IMPROVING CARE FOR SPANISH-SPEAKING PEOPLE WITH DIABETES IN A FREE CLINIC SETTING

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ABSTRACT

Mohamed Hani Ismail: Improving Care for Spanish-Speaking People with Diabetes in a Free Clinic Setting
(Under the direction of Sarah Birken)

Background: The risk for diabetic complications is especially high for those with socioeconomic, health-insurance, and language barriers. Spanish-speaking patients receiving care in free clinic settings experience all these barriers and thus require tailored interventions to meet their diabetic-care goals. A literature review of interventions for Latinos in free clinics found that pharmacist-led education; health education taught by other individual educators; and team-based education improved glycemic control. Potential challenges to the implementation and sustainment of such interventions have also been described.

Objective: My goal was to identify and assess the determinants of implementation and sustainment of health education interventions for Spanish-speaking diabetics getting care at a free clinic. I planned to use these results to develop a plan for change to improve diabetic care at this clinic.

Methods: I conducted focus groups and interviews with patients, providers, board members, a donor, and a peer clinic director based on the Consolidated Framework for Implementation Research (CFIR). I then developed a plan for change based on the Exploration, Preparation, Implementation, Sustainment (EPIS) framework, including the selection of an intervention and preparation of the clinic for its implementation.

Results: Key determinants of an intervention's potential implementation were: an unmet need for inclusive, comprehensive, group health education taught by individual educators; poor staff communication and the lack of a patient registry; and a lack of awareness of patient needs and a lack of

implementation leadership from the providers and board. The key determinants of sustainment were the clinic's networking with external organizations and grant management.

Plan for change: I identified two no-cost, diabetes self-management programs in the community to sustainably meet patient and clinic needs. I recommend educating providers about these programs and using existing funding for site preparation (including an improved communication network and an electronic patient registry). To lead these efforts, I recommended the establishment of an implementation team.

In the name of God, the Most Compassionate, the Most Merciful,

This is dedicated to the patients who rely on free clinics across the United States and the front-line providers of Al-Shifa Free Clinic, San Bernardino, California

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LIST OF ABBREVIATIONS

ADA	The American Diabetic Association
ADA GUIDE	American Diabetic Association's 'Standard of Medical Care in Diabetes Care-2016'
CFIR	Consolidated Framework for Implementation Research
DM	Diabetes Mellitus
EBP	Evidence-based-practice (also refers to evidence-based-intervention)
EMR	Electronic medical record and disease registry (electronic health record)
EPIS	Exploration, Preparation, Implementation, and Sustainment (implementation framework)
FQHC	Federally Qualified Health Care Center: safety net providers that provide outpatient services & include community health centers, migrant health centers, homeless health centers, public housing primary care centers, & health center program "look-alikes." They receive federal funding, serve the poor with Medicaid 60%, charge fees, and bill patients.
HBAIC	The gold standard laboratory test for monitoring blood sugar control; the result being the average level of blood sugar in the prior 3 months.
KPSC	Kaiser Permanente Southern California
NAFCC	National Association of Free & Charitable Clinics
NQF	National Quality Forum

CHAPTER 1: BACKGROUND, SIGNIFICANCE, AND OBJECTIVES

Introduction

Type 2 diabetes is rising at an epidemic rate. In 8 years (2005 -2013), the prevalence of diabetes increased by 17%.[1] In 2015, 23 million people in the United States population had been diagnosed with diabetes, with an additional 7 million undiagnosed.[1] Type 2 diabetes made up 95% of all cases. Marked differences in prevalence exist across ethnic groups. For example, people of Hispanic ethnicity (Latinos) had a 12% prevalence whereas non-Hispanic whites had a 7.3% prevalence (2011-2014; appendix 1, table 1).[1] These differences also exist among children, aged 10-19, with Latino's having more than a threefold increase in the incidence of type 2 diabetes compared to non-Hispanic whites (2011-2012; Figure 2).[1] Overall, the prevalence is equally distributed for men and women and is highest in those aged 45-64 (11 per 1000) followed by those >age 65 (9.4 per 1000).[1]

Diabetics accounts for a large proportion of morbidity, mortality, and healthcare costs. Diabetes was a diagnosis in 7.2 million hospitalizations and a direct cause for 79,000 deaths in 2014; the 7th leading cause of death overall.[1] The total direct and indirect costs of diagnosed diabetes was $245 billion with an average per person of $13,700 in 2012. After adjustment for age and sex, these expenditures were 2.3 times higher for diabetics compared to non-diabetics.[1]

Section 1.1 Disparities in Diabetes Care and Recommendations to Improve these Disparities

The National Quality Forum (NQF) acknowledged that significant healthcare disparities based on race, ethnicity, age, socioeconomic status, insurance status, or gender persist and may be worsening in the

United States.[63] An NQF workgroup concluded that better measurement and reporting are essential to improve healthcare quality for disparate patients. In an effort to close the disparities gap, it developed a set of disparity-sensitive measures for 10 high priority healthcare areas (including diabetes) known as the *National Voluntary Consensus Standards for Ambulatory Care: Measuring Healthcare Disparities*.[63] These standards included diabetes-specific national measures that relate to testing for glycemic control, lipid control, protein in the urine and blood pressure control as well as the receipt of appropriate eye and foot exams. Realizing that these national measures are more suitable for patients with health insurance who get regular ambulatory care but not for those without health insurance (who may only engage with the healthcare system when seen in the emergency room or hospitalized), the NQF also specified four diabetes-specific local measures (community-level) measures (uncontrolled diabetes; lower-extremity amputations amongst diabetics; short-term complications, and long-term complications of diabetes) which could be measured using hospital-discharge data for a particular community. The NQF recommended that healthcare providers should make equitable, quality care for the disparate population a priority and should select from the NQF disparity measures the ones most suitable for their community.[63]

The American Diabetes Association (ADA) published a guideline (ADA guide) covering diabetic care standards in the United States, including a section on those with disparities.[2] The ADA guide noted that up to 50% of diabetics are at higher risk for complications due to not meeting blood sugar, blood pressure and lipid goals. This is especially the case for those with financial, social, language, insurance, and food insecurity barriers, and for Latinos and African Americans.[3]

The ADA guide recommended that improvements in the quality of Diabetes Mellitus (DM) care can be achieved by following the Chronic Care Model's six core elements: (1) delivery system design; (2) self-management support; (3) Decision support; (4) Clinical information systems; (5) Community resources and policies to support healthy lifestyles; and (6) Health systems (Figure 1).[4] For example, with regards to core elements 1, 2, and 5; interventions that integrate culture, language, finance, religion, and literacy skills positively influence patient outcomes.[3] Developing resources to support healthy lifestyles is

essential and doing this through community linkages (e.g. peers, etc.) is recommended particularly in underserved communities. Having a strong social support leads to improved clinical outcomes.[3] The guide further highlighted the importance of measuring and monitoring the delivery of diabetes self-management and lifestyle education, medication management for glycemic control, and blood pressure and lipid management.[5, 6, 7, 8, 9, 10]

The guide also issued a call for research that seeks to better understand how social and environmental determinants of health influence behaviors and how the relationships between these variables might be modified to prevent and manage diabetes.[3]

Section 1.2 Free Clinic Settings in the United States

The uninsured in the US often rely on 'safety-net' sites for their healthcare, defined as sites that maintain an open door to patients regardless of the ability to pay and include federally qualified health centers (FQHCs), public clinics, hospital outpatient departments, emergency departments, and private physicians who care for the uninsured.[11] Most of these options require cost-sharing with the mean cost to an uninsured patient for a physician visit being reported as more than $50.[12, 13] For example, FQHCs bill patients using a fee scale based on a patient's annual income with fees that range from $5 to $87 and public clinics collect fees that range from $22 to $97.[14]

Safety-net sites include free clinics. While they care for the same patient clientele as the other safety net sites, they differ organizationally in that they offer service at little or no cost, neither bill insurance nor mandate payment from their clients, and generally subsist on donations and volunteer effort.[15,16] Free clinics are believed to have started in San Francisco with the Haight-Ashbury Free Clinic in 1967.[15] They became an established part of the health system in the 1990's with three main developments: support by the American Medical Association, a $12 million Robert Wood Johnson Foundation initiative supported their development, and through the Health Insurance Portability and

