and-post outcomes at the same time allowing for potential efficiencies with data analysis (Setia, 2016). Cross-sectional studies are typically cheaper to conduct than other research designs, like cohort or randomized control trials. Cross-sectional studies are widely used in epidemiology and public health to gather data on many issues, like Type II Diabetes or obesity (Setia, 2016). A cross-sectional study can calculate prevalence, relative risk and odds ratio for the outcomes of interest (Setia, 2016; Kamat, Metgud, Pattanshetti, & Godhi, 2010; Rensing, Blettner, & Klug, 2010; Weiner, Puniello, Noland, Ciemnecki, & Turakhia, 2012).

The advantage of calculating descriptive statistics for health outcomes, healthcare utilization and costs in a cross-sectional is that it will allow the student researcher to calculate the prevalence of disease in the population, conduct paired t-tests to measure statistical significance, calculate the relative risk and odds ratio for sub-groups within the dataset.

Prevalence is the measure of the number of diseased patients in the study population divided by the number of persons in the population at a given point in time (CDC, 2012). Prevalence is a preferred measure for chronic diseases like Type II Diabetes because of the duration of disease and the date of onset are difficult to pinpoint (CDC, 2012). In this study prevalence of Type II Diabetes may help to support FNS for PWD through waivers or other policy changes driven by stakeholders.

Paired t-tests are used to test hypotheses to disprove the null hypothesis that is there is no difference between the means of two related groups. A paired t-test is a classic method that dates back to early nineteenth century to analyze pre-and-post data (Hedberg & Ayers, 2015). The main assumption in a paired t-test is that the data are approximately normally distributed and are typically used with small sample sizes (Kirkwood & Sterne, 2003). Paired t-tests are not used for causality, they are used to determine the difference in the means of two samples. A confidence interval is constructed for each sample, but the standard deviation must be taken into consideration because it will provide an overall indication of normality in the distribution (Kirkwood & Sterne, 2003). The standard is to use a 95% confidence interval and will be used as a minimum in this research.

In order to provide dimensionality to the results of the paired t-test for the health outcomes, healthcare utilization and costs, relative risk will be calculated for specific sub-groups within the dataset. Relative risk can be calculated for cross-sectional studies as the probability ratio of a characteristic compared to a control group thus determining the likelihood of the characteristic appearing in the base group (Weiner, Puniello, Noland, Ciemnecki, & Turakhia, 2012). This is applicable to this research because a relative risk can be calculated for characteristics like gender, race and age. In the context of this research it may be possible to say that non-whites are 1.5 times more likely to have Type II Diabetes than whites. This statistical calculation helps to support the main research question by potentially helping stakeholders to target their efforts to specific genders, ages or races.

For cross-sectional study designs, an odds ratio (OR) can be calculated to measure the effect of the prevalence of disease for a specific characteristic, for example age (Ressing, Blettner, & Klug, 2010). A two-by-two table is constructed to understand the association between two characteristics and their cross products are multiplied and then divided by each other to calculate the OR (Setia, 2016). Odds ratio relays the odds of having a particular disease or characteristic. Similar to relative risk, odds ratio supports the main research question by potentially informing stakeholders to sub-groups that may need more targeted support. Weiner et al, cautions that the interpretation of OR for one sample means that the characteristic is present in both groups and relative risk may be easier to comprehend (Weiner, Puniello, Noland, Ciemnecki, & Turakhia, 2012).

Limitations of Cross-Sectional Design and De-identified Data

Cross-sectional studies are limited because it is difficult to determine causal relationships between factors due to the one-time measurement (Setia, 2016). When conducting research bias is inevitable and should be minimized to the best of the researcher's ability. The particular bias that may occur with cross-section studies is confounding, whereby an association between factors is made that may or may not exist (Pannucci & Wilkins, 2010). Another limitation of cross-sectional studies is that they may not be able to accurately capture the prevalence of a disease due to the length of time for disease to present itself, meaning it is not possible to assess disease trends with this research design (Setia, 2016).

Sampling

There were no sampling procedures for this quantitative analysis because it is comprised of all beneficiaries (N=195) diagnosed with Type II Diabetes that were receiving FNS for 12 weeks. The target population for this analysis is Medicaid beneficiaries that receive FNS in the Mid-Atlantic portion of the United States, where each beneficiary has at least one chronic disease and ranged in age from 15 years of age to 70 years of age. The dataset includes beneficiaries who describe themselves as non-Hispanic Caucasians, African Americans, and Asians.

Analysis of Quantitative Data

All data analysis for this portion of the research is conducted in Microsoft Excel v.1912 in order to calculate prevalence, paired t-test, confidence intervals, relative risk, and odds ratio. The paired t-test will use an alpha of .05 to assess the level of significance

and is standard in policy research. Standard deviations will be calculated for all of the paired t-tests in addition to confidence intervals.

Ethical Considerations

The ethical considerations for this portion of the research are minimal because the file is de-identified, and the student researcher will never have access to the personally identifiable information. This secondary analysis of de-identified data has received an exempt status from the Institutional Review Board (IRB) as it poses no risk to participants. Additionally, the student researcher has signed a data sharing agreement with the Medicaid Insurer to protect confidentiality.

Conclusion

In conclusion the methods described in this chapter aim to do the following: 1) assess stakeholder roles in support of FNS policies for PWD; 2) identify a pathway for FIMC organizations to have their services reimbursed under Medicaid 1915(c) waiver; 3) provide qualitative evidence of the potential effectiveness of the *Food Is Medicine* model; 4) discover opportunities and challenges within the *Food Is Medicine* model; and 5) test a methodological approach to quantitative data that may provide support for the use of FNS to reduce healthcare utilization and costs while improving health outcomes for beneficiaries. Based upon these methods, the student researcher will address the research questions posed in this chapter, with results available in the next chapter.

Chapter 4: Results

Introduction

Diabetes is a chronic disease that consistently ranks among the top ten leading causes of death worldwide and in conjunction with cardiovascular disease, cancer and respiratory disease accounts for over 80% of all premature deaths from non-communicable diseases (International Diabetes Federation, 2017). Each year the prevalence of diabetes continues to rise worldwide, with 425 million people currently diagnosed with diabetes (Type I & II). In high income countries, 87-91% of all diabetes diagnoses, are Type II Diabetes (International Diabetes Federation, 2017). The main causes for the global rise of Type II Diabetes are weight and inactivity, i.e., being overweight or obese, coupled with an increasingly sedentary lifestyle.

The treatment of obesity and pre-diabetes has been traditionally medicalized using pharmaceuticals, typically pills or injectable medications, despite that for many the disease can be managed through lifestyle changes such as diet and/or exercise. Moreover, the emphasis is on the diagnosis and treatment of the disease rather than on prevention. Policy priorities have been set to support the medical model of treating diabetes, rather than exploring prevention and/or alternative approaches to reducing the burden of the disease.

The *Food Is Medicine* model asserts that we can reverse chronic disease and its negative health outcomes using food. The model can be realized by Food Nutrition Service (FNS) providers that create medically tailored meals for those suffering from chronic disease. As discussed in previous chapters diabetes is intimately linked to diet,

therefore it stands to reason that if a person is fed their optimal diet, their health could improve, and they can reduce the risk of complications. Given the current policy landscape, FNS services are not reimbursable under federal health policy; however, there are states that have chosen to use Medicaid Home and Community Based Service (HCBS) 1915(c) waivers to provide meals to their residents, although those meals may not be medically tailored.

The purpose of this research is to explore the roles that stakeholders play in Medicaid waiver policies to support FNS for people with Type II Diabetes. The main research question addressed by this study is: *What are the stakeholder roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?* The critical stakeholders selected for this research are: (1) policymakers; (2) Medicaid Insurers; (3) FNS providers; and (4) FNS participants. The four stakeholder groups were chosen for their knowledge, expertise, lived experiences, and characteristics, all of which were discussed in previous chapters.

A mixed-method approach was selected to provide a 360-degree examination of this research question. The two qualitative techniques that were deployed are manifest and latent content analysis of Medicaid HCBS 1915(c) waivers, and semi-structured telephone interviews with stakeholders. One quantitative method was deployed to calculate descriptive statistics on healthcare outcomes and costs for FNS participants. A detailed methodological chart can be found in Appendix A.

This chapter reports the results of the study using a funneling approach of the techniques as shown in Figure 5 of the Methods chapter (Chapter 3). The first technique

is the Medicaid Waiver Content analysis that explores Medicaid HCBS 1915(c) waivers for both manifest and latent content. The second technique is the semi-structured telephone interviews with stakeholders to discuss their role in Medicaid waiver policy. The final technique is the descriptive statistics on health care outcomes and costs for FNS participants. It is the aim of this research to develop a series of policy recommendations to support FNS as part of a prevention and treatment strategy for diabetes within the context of the Chronic Care Model.

Technique 1: Medicaid Waiver Content Analysis

The use of Medicaid HCBS 1915(c) waivers is a policy tool that allows states to provide services that are typically not reimbursable under Medicaid; examples might include, home health aides, counseling, or chore/cleaning services, that allow residents to remain in their homes rather than being institutionalized. Waivers are typically issued for specific conditions such as autism or developmental disability, or specific populations like the elderly (frail). One critical component of each waiver is the state must demonstrate cost neutrality. All applications for 1915(c) waivers must be submitted to the Centers for Medicare and Medicaid Services (CMS) for review. Waivers are issued for 3 or 5 years, and they are amendable and renewable. Attaining a waiver is a non-insubstantial task: when blank, the application is 125 pages. The length of the application is 125 pages when it is empty. CMS maintains a database of all HCBS 1915(c) waivers that have been issued along with their amendments.

To date, there has been no analysis of Medicaid HCBS 1915(c) waivers specifically examining their content for the inclusion of medically tailored meals, home-delivered

meals, dietary services, and Type II Diabetes. In order to provide a retrospective cross-sectional snapshot of Medicaid 1915(c) waivers a data set had to be constructed from the waivers in CMS's database. For the manifest content analysis, the waivers analyzed (N=831) were submitted between February 2007 and April 2018. For the latent content analysis, the waivers (N=14) were submitted between January 2008 and October 2017. Table 4 provides a frequency of waiver characteristics for the manifest content analysis.

The initial approach to this technique was to use a data reduction software package, such as NVivo[®]12 or Deduce to use the functionality of manual coding and data visualization. However, the file format of the waivers was an interactive PDF, meaning that there were open-ended text boxes that could expand and contract accordingly to fit the text. Once the files were imported into the software, they were unable to display properly or capture radial buttons and all the text in the open-ended text boxes when coding. Therefore, the researcher constructed a dataset using Microsoft Excel, v.1912 that included all the elements identified in the codebook. Microsoft Excel was chosen for its functionality of creating pivot tables and filtering capabilities. After some of the initial waivers were coded the codebook needed to be expanded to include additional fields of interest to the researcher.

Table 4. Frequency of Medicaid Waiver Characteristics

	Waiver Length		
	3 Years	5 Years	Total
Waiver Type by Primary Diagnosis			
Amendment	25	462	487
Autism	7	75	82
Children with Complex Medical Conditions		1	1
Developmental Disabilities	5	110	115
Disabled (other)		5	5
Elderly (Frail)	5	104	109
Elderly, Blind, Disabled		5	5
HIV/AIDS	5	15	20
Intellectual Disabilities		7	7
Long Term Care		2	2
Medically Fragile Adults		5	5
Medically Fragile Children	2	19	21
Mental Health	1	5	6
Mental Retardation		5	5
Physical and Developmental Disabilities		1	1
Physical Disabilities		40	40
Serious Emotional Disturbance		16	16
Spinal Cord Injury		3	3

	Waiver Length		
	3 Years	5 Years	Total
Technology Dependent		9	9
Traumatic Brain Injury		35	35
New	6	18	24
Autism	2	2	4
Developmental Disabilities		6	6
Elderly (Frail)	2	6	8
Long Term Care		1	1
Medically Fragile Children	1		1
Technology Dependent		1	1
Traumatic Brain Injury	1	2	3
Renewal	22	298	320
Adults with Complex Medical Conditions		1	1
Autism	3	56	59
Children with Complex Medical Conditions		1	1
Developmental Disabilities	6	44	50
Disabled (other)		1	1
Elderly (Frail)	8	69	77
HIV/AIDS	4	9	13
Intellectual Disabilities		15	15

	Waiver Length		
	3 Years	5 Years	Total
Long Term Care		3	3
Medically Fragile Adults		7	7
Medically Fragile Children		14	14
Mental Health		10	10
Mental Retardation		3	3
Physical and Developmental Disabilities		1	1
Physical Disabilities		29	29
Serious Emotional Disturbance		9	9
Spinal Cord Injury		1	1
Technology Dependent	1	3	4
Traumatic Brain Injury		22	22
Grand Total	53	778	831

Within this technique several sub-questions were proposed, and the results will be reported in this section:

Sub-question 1: *Is there a relationship between the state Medicaid waivers that support FNS and the political party dominating state government at the time of their drafting?* This method could not accommodate this question. During the proposal phase of this research it was thought that legislators were responsible for drafting waiver applications to CMS, which were voted on at the state government level. This expectation

formed the basis of the belief that politics was a determinative factor in the submission and approval of Medicaid waivers. Based on the analysis of the waivers, the authority responsible for signing the Medicaid waiver application was not a legislator, but rather was typically the state Medicaid director or high-ranking employee within the state Medicaid department. The political affiliation of the state Medicaid director and their employees could not be ascertained through this technique. Consequently, an analysis of comparing waivers passed under varying state political party administration could not be conducted. The process by which each state chooses to apply for a waiver will be discussed in Technique 2.

Subsidiary -sub-question 1a: *What is the relative frequency of Medicaid waivers under different political party control of the state waiver process?* The relative frequency of Medicaid waivers by political party was not able to be ascertained because as stated in sub-question 1 the person responsible for signing the waiver application was not a legislator or governor. Furthermore, had this analysis been conducted, it would not likely have demonstrated whether one political party was more likely to put forth a waiver application than another.

Sub-question 2: *Within Medicaid waivers, what language supports FNS for people with Type II Diabetes?* To answer this question both manifest and latent content analysis techniques were used. The following words and their derivatives were chosen by the researcher for the manifest content analysis on the entire sample of Medicaid waivers (N=831): “medically-tailored meals,” “home-delivered meals,” “dietary counseling,” and

“Diabetes.” Table 5 contains the frequency of the words included in the waivers with an emphasis on the number containing none of the selected words.

Table 5. Frequency of Words within waivers

	Medically Tailored Meals	Home- Delivered Meals	Dietary Counseling	Diabetes
1-9	0	75	125	197
10-19	0	22	19	0
20-29	0	168	35	0
30-40	0	21	1	0
Subtotal	0	286	180	197
0	831	545	651	634
Total	831	831	831	831

The analysis of the waivers (N=831) revealed that none included the words “medically-tailored meals” or its derivatives. The percentage of waivers that included the words “home-delivered meals” or its derivatives was 34.4%; the percentage that included the words “dietary counseling” or its derivatives was 21.6%; the percentage that included the word “diabetes” or its derivatives was 23.7%. Within this category, specifically the mention of Type II Diabetes occurred in 17 waivers (2%). Traditionally there has not been a waiver specifically for diabetes, as seen in Table 5: Frequency of Medicaid Waiver Characteristics; however, that possibility exists. Currently, only 25% of the

waivers are disease-specific, which suggests policymakers have not used this policy option to focus on the management and prevention of chronic disease.

While evidence of language does exist in the waivers that supports FNS for people with Type II Diabetes, it must be noted that the words “medically-tailored meals” were not included. As noted in the previous chapters, there is a direct correlation between diet and diabetes, so to simply provide “home-delivered meals” may not be enough to affect positive clinical outcomes for people with Type II Diabetes; in fact, in some instances, it may worsen the condition. Clearly, then, there is an opportunity for stakeholders to work together to ensure that the language within the waivers specifically states “medically-tailored meals.”

Due to the complexity and length of the waivers, a sub-sample was drawn in order to conduct the latent content analysis to explore the meaning and commonality among the words used within the waivers. The criteria for the sub-sample includes: 1) new or renewal waivers only; 2) waiver disease type or population: Elderly (Frail), HIV/AIDS, Mental Health and Physical Disabilities; 3) the count of home delivered meals is greater than one; 4) the count of diabetes is greater than one; 5) the count of dietary counseling is greater than one. The reasoning for choosing only new or renewal waivers was because amendments are just variations of the same new or renewal waiver, for the sake of thoroughness, however, a cursory examination was conducted on the final sample to review the amendments, as well. This cursory examination of the amendments did not yield any changes to the items in the codebook; therefore, amendments were excluded. The logic behind limiting the waiver disease type was to more closely align the waiver

population with the stakeholder FNS beneficiaries in Technique 2. For criterion 3 and 4, to explore the latent content the waiver must contain the words “home-delivered meals,” “diabetes,” and “dietary counseling” or any of their derivatives.

After these criteria were applied to the waivers (N=831), a sub-sample of waivers (N=14) met the criteria for inclusion in the latent content analysis. The coding and analysis were performed in NVivo[®] 12, a qualitative data reduction software application. The states included in this analysis are Florida, Iowa, Montana, North Carolina, New Mexico, New York, Oklahoma, Pennsylvania, and Texas. The waiver applications were submitted to CMS between January 2008 and October 2017. Eleven waivers are directly operated by the State Medicaid Agency itself, while three are operated by another division/unit within the State Medicaid Agency separate from Medical Assistance Unit. The key areas of the waivers that were analyzed were: 1) Participant Access and Eligibility, 2) Participant Services, and 3) Cost Neutrality Demonstration.

Participant Access and Eligibility

Participant Access and Eligibility revealed the following themes: 1) additional criteria, 2) individual cost limit, 3) limitation on the number of participants served at any point in time, and 4) entrants into the waiver.

Participant Access and Eligibility: Additional Criteria.

Additional criteria were present in 12 out of 14 waivers (Table 6), which translates to nine states. Each state can specify groups and sub-groups ranked by age to be eligible to participate in the waiver. The age range was typically 18-64 years of age and age 65 and above. The states were also able to set minimum and maximum age limits. However, if

there were additional restrictions beyond age that the state wanted to include, they would need to document the additional criteria on the application.

Table 6. Participant Access and Eligibility: Additional Criteria Theme Results

Theme: Additional Criteria	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States choosing to include additional entrance criteria for the waiver beyond age	✓	✓	✓	✓	✓		✓	✓	
Sub-Themes									
Place of residence	✓			✓			✓		
Doctor documentation of illness		✓	✓						
Receiving SSD		✓	✓						
Definition of illness		✓	✓		✓		✓	✓	

The additional criteria can be broken down into four sub themes: 1) place of residence, 2) doctor documentation of illness, 3) receiving Social Security Disability, and 4) definition of illness. Three out of the nine states included additional criteria that required the waiver participant to be receiving the waiver services within a private residential setting. The fact that these states chose to specify this additional criterion is curious because HCBS waivers are aimed at providing services to people in their homes,

although there may be state to state exceptions where services can be provided within institutions that was not examined by this research. Iowa and Montana require documentation of disease or illness from a medical doctor and require recipients to be deemed legal disabled by the Social Security Administration prior to receiving waiver services.

Five out of the nine states included additional criteria that provided a more specific definition of illness that the waiver was intended to affect. There was no consistency in the way the illness was defined: one state referenced the International Classification of Diseases (ICD) 9 codes, while the rest relied on definitions from unknown sources.

Participant Access and Eligibility: Individual Cost Limit.

The theme of individual cost limits was present in all waivers (N=14) as it is a requirement on the application to specify whether there is a cost limit associated with the waiver. States have four options when declaring a cost limit for a waiver: 1) no cost limit, meaning the state does not apply an individual cost limit to the services provided in the waiver, 2) cost limit in excess of institutional costs, meaning the state specifies the percentage of costs that waiver services may exceed when compared to institutional care, 3) institutional cost limit, meaning the costs of the waiver services are limited to 100% of the costs of institutional care, and 4) costs limit lower than institutional costs, meaning the costs of the waiver services will be less than those of institutional care. It is important to remember that the waivers must demonstrate and maintain cost neutrality in order to be approved and renewed. Table 7 provides the thematic results for individual cost limits.

Table 7. Participant Access and Eligibility: Individual Cost Limit Theme Results

Theme: Individual Cost Limit	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: State must specify the type of cost limiting strategy they choose for their waiver	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sub-Themes									
No cost limit	✓	✓	✓		✓	✓	✓	✓	
Cost limit in excess of institutional costs									✓
Institutional cost limit				✓			✓		
Cost limit lower than institutional costs									

Seven of the nine states apply a no cost limit to their waivers; under this condition, it is unlikely that a potential waiver recipient will be denied entrance into the waiver. Texas utilizes the cost limit in excess of institutional costs, which provides flexibility to the state to determine the percentage or dollar value that the services provided under the waiver not in excess of institutional care. For example, in Texas, the waiver services can exceed up to 202% of the cost of institutional care per individual. North Carolina and Oklahoma both use institutional cost limits, which means that the cost of services

provided under the waiver cannot exceed 100% of the cost of institutional care. An interesting finding is that Oklahoma, deploys two different types of individual cost limits, either no cost or institutional cost, depending on the waiver.

Participant Access and Eligibility: Limitation on the Number of Participants Served.

The theme of limitation on the number of participants served at any point in time is present in all waivers (N=14). States have the option to specify if they want to limit the number of participants served by a waiver at any point in time in a waiver year. Knowing whether a state limits the number of participants in a waiver year is important because it can be useful for stakeholders to advocate in either position. Table 8 shows the thematic results.

Table 8. Participant Access and Eligibility: Limitation on the Number of Participants Served Theme Results

Theme: Limitation on the Number of Participants Served	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States can limit the number of participants served at any point in a waiver year	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sub-Themes									
State does not limit the number of participants that it serves at any point in time during a waiver year		✓		✓	✓	✓	✓		✓
State limits the number of participants that it serves at any point in time during a waiver year	✓	✓	✓					✓	

Six out the nine states do not limit the number of participants that it serves at any point in time during a waiver year. There are pros and cons to not having a limit on the number of participants served in a year. The pro is that there is not a restriction on the number of people that can receive services; however, the con is that the state may reach its waiver targets quickly. Limiting the number of participants within a waiver has the potential to cause inequity because it institutes a first-in time rule, therefore eliminating

the possibility of entry for participants that apply later; however, the state can increase the number of participants in a service by filing an amendment with CMS. Four of the state set limits on the number of participants that it serves at any point in time during a waiver year. Montana and Pennsylvania decided to impose limitations because they wanted to save several waiver spots for a demonstration project that their states were conducting. Florida proposed a limit to make sure that waiver services are evenly distributed within the waiver service area. Iowa is the only state that chose to limit the number of participants that it serves at any point in time during a waiver year but did specify the criteria for that selection process.

Participant Access and Eligibility: Entrants into the Waiver.

The theme of entrants into the waiver was present in all waivers (N=14). States can determine how participants are admitted into the waiver outside of the criteria; this specification relies on geographic preference or waitlist procedures. Understanding how a state allows entrance into a waiver is helpful for stakeholder's advocacy efforts. Table 9 shows the thematic results.

Table 9. Participant Access and Eligibility: Entrants into the Waiver Theme Results

Theme: Entrants in the waiver	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States must specify entrance conditions of the waiver	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sub-Themes									
Participants must not be enrolled in another Medicaid HCBS waiver	✓								
Participants are served on a first come, first serve basis		✓	✓	✓			✓		✓
Waitlists are arranged by date of application		✓							
Waitlists are arranged and reviewed according to a needs assessment			✓					✓	
Geographic Based					✓				✓
Patient Choice						✓			

Florida requires that eligible participants only receive HCBS waiver services under one waiver. Five of the nine states offer entrance into the waiver on a first come, first serve basis by date of application. Three states choose to specify how their waitlists are

constructed: Iowa organizes its waitlist is based on the date of application, while Montana and Pennsylvania arrange their waitlist based on a needs assessment. New Mexico and Texas structure their waiver so that participants are entered into services based on geographic location, for example county. New York requires that the patient choose to receive the waiver services, meaning they have to elect to use their Medicaid dollars directed to the waiver services.

Participant Access and Eligibility Latent Analysis.

The analysis of the language used in the participant access and eligibility key area yielded neither discernable patterns nor any underlying meaning. There was variation within and across states when open-ended text was included, which may be a function of different staff within the Medicaid Agency drafting the waiver text. Alternatively, states may have received feedback from CMS regarding their applications and were provided guidance on alternative text. The variation might also be explained based on the waiver disease type, although the criteria for this analysis included waiver disease type, it did not require all waivers within that specific disease be analyzed in each state.

Participant Services

Participant Services revealed the following themes: 1) service characteristics, 2) provider qualifications, 3) service definition, 4) limitations on services and 5) verification of provider qualifications.

Participant Services: Service Characteristics.

The theme of service characteristics was present in all waivers (N=14). Service characteristics were defined for each service that proposed under the waiver and were

indicated in the form of either radial buttons or dropdowns from which the state selected from. For the purpose of this analysis only home-delivered meals and dietary counseling services were included. The word diabetes was not included in this analysis because there was only one state (Florida) that referenced diabetes in relation to home-delivered meals, while other states include the word in the context of other services provided in the waiver (e.g., skilled nursing or assisted living), or it was in reference to assessment and monitoring of the waiver, or within the public comments relating to a CMS rule. These service characteristics can be helpful for stakeholder's advocacy efforts. Table 10 reports the thematic results.

Table 10. Participant Services: Service Characteristics Theme Results

[illegible]

Service specification refers to the waiver's type of service, for example statutory services, extended state plan services or other services. All nine states selected home-delivered meals and dietary counseling as an 'other service,' because it is not a statutory service and, in these states, are not covered by any extended state plan services. Provider category covers the type of agency allowed to furnish the services described in the waiver, i.e., either an individual or an agency. Within the category of individuals states can specify that they want a registered dietician or nutritional counselor to provide counseling services and for the home-delivered meals they can specify either a hospital, a nursing home, or a community organization. For home-delivered meals all nine states chose agency as the provider category; for dietary counseling, individual was selected as the provider category. The service delivery method corresponds to which entity will be managing the waiver service, either provider managed, or participant directed. All nine states chose to make home-delivered meals and dietary counseling provider managed, meaning that waiver participants are not allowed to directly elect to have these services. These characteristics are important for stakeholders to know when planning advocacy efforts.