Accountability Act of 1996, in which the United States Congress has extended medical malpractice protection for volunteer free clinic health care professionals.[17]

The most comprehensive information to date about the structures, operations, funding sources, caseload, staffing, and range of services of free clinics was based on a nationwide survey of free clinics where the author did an extensive search using numerous databases to identify potential free clinics and then surveyed them.[16] Darnell used an operational definition of a free clinic as being:

> a private, nonprofit organization or program component of a nonprofit; providing medical, dental, or mental health services and/or medications directly to patients; serving mostly (>50%) uninsured patients; charging no fees or nominal fees of not more than $20; not billing patients, denying services, or rescheduling appointments if the patient could not pay the requested fee/ donation; and not being recognized as a FQHC or Title X family planning clinic.[16]

This definition helped to differentiate free clinics from other types of safety-net clinics such as FQHCs. Out of a potential 2,545 clinics, 1,007 met the definition of a free clinic. She found that most free clinics were independent entities, originated after 1990, were open an average of 18 hours per week, had an average wait time of 12 days, and had an operating budget of $288,000 per year. The average charged to patients was $9 per visit with 54% charging nothing for visits. The clinics served about 1.8 million mostly uninsured patients through more than 3 million medical visits annually. A summary of her results including the services offered by free clinics, the type of staff who work at free clinics, and the characteristics of the patients of free clinics is included in Table 2 (see appendix 1). This research highlights that in addition to free clinics being unique compared to other safety-net clinics, there are also many differences among them. [16]

The demand for free clinic care is not expected to decrease; it is expected to continue to be an important part of our healthcare system.[18] The finding that 92% of patients of free clinics are uninsured, means that 8% have medical insurance but still found free clinics a more suitable site of care than traditional clinics -likely due to being underinsured.[16] Even with the Affordable Care Act (ACA) as law; the uninsured rate rose from 7.9 percent in 2017 to 8.5 percent in 2, amounting to nearly 2 million more uninsured people.[18] Thus, there were still 27.5 million people who were uninsured at any time in 2018.[18]

In December, 2017, the 115th congress repealed the 'individual mandate' as part of a new act (H.R.1) as follows:

> Part VIII- Individual Mandate (Sec. 11081) This section repeals the penalty for individuals who fail to maintain minimum essential health coverage as required by the Patient Protection and Affordable Care Act (referred to as the individual mandate)[56]

It is uncertain how this change, which went into effect in 2019, may affect the number of uninsured and the demand on free clinics. Healthier individuals may be less inclined to purchase health insurance since they will not have to pay the $695 tax penalty for being uninsured and this may increase premiums for those with private insurance by 10%.[57]

Section 1.3 Diabetes in Latino Patients who Receive Care in Free Clinics

Patients with diabetes who have financial, social, language, insurance, and food insecurity barriers are at higher risk for complications.[3] Thus, uninsured, Spanish-speaking, patients attending free clinics can be considered at especially high risk as they tend to have multiple disparity risk factors.[3,16] In a study of Mexican people with diabetes, significant changes were found between those seeking care at a free clinic vs. those seeking care at a hospital-affiliated clinic in Texas. After controlling for gender, acculturation, time since diagnosis, number of diabetes medications, diabetes knowledge, and number of symptoms, those at the free clinic still had higher HBA1C (9.1 vs. 7.7) and a lower quality of life, suggesting that their need for special attention.[19] Patients who seek care for diabetes in free clinics also may fare worse than those without diabetes at free clinics; this was shown in a study that found the former reporting "poorer physical and mental health and higher levels of dysfunction" compared to the latter and even compared to their own family members.[28]

Section 1.4 Studies to Improve Diabetic Care for Latinos in Free Clinics

Overview

Although providing quality diabetic care for Latinos in free clinics is challenging due to both clinic and patient factors, improving diabetic care is achievable.[20] The ADA standard of care for diabetes stresses multi-faceted approaches with an emphasis on patient and family education as the hallmarks of proper patient care.[3,2,5,6,7,8,9,10] We know from extant studies that improving diabetes care for Latinos in free or safety-net clinics includes health education of some type.[33,34,36,37,39,40-44,51] Interventions studied included using pharmacists to educate patients; developing health education programs with an individual, non-pharmacist, educator type; or using a team-based approach that included patient education. All education modalities were effective whether done by pharmacists, medical assistants, diabetes educator trainees, or medical students. They all include multiple-touch points over months to years with follow-up frequencies as often as weekly (see appendix 1; table 3). A gap in the literature is the limited number of studies done only at free clinics as opposed to those done at other safety-net clinic settings. While patient characteristics are similar in both free and safety-net settings, interventions studied at these other sites may face clinic-level implementation challenges if attempted in a free clinic. An example of a challenge that faces free clinics is sustained funding. Free clinics rely on donations and volunteers whereas other safety net sites have broader funding options as described before.[11-16]

Pharmacist-led diabetes education in free clinics

Clinical diabetic care centers around the use of medications to lower blood glucose, blood pressure, serum lipids, and urine micro-albumin with most patients requiring multiple drugs and monitoring for their side effects, thus making pharmacists important diabetes care providers.[9] Four out of five studies that evaluated the effect of having pharmacists (to manage medications) in free or safety-net settings showed a statistically significant improvement in glycemic control.

Davidson et al. (2000) retrospectively evaluated the effect of a pharmacist-managed diabetes care program on a free clinic diabetic population (64% Latino). There were 181 initial subjects; with 89 receiving care by pharmacists who followed detailed algorithms (experimental group) and 92 subjects who received care in the general clinic setting (control group). The patients in the experimental group were sicker at baseline (higher baseline HBA1C, more diabetic complications, more use of insulin) and had a greater initial improvement in HBA1C ($P < .03$) compared to controls. The decrease in HBA1C was related to the number of missed visits (less missed visits = greater decrease in HBA1C; $P < .03$). Limitations included an unclear intervention timeline and many missing values (final data was presented on 50 patients in the experimental and 27 controls).[34]

Congdon (2013) did a retrospective review of 64 uninsured patients with diabetes (67% Latino) who received medication-therapy-management (MTM) delivered by pharmacists at a safety-net clinic, comparing the HBA1C results before and after the implementation of MTM. The average change in HBA1C for all subjects and for the subset of subjects with baseline HBA1C < 9% did not show significant improvement but those with a baseline HBA1C > 9%, did show statistical improvement (drop in HBA1C of 10.9 to 8.8). Limitations included a lack of a control group, the observational design, and being in a safety-net setting rather than a free clinic.[39]

Bluml *et al.* (2014) retrospectively evaluated the effect of integrating pharmacists into interdisciplinary diabetes care teams allowing them to provide customized diabetes education and medication consultations to 1836 high risk diabetic patients (22% Latino) at multiple study sites. Comparing data before and after the intervention for 1667 subjects, with patients serving as their own controls, the mean HBA1C improved significantly (- 0.8%). Limitations included that they did not provide subset data on how many of the patients were in free clinics as opposed to other safety-net clinic types.[45]

Sease (2013) retrospectively evaluated the impact of a pharmacist management program for 95 diabetic patients in a free clinic (4% Latino). The program included pharmacists educating patients on

diabetes and lifestyle modifications, assessing the appropriateness of their drug therapy, and managing their diabetes drug therapy. Comparing pre/post program implementation changes over 24-months, they found significant reductions from baseline in HBA1C values ($p < 0.001$). Limitations include a small number of Latino subjects. [51]

Shane-Mcwhorter *et al.* (2003) prospectively evaluated the effect of a pharmacist-led diabetes management tele-monitoring program on patients utilizing federally qualified safety-net clinics. They included 150 patients with 75 receiving the intervention and 75 receiving usual care (control). The change in HBA1C over 6 months was significantly greater in the tele-monitoring group compared with the usual care group (2% decrease vs. 0.7% decrease; $P < 0.001$). The main limitations were the safety-net setting and the lack of randomization.[52]

Other individual diabetes care educators in free clinics

In addition to pharmacists, other types of educators have been studied in free or safety-net clinic settings. Three out of three studies using an individual type of educator (e.g., only medical students or only health coaches - as opposed to a team-based approach with different educator types) showed a statistically significant improvement in glycemic control.