Participant Services: Provider Qualifications.

The qualifications of each service provider can be specified by the state and are present in all waivers (N=14). The provider qualifications are broken into three distinct sub-themes: 1) certificates, 2) licenses, and 3) other. Knowing what credentials a state has identified in order to provide services under a waiver is helpful to stakeholders. Table 11 provides the thematic results.

Table 11. Participant Services: Provider Qualifications Thematic Results

Theme: Provider Qualifications	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States specify the provider qualifications to provide services under a waiver	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sub-Themes									
Certificate		✓				✓	✓		
License	✓	✓		✓		✓	✓	✓	
Other	✓	✓	✓	✓	✓	✓	✓	✓	✓

Three states required that providers obtain a certificate in order to provide waivers. Iowa and Oklahoma required certificates that either proved the ability to provide services under Medicare as a home health agency, and/or county certificates for food handling and kitchen safety. New York required a certificate of incorporation that met state standards for businesses. Six of the nine states mandated that providers have a license to provide services under the waiver. The types of licenses broke down into two main categories: 1) state statutes, meaning the state just indicated “state regulation” in an open-ended text box, or 2) health code food preparer/handler licensing. All nine states provided some other type of provider qualifications; eight states provided blanket statements requiring the provider to be compliant as a home-delivered meal provider under the Older Americans Act of 1965, while two states specifically required the provider to have a

signed Medicaid waiver provider agreement. Iowa and Pennsylvania listed specifications that the provider have employees that were at least eighteen years of age, qualified by training, and subject to background checks. Montana and New York specified the requirements of a registered dietician in order to provide dietary counseling. These provider qualifications are significant for stakeholders to know should they pursue the ability to provide home-delivered meals or dietary counseling under a waiver.

Participant Services: Service Definition.

The theme of service definition outlines what services will be provided by the agency; this theme was present in all but one waiver (N=13) and was included in all nine states. For home-delivered meals the service definition can be broken down into four sub-themes: 1) one-third of all home-delivered meals are required to meet the dietary recommendations, 2) meals must be prepared offsite, 3) meals may be provided by *Meals on Wheels*, and 4) criteria that would make participant eligible to receive home-delivered meals. For dietary counseling, the service definition can be broken down into three sub-themes: 1) provide nutrition education, 2) provide meal planning resources, and 3) dietary counseling must be performed by a Registered Dietician (RD) or Certified Nutrition Specialist (CNS). Table 12 contains the thematic results for both home-delivered meals and dietary counseling.

Table 12. Participant Services: Service Definition Thematic Results

Theme: Service Definition	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States specify the service that will be provided by agency	✓	✓	✓	✓		✓	✓		✓
Sub-Themes: Home Delivered Meals									
One-third of the home-delivered meal required to meet dietary recommendations	✓	✓					✓		✓
Meals must be prepared offsite	✓	✓							
Meals on Wheels				✓					
Criteria to make participant eligible for home-delivered meals	✓		✓			✓	✓		

Theme: Service Definition	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States specify the service that will be provided by agency	✓	✓	✓	✓		✓	✓		✓
Sub-Themes: Dietary Counseling									
Provide nutrition education			✓			✓		✓	
Provide meal planning			✓			✓		✓	
Consultation must be with an RD or CNS			✓					✓	

Florida, Iowa, Oklahoma and Texas specified that the agencies providing the home-delivered meals must require all meals to meet one-third of the participant's dietary recommendations for calories and macronutrients per the Nutrition Board of the National Research Council of the National Academy of Sciences. Florida and Iowa require that the meals be prepared off-site, meaning they cannot be prepared in participants homes. North Carolina specifically used the term "Meals-On-Wheels" in their waiver application, which is significant because that is a "brand" of home-delivered meals, therefore other stakeholders could potentially include their names in the waivers. Four states listed the criteria of a person that would need home-delivered meals, for example they are unable to

cook or shop for themselves, require a special diet, or have no one else to prepare a meal for them. These sub-themes will help stakeholders work together to include specific language around providing home-delivered meals.

The sub-themes or dietary counseling were present in three states because nutrition counseling was considered a covered service under the waiver. Montana, New York and Pennsylvania require that the dietary counseling provide nutrition education and meal planning as a part of the dietary counseling services provided under their waiver. New York specifically references that the meal planning should be appropriate for the waiver participant's condition. Montana and Pennsylvania require the dietary counseling services should be performed by a RD or CNS; however, New York may have specified this as a criterion in the provider qualifications section of the waiver.

Participant Services: Limitations on Services.

Limitations on services refers to a state's ability to limit the number, frequency, and duration of the service, for example a waiver may be active for five years, but the state does not have to provide home-delivered meals for five years if it chooses. This theme was present in three out of nine states. Table 13 shows the thematic results.

Table 13. Participants Services: Limitations on Services Thematic Results

Theme: Limitations on Services	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States can specify the number, frequency, and duration of service under a waiver		✓	✓				✓		
Sub-Themes									
Number of meals		✓	✓				✓		

The three states, Iowa, Montana, and Oklahoma had some type of limitation on the service that their waiver was providing, including the same sub-theme of limiting the number of meals provided under the waiver, although the number and timeframe varied between states. For Iowa, the state would only reimburse the cost of the meals for a total of 14 meals per week. In Montana, the waiver only provided for two meals per day, because providing the third meal would constitute a full nutrition regimen, which is not allowed under HCBS waivers. Oklahoma restricted the number of meals to one per day. The limitations on services set by states are important for stakeholders to utilize in their advocacy efforts.

Participant Services: Verification of Provider Qualifications.

The theme of verification of provider qualifications documents within the waivers analyzed which entity is responsible for verifying that the provider possesses the proper qualification to carry out the services under the waiver. All states were required to

Theme: Verification of Provider Qualifications	FL	IA	MT	NC	NM	NY	OK	PA	TX
Theme Definition: States must specify the entity responsible for provider qualifications and frequency of verification	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sub-Themes-Frequency of Verification									
Annually	✓			✓			✓		
Every 2 years								✓	✓
Every 3 years					✓				
Every 4 years		✓							
Renewal of licensure			✓						
Ad hoc						✓			

The entities responsible for verifying provider qualifications aligned with the population the waiver was intending to serve. Iowa, New Mexico, and Texas rely on the State Medicaid Agency to perform verification. Surprisingly, for New Mexico and Texas this process was relegated to the Medicaid Managed Care Organization. Three states chose to have their State Department of Health verify the credentials of providers. Florida

and Pennsylvania chose similar entities in the Department of Elder Affairs and Office of Long-Term Living. Montana is the only state to select the Public Health Department.

The frequency of verification may be a factor for organizations considering providing services under a waiver. Florida, North Carolina, and Oklahoma verify provider credentials on an annual basis. Pennsylvania and Texas require verification of credentials every two years, while New Mexico requires every three years, and Iowa requires every four years. Montana requests verification when a provider must renew their license. New York requires verification on an ad hoc basis and places the responsibility on the provider to maintain their credentials. As previously stated, this information is helpful for stakeholders who may be seeking reimbursement for services under a waiver and it helps to document the process for these select states.

Participant Services Latent Analysis

The analysis of the language used in the participant services key area yielded similar patterns of text within states, but there were no patterns observed between states. The similar text within states could point to the author of those waivers or the possibility of shared text between staff in close physical proximity, but this hypothesis will be discussed in Technique 2. Alternatively, states may have received feedback from CMS regarding their applications and were provided guidance on standardizing the text within their waivers; however, this will not be assessed as a part of this research.

Cost Neutrality Demonstration

The key area of cost neutrality provides the dollar value the state has chosen for either home-delivered meals and/or dietary counseling. Table 15 will show the type of

service, the unit the service was specified for, the average cost per unit, and the total cost of the service under the waiver. In the table it is noted if a state had more than one waiver included in the latent analysis denoted by a number after the state name. It is important to note that waivers' length varies between three and five years and some states chose to roll their home-delivered meals into other services so where indicated the totals are not solely reflective of home-delivered meals.

In total all nine states proposed to spend approximately \$421,095,450 on waiver services for home-delivered meals and/or nutritional counseling. For those states that specified home-delivered meals, a total of \$327,133,995 was proposed to spend on providing services. Iowa, Montana, New York, and Oklahoma include nutritional counseling and education as a part of their waivers and proposed to spend \$331,982 on providing those services.

Table 15. Cost Neutrality Demonstration

State	Waiver Service	Unit	Avg. Cost per Unit	Total cost
Florida	Home-delivered meals	Day	\$7.00	\$11,981,522.00
Iowa- 1	Home-delivered meals	Meal	\$8.02	\$341,134.76
Iowa- 2	Self-directed community support and employment*	Hour	\$15.29	\$635,735.13
Iowa- 3	Home-delivered meals	Meal	\$6.98	\$8,052,158.22

State	Waiver Service	Unit	Avg. Cost per Unit	Total cost
Iowa- 3	Nutritional counseling	Hour	\$11.19	\$5,372.16
Iowa- 4	Home-delivered meals	Meal	\$7.50	\$226,126,426.72
Iowa- 4	Nutritional counseling	Qtr. Hour	\$10.10	\$1,313.26
Montana	Meals	Meal	\$6.11	\$226,770.41
Montana	Nutritional counseling	15 Minutes	\$15.22	\$760.09
North Carolina	Preparation and Deliver of Meals	Each	\$3.41	\$14,044.51
New Mexico	Respite Care*	15 Minutes	\$4.76	\$91,622,188.77
New York	Congregate and Home Delivered Meals Services*	Per Meal	\$10.00	\$640,000.00
New York	Nutritional Counseling/ Educational Services	Per Visit	\$86.50	\$156,738.00
Oklahoma- 1	Home-Delivered Meals	1 Meal	\$5.06	\$80,105,546.65

State	Waiver Service	Unit	Avg. Cost per Unit	Total cost
Oklahoma- 2	Home-Delivered Meals	1 Meal	\$5.08	\$286,391.40
Oklahoma- 2	Nutritional Education Services	15 Minutes	\$22.86	\$30,165.78
Oklahoma- 3	Home-Delivered Meals	1 Meal	\$5.24	\$869,181.07
Oklahoma- 3	Nutritional Education Services	15 Minutes	\$23.77	\$50,873.49
Pennsylvania	Nutritional Counseling	15 Minutes	\$112.29	\$86,753.90
Texas	Home-Delivered Meal	Per Meal	\$5.55	\$0**

*This service was not exclusively for meals; ** Totals were not provided by the state

The average cost per unit among the nine states is \$6.36. $\pm$ \$1.70; clearly, then, there is variability in the amount of reimbursement that providers receive under HCBS 1915(c) waivers. Interviews with state policymakers in technique 2 revealed that each state determines the rate of reimbursement through complex formulas within their budgeting office, although there may be room for negotiation. The importance of providing the cost neutrality demonstration information is to examine the potential amount of reimbursement that FNS providers could earn if they sought reimbursement through HCBS 1915(c) waivers.

Limitations of Technique 1

The key limitation of Technique 1 is in the building of the data set. The number of codebook elements was complicated by sheer complexity of the potentially relevant elements; thus, a literature-review-informed selection process was used to identify the most important elements. The most important elements were included in the codebook; however, due to the literature-review-informed selection process the possibility exists that variables that were not selected could deepen the understanding of waivers.

Technique 2: Semi-Structured Telephone Interviews with Stakeholders

In order to address the central question of this research, “What are the stakeholder roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?” semi-structured interviews were chosen to explore potential roles. The stakeholders are policymakers, Medicaid Insurers, FNS providers, and FNS participants. Each group was identified for their perspective and lived experiences. The original intent was to interview policymakers, meaning state Senators and Congressmen. However, Technique 1 revealed that the state Medicaid agencies were filing the applications with the Centers for Medicare and Medicaid Services (CMS) and not state Senators and Congressmen. A total of 26 interviews were conducted over the course of nine months and the breakdown is as follows: Policymakers (4). Medicaid Insurer (1), FNS providers (9), and FNS participants (12).

The following provides additional characteristics of the stakeholders that were interviewed, the policymakers came from three regions of the country: Northeast (1), Mid-Atlantic (2) and South (1). The combined experience of the policymakers amounts

to over twenty years in the field of Medicaid policy. The Medicaid Insurer is from the Mid-Atlantic region of the U.S. and has been in the field for over 15 years. The FNS providers represented the following regions of the country: Northeast (2), Mid-Atlantic (3), South (1), Mid-West (1), and West (2). The interview participants varied in their roles from CEO to Policy Director, with varying levels of experience ranging from two years to over twenty. The FNS participants reside in a Mid-Atlantic state and varied in the number of years they were managing their Type II Diabetes.

All interviews were conducted using semi-structured telephone interview protocols with recording to enable the researcher's ability to focus on the conversation. Once an interview was completed the recording was transcribed using an automatic speech recognition (ASR) transcription service, called Temi. All transcripts were edited to ensure accuracy and then loaded into NVivo[®] 12, the qualitative data reduction software package. Each interview was coded against the codebook for apriori codes as well as any emerging themes that needed to be added. For three out of the four stakeholder groups, the codebook remained unchanged, but for the policymakers five to six new codes were added to accommodate a Medicaid agency staff person versus a Senator or Congressman. Initially it was the aim of the researcher to double code one interview from each stakeholder group, however after the first interview was double coded the percent agreement as 99.4%, with a kappa coefficient of 0.84, and the second interview yielded a 99.6% agreement, with a kappa coefficient of 1.0. A kappa coefficient of greater than 0.75 indicates an excellent level of agreement (QSR International, 2018). A third

interview was coded with similar results; therefore, it was decided that there was no need to double code any additional interviews.

This technique is divided into two parts: part one will contain the answers to each research sub-question by stakeholder (see Methodological Quick Reference chart, Appendix A); and part two consists of an overall thematic analysis of the stakeholders to examine themes within and across stakeholders.

Part One: Sub-questions by Stakeholder

A. Policymakers.

The following research sub-questions were examined for policymakers: Sub-question one: *“How do policymakers choose to support FNS for people with Type II Diabetes?”* The intent of this question was to determine how Congressmen and Senators support people with Type II Diabetes from the perspective of their constituency, however the policymaker interviews were conducted with state Medicaid Agency representatives not Senators or Congressmen. Medicaid policymakers are supportive of FNS for their beneficiaries, but there are constraints attached to providing additional services that will be discussed in the Part Two: Thematic Analysis.

Sub-question two: *“What factors influence their support or non-support of policies for FNS?”* Like sub-question one this question was aimed at Senators and Congressmen, however Medicaid policymakers were able to identify the reduction in healthcare costs and improvements in beneficiary’s health as factors for supporting FNS. Although, only one policymaker thought that FNS would become part of the state Medicaid’s standard benefits to further reduce healthcare costs.

B. Medicaid Insurer.

One research sub-question was proposed for the Medicaid Insurer stakeholder group:

“What was the decision process for deciding to partner with an FNS provider?” The decision process to partner with an FNS provider was a joint effort by the Medicaid Insurer and the FNS provider. The Medicaid Insurer had this to say about the impetus for the partnership:

“I would think that we have always been interested in looking at food as a way to better control some of our disease management. I would say we've looked at many food programs, but none were quite set up in the way that [FNS Provider] is in terms of actually looking at health conditions and figuring out how they impact ability. The other programs were pretty much just around food insecurity.”

There were several factors that were considered by the Medicaid Insurer, for example which beneficiaries would benefit the most from FNS, the size, location and reputation of the FNS provider, as well as the financial health of the organization. One large factor was the fact that the FNS provider had set up meal plans for various health conditions as well as modifications, for example if food needed to be pureed or certain religious dietary preferences adhered to. The menu plans made the partnership more attractive because the FNS provider had already done the “heavy lifting.”

Internally, the decision took about three months to make, including drafting the specifications for the partnership and the budget. Additionally, care managers were consulted to develop referral forms and the legal department was involved in drafting the contract. There were three to four productive internal meetings that were held along with a few meetings with the FNS provider. To execute the contract the entire process took

between six and nine months. The Medicaid Insurer feels like it is a great partnership and the reason for its continued success is ability to get buy in from all internal stakeholders within the organization.

C. FNS Providers.

The following research sub-question was explored for the FNS providers: *“What role does FIMC membership play in individual FIMC organizations?”* Membership in the Food Is Medicine Coalition (FIMC) plays a large role in each of the individual organizations because it provides knowledge, resources, and advocacy capacity. All FNS providers are pleased with the goals and the direction of FIMC, however there is some debate around the ability to come to consensus on the goals as well as the speed of execution of the goals. The largest perceived roadblock by FNS providers to FIMC achieving its goals is bandwidth capacity because the coalition is not always the priority of the individual organizations. A deeper analysis of this question will be provided in the Part Two: Thematic Analysis.

D. FNS Participants.

There are two research sub-questions examined for the FNS participants. Sub-question one: *“What are FNS participant’s perception about the role food plays in their ability to address their Type II Diabetes?”* FNS participants understand that food plays a large role in controlling their Type II Diabetes. The participants are able to make the connection between how their body feels and the foods that they consume. They are acutely aware of the effects of eating too much sugar and what that does to their

hemoglobin A1c. Additionally, they know that the amount of food they eat also effects the way that they feel.

Participants were asked if they follow a specific way of eating and many admitted that they do not always strictly adhere to their diet, but they do possess the knowledge about what they should be eating. This quote illustrates the experiences of an FNS participant being able to stick to a certain diet:

“I'm really supposed to but I'm gonna be honest with you sometimes, I cheat and what I mean by cheat is sometimes I eat sweets, but I don't go overboard with it while I don't know too much of it. Sometimes I'll eat some potato chips, sometimes I eat pizza or pound cake, something like that I really just don't go overboard.”

When asked about the foods eaten pre-FNS and post-FNS several participants reported incorporating some of the foods that they received as a part of their FNS into their daily diet, for example more broccoli and vegetables. Additionally, FNS participants were asked about their snacking habits whether they felt their snack choices were healthy. Examples of snacks include cheese and crackers, chips, berries, peanut butter, and candy cakes. The results were mixed over whether participants felt their snack choices were healthy. Two participants acknowledged that their snack choices were unhealthy but were able to demonstrate healthy snacks that would not exacerbate their condition. The long-term management of a chronic disease takes substantial effort on the part of the patient, however by providing FNS services this may help to eliminate one component, especially for those that have multiple comorbidities. Furthermore, FNS services have the potential to educate patients on the proper diet for their condition.

Research sub-question two: “*What role do FNS participants perceive their medically tailored home-delivered meals play in their ability to address their Type II Diabetes?*”

Respondents were divided on the role that the medically tailored home-delivered meals played. Some respondents felt like the service saved their lives while others felt it did not have a very large role in addressing their condition. Participants generally liked the portion size, taste and the quality of the meals, although some felt that they lacked seasoning. All FNS participants agreed that they would recommend FNS services to others, here’s what one participant had to say when asked if they would recommend FNS services to another person with Type II Diabetes:

“I would tell them to look getting into in [FNS provider] because it's a healthy meal for you. It's better going out and getting unhealthy meals and it comes faithfully, delivering the food to you if you're a diabetic or a cancer patient.”

Two participants compared FNS meals to private meal companies like *Mom’s Meals* and *Meals on Wheels* and stated that they preferred the FNS provider’s meals because of the portion and taste, as well as the reliability of the service. FNS services are provided free to participants, but when asked who should pay for the service the group was divided down the middle between some form of government (city, state, federal) or insurance companies should pay. These research sub-questions will be explored further in Part Two: Thematic Analysis.

Part Two: Thematic Analysis

An overall thematic analysis was conducted to see the connections within and across stakeholders’ roles in Medicaid waiver policy to support FNS for people with Type II

Diabetes. There were six themes that were deduced from collapsing the nodes within the codebook, and the themes are: 1) advocacy, 2) partnership, 3) membership, 4) politics, 5) education, and 6) payment. The theme advocacy in this analysis is defined as advocating for clients or beneficiaries to receive FNS to improve health outcomes while reducing costs. The theme of partnership is defined as the ability for stakeholders to form partnerships to further their mission of improving health while reducing healthcare costs from high-risk beneficiaries. Membership is defined as the benefits that are derived from participation in a group and the group's ability to reach its goals within the next five years. Politics is defined as the stakeholder's perception about the role that politics plays within Medicaid waiver policies. The theme of education is defined as the role of each stakeholder to educate themselves and others on the concept of *Food Is Medicine* to heal and reduce the effects of chronic disease. The payment theme is defined as the perception of a stakeholder as to who should pay for FNS for people with Type II Diabetes and the potential effect it has on overall healthcare costs. Table 16. displays the results of the thematic analysis whereby policymakers and FNS providers appeared in most of the themes, while Medicaid Insurers and FNS participants only appeared in two themes each.

Table 16. Results of thematic analysis

	Policymakers	Medicaid Insurers	FNS Providers	FNS Participants
Advocacy	✓		✓	
Partnership	✓	✓	✓	
Membership			✓	

Politics	✓		✓	
Education		✓	✓	✓
Payment	✓		✓	✓

Advocacy.

The theme of advocacy was present in two stakeholder groups, policymakers and FNS providers. All FNS providers participate in advocacy efforts either at the state or federal level to spread their individual missions and once a year they gather as the FIMC to conduct a national symposium. Since FNS providers are part of a coalition (FIMC) that has no staff or administrative support, advocacy efforts vary among providers, depending on staffing and time constraints. Within FNS providers, some advocate also at the local level to have mayors and councilmen involved to shed light on a service being provided within their community. Most advocacy events are not held year-round, they are typically only during the holiday season when officials and the press are invited or if it is an election year for officials. When the FNS providers were asked to rate their advocacy events on a scale from 1 to 10, nine reported a rating 8 or higher, while one reported a 3 due to staffing capacity. The results are mixed on the best way to engage with policymakers, based on this analysis it is best to utilize email, phone and in-person visits.

Policymakers are often the recipients of the FNS providers advocacy efforts, and it is not that the policymakers are not sympathetic or understanding of FNS provider's missions, for most it comes down to whether or not the state has the budget to add any

additional services be that through waivers or another policy mechanism. One policymaker had the following to say regarding the process for that state:

“We get approached literally every week we have a meeting with somebody who comes to us with something they want us to add in Medicaid. Every week! Every week somebody comes to us with either a code or something they want to have added. Well, you know, we’re not, it’s not that we don’t want to add them, it’s just that we can’t add anything without taking the proper steps, which is first you gotta get money, gotta have the money to cover anything that’s new. And that comes from the legislature because as I tell people, we’re a government agency, we don’t do bake sales. We don’t do car washes. We don’t generate our own income.”

Understanding the process within each state for how and when services are added to Medicaid or if the potential exists for the use of a waiver may be valuable for FNS providers. Based on interviews with policymakers, the process by which a state includes new services starts within the legislature and the state budget office.

Partnership.

Partnership is a central theme for three out the four stakeholders, policymakers, Medicaid Insurers, and FNS providers. Partnerships are the bedrock for each of these stakeholders, because the use of strategic partnerships can help to broaden their reach while potentially helping to improve health outcomes and reduce costs. For policymakers they can use their partnerships with Medicaid Managed Care Organizations (MCO’s) to offer new services. This quote from a policymaker outlines within a state agency that there are key partnerships that need to be formed:

“But we partner very closely with the other offices directly administer those waivers in particular the Office of Long Term Living who used one of its HCBS waivers as a cornerstone for its expansion into a managed long-term services and support.”

For Medicaid Insurers, the decision to partner with an FNS provider was mutual between both parties, specifically each organization realized that there was a population to be served and based on the past performance of the FNS provider the Medicaid Insurer decided to set up a formal agreement. There were several factors that were evaluated by the Medicaid Insurer prior to the partnership, and they included financial performance, disease specific meal plans, and past performance with other MCOs. The following quote from the Medicaid Insurer outlines their decision for partnering with an FNS provider:

“It is really a combination because we looked also at our data on who we thought had impact-able health conditions. We looked at [FNS Provider] information already and some of the programs that were run out of [FNS Provider]. I think for our program we had a great opportunity to sit and say, let’s look at the various health conditions and which one we know could actually change the outcome. And I think we looked at them [FNS Provider] because they were fairly small, we knew they had great results from their previous HIV programs as well, they had done some programs with MCOs in the past. I think they also had already adapted various food based on disease management, a disease specific type of meal plan. Those were all the consideration rather than us having to create menus and all that they’ve already done some of the heavy lifting.”

There were approximately three to four internal meetings at the Medicaid Insurer, and it took approximately 3 months to reach an agreement after review by the legal and contracts department. The final agreement between the two organizations took approximately six to nine months. The results for one cohort of participants in this partnership yielded a 24.5% decrease in overall healthcare costs, a 30.9% decrease in the number of inpatient visits, and a 20.2% decrease in emergency room utilization. Overall the partnership from the Medicaid Insurers perspective is working well, and this quote exemplifies that sentiment:

“I think overall we have a really good partnership. There’s probably some things they [FNS Provider] wish, we could be a little quicker about. We are a fairly large organization and we have a lot of reporting that’s due to the state and we are working on a gazillion other programs. So, it is difficult to have as much focus and resources that we need. But I will tell you that between our admin assistant, our medical director and our case managers, they love the program. They love being able to offer it to their folks who could really use the help. So, we’ve been trying really hard to keep that going.”

FNS providers form partnerships with many kinds of organizations, which may include federal and state policymakers, departments of health, Medicaid Insurers, and universities to spread the message about *Food Is Medicine* and the effect that medically tailored meals can have on both health outcomes and costs. Three of the nine FNS providers reported having partnerships with Harvard’s Center for Health, Law, Innovation and Policy (CHILPI), whereby FNS providers were asked to help with specific policy language recommendations. One FNS provider explains a mutually beneficial partnership with the state’s Medicare Administrator to broaden the scope of their work:

“So [Medicaid Administrator] ensures that everybody that administers Medicare is meeting their quality metric outcomes...but one of their requirements with CMS is the fact that they facilitate diabetes self-management education classes. They have specific target populations, but we’re working with them to recruit our current clients that have not had diabetes self-management education classes to attend theirs. And then similarly, we are providing meals to classes or attendees of their classes that are not currently our clients. We’re collecting outcome metrics and clinical markers associated with those folks, including A1c and lipids and blood pressure, follow-up eye appointments, foot doctor appointments. And then comparing them to a control group of folks that didn’t receive our meals in the past. Then using the rhetoric and with the approval of the [State Congressmen] to get the buy in, we are going to approach CMS for a special innovation project....hopefully getting more money to be able to

provide meals on a broader scale in [State] or create a model that's replicable in other states specific to diabetes.”

One common theme was developing champions within each part of the partnership, because in order to further advance the common goals of the partnership regardless of other demands and priorities of these organizations. Each FNS provider may have partnerships with individual stakeholders and entities. To reach the Food Is Medicine Coalitions (FIMC) goals of providing medically tailored meals for people with serious illnesses on a larger scale, it may be worth examining partnerships within FIMC to be able to scale up services. Moreover, the formation of strategic partnerships may help to make the shift from using a medicalized approach of disease treatment to more of a prevention-based model that includes both the patient and the community.

Membership.

The FIMC organizations as part of the coalition, participate in many activities throughout the year including monthly calls, leadership committees, sign-on petitions, or the National Symposium. Currently this group does not have any membership fees associated with membership. The benefits of membership provided by FIMC for each of the individual organizations was positive, however none listed direct benefits. Listed below are a few quotes by FIMC organizations:

“We feel our advocacy efforts, we feel it's a channel for collaborative advocacy and we believe there's strength in numbers. It's much more empowering to go up to the hill as a coalition of more than 30 agencies than just to go on our own in most cases. We share best practices with each other, and so we learn, and now most recently we have committed to joining in together when the opportunities present themselves to go after regional health care contracts and contract with managed care organizations. We learn a lot about public policy. So, the

webinars, the educational opportunities and professional development through FIMC are really stellar. And there's camaraderie too, you know that you can pick up the phone and call anybody within FIMC and it's like a fraternity or sorority you're obligated to help your partner out."

"I think that having FIMC as a repository for research on our programs has been really helpful too. So, you know, more support, promotion of FIMC agency research, which they've already been doing a great job with. But you know, that's really helpful for us and in all our endeavors."

The quote below references the potential for direct benefits for each organization within FIMC though it does outline some inherent challenges with a group purchasing approach:

"No, not really, other than being part of the hive mind... We actually think that there are a lot of potential direct benefits. So, we think, for example, group purchasing would be something ANSA years ago had a group purchasing contract with Staples. I think if we were able to basically get our shit together and come up with some universal recipes, we could probably do more in terms of group purchasing around food. The problem is that each organization operates a little bit differently and has different kinds of menus and rotations. And so, going from the idea of something like that to actually making it happen has been very difficult."

Within the theme of membership, the sub-theme of FIMC's goals and direction of the coalition was analyzed. The results were mixed, some agencies felt that the coalition was headed in the right direction and was going to achieve its goals, while others were not as optimistic and raised concerns around the coalition's ability to come to a consensus on major issues like what is a medically tailored meal and who can provide them. The quote below illustrates an organization that was positive about the goals of FIMC:

"I feel really good about them [FIMC goals]. I feel like FIMC has a window of opportunity to position ourselves and take our rightful lead as the premier coalition for nutrition services provider. And that such an opportunity to really influence the way that medically tailored meal

providers are viewed. The level of investment that is achievable through the advocacy work that we do in the outreach work that we do so, I think our goals are terrific.”

This quote exemplifies what FIMC agencies that were not positive about the coalition’s ability to achieve its goals:

“We feel like they need to have clearer goals. You’re getting into an area where there’s a lot of struggles...I would say that it seems to be difficult to come to consensus around things. It always boils down to the devil in the details issue where you know when you look at it from a very high-level macro perspective, there is a lot of consensus, but you know when it comes down to how we’re going to get from A to B, that’s when it is an issue. It seems like it would be easy, but there’s enough subtle differences between what we all do that it isn’t. So, when you think about what is a medically tailored meal, what does food is medicine mean, for [FNS provider], our model is [X] meals a day, [X] days a week. We don’t look at things like activities of daily living in our qualified criteria where other organizations might be supplemental meal programs. So, there’s enough differences that make it really hard to kind of come to a consensus, but I think that there is a real imperative to doing just that.”

When respondents were asked if they thought that FIMC would achieve its goals, all nine responded that they believed the coalition would fulfill its goals. There were five respondents that were unsure of the amount of time that it would take to achieve the goals, while some provided what they perceived as potential roadblocks for fulfilling those goals. The number one roadblock to FIMC achieving its goals is bandwidth capacity, meaning that as a coalition, there was no support who worked only on FIMC-related goals. The workload falls onto individual coalition staff who are running non-profit organizations and may not have time to dedicate to the coalition’s goals. The other roadblocks that were mentioned include “the dysfunction in Congress,” limited education on what a medically tailored meal is, scalability to serve nationally, technology, non-

FIMC competitors, and Health Insurance Portability and Accountability Act (HIPAA) compliance as partnerships between insurers and FNS providers are established.

Politics.

The theme of politics was present in half of the stakeholders, specifically for the policymakers and the FNS providers, as it related to Medicaid waivers. FNS providers cite politics as a roadblock to the FIMC coalition's ability to achieve its goals. For policymakers, politics plays a key role in Medicaid waiver policy, because the state Medicaid budgets are set through the state legislature. Based on the interviews conducted with policymakers if there is no political support to advocate for a service to be added to a waiver, then it is typically not added. One representative spoke about the previous governor supporting a waiver initiative; with a new administration, the respondent was unclear how or if the waiver would proceed. The following quote illustrates the role that politics plays within Medicaid waiver policy for policymakers:

“It’s a big role. And not just in what services get added as a big role in for States in general and what the rates are that you get for services. There’s a valid rate methodology for any Medicaid services, but we could have our legislature allocate funding to increase services for the rate of adult day health and then we’re going to increase the rate for adult day health as long as it fits in the PMF methodology...If our legislature wanted us to add home-delivered meals to a waiver, all they would have to do is allocate the money in the budget with a line that says we’ve estimated they would get with our budget people and office of planning and budget, which is the governor’s office. They would say this is probably going to cost us a hundred million dollars. They would go in their big base budget; they would put the money in it and then we would put it in the waiver. You’re going to get a lot of pushback from the state legislature like, well why do we have food stamps? What’s the difference?”

Another set of policymakers had insight into the role that politics plays within managed care organizations providing FNS services for beneficiaries:

“Yeah, I mean, clearly there’s politics in it. You know, within the state we run our SNAP program there’s always politics around that. There’s always politics around how it is that our managed care plans are using the dollars that we give to them. I think to the extent though that we are able to demonstrate that these investments in these social, in addressing the social issues in the long term, saving the medical assistant program money, people that may have initially been somewhat skeptical become less skeptical.”

These stakeholders highlight the need for advocacy and education among legislators regarding services like SNAP versus a medically tailored meal. Additionally, the second quote suggests the use of data to drive policy decisions as a conversion tactic for skeptical legislators.

FNS providers understand the role that politics plays within Medicaid waivers whether it is specially around waiver funding, reimbursement rates, or specific policy language. Several FNS providers cited working with policymakers on specific policy language related to medically tailored meals for legislation that did not yield any results, however they continually seek opportunities to deepen their relationships with policymakers. This quote illustrates the role that politics plays in crafting policy from the FNS providers perspective:

“Last year we, we really had been working on a relationship with [State Senator] office. [State Senator] is the ranking member on the Senate Special Committee on Aging. When budget season came around, [State Senator] actually invited [FNS Provider] to submit language for an appropriation. That didn't really get anywhere, but just the process itself was really helpful and generated some language that then some of the other FIMC agencies have been able to use in other conversations. So, they're building blocks.”

The State Senator chose to reach out to an FNS provider when the budgeting season was open to make changes to current legislation. Both policymakers and FNS providers need to examine the political landscape to be able to leverage their advocacy efforts on a consistent basis to achieve results.

Furthermore, politics plays a role within MCO contracts because insurers are being incentivized by state Medicaid offices to use non-traditional services to improve health outcomes while reducing costs. One provider had the following to say about navigating politics:

“We work with a lobbyist in [State] who has some ins and was, was really helpful and you know, organizing these initial conversations with [State] healthcare finance [in reference to MCO contracts].”

Each FNS provider was asked if they believe the FIMC organization will achieve its goals of furthering Food Is Medicine and what are the roadblocks to achieving their goals. One FNS provider had the following to say:

“I think the hurdles are certainly the sort of dysfunction in Congress right now is one.”

This quote acknowledges the role that politics plays in FIMC’s ability to achieve its goals because of the stagnation within Congress to pass legislation. Additionally, due to the gridlock in Congress new models of care are not being explored or funded. FNS providers cite continued efforts to build relationships with stakeholders in order to further their agenda.

Education.

Education was one of the major themes of this analysis, being represented in three out of the four stakeholder groups. Each stakeholder views education in a slightly different manner, but at the core education in this context refers to the difference between medically tailored meals and non-medically tailored meals and the potential effect on chronic health conditions. The Medicaid Insurer expressed the need for medical providers to understand the purpose and intent of medically tailored meals and the following quote exemplifies the Medicaid Insurers hesitation in reaching out directly to providers to communicate an additional insurance benefit:

“I keep thinking about opening it up to physicians to refer patients, but I have to tell you, we have opened it up to like, we have received requests through our ‘Let Us Know program’, which is a piece that we send to all physician offices that says, ‘Do you have a patient who's struggling that you would like help with?’ And a lot of times we get back, not a lot of times, but we have gotten back where a physician has said, listen, this person really could use something like [FNS Service] and then we will facilitate that and talk to the care manager and have the care manager reach out to the patient. But when we opened it to physicians or we talked to physicians about it, they want to give us a list. Every one of them have like hundreds of people. So that's been kind of, that's been a little overwhelming, so we haven't done that yet.”

Physicians need education around the eligibility criteria for patients to receive medically tailored meals. Medicaid Insurers could think about drafting education materials or holding trainings or conference calls to bring doctors on board. This effort has the potential to shift a physician's mind from traditional pharmaceutical remedies perspective to an illness reduction and prevention perspective.

FNS providers perceive the education of stakeholders as an essential component of

advancing their goals and mission for *Food Is Medicine* model. Policymakers do not necessarily understand the difference between a medically tailored meal compared to a meal service like *Meals on Wheels* that provides nutrition but can potentially exacerbate chronic conditions like Type II Diabetes or hypertension. Medicaid Insurers may not know FNS services exist within their area to be able to serve their beneficiaries.

Individuals living with chronic illness like Type II Diabetes may be biased against trying medically tailored meals because they think that they will not taste good and do not understand the potential impact this form of intervention can have on their condition. The following quote underscores the importance of education from an FNS provider's perspective:

“I think education is really key. People don't know what a medically tailored meal is, average person you walk up to on the street goes, Huh, that sounds terrible. I don't want to eat it. We have a bit of an educational curve to surmount because our roots are so solidly in the HIV crisis, we are often mistaken as serving only that population. Furthermore, the people that truly need to know about us from a health plan perspective and even a provider perspective are the referring nurses and the care coordinators, right? Cause they're the ones like, oh this person needs this. We have this constant onus on us to do outreach and education in the community and make sure these people know who we are because the turnover rate workforce wise for Medicaid is really high. So, the care coordinator, if you spoke to last month, that doesn't work there anymore, they've gone to a different plan. Thankfully, they take that knowledge with them to the next plan or the next provider. And so hopefully we were just building this knowledge base. But you know, half the battle is just helping people understand that you exist and what you do.”

The theme of education was also present for FNS participants in relation to how food effects their Type II Diabetes and by receiving meals it is educating them about foods and portion sizes are appropriate. All respondents understand the role that food plays in their

chronic disease management, despite admitting to non-compliance with a Type II Diabetes diet at times. One participant had this to say about the role food plays in Type II Diabetes:

“It plays a big role in Type II Diabetes what we eating and how we should eat and every now and then when you do good, you can, to me, this is for me, you can have your little favorite snack, your favorite little ice cream but it shouldn't be every day all day that you going overboard with it.

By receiving medically tailored meals participants reported that it taught them how much they should be eating, however some felt that there could have been more food in meal.

Nutritional counseling is what sets FNS apart from home-delivered meals like *Meals on Wheels*. Nutritional counseling provides FNS participants with tools to enable them to make lifestyle modifications after FNS services have ended. Those respondents that reported having nutrition counseling sessions spoke favorably and were able to recall something they had learned, below are two quotes that illustrate the value of nutritional counseling:

“Drink plenty of water and don’t eat fried foods.”

“No matter what you do make sure that you have one good meal that can carry you to the next day”

The participants quoted above had not received FNS services for nine months but were able to maintain the knowledge from the counseling session. This raises the argument for moving away from Wagner’s Chronic Care Model of disease management to a more prevention focused strategy that brings stakeholders together through

community organizations and patient empowerment to reduce the risk disease development or comorbidities.

Payment.

The theme of payment was present in three out of the four stakeholders regarding who should pay for FNS services and the potential effects on healthcare costs.

Policymakers are beholden to the state budget and the will of CMS, conversely, they did feel that waivers were a potential way to pay for FNS. One policymaker had this to say about providing home-delivered meals in the state:

“When you eat properly, your health care costs go down. If were’ able to feed our elderly better, their health care costs are gonna naturally go down. Worth every penny, eating healthy pays for itself.”

Two out of the three policymakers did not feel that FNS services would become a traditional Medicaid benefit in their state due to the cost and programs like SNAP being in place to reduce hunger. This finding reinforces the theme of education to make policymakers understand that difference between SNAP and medically tailored meals, as well as to shift their perspective from a reactive chronic care model to a proactive prevention healthcare model within their states. The third policymaker felt strongly that this would be a covered benefit in the next few years due to the aging population within the state.

FNS providers do not charge their participants for their services leaving the onus on the organization to create funding for their efforts. Many of the FNS providers were established in response to the HIV/AIDS epidemic and were able to receive funding through Ryan White legislation, however as the organizations saw a growing need to

expand their programs to chronic diseases, they had to find additional funding sources. For a portion of the providers some sought funding through Medicaid contracts with MCOs, waivers or pilot projects with the state. For those organizations that utilized waivers as a form of reimbursement there were several issues, for example the billing, denied claims, and staff time to work on eligibility and billing. The first step in the process to be able to provide services under a waiver is to become a direct contractor for Medicaid with the state, this allows you to bill them directly for services. Respondents reported that billing was complicated and cumbersome due to the amount of paperwork and refiling for denied claims. One respondent had the following to say about billing for waivers within the organization:

“We used to do the billing under the waiver in house. It's essentially billing under a waiver is just like medical billing for anything else. It's complicated and it requires a level of knowledge about the waiver, when you're rejected, and you get to rebill and all that other kind of stuff. We weren't getting as good of reimbursements as I would like, so we have subcontracted with somebody else to do the billing.”

There was also frustration around denied claims. A few providers cited that a reason is not often given, and it takes search to determine why the claim was not paid. A common reason for denied claims is participant eligibility or if a participant misses a meal delivery. This quote from a provider interview demonstrates the rules surrounding denied claims regarding missed meal delivery:

“The person must be at home to receive the reimbursement. So, um, and we don't get reimbursed for like mis-delivery delivery. So, if the person happens to miss the delivery or if they happen to go in the hospital, um, we don't get reimbursed for those meals.”

The level of uncertainty surrounding a chronically ill persons health creates an issue for FNS providers because they are at risk of purchasing food, containers and staff resources to deliver meals that will not be reimbursed.

The staff time related to billing varied depending on the organization, two providers reported that it was a full-time job or they had multiple staff working on it at a time, while others reported a few hours a week, however organizational size should be taken into account. Overall the organizations did not feel like it was a detriment to have staff working on the billing of the waivers. Eligibility was spoken about in conjunction with billing. The perception that once you are accepting clients under a waiver that the “flood gates would open” was not the reality. Two organizations spoke about the difficulties of finding potential participants that met all the criteria and it has taken longer than expected. This quote illustrates one provider’s experience with waivers:

“Now we thought, oh my God, we're going to be flooded cause we, we can only take 60 people this first year because those are the ones only ones we're going to get reimbursed for. And we found that the criteria was so strict, it was very, very hard to recruit those 60 people. And we also found that just because you would know, or you have this funding and you have a contract and you have a deal; it doesn't mean the referrals are going to come. You really have to work for the referrals and you have to go to every healthcare provider that you have and find the right people within the healthcare system who are the ones who work and they do the referrals.”

While this respondent didn’t expect the difficulties in recruiting the general perception was that the waivers were worth doing despite the level of effort they required. In general, the FNS providers felt like the waivers were a possible funding

source for their organizations, however entering contracts with MCOs appeared to be a less lengthy process.

The theme of payment was also present for FNS participants with respect to who should pay for FNS services. Respondents were evenly divided in who they felt should pay for FNS services; half said that the city, state, or federal government should pay, while the other half said that insurance companies or Medicare should reimburse the FNS provider. This quote examines why the insurance company should pay for FNS:

“Your insurance, medical insurance companies, I mean because this is like medicine.”

FNS participants perceive that food can be as helpful as medicine, therefore FNS should be a benefit that is provided either through the government or health insurance. This perception supports the theme of education because participants can learn to heal their bodies using food instead of pharmaceutical interventions. The following quotes represent two participant’s perceptions of food as medicine and the impact that it can have:

“Food is much more helpful than medicine, because medicine is just a bunch of chemicals and food is a natural substance that has its own medicine in it naturally that the body craves for, you know, the body doesn’t really crave a medicine.”

“If I learn to eat right and take my medicine all that plays a really big part in my life and helped me to get healthier and to stay healthy. Then I won’t be going to the ER when I won’t have to be going to the doctors every month or every week because my sugars are so out of control that they trying everything they can to get it in control and they will keep me, I won’t be going to the hospital, or staying in the hospital.”

Once more this raises the preference for a less medicalized or pharmaceutical approach to treatment of a chronic illness.

Limitations of Technique 2

There were four limitations identified in technique two. First no pretest interviews were conducted to ensure the internal validity of the questions being asked, therefore the researcher had to adapt the semi-structured script as necessary to ensure that proper probes were being asked to address the research questions. The second limitation of this technique is there may be some recall bias with respect to the FNS participants because they were asked to recall details about the meals they received and for some the length of time since their last FNS meal could have been as long as nine months. Additionally, the third limitation arose with the FNS participants as there were language and comprehension barriers due to the age and education level of the participants. The researcher rephrased where appropriate while maintaining the integrity of the question, however if the participant was unable to answer the researcher skipped that question. The fourth limitation is within the Medicaid Insurer stakeholder group because only one interview was conducted, therefore only one point of view was explored. The researcher attempted to gain additional Medicaid Insurers using a snowball sample from the FNS providers, however after several attempts at outreach no additional Medicaid Insurer interviews were conducted. The intent of the Medicaid Insurer interviews was to document the decision-making process by the insurer to partner with an FNS provider, therefore the implications of this limitation are minimal.

Technique 3: Quantitative Analysis of Health Outcomes and Healthcare Utilization and Costs

The concept of Food Is Medicine posits that when a severely ill person is given food that is specifically designed to address their disease, they will benefit and potentially reduce the risk of complications and comorbidities. To confirm whether Food Is Medicine is efficacious, research examining health outcomes, healthcare utilization and costs must be assessed. The basic process was that a Medicaid Insurer contracts with a Food Nutrition Service (FNS) provider to offer home-delivered, medically tailored meals for 12 weeks to a sub-set of their beneficiaries. The aim of this partnership was to explore if medically tailored meals and nutrition counseling could improve health outcomes and reduce healthcare costs of high-risk beneficiaries. To determine the effect that FNS meals and nutrition counseling had on beneficiaries, the Medicaid Insurer entered into a data sharing agreement with the researcher to conduct data analysis of the partnership between the Medicaid Insurer and FNS provider.

The eligibility criteria to receive FNS included being a beneficiary diagnosed with serious illnesses and be nutritionally at risk due to those illnesses or their treatment(s). This analysis was conducted on 195 beneficiaries who received FNS services for 12 weeks, 71% of whom have Type II Diabetes, 0.5% of whom have Type I Diabetes, and 29.2% of whom have a chronic illness (heart disease, hypertension, dyslipidemia, or cancer). Over 85% of the beneficiaries were diagnosed with at least two serious illnesses or chronic conditions. Analysis was conducted in three stages: 1) health outcomes were analyzed only for beneficiaries diagnosed with Type II Diabetes (N=36) that had

biological lab test results pre/post FNS services; 2) cost of emergency room and inpatient visits were analyzed for the entire population (N=195) and separately for beneficiaries with Type II Diabetes (N=139); and 3) the odds ratio and relative risk were calculated for age, race, and gender to provide dimensionality to the results. This analysis used a pre- and post- design, meaning the timeframe for the analysis of health outcomes and the costs were prior to participants receiving 12 weeks of FNS services and after receiving those services. An apriori power analysis was conducted, and this study reaches the conventional Type II error threshold of 80%; therefore, with 34 participants, it is likely that treatment effects will be detected.

Health Outcomes

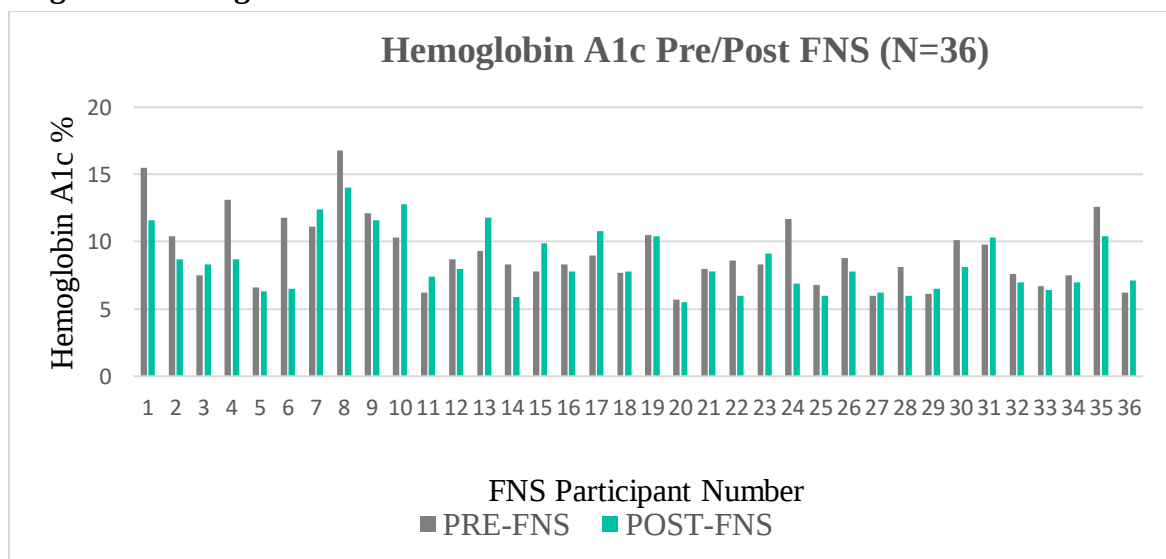
The health outcomes in this section were for a subset (N=36) of the 195 patients who had biological measures collected, as many within the full sample either had pre-data but no post-data or vice versa, which were excluded from this analysis. The possibility also exists that biological information was not collected at all, again making them ineligible for this analysis.

Hemoglobin A1c (HbA1c).

Sub-question one: Does providing 12-weeks of FNS to high-risk beneficiaries have an effect on hemoglobin A1c (HbA1c)? Type II Diabetes is diagnosed using the Hemoglobin A1c (HbA1c) blood test, which measures a patient's blood glucose levels and averages them over an 8-12-week period to determine a percentage. If a patient's HbA1c percentage is over 6.5% they are diagnosed with Type II Diabetes (ADA, 2016). The 36 beneficiaries with Type II Diabetes saw a decrease of 0.69% in HbA1c (± 1.93).

Using a paired t-test, this decrease in HbA1c was found to be statistically significant ($p=0.042$) at the 0.05 level, meaning the reductions in HbA1c were most likely not caused by chance. This statistically significant result strongly suggests that FNS meals and nutrition education had a positive impact on the beneficiaries' HbA1c. Reductions in HbA1c have a direct effect on the risk of complications and co-morbidities. People with Type II Diabetes are automatically at an increased risk of developing co-morbidities, including cardiovascular disease, hypertension, nephropathy, neuropathy, stroke, and retinopathy (World Health Organization, 2016; Centers for Disease Control and Prevention, 2017). The analysis provides evidence that supports the food as medicine concept. Figure 6. shows the pre- and post-values for each of the participants in the study ($N=36$). While an overall reduction was observed it should be noted that some participants saw an increase in their HbA1c, which is reflected in Figure 6.

Figure 6. Hemoglobin A1c Pre/Post FNS



Cholesterol.

Sub-question two: Does providing 12-weeks of FNS to high-risk beneficiaries have an effect on lipid panels? Sub-sub-question 2a-c: Is there a difference in LDL levels after 12-weeks of FNS? Is there a difference in HDL levels after 12-weeks of FNS? Is there a difference in triglycerides after 12-weeks of FNS? Cholesterol is comprised of both high-density lipoprotein (HDL) and low-density lipoprotein (LDL) that is used to create healthy cells within the body. High cholesterol causes fatty deposits in the arteries, which can become clogged leading to heart disease and stroke (Mayo Clinic, 2019). Triglycerides are fat that circulates in the blood, typically measured in conjunction with cholesterol, the measure of which is a predictor of heart disease. In the United States it is recommended that total cholesterol be less than 200 mg/dL, LDL be less than 70 mg/dL, HDL be greater than 60 mg/dL, and triglycerides be less than 150 mg/dL (Mayo Clinic, 2019).

Of the 36 beneficiaries included in the health outcomes analysis total cholesterol, HDL and triglycerides were analyzed for 12 beneficiaries and LDL was analyzed for 8 beneficiaries. Due to the low numbers on these subtests (N=12 for total cholesterol, HDL, and triglycerides, and N=8 for LDL) conventional approaches to analyzing statistical significance are inconclusive. Additionally, these tests may be confounded by comorbidities, body mass index, or medications taken by participant. A relationship exists between hemoglobin A1c and lipid panels because the combination is a predictor of cardiovascular disease, therefore as hemoglobin A1c values decrease, typically reductions in LDL and triglycerides are observed reducing the likelihood of a cardiac

event. Although the lipid panels were inconclusive, in the face of the affirmative outcome on the hemoglobin A1c, were there adequate numbers, it is likely the lipid panels would have followed suit. Table 17 shows the results for the cholesterol and triglyceride analysis. It is also worth noting that these data were not collected in strict protocol therefore introducing confounding factors, for example the timeframe that the pre-and post-data was collected was not consistent for each participant.