Willard-Grace *et al.* (2015) investigated whether coaching by Spanish-speaking, Latina medical assistants improves diabetic control in a safety-net setting by randomizing 441 patients into a coaching and usual care control group (332 subjects included in the final analysis; 90% Latino; 80% uninsured). The coaches received 40 hours of health coach training. They met with patients in the clinic before, during, and after the visit and followed up with patients between visits in person (at least every 3 months) and by telephone (at least once per month). At 12 months, 48.6% of the 167 subjects in the coaching group achieved their HBA1C goal vs 27.6% of the 165 in the usual care group, $P = .01$).[35]

Gorrindo *et al.* (2014) retrospectively reviewed the results of a medical student health educator program for 45 diabetic patients (33% Latino) at a student-run free clinic. They analyzed the relationship between the number of patient-student interactions (touch points) and change in HBA1C values between the initial presentation of the patient to the clinic and 12 months later. The mean HBA1C values improved significantly from 9.6 to 7.9, after a mean of 12.5 months ($p < .0001$). An increasing number of touch points was related to an improvement in HBA1C but with not statistically significant (P = 0.1). The main limitation was a lack of control group.[44]

Kahn *et al.* (2012) retrospectively examined the impact of incorporating certified diabetes educator (CDE) trainees into a safety-net setting. They compared baseline (pre-intervention) with 12-month HBA1C for 645 subjects (14% Latino) with 219 patients seen by a CDE (74 in a diabetes education class; and 145 seen one-on-one visit) and 426 controls (not seen by a CDE). Among all 219 subjects seen by a CDE, the HBA1C changed from a mean of 9.1 to 8.5 (P <0.001). For the subset of 74 patients enrolled in diabetes classes, HBA1C levels decreased from a mean of 8.8% to 8.3% (p= 0.04). Among a subset of patients (35%) with poorly controlled diabetes at baseline (HBA1C ≥ 9), there was a decrease in HBA1C levels from 11.3% to 9.6% ($P < .01$). The 426 subjects in the control group had a mean HBA1C that was 7.7 at baseline and 12 months (p=0.5). The limitations were that the control group was not matched and had a significantly lower HBA1C at start and no control for medication effects.[36]

<u>Team-based care (with more than one educator type) to manage diabetes</u>

Team-based care has been recommended as one of the components of diabetic care and several studies used a team approach, with more than one educator type involved.[3] Two out of three studies using this type of intervention showed a statistically significant improvement in glycemic control.

Schillinger *et al.* (2009) did an RCT of self-management support (SMS) for mostly underserved patients in safety-net clinics. A total of 339 subjects (46% Latino) with poorly controlled diabetes were

randomized into one of three arms: usual care, interactive weekly automated telephone self-management support with nurse follow-up (ATSM), or monthly group medical visits with physician and health educator facilitation (GMV). No differences in HBA1C change were seen in any of the groups.[43]

Khan *et al.* (2010) did a prospective single cohort study of the effect of applying the chronic care model to 1098 uninsured diabetic patients (30% Latino) presenting to an urgent care clinic. They set up a diabetes care program at the urgent care clinic that included diabetic classes, nutrition education, an electronic registry for tracking the patients, and staff dedicated to helping these patients. HBA1C was compared at presentation and after 2-12 months (833 had a repeat HBA1C done during the follow-up period and were included in the analysis). On average, it decreased by 1.5 percentage points ($P < 0.001$). Limitations included the lack of a control, variable follow up period, and the urgent care setting.[44]

Mayes *et al.* (2010) assessed the value of using a system of primary care and endocrinology tele-health provider visits, promatoras (paraprofessional outreach workers), and registered nurses (including certified diabetes educators) on 19 diabetic Latino patients receiving care at a free clinic. The specially trained promatoras served as the primary patient educators and as the points of communication between patients and medical personnel. Patient data (e.g. glucose levels) were sent over the internet and tele-health visits included audio and video. The endocrinologist participated from their own office, while the primary care physician, patient, and Promotora volunteers were at the free clinic. Final data was available for 16 patients followed for 3.5 years. The mean HBA1C was 9.6 at baseline and 7.2% at the end ($p = 0.001$). Limitations included the small sample size, lack of a control, and a lack of description of the frequency of provider interactions with patients.[42]

Several pilots and observational studies also showed that quality care and patient tailored educational programs at free clinics lead to improved glycemic control commensurate to that seen at regular clinics.[21,22,23,24,25]

Establishing Continuous Quality Improvement for Free Clinics on a State level

While the studies mentioned above highlighted promising interventions for diabetics at free clinics, they represent interventions done at discrete clinics. The North Carolina Association of Free (and Chartable) Clinics (NCAFC) is an example of how the coordination of care at the state level can lead to improved diabetic care in free clinics. In 2004, they partnered with the Blue Cross and Blue Shield of North Carolina (BCBSNC) Foundation to fund existing free clinics, establish new free clinics, improve clinic technology and recognize the work done these clinics have done. In 2008, the two groups developed a standardized set of health metrics in further these goals. Their latest metrics show that free clinics can compete with or even outperform commercial and government insured populations. In their 2018 report, the NCAFC compared their free clinic's outcomes on diabetic control (% of patients with diabetes with a most recent HBA1c ≤9%) and hypertension control (% of hypertensive patients with a normal blood pressure defined as <140/90) with national Medicaid and commercial HMO insurance data and found the following: for diabetic control, the free clinics (71%) did better than Medicaid (60%) and commercial (69%). The free clinic patient volume is about 80,000 people per year. Their cost effectiveness suggested that for every $1 spent, $7.38 in healthcare services were provided.[25] These results show that the quality of care provided by free clinics can have a significant impact on outcomes and that patients of free clinics are not necessarily destined to have worse outcomes as had been suggested by the results of other studies.[19,28]

Section 1.5 The Challenges of Implementation and Sustainment of Interventions in Free Clinics

The challenges of implementation of diabetes care improvement initiatives in free clinics

Implementation of an initiative to improve diabetes care is influenced by several constructs. Constructs that have been reviewed in the literature include patient factors (their stage of change, self-efficacy, knowledge, poverty, education, language, transportation, family influence, etc.); clinic factors (structure, networking and communication system, culture, implementation climate, readiness for implementation, willingness of staff to implement it); and initiative factors (quality, adaptability, complexity, cost, etc.).[26]

The ability to implement an intervention can thus be hindered by a patient's poverty. A marker of such poverty is food insecurity -a problem prevalent in Latino patients getting care at free clinics. A study of 430 free clinic patients (using the 6-item United States Department of Agriculture (USDA) Food Security Survey) found that 74% were food insecure, five times more than the national rate of 14%. Of these 430 patients, 420 were Latino (97%). Forty eight percent of them had diabetes. Of those diabetics, 83% were food insecure, compared to 65% of the non-diabetics ($P < 0.001$).[27]

For an intervention to be successfully implemented, patients must be present to benefit from it. The ability of free clinic patients to attend appointments was found to be impacted by distance from the clinic with those living 30 or more miles from their free clinic being more likely to miss more than one scheduled visit.[20] There is also a rising concern (via anecdotal evidence) since the January 27, 2017 executive order titled, *Protecting the Nation from Foreign Terrorist Entry into the United States*, that some immigrants (even those here legally) are missing medical appointments due to fear of being deported.[58,59]

Patients also must have enough confidence in an intervention in order to adhere to it. In a study demonstrating patient-level barriers to implementation, authors surveyed 621 uninsured free clinic

patients and found that participants who had attended health education programs did not believe that there were benefits for healthy food choices and physical activity.[30]

For successful implementation, patients also should have knowledge of their problem, self-efficacy, and the means to adhere to an intervention. In a focus group interview of African American women attending an urban free clinic in Los Angeles, one of the reported barriers to following a dietary recommendation was a disbelief that they have high blood pressure. Women in this study also cited financial problems, medication side effects, and a lack of a convenient place for physical activity as barriers. In addition, depression and stress from the social/family system, including the need for several patients to take custody of their grandchildren were seen as barriers as well.[31]