Table 17. Results from Cholesterol and Triglyceride Analysis

	Sample Size (N)	Increase	Decrease	SD	SS .05 Level
Total Cholesterol	12	13.74 mg/dL		± 103.53	p= 0.66
HDL	12		8.5 mg/dL	± 19.09	p= 0.16
LDL	8		20.65 mg/dL	± 47.84	p= 0.29
Triglycerides (including outlier)	12	106.07 mg/dL		± 224.32	p= 0.14
Triglycerides (excluding outlier)	12	43 mg/dL		± 84.52	p= 0.13

Figure 7. shows the pre/post LDL levels in the FNS participants. A decrease in LDL or “bad” cholesterol has been shown to be beneficial even though the result inconclusive due to subsample size and the other potentially confounding factors. Curiously, here,

triglyceride levels increased; the standard deviation listed in the table is large due to one patient having a very high post reading of 1177 mg/dL. Even after re-running the analysis after excluding that beneficiary, triglycerides rose by 43 mg/dL (± 84.52) Figure 8. shows the comparison of total cholesterol, HDL and triglycerides for each of the FNS participants. Although the cholesterol and triglyceride results were inconclusive under traditional statistical significance analysis, the results show that the decrease in LDL may be clinically meaningful in reducing the risk of heart disease.

Figure 7. Low-Density Lipoprotein (LDL) Pre/Post FNS

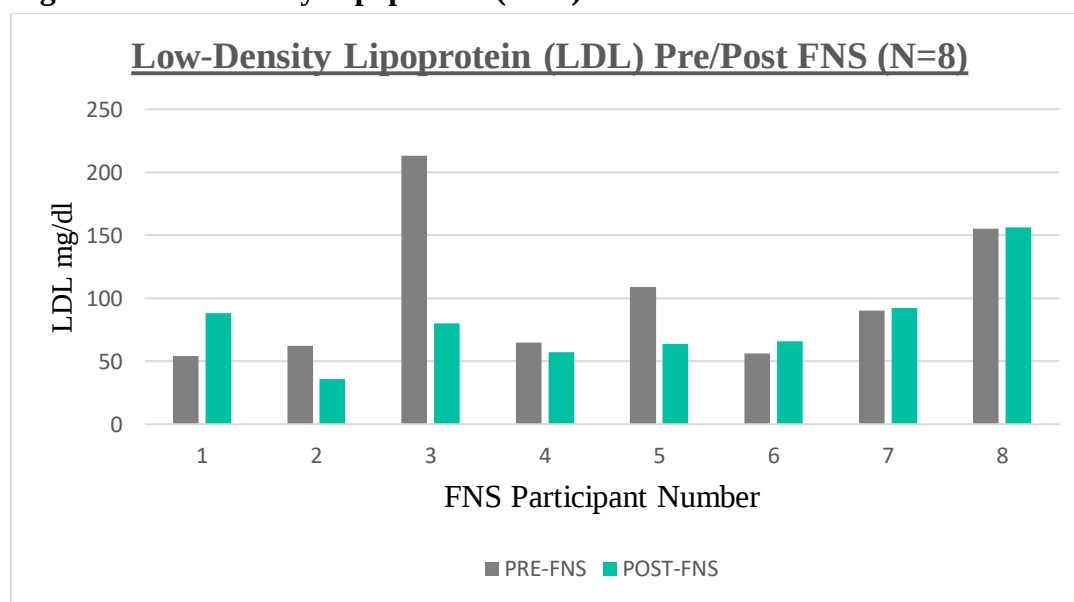
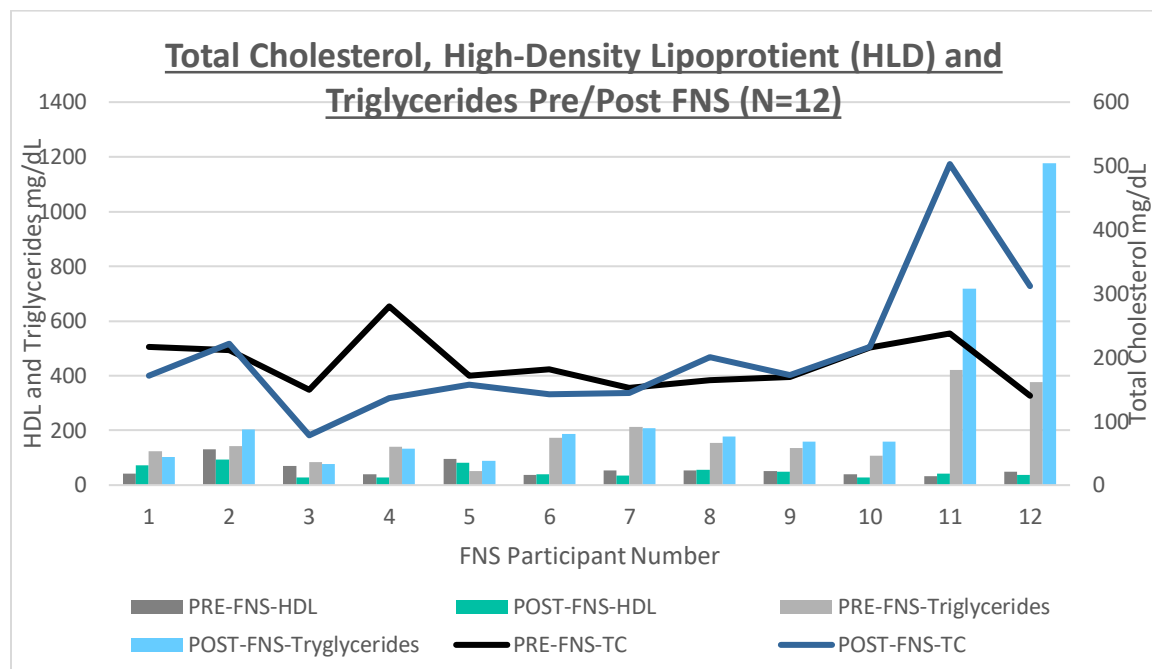


Figure 8. Total Cholesterol, High-Density Lipoprotein (HDL) and Triglycerides Pre/Post FNS



Healthcare Utilization

Sub-question three: *Does providing 12-weeks of FNS to high-risk beneficiaries have an effect on healthcare utilization, specifically emergency room visits, inpatient and total hospital visits?*

Emergency Room Visits.

High risk beneficiaries tend to use higher cost of care services like emergency rooms (ER) more frequently. For the entire population (N=195) the number of ER visits pre-FNS was 138, and post-FNS it was 122, i.e., an 11.6% decrease in the number of ER (n=16, ± 1.55). This decrease, however, does not show as statistically significant (p=0.46). The absence of statistical significance notwithstanding, any reduction in the number of ER visits could mean that FNS services are having some effect, albeit in combination or interaction with other informing factors.

For beneficiaries with Type II Diabetes (N=139) the number of ER visits pre-FNS was 81, and post-FNS it was 77, showing a decrease in the number of ER visits by 4 (± 1.34) visits or a 4.9% decrease; again, this result was not statistically significant (p=0.80). The subsample of beneficiaries with Type II Diabetes also showed a decrease in the number of ER visits, strengthening the argument that FNS services may be advantageous for beneficiaries.

Inpatient Visits.

As with ER visits, high risk patients are at greater risk of needing inpatient services to handle their complex chronic illnesses. For the entire population (N=195) the number of inpatient visits pre-FNS was 187, and for post-FNS it was 82, a 56.1% decrease

(N=105, ± 2). This result was strongly statistically significant ($p=0.00$), indicating that is highly unlikely the reductions in inpatient visits were caused by chance. This reduction in inpatient visits strongly suggests that FNS services reduced the need for higher cost inpatient services.

For beneficiaries with Type II Diabetes (N=139), the number of inpatient visits pre-FNS was 113, and post-FNS it was 60, a 46.9% decrease ($n=53$, ± 1.6). As with inpatient visits for the overall population, this result was strongly statistically significant ($p=0.00$), strongly suggesting that the reduction in inpatient visits was not caused by chance.

Total Hospital Visits.

For the entire population (N=195), the number of total hospital visits pre-FNS was 325, and post-FNS, it was 204, ($n=121$, ± 2.26), i.e., a 62.7% decrease, again, strongly statistically significant ($p=0.00$). This outcome provides strong evidence that, the reduction in total hospital visits was not caused by chance.

For beneficiaries with Type II Diabetes (N=139) the number of total hospital visits pre-FNS was 194, and post-FNS it was 137, a 29.3% decrease ($n=57$, ± 2.1), also statistically significant ($p=0.01$). Again, we see that reduction in total hospital visits was unlikely to have been caused by chance.

Cost

Sub-question four: *Does providing 12-weeks of FNS to high-risk beneficiaries have an effect on healthcare costs, specifically emergency room visit costs, inpatient visit costs, and total healthcare costs?*

A. Emergency Room Visit Costs.

Healthcare costs for high-risk, chronically diseased patients are often exponentially higher than their healthy members of their age-sex-race cohort. People diagnosed with diabetes are shown to have health care expenditures 2.3 times higher than someone not diagnosed with diabetes (ADA, 2013). In 2012, emergency room visits expenditures were predicted to cost \$119 billion, of which \$14 billion is attributable to people diagnosed with diabetes (ADA, 2013). Within that \$14 billion, \$6.6 billion will go for direct treatment of diabetes (ADA, 2013).

For the entire population included in the analysis (N=195) the costs of ER visits pre-FNS was \$40,840, and post-FNS it was \$35,892, a 12.1% decrease (i.e., \$4,948, $\pm$ \$471); however, this value was not statistically significant ($p=0.45$). For those beneficiaries diagnosed with Type II Diabetes (N=139) the costs of ER visits pre-FNS was \$22,239, and post-FNS services it was \$21,186, a 4.7% decrease (\$1,054, $\pm$ \$380); again, this result was not statistically significant ($p=0.81$).

B. Inpatient Visit Costs.

Due to the nature of complications that may accompany it, chronic disease often requires patients to need more inpatient care. The national expenditure for hospital inpatient care was projected to be \$475 billion dollars in 2012, of which \$124 billion—over 25%—would be consumed by people diagnosed with diabetes (ADA, 2013). Within that \$124 billion dollars, \$76 billion can be attributed to the direct treatment of diabetes (ADA, 2013).

The costs of inpatient visits for the entire population (N=195) pre-FNS was \$1,914,843, and post-FNS it was \$619,502, a reduction of \$1,295,341, $\pm$ \$21,720 or a 67.6% decrease; this, result was highly statistically significant ($p=0.00$). Those beneficiaries diagnosed with Type II Diabetes (N=139) had inpatient visit costs pre-FNS of \$1,138,541, and post-FNS costs of \$469,713, a reduction in inpatient visit costs of \$668,828, $\pm$ \$22,345, which is a 58.7% decrease; this result was highly statistically significant ($p=0.01$).

C. Total Healthcare Costs.

As previously mentioned, healthcare costs for high risk chronically ill patients can be dramatically greater than those not ill due to complications and co-morbidities. For the entire population (N=195) total healthcare costs pre-FNS was \$1,955,683, and post-FNS it was \$655,394, a 66.4% reduction in total healthcare costs (\$1,300,289, $\pm$ \$21,724). This result was highly statistically significant ($p=0.00$). Beneficiaries diagnosed with Type II Diabetes (N=139) had total healthcare costs pre-FNS of \$1,160,781, and post-FNS of \$490,899, a 57.7% decrease (\$669,881, $\pm$ \$33,248). As anticipated, this result was also highly statistically significant ($p=0.01$).

Healthcare Utilization and Costs

Figures 9 and 10 compare healthcare utilization of total hospital visits, inpatient visits, and total healthcare costs associated with these facilities to provide visualization of these trends.

Figure 9. Total Hospital Visits, Inpatient Visits and Total Healthcare Costs Pre/Post FNS

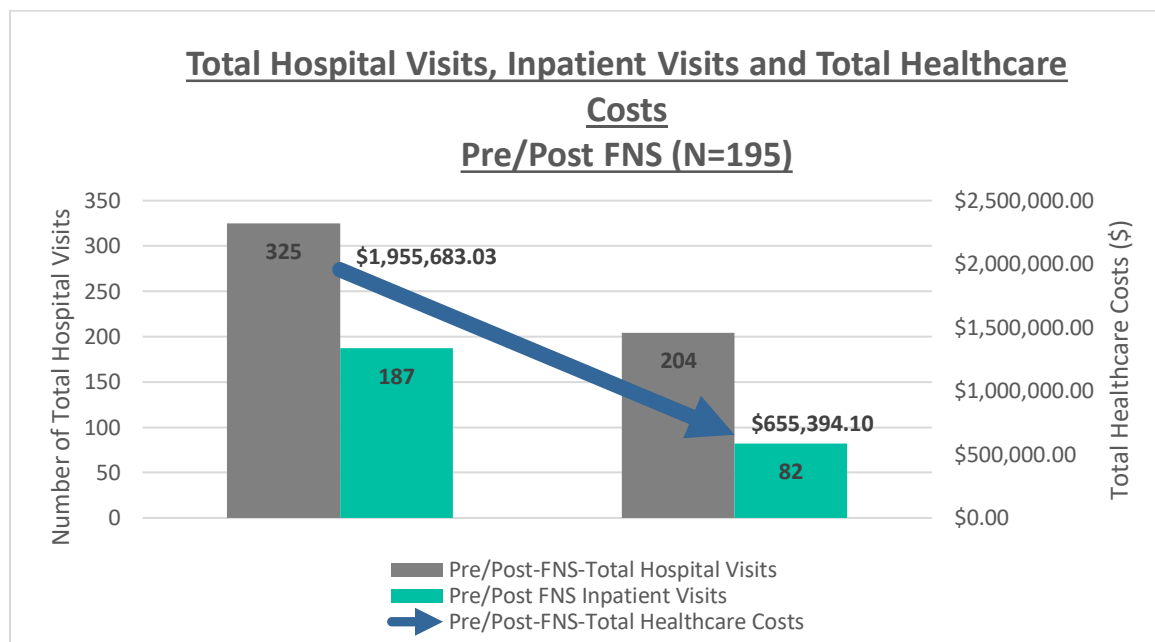
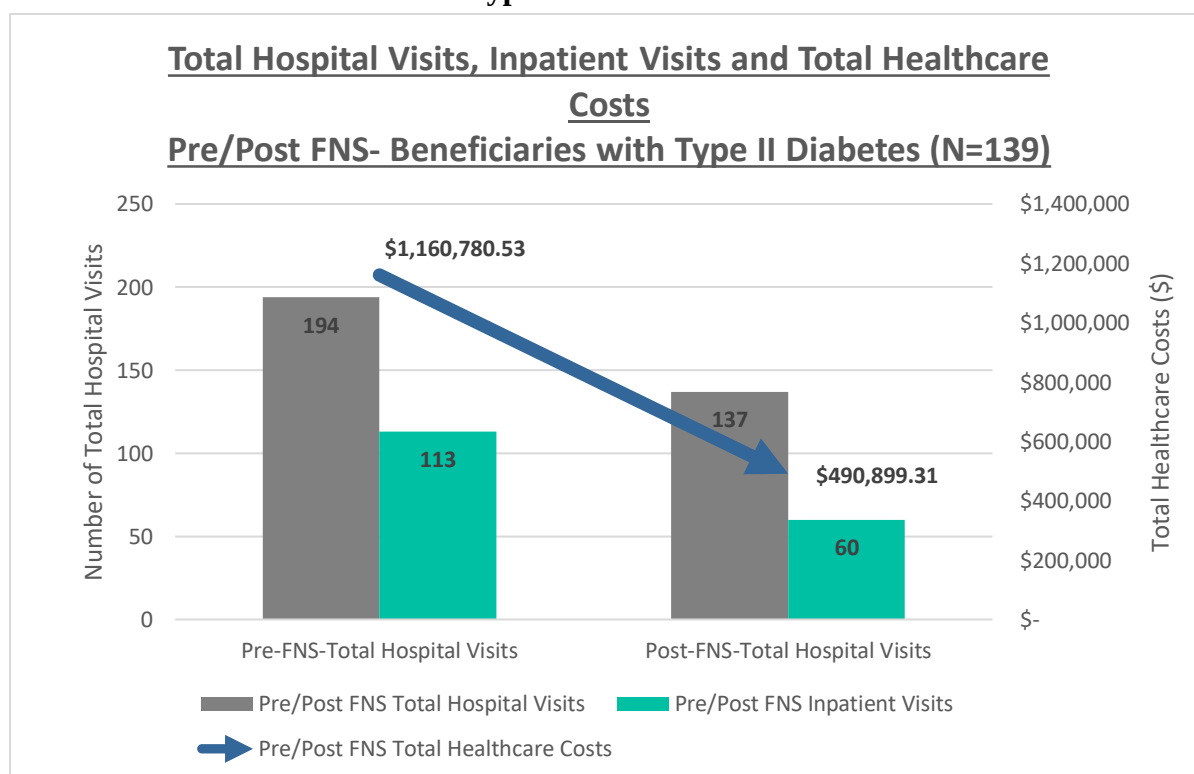


Figure 10. Total Hospital Visits, Inpatient Visits and Total Healthcare Costs Pre/Post FNS- Beneficiaries with Type II Diabetes



Odds Ratio

Odds ratio can be calculated to measure the effect of the prevalence of disease within a population. This statistical technique calculates the odds of having a disease or characteristic. In this analysis the odds ratio was calculated for the following characteristics: age, race, and gender. While for the entire population (N=195), age was not shown to be a factor for developing Type II Diabetes, the subgroup males were slightly more likely (1.07 times) to be diagnosed with Type II Diabetes when over the age of 50. Table 18 shows the odds ratio and the 95% confidence interval calculated for the outcome of interest, age.

Table 18. Odds Ratio Calculations for Age

	Diabetes	Non-Diabetes	Odd Ratio	CI 95%
Overall				
Under 49	37	19	0.71	.36, 1.38
Over 50	102	37		
Female				
Under 49	18	12	0.52	.22, 1.24
Over 50	69	24		
Male				
Under 49	19	7	1.07	.36, 3.14
Over 50	33	13		

Beneficiaries receiving FNS for 12 weeks, were 1.45 times more likely to be non-white than white. A more granular approach to analyzing the effect of race was not pursued because the population was majority non-white, confounding the capacity to conduct any more refined comparative analysis. Table 19. displays the odds ratio as well as the confidence interval for the entire population (N=195).

Table 19. Odds Ratio Calculation for Race

	Diabetes	Non-Diabetes	Odds Ratio	CI 95%
White	27	8	1.45	.61, 3.41
Non-White	112	48		

Gender appears to be associated with having Type II Diabetes; within this population (N=195) males were 1.07 times more likely to have Type II Diabetes than females. Table 20. shows the odds ratio as well as the confidence interval for gender. The odds ratio analysis of these three characteristics (age, race, and gender) suggest that more intensive efforts be directed toward non-white, males over the age of 50 to improve health outcomes and healthcare utilization and costs.

Table 20. Odds Ratio Calculation for Gender

	Diabetes	Non-Diabetes	Odds Ratio	CI 95%
Males	52	20	1.08	.56, 2.05
Female	87	36		

Relative Risk

Relative risk is the probability ratio of a characteristic compared to a control group therefore determining the likelihood of the characteristic appearing in the control group. Like the odds ratio, relative risk was calculated for age, race and gender. When analyzing the characteristic of age, those that are under the age of 49 were 2% more likely to have diabetes compared to those over the age of 50. When gender is added to the calculation, females are 24% more likely to be over the age of 50 with Type II Diabetes; similarly males over the age of 50 are 11% more likely to have Type II Diabetes compared to those who received FNS than to those who did not. Table 21. displays the relative risk calculations for the characteristic age for the entire population (N=195).

Table 21. Relative Risk Calculation for Age

	Diabetes	Non-Diabetes	RR Group 1	RR Group 2
Overall				
Group 1-Under 49	37	19	1.02	0.98
Group 2- Over 50	102	37		
Female				
Group 1-Under 49	18	12	0.81	1.24
Group 2- Over 50	69	24		
Male				
Group 1-Under 49	19	7	0.9	1.11
Group 2- Over 50	33	13		

The relative risk for race is similar to the odds ratio within this population of beneficiaries that received FNS for 12 weeks. Non-white beneficiaries are 10% more likely to have Type II Diabetes than their white counterparts. The race categories were combined due to the lack of diversity among the population for this measure. Table 22. shows the relative risk for the race characteristic for the entire population (N=195).

Table 22. Relative Risk Calculation for Race

	Diabetes	Non-Diabetes	RR
White	27	8	0.91
Non-White	112	48	1.1

The last characteristic of interest, gender, revealed that males were 2% more likely to have Type II Diabetes than females. Table 23. displays the relative risk calculation for gender for the entire population (N=195). The relative risk analysis generates a policy suggestion, similar to the odds ratio analysis, i.e., that more attention should be directed to non-white males over the age of 50, as well as those females over the age of 50 for more targeted services like nutrition education as a form of prevention.

Table 23. Relative Risk Calculation for Gender

	Diabetes	Non-Diabetes	RR
Males	52	20	1.02
Female	87	36	0.98

Limitations of Technique 3

Several limitations were identified through analysis of technique 3. First, the data were not collected according under a strict protocol, raising the possibility of inconsistent data collection parameters; moreover, there is a missing value issue, particularly with pre- and post-FNS lab results. Second, for those patients with full data transformation work was necessary to ensure comparable pre- and post-lab results. Third, without the use of a data collection protocol, the lab tests did not consistently deploy the same codes; if the type of lab test was undiscernible, the patients' data were excluded from this analysis, exacerbating the missing values concern. Finally, even though the apriori analysis revealed adequate statistical power to detect outcomes, several subgroup analyses were stymied by low-n values, which, in turn, diminish the analytical power for those test results. This is most evident, within the lipid panel measurements. These limitations, however, suggest guidelines for sample collection and analysis for future research.

Conclusion

In conclusion the results presented in this chapter achieved the aims set forth in the methods chapter: 1) to assess the stakeholder roles to support FNS for people with Type II Diabetes; 2) determine if HCBS 1915(c) waivers are a possible mechanism for FNS providers to seek reimbursement for meals; 3) examine the stakeholder perspectives surrounding Food Is Medicine to make the argument for a shift from a medicalized chronic care model to a more prevention focused model that includes stakeholders from all levels; 4) opportunities and roadblocks were identified within the *Food Is Medicine* model, chief among them being politics; and 5) the use of quantitative data as a

methodical approach that supports the use of FNS to reduce healthcare costs while improving outcomes.

Medicaid HCBS 1915(c) waivers are a possible funding source for FNS providers to seek reimbursement. The first step of the process is to become a certified Medicaid provider to be able to bill Medicaid directly. Next, FNS providers need to strategically aim their advocacy efforts towards known entities like Senators and Congressmen but the Medicaid Agency directors as well as the budget offices because they write the waivers and control the money respectively. There are millions of dollars at stake through these waivers that could be utilized by FNS providers to broaden the reach of their own organizations but FIMC as well.

The results of this study point towards shift from a chronic care model of disease management to a prevention-based model like Food Is Medicine. The use of HCBS 1915(c) waivers to fund FNS for people with diabetes could be a win-win for all stakeholders, nevertheless there are barriers that were identified by stakeholders like politics and education, but they are not insurmountable. The quotes provided by the FNS participants emphasize the positive impact that FNS services had on their health and the education component that will help to manage their condition after services cease.

Lastly, testing a methodological approach to provide evidence of the *Food Is Medicine* model showed statistically significant reductions in some health outcomes, however the data was not collected according to a protocol therefore cannot be used for generalizability. Reductions in healthcare utilization and healthcare costs provide evidence to support further investigation of the *Food Is Medicine* model under a strict

protocol where results can approximate efficacy. The implications of these results on policy will be addressed in the next chapter.

Chapter 5: Discussion

Introduction

Diabetes is a ubiquitous chronic disease, knowing no socioeconomic boundaries. The global prevalence is predicted to rise 51% by 2045, to include 700 million individuals being diagnosed with the disease (International Diabetes Federation, 2019; World Health Organization, 2019). In 2019, healthcare spending globally on diabetes was estimated to be \$760.3 billion, and is projected to reach \$845 billion by 2045, coinciding with the increase in prevalence (International Diabetes Federation, 2019). The United States ranks third in the world for highest prevalence, and is expected to remain in this position for the foreseeable future based on poor diet and sedentary lifestyle.

Within the United States, one in eight adults has been diagnosed with diabetes, while one in three people remain undiagnosed, increasing their risk of complications (International Diabetes Federation, 2019). Due to trends in obesity and potential environmental factors, children and adolescents are also being diagnosed with Type II Diabetes, presenting a significant public health concern, although more data is needed. Healthcare spending on diabetes in the United States accounts for 39% of the global expenditure, and is predicted to increase by 7% by 2045 (International Diabetes Federation, 2019). The estimates for increases in healthcare cost are conservative; the actual incurred costs will likely be higher given that past predictions were inaccurate and underestimated the costs. Given the U.S. trends in diabetes prevalence and healthcare spending, interventions, especially lower cost ones, aimed at prevention and treatment need exploration to address this public health challenge.

A variety of interventions aimed at improving diabetes are well documented in the literature summarized in Chapter 2; however, interventions utilizing the *Food Is Medicine* model are limited. The *Food Is Medicine* model asserts that food can be as effective as medicine when executed using medically tailored meals that account for an individual's chronic condition(s) and nutrition education in order to achieve improved health outcomes. Food can be a contributing factor to the rise of diabetes, through the pervasive availability and selection of highly processed, sugar-laden products. Conversely, food can be used to manage or prevent this chronic disease, as recommended by the *Food Is Medicine* model. Medically tailored meals offer individualized specific macronutrients and portion sizes that treat diabetes and its complications. It can be argued that providing a meal, like those supplied by *Meals on Wheels* or *Mom's Meals*, aids in reducing food insecurity and isolation, but may not address the nutritional needs of the chronically ill and medically complex. People diagnosed with diabetes and those at risk are vulnerable populations in the fragmented healthcare system, therefore necessitating a model of care to manage and or prevent this disease.

As previously explored in Chapters 1 and 2, the medicalization of diabetes and the structure of the United States healthcare system fostered the need for the Chronic Care Model (CCM) which uses integrated healthcare teams and traditional therapies to address chronic disease. While the Innovative Care for Chronic Conditions (ICCC) model promotes implementing national policy, adopting a population health approach, evidence-based decision making, disease prevention, quality of care, flexibility/adaptability as well as integration. This model emphasizes the use of partnerships between stakeholders at the

micro-, meso- and macro-levels to help reduce burden and prevent chronic disease. The use of interventions like medically tailored meals for people with diabetes could foster partnerships between doctor/insurers and community-based organizations. Additionally, advocacy at the local, state, and federal level to set policy that supports the *Food Is Medicine* model aligns with the aims of the ICCC.

Pairing the ICCC with the *Food Is Medicine* model holds promise to achieve the triple aim of improved population health, reduced cost, and increased patient satisfaction. Since the United States does not have a single payer system, implementing the ICCC would not be a straightforward process, yet, policies like Medicaid Home and Community Based (HCBS) 1915(c) waivers could be used to fulfill both the aims of the ICCC as well as the *Food Is Medicine* model.

A mixed-methods research study investigated three components linked to Medicaid HCBS 1915(c) waivers for people with Type II Diabetes: a content analysis of waivers for all 50 states (N=831); the roles of stakeholders (n=4 types) in Medicaid policies to support FNS services; and an assessment of feasibility for insurance coverage of FNS for this population with one provider. The central research question was: *What are the stakeholder roles in Medicaid waiver policy to support FNS for people with Type II Diabetes?* To address the central question and sub-research questions, a review of the methods can be found in Appendix A. Methodological Quick Reference Chart.

The final chapter provides a discussion of salient results, policy recommendations, and future research. First, Medicaid HCBS 1915(c) waivers are discussed to evaluate the advantages and disadvantages of this policy option for providing FNS to people with

Type II Diabetes. Second, the prominent themes from the stakeholder interviews are explored to assess the feasibility of utilizing waivers to treat chronically ill patients. Next, the chapter focuses on the quantitative evidence to support using data to drive policy decisions. Then, policy recommendations are made that promote the use of Medicaid waiver policy to support FNS as a method to address Type II Diabetes. Lastly, future research is proposed to deepen the knowledge on this topic as well as potentially provide direct evidence of FNS services.

Medicaid Home and Community Based Service 1915(c) Waivers

Increasing prevalence rates of Type II Diabetes amongst all segments of the U.S. population require policy options designed to address core factors and prevention of the disease. Medicaid HCBS 1915(c) waivers are a viable policy option to address the management and prevention of chronic disease through the *Food Is Medicine model*. States that choose to deploy waivers to address chronic disease could focus on caring the sickest and arguably the highest cost beneficiaries regardless of age.

As discussed in Chapter 2, approximately 50% of Medicaid beneficiaries are children, while the other 50% is split evenly between non-elderly adults and persons with disabilities. This division is significant because children diagnosed with Type II Diabetes are at higher risk of complications in early adulthood, potentially increasing their lifetime healthcare utilization and costs. Implementing a Medicaid HCBS 1915(c) waiver has the potential to improve health outcomes and reduce healthcare costs for all, but a waiver specifically for children may see increased returns on investment over their lifetime.

There are several key advantages of Medicaid HCBS 1915(c) waivers identified by this research.

The largest advantage of the HCBS 1915(c) waiver is flexibility to amend the policy. States are required to provide the Centers for Medicare and Medicaid Services (CMS) with an annual reporting of the services under the waiver and the welfare of the participants. If a particular service, for example medically tailored meals, was proving to be efficacious, then states can submit an amendment to modify the number of people receiving the services. Conversely, states have the ability to limit the number of participants receiving services. Amendments provide the option for states to include services that were not included in the original waiver application. The flexibility of 1915(c) waiver policy creates an opportunity for FIMC organizations to differentiate themselves from other meal providers, like Meals on Wheels or Mom's Meals, to advocate for medically tailored meals to be a covered service under a waiver at any time.

Waivers can target specific populations. States are responsible for drafting the waiver application to be reviewed by CMS, creating opportunities to target specific populations with chronic diseases, like those living with diabetes, and evaluate the results from meals that are either medically tailored or not. With this option to target populations, services can be limited to those who need it most and provide FIMC with prospects to advocate for medically tailored meals, using the assistance of additional resources from advocacy organizations like Harvard's Center for Health Law and Policy Innovation (CHLPI).

Another advantage of the Medicaid HCBS 1915(c) waiver notes that services provided under the waiver must remain at least cost neutral for the state budget. The cost neutrality provision of the waivers makes this an attractive option for states, because they directly control the number of participants that are allowed to enter a waiver, compared to 1915(i) waivers that require all eligible participants to be included irrespective of costs. Similarly, the cost of a waiver program to the state budget would be far less than adding FNS services to the standard benefit package. Although, California does have a five-year pilot program in which they have added medically tailored meals as a line item within the state budget for people living with congestive heart failure. The pilot is ongoing, but anecdotal results suggest that the eligibility requirements for the program are very strict, making enrollment difficult.

Since most of the FIMC organizations are non-profits, waivers offer alternative funding sources that may be more reliable than grants or donations. Monies awarded to FIMC organizations through grants or donations are not guaranteed and may take considerable effort to acquire. The ability of FIMC agencies to continually secure funding sources relies on their staffing capacity, whereas waivers would require one effort that could provide a funding source for three to five years. Additionally, waivers provide FIMC organizations with the ability to forecast budgets based on the reimbursement rates in the cost neutrality demonstration section of the waiver. FIMC organizations would directly bill Medicaid for their services, although reimbursement timeframes differ by state.

Despite numerous advantages to Medicaid HCBS 1915(c) waivers, there are disadvantages. A fundamental requirement of the 1915(c) waiver is that the prospective waiver recipient must be sick enough to rise to the level of institutional care in order to be considered under a waiver, meaning some beneficiaries will fall into this category while others will not. Then again, with an aging and chronically ill population, the likelihood exists that more beneficiaries will meet this requirement for institutional care, especially over time.

Another disadvantage of implementing 1915(c) waivers surrounds the individual FIMC agencies ability to comply with all of the state's provider requirements. The latent content analysis revealed some of the requirements included being a Medicaid contractor or must be compliant with the Older American Act of 1965. Individual FIMC agencies may not have the staffing capacity to draft, submit, and follow-up on the paperwork sent to the state. Similarly, individual FIMC agencies may not have knowledge about how to draft waiver language. The language used in the waivers is comparable to contract language in certain states, but existing waiver language does exist that could be adapted or forming a partnership with CHLPI who has extensive policy experience may prove beneficial.

The main disadvantage to HCBS 1915(c) waivers is that politics plays an ever-increasing role because the services are paid out of the state Medicaid budget. The involvement of the state legislators and governors makes the process more challenging, because they receive many requests to add items to the state budget, which is fixed. This disadvantage can be remedied by FIMC organizations using targeted advocacy and

education of legislators and governors about the difference between medically tailored meals and non-medically tailored meals for people with chronic diseases like diabetes. FIMC organizations also offer nutrition education and counseling, differing from other services. FIMC organizations could consider the timing of the targeted advocacy, for example during periods of re-election or changes in political party majority in the state to increase the likelihood of their efforts.

The final disadvantage of 1915(c) waivers is the amount of time taken to draft waivers and to apply to be a contractor. Some states have dedicated staff that work on waivers, but that does not mean that they work on them exclusively. Based on this research, a typical waiver takes at least six to nine months with staff working on it exclusively to submit to CMS. After a state has submitted a waiver application, CMS has 90-days to review and respond. If CMS has questions or needs revisions to the application, each time the 90-day clock restarts, which can be problematic if there are significant issues in the waiver. States do have resources from CMS to aid in their submission, but it depends on how willing that regional person is to help solve issues. While this may be a potentially lengthy process, it is similar to FIMC organizations establishing contracts with Medicaid Managed Care Organizations (MCOs).

These disadvantages with Medicaid HCBS 1915(c) waivers are not insurmountable. The state has control in drafting and executing the waiver and can course correct at any time it sees fit. A challenge lies, in part, with the capacity of individual FIMC organization, through compliance by means of provider requirements and advocate for their services in a timely fashion. It can be argued that the advantages of Medicaid HCBS

1915(c) waiver policy outweigh the disadvantages because states are going to need a plan to take care of residents of all ages with diabetes.

Semi-structured Telephone Interviews with Stakeholders

In planning for the public health challenge that is diabetes, stakeholders need to examine their role in Medicaid HCBS 1915(c) waiver policy as a potential solution to improve health outcomes and reduce healthcare costs. The four most salient themes from technique two are: 1) partnership; 2) education; 3) advocacy; and 4) policy development that will be discussed in this section.

A. Partnership.

Strategic partnerships need to be formed between “natural allies” and “unlikely bedfellows” to help build a consensus on policy. This research suggests that FIMC organizations need to form strategic partnerships beyond state legislators to include state-level bureaucrats. Many have relationships in place, but more specific partnerships need to be formed with those that work within the budgeting departments (state bureaucrats) because those individuals are tasked with the responsibility of finding money to fund waiver services. Ultimately, FIMC organizations will need to cultivate champions within their legislature and state offices to advocate for FNS services. Additionally, program staff within the Medicaid office are not typically viewed as a natural ally, however the staff that draft the 1915(c) waiver applications could advocate to include medically tailored meals as a service provided under the waiver, so it would be beneficial to form partnerships with those staff. The challenge in forming relationships with the program staff is that not all states have a central office for HCBS; some may be housed within the

Division of Aging or the Department of Long-Term Care Services. Finding appropriate state-level bureaucrats that support these efforts will require effort and time to build these strategic partnerships.

Another kind of partnership that can be developed is between FIMC organizations and other local providers. Some areas do not offer medically tailored meals, although meals may be provided to residents through local food banks, pantries, and soup kitchens. FIMC organizations can augment other local organizations meal delivery services through education about the importance of the *Food Is Medicine* model. For example, FIMC organizations could form strategic partnerships with Feeding America[®], which is a nationwide network of food banks, whereby medically tailored meals could be delivered to the food bank and participants could come and pick them up. Alternatively, FIMC organizations could partner with packaging companies to design meals that could be shipped. To gain insight into the process of shipping perishable food, FIMC organizations could partner with companies like Butcher Box that ship frozen meat nationwide or Hello Fresh[™] meal subscription service that ships fresh food to clients.

Little consistency about meal plans is demonstrated by each FIMC organization; some offer one to two meals per day while others offer three meals a day seven days a week. To address this issue, FIMC organizations could design tailored meal plans specific for the waiver participants. This may cause conflict with the individual mission of each organization, but if the waiver program is successful, the implications for the *Food Is Medicine* model is significant.

Meals on Wheels or *Mom's Meals* are “unlikely bedfellows” as they are viewed as potential “competitors” of the FIMC organizations. These organizations possess the means for scalability since meals are provided nationwide. FIMC organizations offer expertise on medically tailored meals as well as dietary preferences and nutrition education. A partnership between the two types of organizations could potentially be beneficial to both entities. The agreements would have to ensure that the “unlikely bedfellows” would not cut out the FIMC organizations nor adopt their processes as their own without consequences of litigation.

The nature of FIMC as a coalition with no staff for the organization hinders its capacity to advocate due to competing demands and staff availability. FIMC organizations could partner with local universities and colleges to have graduate students help with research and advocacy work. The benefits of partnering with a university is mutual: students are provided with opportunities to experience advocacy firsthand, while expanding the capacity of FIMC organizations to advocate and form new partnerships.

Lastly, FIMC organizations could form partnerships with MCOs, which are a natural ally, to provide services to beneficiaries. Some states have started to foster these agreements, but this has not been scaled to a national level. Similar to the waivers, these agreements could be set up to cover specific populations of beneficiaries, for example people with Type II Diabetes, cardiovascular disease, or those with the highest utilization. If the partnership achieves its goals the partnership could be expanded to include additional diagnoses.

The formation of strategic partnerships may expand the reach of FIMC beyond its current level and build a policy consensus. Moreover, the individual FIMC organizations may benefit through additional clients and potential reimbursement through waivers. At the state level, the key is to identify a champion for the *Food Is Medicine* model at multiple agencies, not just legislators. By diversifying the strategy of identifying allies, a consistent message could be disseminated and generate interest among state agencies to support this model. Partnering with an “unlikely bedfellow” is an approach to create mutual benefits and share knowledge among organizations. Through academic partnerships, FIMC organizations can provide unique opportunities for graduate students to assess programs and advocate for the *Food Is Medicine* model. Another option is Medicaid Insurers to further the *Food Is Medicine* model, while addressing ways to reduce healthcare costs and improve health outcomes.

B. Education

Education of stakeholders may help to build a stronger coalition around using Medicaid HCBS 1915(c) waivers as a policy tool to pay for FNS services for people with Type II Diabetes. FIMC organizations have the opportunity to provide education to legislators, Medicaid staff, and state budgeting staff about the importance of medically tailored meals and the differences between home-delivered meals and medically tailored meals. During the policymaker interviews two states shared that *Mom’s Meals* and *Meals on Wheels* were service providers under a waiver, however their services are more concentrated on providing nutrition and human contact rather than providing food that will help reduce the burden of chronic disease. FIMC organizations should develop an

educational package that highlights the differences between their services and those of their “competitors” to be able to advocate for their inclusion in waiver policy.

Educating policymakers and the public about the benefits of medically tailored meals could be done through personal stories and testimonials. Several FNS participants reported that they helped other chronically ill people obtain medically tailored meals by word of mouth. Additionally, the Medicaid Insurer has participant spotlights for clients receiving FNS that go in a magazine that is mailed to beneficiaries. However, the insurer noted that it was difficult to get participants to share their stories if they were no longer doing well after FNS services ceased. Education of the general public and healthcare professionals about the significance of medically tailored meals to potentially improve health and quality of life could be done through stories. These anecdotes could be shared through television and online advertisements, radio advertisements, YouTube videos, online webinars, newspaper articles, etc.

FIMC organizations may want to attend the National HCBS waiver conferences to increase education of policymakers and staff, similar to their advocacy day on Capitol Hill. FIMC may be able to make a presentation and network with policymakers to increase knowledge and visibility among key stakeholders. Working in conjunction with academic groups, FIMC could partner with these groups to create educational materials for this conference and provide chances for graduate students to participate in education and advocacy activities.

FNS services generally consist of two parts: 1) medically tailored meals and 2) nutrition education with a registered dietitian. Nutrition education should play a central

role for FNS participants thus potentially reducing the need for FNS services over the long term. Based on the FNS participant interviews, they could recall some things from nutritional education they had learned post-FNS services. Some reported that the education was redundant since they already knew the material they were taught. The nutrition education may need to be tailored for specific conditions instead of general nutrition advice and could be provided in equal measure as medically tailored meals. Currently, it is often provided for several sessions before transitioning from FNS meals. Furthermore, FIMC organizations may want to consider educational experiences like taking participants grocery shopping to show them what is available, what is a serving size, and how to manage food costs on a budget especially for fresh produce or fruit. Another educational experience is to hold cooking demonstrations that could be done in-person or virtually if participants are too sick to travel. While the medically tailored meals are an important component, nutrition education would provide possibilities for participants to learn how to improve their health through their efforts in eating healthier.

Education of stakeholders is a critical component to building a coalition and involving stakeholders around the use of Medicaid HCBS 1915(c) waivers to provide FNS for people with Type II Diabetes. The ability of FIMC organizations to differentiate themselves from their competitors provides an advantage to securing the role of a service provider under waivers. By using participant testimonials of FNS services it helps to educate all about the benefits, but also demonstrates the potential outcomes from the *Food Is Medicine* model in an accessible way. FIMC organizations attendance at the annual HCBS waiver conference could provide openings to advocate and network with

policymakers and their staff. Lastly, nutrition education may need to be prioritized as much as the medically tailored meals to empower participants to manage their chronic disease. These suggestions remind us of the Maimonides quote: “Give a man a fish and you feed him for a day; teach a man to fish and you feed him for a lifetime.” Nutrition education could help provide the tools and skills to feed the chronically ill for a healthy lifetime.

C. Advocacy.

Advocacy is a central theme for policymakers, Medicaid Insurers, and FIMC organizations. FIMC organizations must advocate for waiver language that specifies medically tailored meals under the service definition. The use of medically tailored meals in the service definition has the potential to keep FIMC’s competitors from waivers because they lack the expertise to create medically tailored meals. Policymakers thought that using specific language in waivers was a viable option. Conversely, through the use of strategic partnerships FIMC and their competitors could join forces to provide services under waivers, with the competitors providing scaling expertise and FIMC organizations providing nutrition education and medically tailored meals.

Individual FIMC organizations could advocate at their state legislatures offices, state budget offices, or Medicaid offices about the use of HCBS 1915(c) waivers to support FNS for people with Type II Diabetes. The FIMC organizations should be aware of how waiver services are funded in their state, meaning they could work with budgeting staff to help identify monies to finance waiver services. Advocacy has the potential for a significant reward because it could provide participants with services as well as a

mechanism for reimbursement for FIMC organizations, which may reduce the cost of healthcare for the state.

Medicaid Insurers and FIMC organizations could advocate for pilot programs within their state to supply medically tailored meals to beneficiaries. The process for creating a pilot program would involve the insurer drafting a proposal of the program, complete with a budget for their Medicaid office to review. This is very similar to the contracts that are already in place in some FIMC organizations. As previously mentioned, one state has an initiative that is in year three to focus on value-based care rather than fee for service. There is a general movement towards value-based care. In some states, insurance companies are being incentivized to reduce healthcare costs through the use of non-traditional benefits, which medically tailored meals and nutrition education would fall under.

The ability to advocate for the use of Medicaid HCBS 1915(c) waivers to support FNS for people with Type II Diabetes has implications for all stakeholders. A consensus among stakeholders exists that the use of medically tailored meals language in the service definition of a waiver is an option. The advocacy efforts of FIMC organizations among other stakeholders will help to further the *Food Is Medicine* model and is a primary goal of FIMC. Pilot programs with Medicaid Insurers to provide medically tailored meals to beneficiaries with chronic disease like diabetes holds promise for expansion into additional diagnoses and provide evidence of the effectiveness of the *Food Is Medicine* model.

D. Policy Development.

A need exists for more involvement by stakeholders in policy development. Policy development is a difficult process because politics, stakeholders, and budgets are involved, and the need to balance competing interests can be challenging. One reason that may contribute to the difficulty of policy development is that stakeholders are siloed in their interests, leading to a lack of coalition building to support FNS for people with Type II Diabetes. Unfortunately, this places more of the burden on the FIMC organizations to do the initial advocacy work, but arguably they have a considerable amount of potential benefit from their efforts.

States typically do not talk to each other about their waivers, but the potential exists for cross collaboration between states to improve the waiver drafting process. All Medicaid HCBS waivers are listed on CMS's website providing opportunity for states that are struggling with language to see what language other states used. This online resource provides the contact information for the person that is responsible for the waiver in each state, therefore if a state was considering a waiver, they could have a discussion with the waiver manager to help guide their decision.

Some FIMC agencies do not have the staffing capacity to advocate. This lack of resources limits their ability to advocate about their services within their state. As previously suggested in the strategic partnership theme, partnering with local universities or colleges to help with advocacy might assist in developing capacity for organizations. Alternatively, FIMC as a coalition could consider partnering with an academic-like think-tank such as CHLPI, to help those individual organizations with capacity to advocate.

This could potentially provide a direct benefit of FIMC membership for those organizations while reducing the burden.

The results of partnerships between Medicaid Insurers and FIMC organizations to provide FNS services to beneficiaries are being shared within states to entice more insurers to establish partnerships. The results and successes are not being shared more widely or with other stakeholders. Sharing results and successes of partnerships is encouraging, but insurers need to establish a mechanism to promote their results to a broader audience. This can be achieved through developing a media presence, using press releases, reports on the insurer's website, television spotlights, presentations at conferences, newspaper articles, etc. Even though these partnerships are not funded through HCBS 1915(c) waivers, the results and successes could lead to policy development within states. States could cite the results of the partnership as evidence of the effectiveness of the *Food Is Medicine* model when advocating the use of HCBS 1915(c) waivers to cover FNS services.

While most of the discussion has surrounded policymakers, Medicaid Insurers, and FIMC organizations, FNS participants are often not part of the conversation, despite their perception that FNS should be a covered benefit of medical insurance. FNS participants could engage in advocacy efforts by interacting with their legislators either in in-person or virtually to let them know how receiving FNS services has changed their health and potential of their disease outcomes. The timing of the advocacy could be timed to match up with the beginning of legislative sessions or around times of re-election where politicians are more likely to listen to constituent's concerns. Similar to the FIMC

organizations, finding a champion for their cause with policymakers, the organizations could identify champions among their participants that could act as the faces of *Food Is Medicine* and provide testimonials to its efficacy, therefore engaging them in the advocacy process. The advocacy efforts of FNS participants could help to humanize the need for these services to be covered by HCBS 1915(c) waivers.

Challenges to policy development exist, however there are resources that can be creatively leveraged to provide FNS services under Medicaid HCBS 1915(c) waivers. Information on the *Food Is Medicine* model is the greatest resource because it can inform all stakeholders and help to build support for waivers. States could also share challenges and successes with drafting waivers to make the process less burdensome, as well as to attract other states to use this policy option. Medicaid insurers could more broadly promote the results of their partnerships with FIMC organizations to increase the likelihood of policy development. Lastly, FNS participants could provide additional advocacy support for the *Food Is Medicine* model, while providing them with a voice as a stakeholder.

Quantitative Analysis of Health Outcomes and Healthcare Utilization and Costs

In order to form a consensus on the enactment of a policy option to address a problem, evidence is important to support a particular policy and drive decision making. Direct evidence on the efficacy of the *Food Is Medicine* model is limited and out of date, despite the availability of evidence from partnerships between stakeholders. Few critical evaluations have been conducted on FIMC services and their impact upon on disease or health outcomes. The quantitative data analyzed for this research does not provide direct

evidence of the efficacy of the *Food Is Medicine* model, but does test a methodological approach for future research on the health outcomes and healthcare utilization and costs of the model. In testing this methodological approach there were two advantages and several challenges revealed that could impact the ability to support and influence policy.

Two advantages of testing this methodological approach were identified: 1) availability of retrospective data and 2) the use of electronic medical records. Retrospective studies have value because the health condition or exposure has already occurred, for example in this research all participants were already diagnosed with Type II Diabetes. Using retrospective data allows research to be conducted efficiently and cost effectively because the data is already collected.

The use of electronic medical records provides flexibility for designing research studies to support the efficacy of the *Food Is Medicine* model. Typically, electronic medical records are stored within databases making retrieval a simplified process. While conducting research with paper medical charts is feasible, the electronic medical record reduces the burden on the researcher by having the ability to search large volumes of patients for a particular health condition or outcome.

Through piloting of this methodology, several challenges were identified: 1) data on FNS participants is hard to access; 2) pathways do not exist for researchers to gain access to data; 3) insurers may not have the proper level of methodological training to produce reliable research; 4) retrospective studies have an increased risk of biases, confounding factors and availability of data; and 5) reporting of data is both incomplete and not in a timely manner.

The availability of health outcomes, healthcare utilization and cost data on FNS participants is difficult to access because insurers maintain the electronic medical records. Medical records are protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It is reasonable for insurers be extremely cautious about releasing those records. Yet, the data does not need to contain personally identifiable information to be shared. De-identified data protects both the insurer as well as the researcher because it would be nearly impossible to attach data to a particular beneficiary. Protections could be put in place by those receiving the data such as the use of encrypted file transmission, storage, and destruction of data. The study should be reviewed and approved by an Institutional Review Board (IRB) that assesses the methods, risks, and ethical concerns of proposed research, whether conducted in an academic or governmental setting.

Since data on FNS participants is maintained by insurers and is hard to access, pathways need to be created to make access easier for scholars and external evaluators outside of the insurance company. To test the methodological approach for this study, the researcher had to enter into a data sharing agreement with the insurer. The process of executing the data sharing agreement took over two years to accomplish for this research. One reason the process was lengthy was due to the fact that the insurer did not have a tailored data use agreement. The insurer was able to provide a boiler plate form that included many aspects that were not applicable. Additionally, there were issues surrounding the ownership of the analysis and how it could be used by the insurer without the researcher's permission. The need exists for a customizable data use

agreement specifically for researchers/academics to be able to have access to at a minimum de-identified data from insurers.

Independent research is considered the gold standard approach to analyzing a problem because it reduces the likelihood of biases and conflicts of interest. Partnerships between insurers and researchers could bring a level of rigor to the research that may not currently exist. Staff within insurance companies may not have the training in research methods to assess outcomes. Independent researchers can provide the expertise for these assessments. Additionally, the independence of the researchers may reduce perceived biases of research results instead of the insurer publishing their own findings, which may be viewed as self-serving or questionable. The results of studies conducted by insurers need to be accurate because data may be reported to the state and may be used to inform policy. If the results of a study are incorrectly reported to a state, there may be costly ramifications for the insurer. Additionally, partnerships with researchers could potentially reduce the burden on the insurers staff and provide researchers with data sources. Partnerships between insurers and researchers is a win-win for both entities because it helps to provide rigor using more complex research designs and there is a built-in dissemination mechanism to report results.

Selection of a research study design is critical to the success of the study because it provides the structure for the study. Each study design has advantages and disadvantages. This research deployed a retrospective pre/post cross sectional design to calculate descriptive statistics, odds ratio, and relative risks for FNS participants. The disadvantage of testing a retrospective methodological approach is that the data was not collected

consistently, using a clear methodological protocol. Using data previously collected provided information that was inconsistent and missing pre- and post-FNS lab results. The quality of the data was very limited, requiring data transformation to ensure that the proper pre- and post-lab results were being compared. Inconsistent codes within the data caused patients to be excluded from the analysis thus reducing the sample size.