Ineffective coordination of a team approach to initiative implementation was demonstrated to be a negative determinant in a study of a free clinic collaborative practice model. Led by the University of Alabama's school of nursing and a local ministry that runs a free clinic; a new clinic model was developed to improve the care of diabetics. The team included nurse practitioners with advanced diabetes training, a dietician, internists, an optometrist, and psychologist. Although this clinic model centered around a team approach, an evaluation of the clinic found that there was confusion regarding the collaboration, and the roles of team members from the partnering institutions in the collaboration and this led to lower levels of care coordination and inefficient use of team and clinic resources at the outset of the partnership.[32]

<u>The challenge of sustainment of diabetes care improvement initiatives in free clinics</u>

Sustainment has been defined as "*The provision of personnel, logistic, and other support required to maintain and prolong operations until successful accomplishment or revision of the national objective*".[53] Since diabetes is a chronic disease, sustainable interventions should be able to last as long as the clinic is in operation or until the intervention can be revised or replaced with a better one. Most of the

studies mentioned under the previous section ‘studies to improve diabetic care for Latinos in free or safety-net clinics’ did not last beyond one year leaving the question of sustainment as a gap in the literature.[33,34,36,37,38,40-44] Furthermore, researchers evaluating a free clinic and community-based action initiative found a significant number of patient-level barriers to sustainment of their chronic disease self-management attempts. These were financial costs associated with pharmaceuticals and monitoring supplies; a lack of time to return to see a doctor; and lack of health education. These patients typically returned for appointments every 5 to 6 months; an inadequate frequency for the management of uncontrolled, chronic disease.[45]

Objective: To understand the determinants of implementation and sustainment of diabetic care interventions for a primarily Spanish-speaking population getting care at a specific free clinic and to use this to create a plan for change to implement a suitable intervention.

Research Questions:

1) What are the determinants of implementation and sustainment of diabetic care interventions from the perspective of:
    a. Spanish-speaking patients at a free clinic
    b. the clinic's board and providers
    c. donors to the clinic
2) How can knowledge of these determinants be used to create a plan for change to implement and sustain a suitable intervention for Spanish-speaking diabetics at this clinic and prepare the clinic for this intervention?

CHAPTER 2: RESEARCH DESIGN AND METHODOLOGY

Introduction

The study has two main aims described below and visualized in figure 10.

Aim 1: to identify and detail potential determinants of implementation and sustainment of diabetic care interventions at a specific free clinic. I gathered information from diverse stakeholders to understand determinants.

Method: I conducted a case study at Al-Shifa free clinic, including focus groups with patients with diabetes, providers, and board members; and interviews (for providers unable to attend the focus groups and donors) using the CFIR (Consolidated Framework for Implementation Research) as a framework.

Aim 2: to develop a *plan for change* to improve the care for diabetic patients at this free clinic. This included the selection of the most appropriate intervention, recommending adaptations of that intervention, and recommending preparation of the clinic site to allow the implementation and sustainment of the intervention.

Method: I analyzed data collected from the interviews and focus groups of the stakeholders to identify an intervention that addressed patients' most critical needs, was considered compatible, beneficial, and a priority by the clinic staff to implement, and considered fundable by the board (from existing funds), and by donors (via grant money). I identified necessary adaptations to the intervention by comparing it to the needs of the patients, providers, and the board. I identified the necessary preparations for successful implementation that are needed for the clinic site based on feedback from providers, board members, and the donor. I used the Exploration, Planning, Implementation, and Sustainment (EPIS) framework to create a plan for change with four distinct implementation phases for this (detailed under the plan for change

chapter). I chose the EPIS framework for this *plan for change* as it fits well with the CFIR constructs (see figure 1, figure 2, & 3 for a comparison between the two), fits well with this study as it emphasizes the service delivery organization (Al-Shifa, in this case), and has been tested successfully in the public health sector.[5]

Section 2.1 Case Study Site: Al-Shifa Free Clinic

Al-Shifa free clinic (hereafter: 'Al-Shifa') in San Bernardino County, CA is a volunteer physician based, outpatient, non-profit, clinic open to serving the uninsured population of one of the nation's poorest counties. It does not charge insurance nor mandate payments from patients and its limited paid staff and services are funded via grants and donations.[46,47] It offers primary medical, dental, and specialty care (e.g. cardiology); laboratory services; limited prescription dispensing, and networks with local county hospitals and imaging centers for referrals.[48] It serves over 250 patients per month, >60% of whom are Latino, with Spanish as their first language, and many of whom have diabetes.[49] The clinic uses paper charting except for appointment scheduling which is done via a limited electronic record system. It does not collect outcome data. I selected this as the study site due to my personal experience there as a volunteer physician (prior to 2016) and as a board member (2017 through the present).

Section 2.2 Conceptual Model

Model selection

The Consolidated Framework for Implementation Research (CFIR) accounts for determinants of implementation. The model consists of five domains (patient, clinic, individuals, intervention and the process of implementation), each comprised of several constructs that have been shown to affect implementation. Developed in 2009, the CFIR incorporates constructs from 20 different sources. The main purpose of the framework is to allow us to assess potential barriers and facilitators in preparation for implementing the innovative intervention.[26] The CFIR is closely linked to the EPIS conceptual model. The use of the CFIR for Aim 1 is to identify potential determinants of implementation and sustainment as an exploratory effort (this corresponds to the 'exploration' phase of EPIS).

CFIR model constructs and their application to Al-Shifa

To identify the different barriers and facilitators that may affect the implementation of a novel intervention to improve the care given to diabetic patients at Al-Shifa, I adapted the CFIR to the clinic situation. The five domains with short descriptions of the all of Damschroder's constructs (appendix 2; figure 2 and table 4).[26] Key informant interviews were the main approach to better understand these domains (*inner setting*, *individual characteristics*, *intervention characteristics*, *outer setting*, and the *process).*

The *Inner Setting* is Al-Shifa and includes the clinic's networking and communication system (the webs of social networks, quality of formal and informal communications), culture (norms, values, and basic assumptions), implementation climate (tension for change, compatibility, relative priority, benefits to the clinic) and readiness for implementation (leadership engagement with the intervention, available resources for implementation, and knowledge about the intervention).

The *Individuals Involved* are the administration (clinic board of directors and clinic manager) and the volunteer providers.

The *Outer Setting* includes the patients with diabetes (their needs and their resources -both barriers and facilitators); peer pressure (from other free or safety-net clinics in the area); external policies (from donors); cosmopolitanism (networking and collaboration with donors and other community groups); and incentives (organizational donors and their grant-award guidelines).

The *Interventions* under consideration are those tested and proven effective for Latinos in a free clinic setting and were described earlier. Their core components are those that cannot be changed (e.g., a pharmacist-led educational intervention might require pharmacist involve for it to be effective). Their adaptable periphery components include things that could be adapted based on the needs of the clinic and the patients (e.g., an intervention based on the addition of health education classes might offer classes weekly or monthly without compromising the intervention's effectiveness).

The *Process* to go from an un-adapted intervention to one that is well adapted to the clinic/patient situation is discussed in the final chapter, *plan for change,* and follows the EPIS key stages.

Section 2.3 Study Design for Aim-1 (Key Informant Focus Groups and Individual Interviews)

Design

Using an observational design, I conducted focus groups of Spanish-speaking, patients with diabetes and their families at Al-Shifa; volunteer providers at the clinic; the clinic board; a representative of a major donor organization; and the director of the other free clinic in the same neighborhood (recommended by the donor).

Data Collection

I explored the major CFIR constructs by interviewing the following stakeholders in sequence:

I. Patients (as the clinic considers interventions, it must make sure they address patient-level determinants of implementation (patient needs & resources) which will not change regardless of the rest of the constructs (appendix 2; table 3).

II. Providers (they are on the front line and have the most interaction with patients and have insight about what patients need medically. Their involvement and support is also essential for implementation of interventions (appendix 2; table 4).

III. Board members: after understanding the patient and provider level determinants, I explored the board's feelings and priorities are about these interventions to determine board-level determinants especially with regards to initial and sustained funding. The board makes the final adoption decision and is responsible for an implementation team (appendix 2; table 5).

IV. Donor: I conducted an interview with a community benefit manager of a major donor organization which has provided money and staff to the clinic to understand 'outer-setting'-determinants (how fundable the interventions that meet patients/providers/board desires were). Knowing what donors value is important to maximize initial and sustained funding (appendix 2; table 6).

V. At the recommendation of the interviewed donor, I also conducted an interview with a director of another free clinic in the area which has implemented a chronic care program for diabetes (appendix 2; table 7).

The interview/focus group questions were based on the CFIR, anchoring on the CFIR constructs. They varied based on the participant type. This is detailed in the interview guides and CFIR table (appendix 2; tables 2-7).

Recruitment/ Eligibility

The sample size was determined based on the goal of interviewing enough patients and staff to reach thematic saturation (enough data collected or analyzed so that further data collection and/or analysis are unnecessary and do not add new information).[54] For the focus groups with patients and providers, the expectation was that 2-3 focus groups with 8-12 individuals per group would be enough to reach saturation.[54] The goal was to recruit as many of the providers who volunteer at the clinic as possible and 24 or more out of the hundreds of Spanish-speaking, patients (and their families) who come for care at the clinic. To recruit participants, we invited all patients with diabetes who had appointments at the clinic starting about 3 weeks prior to the first scheduled focus group with a goal to schedule about 20-25 per group (assuming that 50-75% may not show up). The patients were informed that they could bring family members or friends with them to the focus groups. There were no specific inclusion criteria for selecting family members. Anyone who patients brought were welcome to join (with the underlying assumption that, if they brought someone, that person was supportive in some way to them and therefore was eligible for inclusion).

For the board, one focus group with 7 people was the maximum possible as there are 8 volunteer clinic board members (including myself). There are three large donor groups (recently donating $25,000 or more to the clinic) and the goal was to interview as many of them as possible individually. Potential focus group attendees were identified via the clinic board and clinic manager as they have access to the patient registry, charts, the staff contact information, and information about all the donors. I asked the clinic manager (who speaks Spanish) to approach diabetic patients in person when they come in for appointments and invite them to attend the focus group. I invited board members to participate during a bi-monthly board meeting. I contacted providers via email and via the clinic manager in-person when they came in for their shifts. I contacted donors via email. To account for busy schedules of focus group participants, I scheduled multiple focus groups for each group at different times. A standardized verbal (and email) script in English (for staff and donors) and in Spanish (for patients) was used to invite them.

Section 2.4 Consent and Confidentiality

Informed Consent process

This was reviewed and approved by the institutional review board (IRB) at the University of North Carolina, Chapel Hill (UNC). Verbal consent was sought just before starting focus groups and interviews to minimize any document that linked subjects to the study. All subjects in the study consented and none dropped out.

Disclosure regarding the rights of vulnerable populations

Patient subjects recruited in this study were considered part of a vulnerable group as they have no or limited ability to understand English, are immigrants and may be economically disadvantaged.[64] Since all these vulnerabilities are believed to be common in the population seeking care at Al-Shifa, none of these conditions warranted study exclusion. To ensure that subjects were able to provide proper informed consent, the consent and for the focus group questions were professionally translated into Spanish by the interpreter.

Focus Group and Interview Procedures and Data Management

I conducted the patient focus groups in person, in the clinic's private conference room. I facilitated the discussion in English, with the support of a Spanish interpreter, who translated from English to Spanish and Spanish to English in real-time. I conducted individual interviews over the telephone to accommodate stakeholders schedules. The focus groups/ interviews required the collection and storage of confidential data in several formats (audio files, transcriptions of audio files, data analysis software files, and hand-written notes). During the key informant interviews and focus groups, I took hand-written notes which did not include any patient names or identifiers. All data files were password protected. The key informant telephone interviews were recorded using an iPhone app (*Rev Call Recorder*) and the focus group recordings using an iPhone app (*voice recorder*). Audio files were securely transcribed with a professional transcription service (*www.rev.com*). I uploaded transcriptions to

a coding software (*www.dedoose.com*) as well to facilitate co-coding. For the patient focus groups, I had only the verbal English translations transcribed for analysis (as the interpreter had already translated from Spanish to English in real time).

Section 2.5 Data Analysis

Exhaustive categories which correspond to the CFIR domains and CFIR constructs under each domain were created (see codebook). Transcript statements were coded under corresponding categories. The interview/focus group questions were designed to correlate with the CFIR constructs (see appendix 2 for interview/focus group guides).

I read and reread my notes and transcripts and looked for *repetitions, strength of convictions, conflicting perspectives,* and *significant omissions* (issues not mentioned which I expected to be mentioned) as suggested in the literature.[50] In addition, a colleague coded one focus group from each stakeholder group (patients, providers, board) independently prior to my coding of the full set of focus group and interview transcripts. We compared our coding of these transcripts, reconciled differences and recoded when necessary. Items that were often repeated, representative of strong convictions, or omitted by most of the stakeholders in a group were categorized as themes corresponding to the codes.

Section 2.6 Aim-2: Plan for change

From the literature review and the different groups interviewed (during Aim-1), I noted which of the potential health education interventions (individual health educator-led, pharmacist-led, or team-based approach) was most suitable to the needs of these different groups. I followed these sequential steps: 1) identify interventions for consideration, 2) evaluate whether it is acceptable to stakeholders, 3) determine what adaptations are needed, and 4) adapt the intervention. To reconcile conflicting perspectives between stakeholders groups when selecting an intervention, I took a patient-centered approach by making the priority to identify intervention/s that met patient needs.[60] These interventions were then filtered by which would be supported by providers. Those were then filtered by which would be supported by the board and which would be fundable by the donor. Finally, they were filtered by which could be implemented now and sustained in the future. Furthermore, to evaluate the success of the intervention in terms of patient outcomes, frequency and type of measures (e.g. drawing lab tests for HBAIC every 3 months for monitoring glycemic control), and outcome measures (e.g. the % of HBAIC lab tests that are <9) were selected based on the standard of care for diabetes.[2]

CHAPTER 3: RESULTS

Section 3.1 Focus Group and Interview Participants

Patient focus groups: seventy-five Spanish-speaking, diabetic patients of Al-Shifa were invited to participate in the patient focus groups. Twenty-six subjects came to the focus groups and all agreed to participate. Four in-person focus groups (mean duration 72 minutes; range 65 - 79 minutes) were completed with a total attendance of 17 patients and 9 patient family members (spouses and children of the patients).

Provider focus groups: 20 providers were found to be involved in diabetic care and were invited to participate with a total of 11 participating. Two in-person focus groups (48 minutes each) were completed with a total of 9 providers including 2 attending (supervising) physicians, 4 resident/fellow physicians (in training), one American medical student, one international medical graduate, and one pharmacist. All were clinic volunteers. Two individual phone interviews about 30 minutes in duration (one attending physician and one resident/fellow in training) were completed as well. Board focus groups: 7 board members and the clinic manager were invited to participate. A total of 5 board members and the clinic manager participated in a single, in-person focus group lasting 12 minutes. Donor interview: One phone interview lasting 50 minutes was done with a donor. Finally, one phone interview lasting 40 minutes was done with the director of a neighboring free clinic (at the advice of the donor).

Section 3.2 Codes and Themes based on the Outer Setting Domain, Construct: Patient Needs

The key themes that emerged under the patient needs codes from the patient perspective (during patient focus groups) were the need for 1) knowledge, 2) convenience, 3) support, and 4) dignity. There was a high priority placed on the need for nutrition education and proper use of medication/ side effects. These themes were expressed often and with strong conviction (preceded by terms like 'very', really, must, etc.). Example quotes were:

> "very important that we have a nutritionist"
> "Should teach the people what the side effects are.

Several patients also expressed interest in general diabetes education. While this was not repeated as often, it was stated with strong conviction. An example was:

> "…what's really important is that they inform us about the consequences…of diabetes if you don't care for yourself."

The need for convenience related to having readily available medication refills and blood tests. This was expressed often, with two examples being:

> "the convenience and the time and getting it in one place is very important."