A different methodological design would have been helpful. The use of a prospective cohort study or randomized control trial potentially could provide data to inform the efficacy of the *Food Is Medicine* model. For the cohort study, participants would be enrolled in the study and followed for a specified period of time with pre- and post-labs being collected at specific intervals. In the case of the randomized control trial, two groups would be compared, a treatment group that receives FNS services and a control group that does not. The results of the treatment group could be compared to the results of the control group to determine if a difference exists, the statistical size of that difference, and if that difference is significant and generalizable. It is important to note that if favorable results are found from either methodological approach, it does not prove causation, meaning that the results can only suggest efficacy as human beings are complex and it would be difficult to specifically test for the results of FNS services only. Additional factor analysis may be needed to assess the role medically tailored meals can play in disease progression, health outcomes, and other perceived benefits.

Reporting study results in a timely manner is essential because the results can be used to educate, inform decision making, and drive policy. For insurers that are collecting data on beneficiaries that receive FNS services, the results need to be reported and shared

to educate others on the benefits of FNS. Conversely, if there are disadvantages of FNS, it is important to report negative findings as well to improve the *Food Is Medicine* model. Additionally, data must be collected according to a consistent protocol to ensure in order to improve accurate analysis and reporting. Based on the length of time elapsed to execute the data sharing agreement for this research, there needs to be a pipeline as discussed above to share the results of these partnerships in a timelier manner.

The release of study results to a wider audience may cause concern for insurers. Insurers can decide if they would like to have their names associated with the research. This measure provides anonymity to the insurer but still reports the results and does not hold the data from dissemination. As previously discussed, insurers could have their legal departments draft boiler plate data use agreements for researchers to expedite the process. Alternatively, in states that have FIMC organizations contracted with MCOs, a public data exchange could be created so that researchers could independently evaluate outcomes and costs. The data would be de-identified reducing the risk for the MCO and the database could be managed by the MCOs. A public data exchange would also provide access to data for the FIMC organizations, who cite frustrations with gaining access to data on their participants. The information could be used by the individual organizations as well as the coalition to inform their advocacy efforts and helping to build a consensus on policy.

The methodological approach tested in this research revealed advantages and challenges that may influence building a consensus on policy to further the *Food Is Medicine* model. While more challenges were identified than advantages, each of the

challenges possess a solution to turn the challenge into an advantage for future research. Access to data on FNS participants is vital to building support for the model, as well as informing partnership decisions and policy. Pathways could be created to ensure that data is being independently analyzed and validated through rigorously designed studies and reported in a timely manner to provide evidence to support the *Food Is Medicine* model. Increased availability of evidence to support the model will make it difficult for policymakers to disregard and potentially help to move the needle to include FNS services in policies, like the Medicaid HCBS 1915(c) waivers.

Policy Recommendations

The structure of the United States healthcare system favors the traditional medical model of care for diabetes, despite the existence of alternative models like the ICCC. The current policy landscape does not fully support the use of the *Food Is Medicine* model. As the preponderance of evidence is amassed, this model is supported for its efficacy. More states may find it an attractive intervention to include as part of policy. The research conducted in this dissertation identified four policy recommendations to support the inclusion of FNS services into Medicaid policy.

First, Medicaid HCBS 1915(c) waivers should be used and expanded to fund FNS services for people with Type II Diabetes. The potential exists to see improvements in health outcomes and reductions in healthcare utilization and costs through the use of FNS services funded by waivers. This policy option allows for control of costs by the state while providing a pipeline of clients and a reimbursement stream for services to the FNS provider. The additional monies provided by waivers could help non-profits, like

individual FIMC organizations, provide needed services or participate in research instead of searching for additional funds through grants or philanthropy. The service definitions within the HCBS 1915(c) waiver should include language that specifies the use of medically tailored meals. To address hunger, food is important. But to address a disease, the need for medically tailored meals is essential. Non-medically tailored meals provided by organizations like Meals on Wheels or Mom's Meals should not be part of the waivers because this kind of service does not address the nutritional needs of the medically complex.

Second, a need exists for stakeholders to form strategic partnerships in order to promote the use of HCBS 1915(c) waivers. FIMC organizations should establish relationships with their state legislators, Medicaid staff, and budgeters to advocate for the use of waivers to fund services. This type of advocacy can be done in a variety of mediums, either in-person or virtually, to help educate the stakeholders on the benefits of FNS services for their beneficiaries. Research should be used to strengthen the argument by providing data on the efficacy of FNS services. FIMC organizations should partner with universities and colleges to have graduate students draft advocacy materials and conduct research, thus eliminating the burden on the organization's staff. Additionally, education of stakeholders on how waivers can be used to fund FNS services is key to identifying a "champion" that will advocate for the *Food Is Medicine* model.

Third, FIMC organizations should form strategic partnerships with "unlikely bedfellows" to shift the focus from treatment with meals to include a prevention component. The amount of nutrition advice that exists is confusing for a healthy person

and can become more complicated in the face of chronic disease. For those with chronic disease, nutrition education is arguably just as important as medically tailored meals because it provides knowledge about the proper diet for a participant's condition(s). FIMC organizations do provide nutritional counseling with a Registered Dietician (RD), however it is unclear how many sessions are needed to be beneficial.

Partnerships with researchers could help to identify dose-response relationship through its designed study. Based on the results of the studies, FIMC organizations could partner with an “unlikely bedfellow” like the Academy of Nutrition and Dietetics, which is the national professional organization of RDs, to be able to provide nutrition education capacity to FIMC organizations. Another option would be to partner with the American Medical Association (AMA) to educate doctors on the role of nutrition in chronic disease because they receive very little nutrition training in medical school, although there is a push by medical students to incorporate more nutrition education into the curriculum. This partnership may help to reinforce the transition from the traditional medical model toward the *Food Is Medicine* model. The formation of these partnerships could lead to the prevention of comorbidities for patients as well as a reduction in healthcare utilization and costs. Moreover, nutrition education provided to FNS participants could reduce the likelihood for recurrence of re-enrollment in FNS services.

Fourth, states that have MCOs should be incentivized to provide FNS services for beneficiaries to improve health outcomes and reduce utilization and costs as part of state policy. Currently, there are some states that are incentivizing the use of FNS services by MCOs, however this is done through contracts, not state policy. The use of contracts

allows for an “opt-in” process by MCOs rather than a policy mandate that all MCOs must follow. If a policy mandate was issued, essentially a statewide pilot program would be conducted to evaluate FNS services. It is recommended that within the state policy mandate, that researchers be provided access to de-identified data to be able to conduct independent research to validate any findings by insurers.

The policy recommendations revealed during this research document the processes to integrate the *Food Is Medicine* model into policy. Medicaid HCBS 1915(c) waiver policies offer multiple benefits for stakeholders, including a reimbursement mechanism and pipeline of participants for FIMC organizations and cost containment for the state. The results of the cost neutrality demonstration in the latent content analysis of the HCBS 1915(c) waivers revealed that nine states paid \$421 million dollars for home-delivered meals and nutrition education, therefore FIMC organizations should capitalize on this policy option as a source of reimbursement for services. Strategic partnerships with “natural allies” and “unlikely bedfellows” are crucial to moving the *Food Is Medicine* model forward through education, advocacy, and research. Lastly, the use of state policy to require MCOs to provide FNS services could lead to improved health outcomes and reductions in healthcare utilization and costs.

Future Research

This research suggests several areas for additional inquiry: 1) exploring other stakeholder’s perspectives on policy options for FNS services; 2) studying if contracts with MCOs differ by state; 3) examining the efficacy of the *Food Is Medicine* model; and

4) assessing the viability of transitioning from the focus on treatment to prevention within FIMC organizations. The proposed future research studies are listed below:

- Conduct a qualitative research study that examines the use of Medicaid HCBS 1915(c) waivers to support FNS for people with Type II Diabetes from the perspective of additional stakeholders not included in this research. The main stakeholders of interest would be staff that work on waivers at CMS, state legislators, and budgeting staff. CMS is of interest because they are the agency responsible for approval of waivers and could provide insight into the approval process as well as offer guidance on the waiver language. This research was not able to capture the roles of legislators; therefore, this project would highlight their knowledge about *Food Is Medicine* to identify gaps in their knowledge and what factors would lead them to support or not support FNS services for their constituents. The budgeting staff are in the unique position because they are responsible for managing the state budget and determining if additions are feasible. To capture their perspective and document the process of adding services to the Medicaid state budget may prove beneficial for FIMC organizations. To assess the stakeholder perspectives, semi-structured in-depth interviews would be conducted, transcribed, and apriori and emerging themes would be analyzed.
- A comparison of states that incentivize the use of contracts between MCOs and FIMC organizations to document the process for other FIMC organizations or states that may be looking to pursue this option. This study would use mixed methods, the qualitative technique would be semi-structured in-depth interviews and the

quantitative technique would be a retrospective analysis of claims data to calculate the potential cost savings.

- Design a prospective cohort study to analyze the effect of FNS services on health outcomes and healthcare utilization and costs for people with Type II Diabetes. This research could aid in evaluating a potential dose response relationship because cohorts could be given FNS services for different lengths of time. In order to participate in the study, participants would be required to go for blood work the day prior to receiving FNS services and then again, the day after FNS services ceased to reduce the likelihood of missing data. To analyze the effects on healthcare utilization and costs, healthcare claims would be assessed using the International Statistical Classification of Diseases (ICD)-10 codes to ensure that all costs related to Type II Diabetes are being captured. Finally, semi-structured in-depth telephone interviews would be conducted with FNS participants to understand the impact that FNS has had on their health and consider if the nutrition education influenced food decisions. Interviews could be coded for apriori and emerging themes.
- Perform a qualitative study to assess the perspective of FIMC organizations on the transition from using treatment with medically tailored meals to prevention through nutrition education. This study would utilize semi-structured in-depth interviews to capture the perspectives of the FIMC organizations as well as the FNS participants to determine the gaps in nutritional understanding so that materials could be tailored. All interviews would be transcribed, coded and apriori and emerging themes would be analyzed.

Each proposed study aims to provide additional evidence to help further the *Food Is Medicine* model and add to the literature through publication and presentation.

Conclusion

According to the World Health Organization and International Diabetes Federation, diabetes ranks as a leading global public health crisis due to continual increases in prevalence and health care expenditures (International Diabetes Federation, 2019; World Health Organization, 2019). The United States possesses the highest prevalence and healthcare expenditures for the treatment of this chronic disease. A systematic approach to reversing this public health issue is through policy, like Medicaid HCBS 1915(c) waivers. The current model of care for chronic disease does not take policy into account. Integrated healthcare models like the ICCC foster the development of policy to aid in the reversal of disease as well as hold stakeholders accountable for patient's health outcomes. While full implementation of the ICCC may not be possible in the U.S., elements can be put into practice to improve public health, like establishing policy waivers at the state level for diabetes.

State level policies, like Medicaid HCBS 1915(c) waivers, provide the ability to fund interventions like FNS services for people with Type II Diabetes. FNS services utilize medically tailored meals that are specifically designed to minimize the effects of chronic disease, unlike *Meals on Wheels* or *Mom's Meals*, that may be customizable but cannot address multiple chronic diseases and comorbidities. As previously stated, diabetes is a chronic disease that responds well to a diet that decreases the consumption of carbohydrates because blood glucose and insulin levels remain steady. Food can either

exacerbate or mitigate the disease to the point of remission, hence the need for implementation of the *Food Is Medicine* model in the healthcare system.

The *Food Is Medicine* model theorizes that food can be effective in the treatment of chronic disease, as though it is medicine. The model is implemented through the use of FNS services that encompass medically tailored meals and nutrition education. Limited research exists on the model that points towards efficacy, however future research studies like those suggested above could be conducted to approximate efficacy. Furthermore, if researchers are provided access to data on FNS participants then the model can be independently validated and reported in a timely manner. The *Food Is Medicine* model can be incorporated into Medicaid HCBS 1915(c) waivers seamlessly by specifying the services under the waivers must consist of medically tailored meals.

The need for strategic partnerships that include “natural allies” or “unlikely bedfellows” became evident from this study. These partnerships will provide stakeholders the opportunity for education, advocacy, and research into the *Food Is Medicine* model. Issues such as organizational capacity and scalability are identified as potential stumbling blocks. Innovative solutions can be leveraged, like partnering with a competitor (“unlikely bedfellow”) to distribute meals statewide or working with universities and colleges (“natural ally”) to assist in research or draft advocacy and education material. Additionally, the opportunity exists to incorporate the *Food Is Medicine* model into policy of states that are incentivizing contracts between MCOs and FIMC organizations to provide value-based care to beneficiaries. Inclusion of the model into any state policy has potential benefits for all stakeholders, however, to more fully

address the issue of diabetes, prevention must be made an equal priority within the model.

Two types of prevention can be addressed through the *Food Is Medicine* model: 1) prevention of comorbidities and 2) decreased likelihood of re-enrollment in FNS services. A greater emphasis needs to be placed on the nutritional education component for people with Type II Diabetes because as previously discussed food choice can mean complications of the disease or improved health. FIMC organizations could form partnerships with professional organization's that could offer capacity on nutrition education. Further research is needed to determine the dose-response relationship between the number of counseling sessions and health outcomes. An increased level of effort on prevention has the potential to reduce complications, comorbidities, healthcare utilization and cost.

In the past solutions aimed at the treatment and prevention of diabetes have been medical interventions, like pills, insulin, or surgical interventions. More recently, there has been a shift towards a more wholistic model of care, with an examination of the effect that diet has on chronic disease. Articles have been published in mainstream media questioning the role that food plays in disease and the potential solutions to the problem, some directly naming the *Food Is Medicine* model. A New York Times article entitled, "Our Food Is Killing Too Many of Us," explores the idea that "healthcare is expensive, and people are sick," and calls for the use of the *Food Is Medicine* model as one intervention to treat chronic conditions and obesity with the proper diet to reduce mortality and economic loss (Mozaffarian & Glickman, 2019). The article also suggests

the use of policy and public/private partnerships to focus on nutrition education to achieve better health outcomes and reduced healthcare costs. The research in this study seems to support similar suggestions from this article.

An article by The Washington Post discusses the use of a “food pharmacy,” where patients receive vouchers to be used at the grocery store or a “food pharmacy” for fresh produce in an attempt to get at the root cause of chronic disease like diabetes through diet (Nirappil, 2019). The article cites the *Food Is Medicine* model, however, also encourages medication compliance to help see a return on investment. It also profiles other “food pharmacies” throughout the country that are placing an emphasis on the nutrition education component of the model. In Pennsylvania, the article highlighted a “Fresh Food Pharmacy” program by an insurer to provide fresh produce, cooking demonstration and diabetes management lessons to 700 beneficiaries (Nirappil, 2019). An insurance executive had this to say about the “Fresh Food Pharmacy”:

“It’s kind of a no-brainer,” Hess said. “We are going to either pay for this medical expense or pay for this food and education that’s going to be more of a lifelong benefit.”

While “food pharmacies” are not FNS services they serve as a step in the right direction towards implementation of the *Food Is Medicine* model’s prevention component.

Main-stream media are not the only ones suggesting the role of *Food Is Medicine* in healthcare. In a recent podcast, *Tradeoffs*, sponsored by The University of Pennsylvania, the Robert Wood Johnson Foundation and the California Healthcare Foundation, bring issues related to healthcare, policy, and people to the spotlight using evidence. The

episode entitled, “Feeding the Sick,” profiles the use of medically tailored meals as an intervention to treat chronic disease through vignettes with stakeholders, similar to the ones included in this research: a FIMC organization, an FNS participant, and a policymaker (Gorenstein, 2019). Each stakeholder provided their opinion on the advantages and disadvantages of the intervention, especially for the policymaker she was clear that this intervention would only be provided to a specific population in her state. The policymaker did highlight a pilot program being conducted by the state to implement the intervention, which could have implications for policy.

The *Food Is Medicine* model is gaining acceptance as both a treatment and prevention option for people with chronic diseases like diabetes. To amplify that acceptance, a more systematic approach is needed through the development and implementation of policies. The results reported in this study suggest a pathway for stakeholders to advocate and educate one another on how to incorporate the model into Medicaid HCBS 1915(c) waiver policy. The use of strategic partnerships will help to address the roadblocks identified, for example staffing capacity or the ability to scale current operations. Opportunities for independent research of health outcomes, healthcare utilization, and costs need to be created to ensure that results are validated.

Without drastic interventions, the prognoses for populations diagnosed with chronic diseases, such as Type II Diabetes and those at risk for developing this disease, are dire and grim. In order to improve the outlook for the chronically ill, the *Food Is Medicine* model must be adopted and institutionalized as a premier treatment and prevention model for chronic diseases among stakeholders. The consistent engagement of stakeholders is

essential to incorporating the model into Medicaid HCBS 1915(c) waiver policy. The implications of the model are profound for Type II Diabetes and chronic diseases overall, through restored health and ameliorated complications and comorbidities in conjunction with reductions in healthcare utilization and costs. The treatment and maintenance of diabetes requires more than the current standard of care, it demands solutions that are “outside of the pill bottle.” Policy solutions are one way to address this challenge because they can be customized for specific purposes, like diabetes or other chronic illnesses. Medicaid HCBS 1915(c) waivers offer policy solutions that are flexible and adaptable to reinforce non-medicalized treatments, such as medically tailored meals and nutrition education. Implementation of Medicaid HCBS 1915(c) waivers increases the possibility of securing a healthier future for those affected by diabetes and chronic disease.

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Appendix A: Methodological Quick Reference Chart

Method	Sub-question(s)	Supports main research question	Advantages of choosing this method	Disadvantages of choosing this method
Medicaid waiver content analysis	1. Is there a correlation between the state Medicaid waivers that support FNS and the political parties that drafted these waivers? 2. What is the frequency of Medicaid waivers implemented by political party? 3. Within Medicaid waivers, what language supports FNS for people with Type II Diabetes?	• Provides a retrospective cross-sectional snapshot of Medicaid HCBS 1915(c) waivers that were implemented prior to 2017 • Latent content analysis will explore the apriori and emerging themes that will be helpful to stakeholders seeking reimbursement for FNS under Medicaid • Examines the number of waivers that were implemented between the period of 1981 and 2016 to assess the influence that political party plays on waiver implementation	• Relatively unobtrusive form of data collection • Cost effective • Longer retrospective period	• Reliant on previously recorded text, interviews, audio, etc., on topic • Does not allow you to establish causal relationships
Semi-structured in-depth telephone stakeholder interviews	Policymakers: 1. How do policymakers choose to support FNS for people with Type II Diabetes?	• Captures stakeholder role in policymaking and advocacy of FNS for people with Type II Diabetes	• Cost effective • Reduced data collection time compared to in-person interviews	• Rapport building is more difficult • Non-verbal and visual cues cannot be collected

Method	Sub-question(s)	Supports main research question	Advantages of choosing this method	Disadvantages of choosing this method
	2. What factors influence their support or non-support of policies for FNS? Medicaid Insurers: 1. What was the decision process for deciding to partner with an FNS provider? Food Is Medicine Coalition (FIMC): 1. What role does FIMC membership play in individual FIMC organizations? FNS Participants: 1. What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes? 2. What role do FNS participants perceive their medically tailored home-delivered meals play in their ability to address their Type II Diabetes?	• Identify factors that influence support or non-support of policies for FNS • Examine the decision-making process of a stakeholder who chooses to partner with another stakeholder for FNS • Explore the opportunities and challenges that stakeholders face during advocacy work • Assess stakeholder knowledge about nutrition relative to Type II Diabetes • Provide direct evidence of stakeholder support for Food Is Medicine	• Inclusion of more geographically diverse sample • Scheduled at convenience of participant • Potential for reduced social desirability compared to in-person interviews and focus groups • Provides thick and rich descriptive data • Ability to alter the protocol	• Participant can terminate the interview at any time • Participant may not give as in-depth answers

Method	Sub-question(s)	Supports main research question	Advantages of choosing this method	Disadvantages of choosing this method
Quantitative Analysis Of Health Outcomes And Healthcare Utilization And Costs	1. Does providing 12 weeks of FNS to high-risk beneficiaries have an effect on hemoglobin A1c? 2. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on lipid panels? a. Is there are difference in low-density lipoprotein (LDL) levels after 12 weeks of FNS? b. Is there a difference in high-density lipoprotein (HDL) levels after 12 weeks of FNS? c. Is there a difference in triglyceride levels after 12 weeks of FNS? 3. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on healthcare utilization, specifically emergency room visits, inpatient visits, and total hospital visits?	• Testing a methodological approach on how to design a study to measure the effectiveness of the <i>Food Is Medicine</i> model • Provide evidence to support the use of medically tailored meals and nutrition education to reduce healthcare costs and improved health outcomes	• Pre-and-post outcomes are measured at the same time • Cross-sectional studies are cost effective • Cross-sectional studies can calculate prevalence, relative risk, and odds ratio for outcomes of interest	• Difficult to determine causal relationships between factor in cross-sectional studies • Confounding may exist in cross-sectional studies • Disease trends cannot be assessed through cross-sectional studies.

Method	Sub-question(s)	Supports main research question	Advantages of choosing this method	Disadvantages of choosing this method
	4. Does providing 12 weeks of FNS to high risk beneficiaries have an effect on healthcare costs, specifically emergency room visit costs, inpatient visit costs, and total healthcare costs?			

Appendix B: Semi-Structured Interview Protocols

Policymaker Stakeholder Telephone Interview Script

This interview script is a part of a larger qualitative study that will examine stakeholder's roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes. The questions that will be addressed by these interviews are:

1. How do policymakers choose to support FNS for people with Type II Diabetes?
2. What factors influence their support or non-support of policies for FNS?

Within each state government, policymakers initiate the Medicaid waiver process. Yet, little is known about how policymakers choose to support FNS or the factors that influence their support or non-support of policies for FNS for people with Type II Diabetes. Semi-structured in-depth telephone interviews will allow policymakers and/or their staff members to report about the advocacy work they are engaged in or would like to be to support FNS at the state level. The ability to record this information from policymakers and/or their staff members will give other stakeholders more information on the types of materials or aides that might be helpful to this group when they are engaged in advocacy. The information gathered from those questions could create opportunities for stakeholders to partner with each other to further enhance FNS advocacy.

The purpose of these interviews is to identify factors that either motivate or dissuade policymakers from supporting/non-supporting FNS policies for people with Type II Diabetes. Through theme analysis as a result of these interviews, the emergence of

potential factors that influence policymakers may be detected as well as the assessment of the role that politics plays in this process.

In-Depth Interview Script

Thank you for speaking with me. My name is Amanda Reiter, and I am a PhD candidate in the Health Policy Department at the University of the Sciences in Philadelphia. I am interested in learning about the role of policymakers in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes.

The information you share with me is confidential, meaning it will not be shared with anyone besides me and my assistant. My notes from our discussion will describe your thoughts and opinions, but will not identify you by name. When I report the information, it will either be reported as, “a group of participants suggested...” or “a respondent said.” The name of your state or any identifying information will be left out of a direct quote in order to maintain confidentiality. Please understand I really appreciate your responses and your participation in this interview is voluntary.

I am recording our discussion so that I can direct my full focus to your answers and to this conversation. By having my full attention towards your responses, I can listen to the recording later for analyzing what you said. No one except me and my assistant will have access to the recording. If you want to say something that you do not want recorded, please let me know and I will be happy to pause the recorder. Do I have your verbal consent to record the interview?

Now that I have explained the nuts and bolts of the process and what will be done with your answers, do you have any questions before we get started?

[Pause]

Please tell me your full name, your email address and phone number in case we get disconnected or I have any follow up questions. [Pause] Thank you.

Contact Info and Role

- Please tell me about your role:
 - What is your title?
 - How long have you been in this position?
 - Why did you choose this profession?

Medicaid Waiver

- Now we are going to talk about Medicaid waivers. Medicaid waivers are a policy tool that allow states to provide services that fall outside of the standard benefits, for example Food Nutrition Services.
- In a word or phrase please tell me about your experience with Medicaid waivers.
 - Why did you choose that word or phrase?
- If experienced:
 - How did you become involved with waivers?
 - Was it through the Centers for Medicare and Medicaid Services (CMS)?
 - Was it through a Food Nutrition Service (FNS) provider?
 - Was it through the Food Is Medicine Coalition?
 - Or was it some other way?

- Please describe your experience with waivers:
 - What was your role in the waiver?
 - What factor(s) caused you take part in the waiver?
 - Were you involved in drafting or submitting the waiver form to CMS?
 - ✓ If yes, were there any resources you consulted when drafting the waiver application?
 - Did you consult with other policymakers who had previously submitted a form?
 - Why or why not?
 - Please rate the level of difficulty in filling out the waiver application form on a scale from 1 to 10. 1 being very difficult and 10 being not at all difficult.
 - Why did you choose that number?
 - ✓ If not, tell me about the staff that worked on the waiver application:
 - What is their position(s)?
 - Approximately how many hours did they typically spend on a waiver?
 - Did you feel affected in any way?
 - Why or why not?
 - Was the waiver for a specific health condition or disease, for example HIV/AIDS, Cancer or Diabetes?

- How would you rate your overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.
 - ✓ Why did you choose that number?
- If inexperienced:
 - Would you like to become involved with waivers to provide non-traditional services for beneficiaries?
 - Why or why not?
 - ✓ Why: How do you think you could become involved with waivers?
- What percent out of 100 would you say it is your duty to advocate on behalf of Medicaid beneficiaries?
- In your opinion do you feel that Medicaid waivers have affected beneficiaries' health outcomes?
 - Why or why not?
- Do you think Medicaid waivers for FNS have either positively or negative impacted your states' Medicaid budget?
 - Why or why not?
- Do you think FNS should be a traditional Medicaid benefit in your state?
 - If not, are there policy alternatives that you prefer?
 - Why?
 - On a scale from 1 to 10 how likely do you think it would be for FNS to become a traditional Medicaid benefit? 1 being very unlikely and 10 being very likely.

- What role do you believe that politics plays in your response?
- Those are all of the questions I have for you today. Do you have any questions for me? When I finish my research, would you like a copy of my results? (Pause)
Thank you very much for your time and helping me with my research.

Medicaid Insurer Stakeholder Telephone Interview Script

This interview script is a part of a larger qualitative study that will examine stakeholder's roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes. The questions that will be addressed by these interviews are:

1. What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?
2. What was the decision process for deciding to partner with a FNS provider?

This first question seeks to understand the roles of Medicaid Insurers within Medicaid waiver policy to support reimbursement of their services for people with Type II Diabetes.

Medicaid Insurers often are perceived as “middlemen” between CMS and the FNS providers to facilitate FNS for people with Type II Diabetes, juxtaposed against any of their own corporate agendas. Semi-structured in-depth telephone interviews address the sub-question by aiming to understand at the organizational level what decision-making process was followed when deciding to form a partnership with an FNS provider. This data will be useful for FNS providers as well as other Medicaid Insurers that may be looking into starting an agreement with an FNS provider. Moreover, these interviews will illuminate the challenges and opportunities that Medicaid Insurers are presented with when engaging in such agreements with CMS and FNS providers.

In-Depth Interview Script

Thank you for speaking with me. My name is Amanda Reiter, and I am a PhD candidate in the Health Policy Department at the University of the Sciences in

Philadelphia. I am interested in learning about the role of Medicaid Insurers in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes and understanding your organizations process for deciding to partner with a Food Nutrition Service (FNS) provider.

The information you share with me is confidential, meaning it will not be shared with anyone besides me and my assistant. My notes from our discussion will describe your thoughts and opinions, but will not identify you by name. When I report the information, it will either be reported as, “a group of participants suggested...” or “a respondent said.” The name of your state or any identifying information will be left out of a direct quote in order to maintain confidentiality. Please understand I really appreciate your responses and your participation in this interview is voluntary.

I am recording our discussion so that I can direct my full focus to your answers and to this conversation. By having my full attention towards your responses, I can listen to the recording later for analyzing what you said. No one except me and my assistant will have access to the recording. If you want to say something that you do not want recorded, please let me know and I will be happy to pause the recorder. Do I have your verbal consent to record the interview?

Now that I have explained the nuts and bolts of the process and what will be done with your answers, do you have any questions before we get started?

[Pause]

Please tell me your full name, your email address and phone number in case we get disconnected or I have any follow up questions. [Pause] Thank you.

Contact Info and Role

- Please tell me about your current role at your organization:
 - How long have you been in this position?
 - What type(s) of Medicaid clients do you typically serve?
 - About how many clients are enrolled in your plans?

Medicaid Waiver

- Now we are going to talk about Medicaid waivers. Medicaid waivers are a policy tool that allow states to provide services that fall outside of the standard benefits, for example Food Nutrition Services.
- In a word or phrase please tell me about your organization's experience with Medicaid waivers.
 - Why did you choose that word or phrase?
- If experienced:
 - How did your organization become involved with waivers?
 - Was it through a State Congressman, Senator or Medicaid Director?
 - Was it through the Centers for Medicare and Medicaid Services (CMS)?
 - Was it through a Food Nutrition Service (FNS) provider?
 - Or was it some other way?
 - Please describe your organization's experience with waivers:
 - What was your organization's role in the waiver?
 - Was the waiver for a specific health condition or disease, for example HIV/AIDS, Cancer or Diabetes?

- Were there any restrictions placed on your organization in terms of the providers that you could partner with?
- Were there restrictions around the reimbursement to providers?
 - ✓ If so, please describe them.
 - How did your organization feel about these restrictions?
 - On a scale of 1 to 10 how difficult was it to comply with these rules? 1 being very difficult and 10 being not at all difficult. What number would you say?
 - Why did you pick that number?
- How would you rate your organization's overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.
 - ✓ Why did you choose that number?
- Tell me about the staff that worked on the waivers:
 - What is their position(s) in your organization?
 - Approximately how many hours did they typically spend on a waiver?
 - ✓ Did your organization feel affected in any way?
 - Why or why not?
- If inexperienced:
 - Would your organization like to become involved with waivers to provide non-traditional services for beneficiaries?
 - Why or why not?
 - How do you think your organization could become involved with waivers?

Decision Process for Partnership with FNS Provider

Now we are going to talk about your organization's decision-making process to enter into a partnership with a Food Nutrition Service (FNS) provider.

- At the start of the process, was the process altered depending on who was proposing the partnership? For example, is the process different if a state senator proposes it or if a FNS provider proposes it.
 - What do you think is the cause of this difference?
 - Why?
- What FNS provider factors are assessed prior to decision making?
 - Size of the agency?
 - Types of health conditions or population served?
 - Number of individuals served?
 - Financial health of agency?
 - Any other factors?
- Are separate internal meetings held when making this decision?
 - If so, how many?
 - Do you feel these meetings are productive?
- Are meetings held with the prospective partner(s)?
 - If so, how many?
 - Are agencies allowed to make presentations?
 - Do you feel these meetings are productive?
- What departments are involved in drafting the agreement?

- Contracts?
- Legal?
- Corporate compliance?
- Accounting?
- Who makes the final decision to form the partnership?
 - Management?
 - CEO or COO?
 - Executive Board or Board of Trustees?
 - On average how long does it take for the decision process to be complete and the partnership implemented?
- On a scale from 1 to 10 how would you rate your organization's internal process for deciding to partner with an FNS provider? 1 being very difficult and 10 being not at all difficult.
 - Why did you choose that number?
 - Do you think the process could be improved?
 - ✓ If so, how?
- Has your organization seen any financial impact due to the FNS partnerships?
 - Why or why not?
- In your personal opinion, do you think that the decision to partner with FNS providers has affected beneficiary's health?
 - Why or why not?

- Those are all of the questions that I have for you today. Do you have any questions for me? I would like to thank you for your time in helping me with my research.

FIMC Stakeholder Telephone Interview Script

This interview script is a part of a larger qualitative study that will examine stakeholder's roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes. The questions that will be addressed by these interviews are:

1. What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes?
2. What role does FIMC membership play in individual FIMC organizations?

This first question seeks to understand the roles of FIMC organizations within Medicaid waiver policy to support reimbursement of their services for people with Type II Diabetes. It will also explore the opportunities and challenges they encounter with their advocacy work.

The second sub question focuses upon the FIMC organization to assess what each organization gets from participating in the coalition. Often, professional organizations use institutional and organizational theory to further the influence of their professional membership. The goal of this sub question is to assess if that is a possibility through the FIMC umbrella organization. These interviews will be conducted over the phone as a semi-structured interviews beginning in early 2018.

In-Depth Interview Script

Thank you for speaking with me. My name is Amanda Reiter, and I am a PhD candidate in the Health Policy Department at the University of the Sciences in Philadelphia. I am interested in learning about [Insert FIMC agency]'s role in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II

Diabetes, [Insert FIMC agency]'s advocacy work and membership in the Food Is Medicine Coalition (FIMC).

The information you share with me is confidential. Confidential means that your answers will be will not be shared with anyone besides myself and an assistant. My notes from the discussion will describe your thoughts and opinions, but will not identify you by name. Your participation is voluntary.

I am recording our discussion so that I can direct my focus to your answers to my questions. Additionally, I can listen to the recording later for analyzing what you said. No one except me and my assistant will have access to the recording. If you want to say something that you do not want recorded, please let me know and I will be happy to pause the recorder. Do I have your verbal consent to record the interview?

Now that I explained the nuts and bolts, do you have any questions before we get started? [Pause]

Please tell me your full name, your email address and phone number in case we get disconnected or I have any follow-up questions. [Pause] Thank you.

Contact Info and Role

- Please tell me about your current position at your agency:
 - How would you describe this position?
 - How long have you been in this position?
 - Why did you choose this field of work?
 - What types of clients does your agency serve?
 - About how many meals a year does your agency serve?

Medicaid Waiver

- Now we are going to talk about Medicaid waivers. Medicaid waivers are a policy tool that allow states to provide services that fall outside of the standard benefits, for example Food Nutrition Services.
- In a word or phrase please tell me about your agency's experience with Medicaid waivers.
 - Why did you choose that word or phrase?
- If experienced:
 - How did your agency become involved with waivers?
 - Was it through a State Congressman, Senator or Medicaid Director?
 - Was it through a Medicaid insurance company?
 - Please describe your agency's experience with waivers:
 - Was the waiver for a specific health condition or disease, for example HIV/AIDS, Cancer or Diabetes?
 - What was your agency's role in the waiver?
 - Did your agency receive money in exchange for services?
 - ✓ Were there any rules in place in order to receive money for services?
 - If so, please describe them.
 - How did your agency feel about these rules?
 - On a scale of 1 to 10 how difficult was it to comply with these rules? 1 being very difficult and 10 being not at all difficult. What number would you say?

- Why did you pick that number?
 - How would you rate your agency's overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.
 - Why did you choose that number?
- Tell me about the staff that worked on the waivers:
 - What is their position in your agency?
 - How many hours did they typically spend on a waiver?
 - ✓ Did your agency feel affected in any way?
 - Why or why not?
- If inexperienced:
 - Would your agency like to become involved with waivers to pay for services?
 - Why or why not?
 - How do you think your agency could become involved with waivers?
 - What types of advocacy resources does the agency have?
 - ✓ Would any of those resources be able to work on waivers?
 - If not, why not?

Advocacy

Now we are going to talk about your agency's advocacy work.

- What type of advocacy work does your agency do?
 - Do you advocate for your clients, agency, or both?
 - Do you hold advocacy events?

- What types of events?
 - ✓ Is the community involved?
 - What overall rating would you give your advocacy events on a scale from 1 to 10? 1 being poor and 10 being excellent.
 - ✓ Why did you choose that number?
- Does your agency advocate at the state level?
 - What activities do you do?
 - Does your agency call or email State Congressmen and/or Senators?
 - What effect, if any, do you think these efforts have?
 - Does your agency hold face-to-face meetings with State Congressmen and/or Senators?
 - What effect, if any, do you think this effort has?
 - Do you think that phone and email are more or less effective than face-to-face meetings?
- Does your agency advocate at the federal level?
 - What activities do you do?
 - Does your agency call or email Congressmen, Senators or Agency Directors?
 - What effect, if any, do you think these efforts have?
 - Does your agency hold face-to-face meetings with Congressmen, Senators or Agency Directors?
 - What effect, if any, do you think this effort has?

- Do you think that phone and email are more or less effective than face-to-face meetings?

FIMC Membership

Now we are going to talk about the Food Is Medicine Coalition.

- In a word or phrase please tell me about your agency's membership in FIMC.
 - Why did you choose that word or phrase?
- Tell me about how your agency first learned about the Food Is Medicine Coalition.
 - When did your agency become a member?
 - What FIMC activities does your agency take part in?
 - Weekly calls?
 - Petitions?
 - National Advocacy Day on Capitol Hill?
 - National Conference?
- Does your agency receive any direct benefit from FIMC membership?
 - How does your agency view FIMC membership benefits?
- How does your agency feel about FIMC's goals?
 - Are there ever times where your agency disagrees with the goals of FIMC?
 - If yes, did your agency do anything about it?
 - Does your agency believe that FIMC will achieve its goals?
 - Why or why not?

Other Stakeholders

- I am also interested in speaking with other stakeholders such as state policymakers and Medicaid Insurers. Do you or your organization have relationships with either stakeholder?
 - If yes, if you think they would be amenable to take part in this research would you provide their contact information? [Pause]
- Those are all of the questions that I have for you. Do you have any questions for me? Thank you very much for your time and helping me with my research.

FNS Participant Telephone Interview Script

This interview script is a part of a larger qualitative study that will examine stakeholder's roles in Medicaid waiver policies to support Food Nutrition Services (FNS) for people with Type II Diabetes. The sub-questions that will be addressed by these interviews are:

1. What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?
2. What role do FNS participants perceive their medically tailored home-delivered meals play in their ability to address their Type II Diabetes?

Exploring FNS Type II Diabetes participants' perceptions about the role food plays in their ability to address their Type II Diabetes three months post FNS services may expose gaps in nutritional education provided by [FNS Provider]. To be able to understand nutrition from a non-clinical persons' perspective could lead to meaningful insights that generate a better nutrition education component of the FNS program.

The second sub-question will gain insight into whether FNS participants view the food that they are receiving as medicine in order to control or improve their type II diabetes. The purpose in asking this question is to provide direct evidence from the FNS participants as stakeholders supporting the concept of food is medicine. If FNS participants believe the food that they are receiving is medicine than this intervention should be paid for by Medicaid. The use of this intervention to treat type II diabetes has the potential to reduce costs to Medicaid while improving health outcomes for persons diagnosed with Type II Diabetes.

These interviews will be conducted over the phone as a semi-structured interview three months after cessation of FNS services.

In-Depth Interview Script

Thank you for speaking with me. My name is Amanda Reiter, and I am a PhD candidate in the Health Policy Department at the University of the Sciences in Philadelphia. I am interested in learning about [FNS Provider] participant's health, Type II Diabetes, and the [FNS Provider] meals they received.

The information you share with me is confidential. Confidential means that your answers will not be shared with anyone besides myself and a coder. My notes from the discussion will describe your thoughts and opinions, but will not identify you by name. I am recording our discussion so that I can listen to it later to make sure I have captured your answers correctly in my notes. No one except me and the coder will have access to the recording. If you want to say something that you do not want recorded, please let me know and I will be happy to pause the recorder. Do I have your verbal consent to record the interview?

Do you have any questions before we get started?

Prior to Receiving FNS Services

- Please think back to the time before you received [FNS Provider] meals and services. In a word or phrase, how would you describe your health BEFORE [FNS Provider] meals?
 - Why did you pick that word/phrase?

- Now think about the [insert number of months] months since your last [FNS Provider] meal, in a word or phrase how would you describe your health now?
 - Why did you pick that word/phrase?
- Please describe what your body feels like when you feel healthy.
 - How did you define healthy?
- Over the last [insert number of months] months, how would you compare your health now to when you were receiving [FNS Provider] meals?
- Please tell me a little about your Type II Diabetes:
 - When were you told you have Type II Diabetes? (If needed: What age were you? Or what year?)
 - How did this diagnosis make you feel?
 - Who did you tell?
 - PROBE: Family or friends?
 - Do you face any challenges coping with your diabetes?
 - Are you able to resolve them? If so, how?
- Now we are going to talk about food. Please think about your diet and the foods you eat now.
 - Do you follow a certain diet? If so, why?
 - How long have you been eating this way?
 - What types of foods do you usually eat for breakfast?
 - What do you usually eat for lunch?
 - Tell me about a typical dinner you would eat.

- How often do you eat outside of your home?
 - What types of restaurants do you eat at?
 - How do you choose which restaurant to eat at?
- When you are craving a snack, what do you typically eat?
 - Would you describe this food as healthy or unhealthy? Why?
- On a scale from 1 to 10, how would rate the quality of your diet?
 - Why did you choose that number?
- Are there any foods that you eat now that you **didn't** eat before receiving [FNS Provider] meals?
 - If yes, what type(s) of foods?
 - ✓ Why do you eat [insert food(s)] now?
- How often do you eat a meal?
 - How do you feel after you eat?
 - Do you eat in between meals?
 - Do you feel different after eating certain foods?
 - Do you notice changes in your blood sugar? (If monitoring)
- Where do you buy the food you eat?
 - How would you describe the quality of the food you buy?

FNS Meals

- Now we are going to talk about the home-delivered meals you received from [FNS Provider]. Please think only about the meals you received from [FNS Provider] and then describe a meal

- What were the main components of the meal?
- How would you describe the size of the meals?
- How did the meals taste?
- What was your favorite meal? Why?
- Was there a type of meal you wished you could have more of? Why?
- Were you on a special diet with the [FNS Provider] meals?
 - Probe: did you meals have a dot?
- If so, do you think [FNS Provider] meals had an effect on your Type II Diabetes?
- Were there changes in your activity level?
- Were there any changes in how much you move during the day? Do you exercise at least once a day, every other day, 1 or 2 days a week?
- Do you think there were changes in your energy level?
- Were there any changes in your mental state? On a fuzziness scale from 1 to 10 how would you rate your mental ability?
- Were there any changes to the medicine(s) you take?
- Were there any changes in the number of times you went to the doctor?
- Were there any changes in the number of times you went to the hospital?
- After having [FNS Provider] meals, how would you rate your health?
- If you had to rate the role [FNS Provider] meals played in your health, what number would you choose? 1 being worst and 10 being best
 - Why did you choose that number?

- Please imagine that you **did not** receive [FNS Provider] meals, how would you have described your health?
 - How does that make you feel?
 - What role do you think food plays with Type II Diabetes?
 - Why do you feel that way?
 - Do you think food can be as helpful as medicine?
 - Why or why not?
 - If you met someone with Type II Diabetes, what would say about [FNS Provider] meals and services?
 - If you think [FNS Provider] services are helpful, who do you think should pay for them?
 - Those are all of the questions that I have for you. Do you have any questions for me?
- Thank you very much for you time. I am going to confirm your address to be sure that I am mailing your gift card to the correct address. [Relay information and make corrections if needed] Thanks again and have a great day/afternoon/evening.

Appendix C: Medicaid HCBS 1915c Waiver Codebook

Variable Name	Variable Type	Variable Definition	Descriptive Statistics	Notes
Numberof1915cwaivers	Nominal	0-1000	This variable will be used to create a frequency of the number of waivers by state	This will be the number of 1915(c) waivers by state as of 2017. According to CMS on average states operate 6.6 waivers. There are 3 states that do not operate 1915(c) waivers: 1) Arizona, 2) Rhode Island, 3) Vermont. These 3 states chose to expand Medicaid
MedicallyTailoredMeals	Dichotomous	Yes, No	This will be used to establish the number of times the word appears in the waivers	
HomeDeliveredMeals	Dichotomous	Yes, No	This will be used to establish the number of the word appears in the waivers	
Dietary services	Dichotomous	Yes, No	This will be used to establish the number of the word appears in the waivers	
TypeIIDiabetes	Dichotomous	Yes, No	This will be used to establish the number of the word appears in the waivers	

Variable Name	Variable Type	Variable Definition	Descriptive Statistics	Notes
SSI_FederalBenefitRate	Nominal	% of FPL	This will be used to create a frequency of thresholds for the country	
Waiver_ReportingRequirement	Categorical	Weekly, monthly, quarterly, annually	This will help to determine the frequency of reporting for waivers	According to CMS, all waivers must submit yearly reports, however the states can specify more frequent reporting by service
Waiver_DiseaseType	Categorical	Physical disabilities, developmental disabilities, HIV/AIDS, Mental health, Pediatric, Intellectual disabilities, Traumatic brain injury, Autism, Serious Emotional Disturbance, Elderly (Frail), Family support, Adult day care, Long Term Care, Medically Fragile (Children and/or Adults), Chronic disease	This will be used to quantify the types of waivers that currently exist	
Waiver_Period	Dichotomous	3 years, 5 years	This will be used to determine how many 3- and 5-year waivers exist throughout the country	

Variable Name	Variable Type	Variable Definition	Descriptive Statistics	Notes
TitleofWaiverApplicant	Categorical	Director, Associate Director, Long Term Care Specialist	This may be useful for stakeholder to target advocacy future advocacy efforts	
Proposed#ofUnduplicatedWaiverParticipants	Nominal	0-infinity	This will be used to create a frequency of proposed waiver participants to assess the size of waiver programs throughout the country	
Ageofwaiverparticipants	Categorical	Under 65 years old, Over 65 years old, both	This will help to determine the age of the population that waivers are aimed to serve	
CostNeutral	Dichotomous	Yes, No	This will help to serve as a count of how many waivers are cost neutral and those that are not	
ReasonsforCMSTermination	Categorical	Health and welfare of waiver participants has been jeopardized, Waiver was not cost neutral, State did not submit required annual reports, Accurate financial records have not been maintained to document the cost of waiver services, Waiver has not operated in a manner consistent with approved waiver, Waiver	This variable will be will used to determine the reason for CMS termination of a waiver	

Variable Name	Variable Type	Variable Definition	Descriptive Statistics	Notes
		has not been operating in accordance with other Federal requirements		
StateMedicaidEligibilityType	Categorical	1634 state, SSI-criteria, 209(b)	This variable will be used see if there is variation among the states in terms of eligibility	A 1634 state is one where the Social Security Administration determines the Medicaid eligibility and residents do not have fill out a separate Medicaid application; SSI-criteria: SSI beneficiaries automatically get Medicaid but they must fill out a separate application; 209(b): State applies stricter rules eligibility rules for Medicaid
MillerTrust	Dichotomous	Yes, No	This will be used to determine if the state has an eligibility based in a Miller Trust	

Variable Name	Variable Type	Variable Definition	Descriptive Statistics	Notes
FrequencyofWaiverService	Categorical	Daily, weekly, monthly, quarterly, annually	This variable will be used to categorize how often waiver services are provided to participants	
ServiceWavierType	Categorical	Statutory services, Other services, Extended state plan services	This will be helpful to know which type of services the waiver services fall under to see if there is a common theme	
PaymentServiceProvidersMMIS	Dichotomous	Yes, No	This variable will be used to determine how the state pays waiver service providers either through MMIS or not	

Appendix-D: Semi-structured Stakeholder Interview Codebook

Code	Definition	Rules	Research Question	Interview Question
FIMC Stakeholders				
Parent Node: Role				
FIMC.Role	Description of position in the organization		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How would you describe this position?
FIMC.RoleResponsibilities	Description of respondent's responsibilities		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How would you describe this position?
FIMC.RoleLength	How many months/years are they in their current position		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How long have you been in this position?
FIMC.RoleWhy	Description of what lead the respondent to choose this field of work		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Why did you choose this field of work?
FIMC.RoleAgencyClients	Description of the types of clients the agency serves		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What types of clients does your agency serve?

Code	Definition	Rules	Research Question	Interview Question
FIMC.RoleNumMealsServ	Description of the number of meals the agency serves per year		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	About how many meals a year does your agency serve?
Parent Node: Medicaid Waivers				
FIMC.MWExperience	Description of the respondent's experience with Medicaid waivers	Include the reason why they chose the word or phrase in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	In a word or phrase please tell me about your agency's experience with Medicaid waivers.
FIMC.MWExpInvolve	Description of how the agency became involved with waivers	Include if it was another stake holder group, like policymaker or Medicaid Insurer	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How did your agency become involved with waivers?
FIMC.MWExpHealth	Description of the waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Was the waiver for a specific health condition or disease, for example HIV/AIDS, cancer, or diabetes?
FIMC.MWExpRole	Description of agency's role in the waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What was your agency's role in the waiver?
FIMC.MWExpPayment	Description of payment for services under the Medicaid Waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Did your agency receive money in exchange for services?

Code	Definition	Rules	Research Question	Interview Question
FIMC.MWExpPayRule	Description of rules around reimbursement for services under Medicaid waiver	Include any description of the rules in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Were there any rules in place in order to receive money for services?
FIMC.MWExpPayRuleFeel	Description of how the agency felt about the rules surrounding reimbursement for services		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How did your agency feel about these rules?
FIMC.MWExpPayRuleComply	Number from 1 to 10 on difficulty of complying with rules for reimbursement	Include the reason why they chose the number in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	On a scale from 1 to 10, how difficult was it to comply with these rules? 1 being very difficult and 10 being not at all difficult
FIMC.MWExpOverExp	Number from 1 to 10 on agency's overall experiences with waivers	Include the reason why they chose the number in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How would you rate your agency's overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.
FIMC.MWExpStaff	Description of the staff that work on waivers		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What is their position in your agency?

Code	Definition	Rules	Research Question	Interview Question
FIMC.MWExpStaffHours	Description of the number of hours they spend on a waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How many hours did they typically spend on a waiver?
FIMC.MWExpStaffAffect	Description of the time spent on waivers affecting the agency	Include the reason why or why not	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Did your agency feel affected in any way? Why or why not?
FIMC.MWInexpBecomeInvolved	Description of the agency's wanting to become involved with waivers	Include the reason why or why not	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Would your agency like to become involved with waivers to pay for services? Why or why not?
FIMC.MWInexpHowInvolve	Description of how the agency could become involved with waivers		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How do you think your agency could become involved with waivers?
FIMC.MWInexpHowInvolveAdvocacy	Description of advocacy resources at the agency	Include if those resources could work on waivers, why or why not?	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What types of advocacy resources does the agency have?
Parent Node: Advocacy				
FIMC.AdvType	Description of what type of advocacy work the agency does		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What type of advocacy work does your agency do

Code	Definition	Rules	Research Question	Interview Question
FIMC.AdvWho	Description of who they advocate for		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you advocate for your clients, agency or both?
FIMC.AdvEvents	Description of advocacy events	Include type of event and if the community is involved	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you hold advocacy events?
FIMC.AdvEventRate	Number from 1 to 10 on overall rating of advocacy events	Include why they chose that number	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What overall rating would you give your advocacy events on a scale from 1 to 10? 1 being poor and 10 being excellent?
FIMC.AdvStateLevel	Description of advocacy at the state level	Include activities that they do	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does your agency advocate at the state level? What activities do you do?
FIMC.AdvStateContact	Description of contact with State Congressmen and/or Senators		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does your agency call or email state congressmen and/or senators
FIMC.AdvStateContactEffect	Description of the perceived effect contact with State Congressmen and/or Senators		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What effect, if any do you think these efforts have?

Code	Definition	Rules	Research Question	Interview Question
FIMC. AdvStateContactFace	Description of face-to-face contact State Congressmen and/or Senators		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does your agency hold face-to-face meetings with State Congressmen and/or Senators?
FIMC.AdvStateContactFace Effect	Description of the perceived effect face-to-face contact with State Congressmen and/or Senators		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What effect, if any do you think this effort has?
FIMC.AdvStateContactEffective	Description of which mode of contact is best for State Congressmen and/or Senators		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you think that phone and email are more or less effective than face-to-face meetings?
FIMC.AdvFedLevel	Description of advocacy at the Federal level	Include activities they do	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does your agency advocate at the federal level?
FIMC.AdvFedContact	Description of contact with Congressmen, Senators or Agency Directors		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does you agency call or email Congressmen, Senators, or Agency Directors?
FIMC.AdvFedContactEffect	Description of the perceived effect contact with Congressmen, Senators or Agency directors has		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What effect, if any, do you think these efforts have?