The need to preserve dignity was a prominent theme expressed under the subthemes of self-sufficiency & self-efficacy. This was notable in quotes such as

> "…must focus on oneself…" and "I'll do whatever possible and necessary."

and in several patient's hesitancy to accept the small stipend of $10 for participating in the focus groups:

> "I want to give this money back as a donation to Al-Shifa…"

During the provider interviews/focus groups, the theme that emerged was a disconnect between their perception of patient needs compared to patients' perceptions of their own needs. For example, a provider noted:

> "patients' motivation is most important… people need gift cards as a reward to improve health… financial incentive - $10"

In sum, patient's perspectives about their needs were based on intrinsic motivations. In contrast, provider's perceptions about needs focused more on the potential need for extrinsic motivators.

Section 3.3 Codes and Themes based on the Outer Setting Domain, Construct: Patient Resources

For this construct, patients were asked to describe barriers that made it harder for them to control diabetes or facilitators that helped them control diabetes. Most people brought up barriers. The most often repeated barrier was a lack of nutrition and medication knowledge as already highlighted in the patient needs section. Another important barrier was financial. An example quote was:

> "One has a big family…we can't put a whole lot of money into resources…sometimes we can't eat what we want to eat that's healthy..."

While this was repeated several times, it was stated more as a matter of fact that the patient had accepted rather than as a request for financial assistance as mentioned earlier. Several people also mentioned a time barrier. An example was:

> "lack of time…to make the meal that's going to be good for me so end up eating fast food"

Habits as barriers were mentioned a few times as well with strong conviction. An example was:

> "Money is NOT necessarily the barrier, what makes it difficult is our habits, our custom, our culture."

Family support was viewed differently across participants. Some participants viewed their family as a barrier to and others viewed their family as facilitating their ability to control their diabetes. An example of the former is the patient statement:

> "seems like [my family] don't really care because everybody has diabetes"

An example of the latter is the patient statement:

> "I do have the support of my family especially my wife helping me with, telling me I need to go walk more, and I need to eat healthier."

Patients also had sometimes conflicting views regarding whether Al-Shifa was a barrier or a facilitator to their controlling their diabetes. Most people expressed gratitude that Al-Shifa provided them the healthcare it did as exemplified in this patient statement:

> "I am really grateful for all the services they have here [Al-Shifa]"

At the same time, many also highlighted barriers to achieving diabetic control that can be blamed on the clinic. An example is the following patient statement:

> "…greatest barriers…sorting all my medications out, because sometimes when I come in, it is a different doctor… I don't know the days and times in which I could speak to my doctor regarding the medications."

Finally, several patients and family members also expressed the language barrier. For example, a daughter said the following regarding her mother, a diabetic patient at Al-Shifa:

> "she doesn't know how to read English… Sometimes I'll write [instructions] in Spanish on the bottles. She takes different medications…so that's really important."

Section 3.4 Codes and Themes based on the Outer Setting Domain, Constructs: Cosmopolitanism

The key theme that emerged under this construct was that Al-Shifa has not been as involved with the community or with granters as it should be and has not utilized freely available patient management resources in the community. From the interview with the director of a neighboring free clinic (director), I learned that his clinic has been utilizing available educational programs in the same community that are offered at no cost but Al-Shifa has not been doing so. This neighboring clinic is only minutes away from Al-Shifa, serving the same population. The director stated:

> "We have full access to [Saint Bernadine's] health education. If you want to utilize [their] health education [then]… you put this… software in [at Al-Shifa] … you put health education [referral]… and that referral goes to [St Bernardine's]. They'll contact the patients and set up an appointment… in our system too, we also have specialty care, which I rarely ever see a referral from [Al-Shifa] … We have [tried to reach out to Al-Shifa to collaborate] …"

The donor also confirmed that Al-Shifa has not been as involved with the community. The donor stated:

> "... I haven't seen the new [Al-Shifa] administrator in any coalitions, collaboration meetings, partnership meetings, but prior to a year ago, Al-Shifa had a presence in the community."

Section 3.5 Codes and Themes based on the Outer Setting Domain, Constructs: External Policy & Incentives

The other key theme that emerged during the donor interview, was that Al-Shifa was not meeting the grant agencies' expectations post-reward. This is despite Al-Shifa having a monetary incentive to do so, as it may increase their likelihood of getting future grants. The donor stated:

> "… if we have funded something in the past… and if we haven't seen progress or … the final report is not kind of what was proposed than that would affect funding… it is difficult to continue to fund …"

Section 3.6 Codes and Themes based on the Outer Setting Domain, Constructs: Peer Pressure

Under this construct, the key theme that emerged was that Al-Shifa was behind other free clinics in chronic disease management despite having similar opportunities/ challenges. For example, the neighboring free clinic has developed a chronic care management program for diabetes. The donor stated:

> "we are seeing less requests for grants from community clinics because over the 10 years, community clinics have made tremendous progress in their chronic disease management... that's covered now by their core operations and it is just part of regular patient care management… the other free clinic in San Bernardino… they're very successful in their fund development. So, they have core operating funds to hire people so that they are full-time permanent…"

The director of that free clinic confirmed they are a peer group to Al-Shifa with similar local resources and challenges but are more organized with less turnover despite similar staff benefits. He stated:

"We have 330 doctors that volunteer… 14 locations … we see 30,000 visits a year … We're a free clinic system… I think [we pay] $14.50 an hour…all Mas… we have an RN volunteer that annually does all the foot exams and … make sure that all our diabetic patients are getting their annual stuff. [Medical assistants] go in the rooms to translate [Spanish] when needed… some doctors speak Spanish. We get [over 1000] volunteer pre-med students, and we teach them how to translate… [they] love it because it is like shadowing the doctor…. We're also going to have the [school of] pharmacy [students] do med refills [with an overseeing physician]"

He added:

> "I've never had any turnover. [Our secret for retention is] Be nice to [staff]… we make sure that the atmosphere at the clinic is happy… make time to take the doctors and my staff maybe once every three or four months out to dinner to say thank you for what you do…"

Section 3.7 Codes and Themes based on the Intervention Characteristics Domain, Construct: Design Quality & Packaging

During patient focus groups, the need for community support was especially highlighted in an almost unanimous desire to have education provided in a group setting. Several also added that they would want family members (spouse, kids) involved. This was supported by family members who attended the focus groups who expressed a strong desire to help taking care of their afflicted spouse or parent.

> "[It] is really important to know the right information as well as to be in a group, so we can guide [and help] each other."
> "The support is the most important thing…" the interpreter explained [once he didn't have her wife support, his health declined again]
> "It'd be beneficial to have your children here- my daughter is 9…always ask me why are you poking yourself all the time?"

Board members had a consensus that general health education (as compared with having a pharmacist or a care management team) would be top priority as well. The first theme to emerge from the providers under this construct was that they 'preferred non-group formats for patient education'. While they had different ideas (without one being more prominent than the other as to the best education format) – what was clear was that it would not be in a group. For example, providers statements included:

> "nice to get informational classes but 1:1 better"
> "…we should have the brochures…also…one-on-one talking about what diabetes is"
> "implement something [like] social media…Facebook page with Q & A"

This contrasts with a strong patient preference for group education which they preferred vs. 1:1, or written materials although two patients specifically preferred written pamphlets that they could review on their own time rather than education given in the clinic. This patient statement is one of those examples:

> "[I] prefer… [a] pamphlet, because … with my work schedule, I can't just come in…[A] pamphlet would be much easier."

Section 3.8 Codes and Themes based on the Intervention Characteristics Domain, Constructs: Adaptability, Trialability, Complexity, and Cost

The donor was the only participant who commented on these areas and confirmed that adaptability, trialability, a lack of complexity, and cost-effectiveness are favorable characteristics for an intervention that they would consider funding. The donor stated:

> **"**If it is too complex, I think it becomes an inherent barrier to already basic normal barriers like timing, transportation, length of time. So, I think more simple interventions would be useful."