Code	Definition	Rules	Research Question	Interview Question
FIMC.AdvFedContactFace	Description of face-to-face contact with Congressmen, Senators, or Agency Directors		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Does your agency hold face-to-face meetings with Congressmen, Senators or Agency Directors?
FIMC.AdvFedContactFaceEffect	Description of the perceived effect face-to-face contact with Congressmen, Senators or Agency Directors		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What effect, if any, do you think this effort has?
FIMC.AdvFedContactEffective	Description of which mode of contact is best for Congressmen, Senators, or Agency Directors		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you think that phone and email are more or less effective than face-to-face meetings?
Parent Node: FIMC Membership				
FIMC.FIMCMembership	Description of agency's membership in FIMC	Include the reason why in this code	What role does FIMC membership play in individual FIMC organizations?	In a word or phrase tell me about your agency's membership in FIMC
FIMC.FIMCBecomeMember	Description of how the agency first learned about FIMC	Include how long they have been a member	What role does FIMC membership play in individual FIMC organizations?	Tell me about how your agency first learned about the Food Is Medicine Coalition; When did your agency become a member?

Code	Definition	Rules	Research Question	Interview Question
FIMC.FIMCActivitiesWeeklyCalls	Description of FIMC activities that the agency takes part in		What role does FIMC membership play in individual FIMC organizations?	What FIMC activities does your agency take part in? Weekly calls?
FIMC.FIMCActivitiesPetitions	Description of FIMC activities that the agency takes part in		What role does FIMC membership play in individual FIMC organizations?	What FIMC activities does your agency take part in? Petitions?
FIMC.FIMCActivitiesNationalAdvoDay	Description of FIMC activities that the agency takes part in		What role does FIMC membership play in individual FIMC organizations?	What FIMC activities does your agency take part in? National Advocacy day on Capitol Hill?
FIMC.FIMCActivitiesNationalConfer	Description of FIMC activities that the agency takes part in		What role does FIMC membership play in individual FIMC organizations?	What FIMC activities does your agency take part in? National Conference?
FIMC.FIMCDirectBenefit	Description of perceived direct benefits from FIMC membership		What role does FIMC membership play in individual FIMC organizations?	Does your agency receive any direct benefit from FIMC membership?
FIMC.FIMCDirectBenefitAgency	Description of agency's perception of direct benefits		What role does FIMC membership play in individual FIMC organizations?	How does your agency view FIMC membership benefits?
FIMC.FIMCGoals	Description of how agency feels about FIMC's goals		What role does FIMC membership play in individual FIMC organizations?	How does your agency feel about FIMC's goals?

Code	Definition	Rules	Research Question	Interview Question
FIMC.FIMCDisagree	Description of when an agency disagrees with FIMC's goals	Include if the agency did anything about it in this code	What role does FIMC membership play in individual FIMC organizations?	Are there ever times where your agency disagrees with the goals of FIMC?
FIMC.FIMCGoalsAchieve	Description of perception about FIMC achieving its goals	Include why or why not in this code	What role does FIMC membership play in individual FIMC organizations?	Does your agency believe that FIMC will achieve its goals? Why or why not?
Parent Node: Other Stakeholders				
FIMC.OtherStakeholders	Offered or provided additional stakeholder contacts		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you or your organization have relationships with either stakeholder?
Parent Node: Additional Questions				
FIMC.AdditionalQuestions	Any additional questions that were asked by the respondent		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you have any questions for me?

Code	Definition	Rules	Research Question	Interview Question
FNS Participants				
Parent Node: Prior to Receiving FNS Services				
FNS.PriorHealthBeforeFNS	Description of health prior to FNS	Include why that word or phrase was chosen in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	In a word or phrase, how would you describe your health before [FNS Provider] meals? Why did you pick that word/phrase?
FNS.PriorHealthAfterFNS	Description of health after FNS	Include why that word or phrase was chosen in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Now think about the [insert number of months] months since your last [FNS Provider] meal, in a word or phrase how would you describe your health now? Why did you pick that word/phrase?
FNS.PriorFeelHealthy	Description of what participants body feels like when healthy		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Please describe what your body feels like when you feel healthy.
FNS.PriorHealthyDefinition	Definition of healthy		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How did you define healthy?

Code	Definition	Rules	Research Question	Interview Question
Parent Node: Diabetes				
FNS.DiabetesDiagnosis	Description of when participant was told they have Type II Diabetes	Include age or year in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	When were you told you have Type II Diabetes? What age were you or what year?
FNS.DiabetesDiagnFeel	Description of how the diagnosis felt		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How did this diagnosis make you feel?
FNS.DiabetesDiagnTell	Description of who the participant told about their diagnosis	Include probe Family or friends in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Who did you tell?
FNS.DiabetesDiagnChallenge	Description of challenges participant faces related to coping with diabetes	Include how they resolve them in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you face any challenges coping with your diabetes?
Parent Node: Food Consuming Now				
FNS.FoodDiet	Description of the certain diet the participant follows	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you follow a certain diet? If so, why?

Code	Definition	Rules	Research Question	Interview Question
FNS.FoodDietLength	Description of how long the participant has been eating the certain diet		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How long have you been eating this way?
FNS.FoodBreakfast	Description of what the participant typically eats for breakfast		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	What types of foods do you usually eat for breakfast?
FNS.FoodLunch	Description of what the participant typically eat for lunch		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	What do you usually eat for lunch?
FNS.FoodDinner	Description of a typical dinner meal		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Tell me about a typical dinner you would eat.
FNS.FoodOutside	Description of how often the participant eats outside the home		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How often do you eat outside of your home?

Code	Definition	Rules	Research Question	Interview Question
FNS.FoodOutsideType	Description of the types of food eaten outside of the home		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	What types of restaurants do you eat at?
FNS.FoodOutsideChoice	Description of how the participant chooses which restaurants to eat at		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How do you choose which restaurants to eat at?
FNS.FoodSnack	Description of a typical snack		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	When you are craving a snack, what do you typically eat?
FNS.FoodSnackHealthy	Description of participants perception of whether their snack is healthy or unhealthy	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Would you describe this food as healthy or unhealthy? Why?
FNS.FoodOverallQualityDiet	Number between 1 and 10 to rate the overall quality of the participants diet	Include why the participant chose that number in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	On a scale from 1 to 10, how would you rate the quality of your diet? 1 is poor and 10 is excellent. Why?

Code	Definition	Rules	Research Question	Interview Question
FNS.FoodDidntEatBeforeFNS EatNow	Description of foods that were not eaten before FNS but eats them now	Include types of foods and why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Are there any foods that you eat now that you didn't eat before receiving [FNS Provider] meals? If yes, what type(s) of foods? Why do you eat [insert food(s)] now?
FNS.FoodFrequency	Description of how often the participant has a meal		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How often do you eat a meal?
FNS.FoodFeelAfter	Description of how participant feels after they eat		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How do you feel after you eat?
FNS.FoodEatBetweenMeals	Description of how often the participant eats between meals		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you eat in between meals?
FNS.FoodBloodSugar	Description of changes in blood sugar (if monitoring)		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you notice changes in your blood sugar? (If monitoring)

Code	Definition	Rules	Research Question	Interview Question
FNS.FoodGrocery	Description of where the participant purchases their food		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Where do you buy the food you eat?
FNS.FoodGroceryQuality	Description of the quality of the food purchased		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How would you describe the quality of the food you buy?
Parent Node: FNS Meals				
FNS.MealsDescribeMeal	Description of FNS meals	Include what are the main components of the meal in this code	What role do FNS participants perceive their medically tailored home-delivered meals play in their ability to address their Type II Diabetes?	Please think only about the meals you received from [FNS Provider] and then describe a meal. What were the main components of the meal?
FNS.MealsSize	Description of the size of FNS meals		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How would you describe the size of the [FNS Provider] meals?
FNS.MealsTaste	Description of how the FNS meals taste		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	How did the meals taste?

Code	Definition	Rules	Research Question	Interview Question
FNS.MealsFavorite	Description of favorite meal	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	What was your favorite meal? Why?
FNS.MealsMoreOf	Description of the meals the participant wished they could have had more of	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Was there a type of meal you wished you could have more of? Why?
FNS.MealsSpecialDiet	Was the participant on a special diet with [FNS Provider] meals?	Include probe: Did your meals have a dot in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were you on a special diet with the [FNS Provider] meals?
FNS.MealsEffect	Description of the effect FNS meals had on the participants Type II Diabetes		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you think [FNS Provider] meals had an effect on your Type II Diabetes?
FNS.MealsMove	Description of how much the participant moved during the day	Include exercise in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were there any changes in how much you move during the day? Do you exercise at least once a day, every other day, 1 or 2 days a week?

Code	Definition	Rules	Research Question	Interview Question
FNS.MealsEnergy	Description of any changes in energy level		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you think there were changes in your energy level?
FNS.MealsMentalState	Description of changes in mental state		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were there any changes in your mental state?
FNS.MealsMentalFuzzy	Number on a scale from 1 to 10 to assess mental clarity		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	On a fuzziness scale from 1 to 10, how would you rate your mental state while you were receiving [FNS Provider] meals? 1 being clear and 10 being very fuzzy.
FNS.MealsMedicine	Description of changes in medicine while receiving FNS		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were there any changes to the medicine(s) you take?
FNS.MealsDoctor	Description of any changes in the number of times the participant went to the doctor while receiving FNS		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were there any changes in the number of times you went to the doctor?

Code	Definition	Rules	Research Question	Interview Question
FNS.MealsHospital	Description of any changes in the number of times the participant went to the hospital while receiving FNS		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Were there any changes in the number of times you went to the hospital
FNS.MealsRole	Number between 1 and 10 that [FNS Provider] meals played in the participants health	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	If you had to rate the role [FNS Provider] meals played in your health, what number would you choose? 1 being a very large role and 10 being a very small role. Why did you choose that number?
FNS.MealsDidNotReceive	Description of participants health if they did not receive FNS	Include how their response makes them feel in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Please imagine that you did not receive [FNS Provider] meals, how would you have described your health? How does that make you feel?
Parent Node: Food Is Medicine				
FNS.FIMFoodRoleDiabetes	Description of the role that food plays in Type II Diabetes	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	What role do you think food plays with Type II Diabetes? Why do you feel that way?

Code	Definition	Rules	Research Question	Interview Question
FNS.FIMFoodAsMedicine	Description of whether food can be as helpful as medicine	Include why in this code	What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you think food can be as helpful as medicine?
FNS.FIMRecommend	Description of what participant would tell another person with Type II Diabetes about FNS		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	If you met someone with Type II Diabetes, what would you say about [FNS Provider] meals and services?
FNS.FIMPayment	Description of who should pay for FNS		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	If you think [FNS Provider] services are helpful, who do you think should pay for them?
Parent Node: Additional Questions				
FNS.AdditionalQuestions	Any additional questions that were asked by the respondent		What are FNS participant's perceptions about the role food plays in their ability to address their Type II Diabetes?	Do you have any questions for me?

Code	Definition	Rules	Research Question	Interview Question
Medicaid Insurer				
Parent Node: Role				
MI.Role	Description of role at organization		What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes	Please tell me about your current role at your organization.
MI.RoleResponsibilities	Description of the respondent's responsibilities at the organization		What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes	Please tell me about your current role at your organization.
MI.RoleLength	How many months/years are they in their current position		What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes	How long have you been in this position?
MI.RoleClientType	Description of the types of clients the organization serves		What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes	What type(s) of Medicaid clients do you typically serve?
MI.RoleNumClients	How many clients the organization serves		What are the stakeholder roles in Medicaid policies to support Food Nutrition Services (FNS) for people with Type II Diabetes	About how many clients are enrolled in your plans?

Code	Definition	Rules	Research Question	Interview Question
Parent Node: Medicaid Waivers				
MI.MWExperience	Description of the organization's experience with Medicaid waivers	Include the reason why they chose the word or phrase in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	In a word or phrase please tell me about your organization's experience with Medicaid waivers.
MI.MWExpInvolve	Description of how the agency became involved with waivers	Include if it was another stakeholder group, like policymaker, CMS, or FNS provider	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How did your agency become involved with waivers?
MI.MWExpHealth	Description of the waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Was the waiver for a specific health condition or disease, for example HIV/AIDS, cancer, or diabetes?
MI.MWExpRole	Description of organization's role in the waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What was your organization's role in the waiver?

Code	Definition	Rules	Research Question	Interview Question
MI.MWExpRestrict	Description of any restriction placed on organization around who they could partner with		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Were there any restrictions placed on your organization in terms of the providers that you could partner with?
MI.MWExpReimbursement	Description of reimbursement for services under the Medicaid Waiver	Include explanation in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Were there restrictions around reimbursement to providers?
MI.MWExpPayRestrictFeel	Description of how the organization felt about the restrictions surrounding reimbursement for services		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How did your organization feel about these restrictions?
MI.MWExpPayRuleComply	Number from 1 to 10 on difficulty of complying with rules for reimbursement	Include the reason why they chose the number in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	On a scale from 1 to 10, how difficult was it to comply with these rules? 1 being very difficult and 10 being not at all difficult

Code	Definition	Rules	Research Question	Interview Question
MI.MWExpOverExp	Number from 1 to 10 on agency's overall experiences with waivers	Include the reason why they chose the number in this code	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How would you rate your organization's overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.
MI.MWExpStaff	Description of the staff that work on waivers		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	What is their position(s) in your organization?
MI.MWExpStaffHours	Description of the number of hours they spend on a waiver		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How many hours did they typically spend on a waiver?
MI.MWExpStaffAffect	Description of the time spent on waivers affecting the agency	Include the reason why or why not	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Did your organization feel affected in any way? Why or why not?
MI.MWInexpBecomeInvolved	Description of the agency's want to become involved with waivers	Include the reason why or why not	What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Would your organization like to become involved with waivers to provide non-traditional services for beneficiaries? Why or why not?

Code	Definition	Rules	Research Question	Interview Question
MI.MWInexpHowInvolve	Description of how the agency could become involved with waivers		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	How do you think your organization could become involved with waivers?
Parent Node: Decision Process for Partnership with FNS Provider				
MI.DecisionPartnership	Description of the processed based upon who proposed it	Include what they think the cause is and why in this code	What was the decision process for deciding to partner with a FNS provider?	At the start of the process, was the process altered depending on who was proposing the partnership? For example is the process different if a state senator proposes it or if a FNS provider proposes it.

Code	Definition	Rules	Research Question	Interview Question
MI.DecisionFNSProvFactor	Description of factors that were assessed prior to the partnership	Include all factors: 1. Size of the agency 2. Type of health conditions or populations served 3. Number of individuals served 4. Financial health of agency 5. Other factors	What was the decision process for deciding to partner with a FNS provider?	What FNS provider factors are assessed prior to decision making?
MI.DecisionMeetings	Description on the internal meetings that were held prior to making the decision to partner	Include how many meeting were held	What was the decision process for deciding to partner with a FNS provider?	Are separate internal meetings held when making this decision? If so, how many?
MI.DecisionMeetingProductive	Description of whether the respondent felt the meetings were productive		What was the decision process for deciding to partner with a FNS provider?	Do you feel these meetings are productive?
MI.DecisionProspectPartner	Description of meetings that are held with prospective partners	Include how many meetings were held	What was the decision process for deciding to partner with a FNS provider?	Are meetings held with the prospective partner(s)? If so, how many?

Code	Definition	Rules	Research Question	Interview Question
MI.DecisionPresentation	Description of whether FNS agencies are able to make presentations to the Medicaid Insurer		What was the decision process for deciding to partner with a FNS provider?	Are agencies allowed to make presentations?
MI.DecisionMeetingProspProductive	Description of whether the respondent felt the meetings with prospective partners were productive		What was the decision process for deciding to partner with a FNS provider?	Do you feel these meetings are productive?
MI.DecisionDepartments	Description of the departments involved in drafting the partnership agreement	Include contracts, legal, corporate compliance, and accounting and others in this code	What was the decision process for deciding to partner with a FNS provider?	What departments are involved in drafting the agreement?
MI.DecisionFinal	Description of who makes the final decision on the partnership	Include management, CEO or COO or Executive Board or Board of Trustees in this code	What was the decision process for deciding to partner with a FNS provider?	Who makes the final decision to form the partnership?
MI.DecisionLength	Description of the length of time it takes to finalize the partnership and it be implemented		What was the decision process for deciding to partner with a FNS provider?	On average how long does it take for the decision process to be complete and the partnership implemented?

Code	Definition	Rules	Research Question	Interview Question
MI.DecisionInternalProcess	Number between 1 and 10 to rate the organization's internal process for deciding to partner with an FNS provider	Include why they chose that number in this code	What was the decision process for deciding to partner with a FNS provider?	On a scale from 1 to 10 how would you rate your organization's internal process for deciding to partner with an FNS provider? 1 being very difficult and 10 being not at all difficult
MI.DecisionInternalProcessImprove	Description of how the internal process could be improved	Include how in this code	What was the decision process for deciding to partner with a FNS provider?	Do you think the process could be improved? If so, how?
MI.DecisionFinancialImpact	Description of the financial impact the partnership has had on the organization	Include why or why not in this code	What was the decision process for deciding to partner with a FNS provider?	Has your organization seen any financial impact due to the FNS partnership? Why or why not?
MI.DecisionBeneHealth	Description of perceived effect of the partnership on beneficiary's health	Include why or why not in this code	What was the decision process for deciding to partner with a FNS provider?	In your personal opinion, do you think the decision to partner with FNS providers has affected beneficiary's health? Why or why not?

Code	Definition	Rules	Research Question	Interview Question
Parent Node: Additional Questions				
MI.AdditionalQuestions	Any additional questions that were asked by the respondent		What are the stakeholder roles in Medicaid policies to support FNS for people with Type II Diabetes	Do you have any questions for me?

Code	Definition	Rules	Research Question	Interview Question
Policymakers				
Parent Node: Role				
PM.Role	Description of policymaker's role	Include title and political party affiliation in this code	How do policymakers choose to support FNS for people with Type II Diabetes?	Please tell me about your role.
PM.RoleLength	How many months/years are they in their current position		How do policymakers choose to support FNS for people with Type II Diabetes?	How long have you been in this position?
PM.RoleWhy	Description of what lead the respondent to choose this field of work		How do policymakers choose to support FNS for people with Type II Diabetes?	Why did you choose this profession?
Parent Node: Medicaid Waivers				
PM.MWExperience	Description of the policymaker's experience with Medicaid waivers	Include the reason why they chose the word or phrase in this code	How do policymakers choose to support FNS for people with Type II Diabetes?	In a word or phrase please tell me about your experience with Medicaid waivers. Why did you choose that word or phrase?
PM.MWExpInvolve	Description of the policymaker's involvement in Medicaid waivers	Include probes in this code: 1. CMS 2. FNS provider 3. FIMC	How do policymakers choose to support FNS for people with Type II Diabetes?	How did you become involved with waivers?

Code	Definition	Rules	Research Question	Interview Question
		4. Some other way		
PM.MWExpRole	Description of the policymaker's role on the waiver		How do policymakers choose to support FNS for people with Type II Diabetes?	What was your role in the waiver?
PM.MWExpFactor	Description of the factors that lead to the policymaker's decision to take part in the waiver		What factors influence their support or non-support of policies for FNS?	What factor(s) caused you to take part in the waiver?
PM.MWExpDraftWaiver	Description of whether the policymaker was involved in drafting or submitting the waiver application to CMS		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Were you involved in drafting or submitting the waiver form to CMS?
PM.MWExpDraftWaiverResources	Description of any resources consulted when drafting the waiver application		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Were there any resources you consulted when drafting the waiver application?
PM.MWExpDraftWaiverConsult	Description of whether the policymaker consulted with other policymakers who had	Include why or why not in this code	How do policymakers choose to support FNS for people with Type II Diabetes?	Did you consult with other policymakers who had previously submitted a form?

Code	Definition	Rules	Research Question	Interview Question
	previously submitted a form		What factors influence their support or non-support of policies for FNS?	
PM.MWExpDraftWavier Application	Number from 1 to 10 on the level of difficulty of completing the waiver application form	Include why or why not in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Please rate the level of difficulty in filling out the waiver application form on a scale from 1 to 10. 1 being very difficult and 10 being not at all difficult. Why did you choose that number?
PM.MWExpDraftWaiverStaff	Description of staff that worked on drafting the waiver application		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Tell me about the staff that worked on the waiver application: What is their position(s)?
PM.MWExpDraftWaiverStaffHours	Number of hours staff typically spend on drafting a waiver		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Approximately how many hours did they typically spend on a waiver?

Code	Definition	Rules	Research Question	Interview Question
PM.MWExpDraftWaiverStaffAffect	Description if policymaker felt affected in any way	Include why or why not in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Did you feel affected in any way?
PM.MWExpHealth	Description of the waiver		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Was the waiver for a specific health condition or disease, for example HIV/AIDS, cancer, or diabetes?
PM.MWExpOverExp	Number from 1 to 10 on agency's overall experiences with waivers	Include the reason why they chose the number in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	How would you rate your agency's overall experience with waivers on a scale from 1 to 10? 1 being poor and 10 being excellent.

Code	Definition	Rules	Research Question	Interview Question
PM.MWInexpBecomeInvolved	Description of the policymaker's wanting to become involved with waivers		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Would you like to become involved with waivers to provide non-traditional services for beneficiaries? Why or why not?
PM.MWInexpPoliticalParty	Description of whether political affiliation is a factor		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Is your political party affiliation a factor
PM.MWInexpHowInvolve	Description of how the agency could become involved with waivers		How do policymakers choose to support FNS for people with Type II Diabetes?	How do you think you could become involved with waivers?

Code	Definition	Rules	Research Question	Interview Question
Parent Node: Advocacy				
PM.Advocacy	Percentage out of 100 regarding the policymaker's duty to advocate on behalf of Medicaid beneficiaries		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	What percent out of 100 would you say it is your duty to advocate on behalf of Medicaid beneficiaries?
Parent Node: Medicaid Waiver Outcomes and Benefits				
PM.MWOutBeneHealth	Description of whether Medicaid waivers affect beneficiary's health in constituency	Include why or why not in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	In your opinion do you feel that Medicaid waivers have affected beneficiaries' health outcomes in your state?
PM.MWOutBudget	Description of whether Medicaid waivers for FNS have either positively or negatively impacted the policymaker's states' Medicaid budget	Include why or why not in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Do you think Medicaid waivers for FNS have either positively or negatively impacted your states' Medicaid budget? Why or why not?

Code	Definition	Rules	Research Question	Interview Question
PM.MWOutTradBenefit	Description of whether FNS should be a traditional Medicaid benefit in the policymaker's state	Include policy alternatives in this code	How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	Do you think FNS should be a traditional Medicaid benefit in your state? If not, are there policy alternatives that you prefer
PM.MWOutTradBenefitLikely	Number from 1 to 10 on the likelihood of FNS becoming a traditional benefit in the policymaker's state		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	On a scale from 1 to 10 how likely do you think it would be for FNS to become a traditional Medicaid benefit? 1 being very unlikely and 10 being very likely.
PM.MWOutTradBenefitPolitics	Description of the role that politics plays in the likelihood of FNS becoming a traditional Medicaid benefit		How do policymakers choose to support FNS for people with Type II Diabetes? What factors influence their support or non-support of policies for FNS?	What role do you believe that politics plays in your response?

Code	Definition	Rules	Research Question	Interview Question
Parent Node: Additional Questions				
PM.AdditonalQuestions	Any additional questions that were asked by the respondent		How do policymakers choose to support FNS for people with Type II Diabetes?	Do you have any questions for me?

Appendix E: IRB Approval Letter



INSTITUTIONAL REVIEW BOARD

www.irbnet.org · www.usciences.edu · 215-596-7490 · Mail Stop 109

Date: July 12, 2018
Principal Investigator: Amanda Reiter
Project Title: [1156268-4] Assessing the Roles of Stakeholders through Medicaid Waivers and Food Nutrition Services for Type II Diabetic

The Institutional Review Board has reviewed and approved using the *Expedited Review* process for the research protocol referenced above. **The study is approved: Start date: July 2, 2018 End date: October 30, 2020.** As the Principal Investigator of this study you assume the following reporting responsibilities:

COMPLIANCE: Principal Investigators and Co-investigators agree to: perform research as outlined and approved by the USciences IRB at all times during the active study; and disclose any financial conflicts of interests when research is sponsored and agree to notify the IRB in writing of any changes in interest during the study.

AMENDMENTS: Any changes in the approved research protocol or consent form must be approved by the IRB prior to implementation. Submit a request for protocol review form, completing only the sections that will change and check the "Amendment" box at the top of the form.

CONTINUING REVIEW: Investigators are required to apply for renewal of study at least 30 days prior to the study expiration listed above for as long as the study is active. IRBNet will attempt to notify you by e-mail before approval expires, but it is ultimately your responsibility to make sure your approval does not expire.

AUDIT OR INSPECTION REPORTS: Investigators are required to provide to the IRB a copy of any audit or inspection reports or findings issued to them by regulatory agencies, cooperative research groups, contract research organizations, the sponsor, or the funding agency.

ADVERSE EVENTS: Investigators must promptly report unanticipated problems or deviations from the approved protocol to the IRB using IRBNet. Serious events should be reported within 24 hours to Dr. Jean-Francois Jasmin at (irb@usciences.edu, 215-596-8512). Non-serious events should be reported in IRBNet to the IRB administrator (irb@usciences.edu, 267-295-3295).

COMPLETION: Notify the IRB when your study is completed (data analysis finished) or terminated. Please complete the continuing review or termination report form which can be found in the IRBNet document library.

CONSENT FORMS/APPROVED DOCUMENTS: Investigators may only use the approved forms enclosed with this letter. All subjects should be given a copy of **the stamped approved** consent form. You must retain signed consent documents for at least three years past completion of the research activity.

Thank you for following up with this paperwork.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within the IRB Administrator's records.

Appendix-E: IRB Stakeholder Partnership Approval Letter



INSTITUTIONAL REVIEW BOARD

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Date: January 31, 2019
Exempt Date: January 31, 2019
Principal Investigator: Amanda Reiter
Project Title: [1379367-1] Analysis of partnership between a Medicaid Insurer and Food Nutrition Service Provider

The IRB at University of the Sciences has reviewed your project and has deemed the research to be exempt per the Regulations for the Protection of Human Research Subjects at 45 CFR 46.104(d). The project meets the specifications described in exempt category:

- ☒ 4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)

Though the above referenced Protocol is exempt; if there are any changes to this Protocol you are required to submit an amendment to the IRB Committee before instituting these changes.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within the IRB Administrator's records.