Section 3.9 Codes and Themes based on the Inner Setting Domain, Constructs: Networks & Communications and Culture

Under the domain of the inner setting, conflicting themes emerged regarding the effect of culture and the communication network within Al-Shifa on implementation. When asked about culture, one provider stated:

> "…[It] could be challenging to get everybody on board with new programs … they may not have the time or energy to dedicate to making that program successful."

Another stated:

> "I think the culture here is pretty positive. I mean everybody here works collaboratively pretty well."

When asked about communication, one provider stated:

> "I don't know anything about the clinic… need more tight communication to have hand-offs

Another stated:

> "[The clinic manager] is here, and she's very knowledgeable about what's going on…she's my go-to person for finding out what's changed."

During the board member focus group, board members stated that it was essential for the clinic to have a networking process (between the providers and administration to facilitate implementation), as this process was non-existent at the time. Regarding culture, board members expressed both positive and negative aspects of the effect of the culture on implementation, as expressed in this statement:

> "It is tougher because you don't have a captive audience because it is volunteer-based … despite that, it wouldn't be difficult [to implement]. We have our clinical manager… & our clinicians, and a good education of what the program is. "… [an intervention] will be well-received".

Section 3.10 Codes and Themes based on the **Inner Setting Domain, Construct: Implementation Climate (tension for change; relative priority, compatibility and organizational incentives for interventions; and readiness for implementation)**

When providers were asked about the implementation climate, they expressed varying priorities for change (e.g. health education classes; clinical pharmacists; a team-based approach; stabilizing the clinic administratively; setting up an EHR/ data collection mechanism; having a medication dispensary). but the theme that emerged was that providers prioritized reforming the clinic infrastructure and organization before any educational intervention. Examples include:

> "[There is a need for] education …community health aid, physician extender, or diabetic nurses … [clinical pharmacists] could be beneficial to reinforce what the physician is explaining… [but] trying to stabilize the clinic … [is the] higher priority" because of the recent [administrative] changes"
> "Coordinating management of diabetes [is the first priority]."
> "Getting more information to understand population better [EMR, etc.] is the primary goal."

Most providers thought health education classes would be compatible with the clinic but were skeptical about the compatibility of other interventions. At the same time, most providers thought that if an intervention was successfully implemented, it would lead to rewards to the clinic as well as to patients. When asked about their readiness for implementation, the theme was that 'providers were not interested in leading implementation' but were willing to support them and refer patients to them. Board members had a consensus that health education classes were the top priority and were very compatible with the clinic. They thought that a team-based approach or clinical pharmacist would be less compatible. They thought that a health education class would benefit the clinic especially if open to the community by recruiting patients to the clinic. Regarding the construct of Readiness for Implementation (Inner Setting Domain0, board members did not want to lead the intervention themselves. One stated:

> "I'll be happy to help you, but you will have to take the lead."

They felt that the clinic had the physical space to support a class and minimal funds to support a nutritionist (like paying for their gas/ transport if they would volunteer their time) but did not want to compensate them beyond that. Based on their statements, I found the major themes were that the board was concerned about saving money but confident about implementing an educational program. They noted:

> "The nutritionist, the dietician... [should be volunteers] … we might be able to compensate a little bit. Not at full, but some compensation for their gas or to give them appreciation that way."
> "I don't think we currently have a health nutritionist... We do have resources through Kaiser [Permanente], which is very good about patient education. If we approach them, that would be our number one resource, to actually have them send somebody [dietician]".

Section 3.11 Codes and Themes based on the **Characteristics of Individuals Domain, Construct: Knowledge & Beliefs about the Intervention**

Providers believed all the interventions to be beneficial but did not know of any evidence to support this belief. For example, a provider stated:

> "I could [not] give you statistics and percentages [regarding outcomes of studies of educational interventions to improve diabetic care] … I know that [health education/diet/exercise] can lead to overall control of diabetes."

Chapter 4: Discussion

Introduction

The objective of this study was to identify and detail potential determinants of implementation and sustainment of diabetic care interventions at Al-Shifa using the CFIR as an implementation framework. It was also to draft a plan for change to implement a specific intervention/s at this clinic.

Section 4.1 Summary of the Results

Based on the CFIR constructs, I found that there was an important unmet need for a Spanish language, educational class for Al-Shifa's patients with diabetes. Patients were specific in requesting a class that combined teaching by educators as well as the chance for them to learn from their peers. I found that there was a deficient network and communication platform and the lack of a mechanism to keep track of patient outcomes. I also found that there was a lack of awareness among providers of patient needs and that providers were willing to support but not to lead interventions. This disconnect might be due to cultural differences as the Al-Shifa providers were not Latino and most of their patients are not Latino. It is possible that Latinos prefer a greater involvement of family and friends in their healthcare than other cultures. Focus group participants indicated that design and packaging was a critical part of a diabetes education intervention. Specifically, I found that group settings were preferable to patients. These classes should be inclusive of family and community members, in-person, and comprehensive in educational scope. From the interviews with the donor and the director of a neighboring free clinic, I learned that Al-Shifa could benefit from improving its networking with other organizations in the community to offer services, including educational classes. This went against my initial expectation that an educational

program would need to be developed and taught at Al-Shifa. I will discuss this in detail in the plan for change. I learned from the donor that our neighboring free clinic was educating patients with diabetes by utilizing existing diabetes classes at a nearby hospital at no cost to the free clinic or to patients. I also learned from the donor that Al-Shifa may benefit from submitting applications for grants to support an intervention. The clinic board expressed interest in supporting interventions and identified money as their main barrier. Grant applications should explain how a proposed intervention is evidence-based, adaptable, and not too complex; how the outcomes will be measured and monitored; and how the clinic aims to sustain the intervention on its own. These perspectives are particularly relevant given that the donor contributes the most funds to the clinic and oversees one of the most successful health maintenance organizations in the country, and the director of the neighboring clinic leads the largest free clinic group in the state of California (14 free clinics). If successfully implemented, an educational intervention as mentioned above could potentially lead to improved glycemic control for Al-Shifa patients. This is supported by studies cited in the background including Willard-Grace *et al.* (2015), Gorrindo *et al.* (2014), and Kahn *et al.* (2012).[19,35,36]

Section 4.2 Limitations

This study has some limitations. The literature review (used to select potential interventions) was limited to studies that had glycemic control as an outcome. Diabetes care encompasses other things as well such as lipid control, blood pressure control, and regular eye and foot exams. Thus, the interventions selected for discussion during the focus groups and interviews may not necessarily be ideal for improving other aspects of diabetic care, such as ensuring regular eye exams. While this is barrier to achieving comprehensive diabetic care, it did allow the prioritization of the most important aspect of diabetic care, which is glycemic control. The study included only diabetic patients and their families, and the interview questions focused on diabetes. Diabetes may be influenced by other medical conditions such as chronic pain, etc. This study did not examine the influence of other conditions except what was otherwise

mentioned by patients. The study was also intentionally restricted to Al-Shifa and to Spanish speaking patients at this clinic due to the great need for help in this demographic. Ideally, the learnings would be applicable to free clinics in general, but this may not be true for other patient populations of free clinics (e.g. homeless people and those suffering from mental health). Another limitation is that the almost unanimous desire for a group education setting (expressed by patients) comes from a potentially biased sample – i.e.., individuals who self-selected to attend a focus group that involved patients and family members.

Section 4.3 Conclusion

In conclusion, the most suitable intervention for Al-Shifa's diabetic patients is a Spanish language, convenient, inclusive, and comprehensive educational class. This intervention can be implemented by networking with other organizations in the community that already offer the class. Implementation should be preceded by the establishment of a communications and networking platform for the Al-Shifa providers, staff, and board; an electronic patient registry to track outcomes; and the development of an implementation team that will lead all aspects of the project including grant writing and budgeting.

CHAPTER 5: PLAN FOR CHANGE

Introduction

In this section, I fulfill Aim 2 by describing an implementation and sustainment strategy for the selected intervention. I chose the EPIS framework for this *plan for change* as it fits well with the CFIR constructs (see figure 1, figure 2, & 3 for a comparison between the two), fits well with this study as it emphasizes the service delivery organization (Al-Shifa, in this case), and has been tested successfully in the public health sector.[55]

EPIS is a conceptual framework that describes variables hypothesized to play important roles in achieving effective implementation of evidence-based practices (EBPs) in publicly funded settings serving children and families and in public sector services in general. It emphasizes the role of service delivery organizations (inner context) and the systems within which they operate (outer context) with less focus on the clients (patients). This complements the work of Aim 1, which led to my selection of the intervention and site preparation - using a patient centered approach. In EPIS, the 'inner context' is similar to the CFIIR constructs of 'inner setting' and 'individuals involved'. EPIS recognizes that different variables may play crucial roles at different points in the implementation process and thus divides implementation into four distinct phases -Exploration, Preparation, Implementation, and Sustainment.[55] The most important variables for each phase, their correlation to the CFIR constructs, and their correlation to the data that I gathered during the interviews and focus groups are depicted in appendix 2; tables 2 and 8. Some additional planned steps for each phase are detailed under each phase as follows. My recommendations are summarized in appendix 4; table 11.

Section 5.1 Exploration Phase

Inner context

Through Aim 1, I explored interventions and determinants of their implementation and sustainment and concluded that the most suitable intervention for Al-Shifa to implement is a comprehensive educational class. I also concluded that establishing a communications and networking platform, a mechanism to monitor patient outcomes (e.g. electronic patient registry), and developing an implementation team will be critical for implementing and sustaining the intervention. I also learned that classes are offered in the community that could meet the patient's educational needs and save the clinic the burden of establishing on site classes. Al-Shifa would need to make referrals and monitor attendance. Al-Shifa should ensure that the class is inclusive (open to family, friends, and the community at large) and convenient (offered during the evening or weekend hours). Al-Shifa should also ensure that the class covers lifestyle (with an emphasis on nutrition, stress management and exercise); behavior change (to help improve habits); medication management (types of, proper usage of, and potential side effects of medications); and general diabetic self-care knowledge (e.g. mechanism of diabetes, consequences, glucometer use, and schedule for lab tests, eye exams, and foot exams).

Outer Context

Through my interviews with the director of a neighboring free clinic, I learned of detailed steps that he has taken over the years to ensure sustained education for his patients by utilizing community resources; utilize technology to monitor the care his diabetics receive; and how he minimizes staff turnover. I learned that the main community resource he relies on is could also be utilized by Al-Shifa to meet its patient's educational needs. This program exists in a local hospital system (Dignity Health – St. Bernardine's Community Hospital of San Bernardino).[61] It is called the Diabetes Self-Management Workshops and includes the following topics:

- Techniques to control diabetes
- Risk factors for diabetes
- Testing: Criteria for diagnosis
- Let's Get Moving!
- Health eating
- Diabetes complications
- Appropriate use of medications
- Diabetes and Depression

This program meets the needs expressed by most of Al-Shifa patients and is offered only 0.7 miles from Al-Shifa with easy access by car (3 minutes), public transport (10 minutes by bus), or walking (15 minutes). I learned that the neighboring free clinic utilized technology by developing a software to allow referrals to this diabetic class at St. Bernardines and that Al-Shifa can adopt this software (known as community referral network -CRN) at no cost.[65]

Through my interview with the donor and with providers, I learned of a second potential program that could serve as an educational intervention for Al-Shifa to send its diabetic patients. It exists in a local health maintenance organization hospital system (Kaiser Permanente Southern CA- KPSC) which has helped the clinic in the past (both financially & by sending providers to see patients at the clinic) and consists of a four-session class known as living well with diabetes. This class comes with a Spanish curriculum in addition to the English one. One of the board's preferences was to seek a health education program via KPSC (Kaiser Permanente Southern California). This program should be agreeable to Al-Shifa's providers, several of whom come from KPSC. The closest location of it is 15 miles from Al-Shifa (21 minutes by car; 86 minutes by bus).[62]

Section 5.2 Preparation Phase

Inner context (site preparation)

To lead the initial implementation effort, I recommend that the clinic manager and designated board member partner to form the initial implementation team who will oversee relevant staff roles,

database management, and board updates as well as medication refills. This may help improve the ability of Al-Shifa to network with external organizations as a lack of designated staff in the past may have led to the current state of 'poor networking'.

I recommend establishing a network that includes reliable and timely two-way communication between the clinic board and providers. I recommend that providers be educated about the rationale for the educational intervention. The fact that providers preferred non-group education for the patients can be rectified by educating the providers about patients' strong desire for group visits. Providers stated their willingness to support educational programs by referring patients to them.

I recommend improving patient-staff communication, as patients expressed communication barriers to care. This should include a policy that all front and back office staff be fluent in conversational Spanish and that patients have a reliable way to leave messages for staff after hours. I recommend that the clinic revise its mechanisms for medication refills to allow for timely refills of medications, one of the main clinic barriers mentioned by patients.

For the patient registry, I recommend creating and regularly updating a database of all the diabetic patients at Al-Shifa and using this database to improve care (e.g. reaching out to patients to complete care gaps) and to show the outcomes of the program to potential granters for sustained funding.

Outer context

I recommend that the implementation team contact the Dignity Health and KPSC managers for educational classes and agree on a process to refer Al-Shifa patients to their classes. This will require downloading the community referral network -CRN software to all patient-care computers used by Al-Shifa to facilitate referrals to Dignity Health. It will require following the KPSC manager directions for referring patients to KPSC. I recommend that Al-Shifa prepare and budget for promotional materials for this class include a flyer in English and Spanish with program details (description, address, phone numbers, and how to book a class with them). This way, patients can be empowered to arrange for the

classes once the referrals are placed. The time, space, and funds saved by utilizing the Dignity Health or KPSC classes (that would have otherwise gone towards establishing a new class at Al-Shifa) will help in the cost of the inner context recommendations described before.

Section 5.3 Implementation Phase

Inner context

I recommend the implementation team meet regularly during the pilots to monitor implementation and oversee the database. They should contact the providers and other staff to ensure proper referrals. They should send regular updates to the board and providers and should check their email for board/ provider feedback. I recommend that they designate the clinic manager to receive patient questions /requests via an Al-Shifa cell phone during. I also recommend that a schedule of covering providers be set up to manage refill requests and any clinical questions. I recommend that the board ensure that the clinic manager has protected time to fulfill all duties.

Outer context

I recommend that the implementation start with a pilot with designated referrals to Dignity Health and to KPSC classes. This is to ensure that we compare the two programs to see if one is more suitable than the other. I recommend that a subsequent pilot have patients who are given the choice of which class to attend to see if patients have an initial preference for one or the other. The results of these pilots should be considered, and the referral mechanism / follow up adjusted as necessary before full implementation (with clinic-wide marketing of the classes). I recommend that full implementation ideally start within one year of the initial trial as that should give enough time for the two pilots to be completed and evaluated without losing enthusiasm for the project as a whole.

I recommend that the initial trial be followed by a formal evaluation of each component of the process and the outcomes (a comparison between Dignity Health & KPSC). I recommend that the key process outcomes include the completed referral rate; staff perception of the ease to refer; and patient feedback about program accommodation, convenience, and comprehensiveness (reflecting patient and staff needs from the focus groups). It will be important to see if patients are comfortable leaving the familiarity of Al-Shifa to go to an external organization. This could be especially challenging for those with immigration issues (Al-Shifa doesn't ask about residency status). I recommend that the key outcome measures include pre/ post class HBAIC comparisons, patient wellbeing and patient confidence in self-management of their diabetes (reflecting patient needs and the standard of care for diabetes). Evaluation reports should include budgeted/ actual expense reports reflecting the needs of the board to minimize expenses (appendix 4; table 11).

Section 5.4 Sustainment Phase

Inner context

I recommend that the board commit to funding for the protected staff time needed to sustain the intervention from Al-Shifa's core-operations budget and that efforts be made to reduce staff turnover, especially of the implementation team. To further improve care, I recommend that the database include other components related to diabetes care (e.g. annual eye exams) and be used to reach out to patients to complete any care gaps. I recommend that the clinic work towards acquiring an EMR as soon as it can sustain one. I recommend that the implementation team discuss with students from local medical and nursing schools (who have rotations at Al-Shifa) the possibility of taking on enhanced roles with regards to translation (for those who speak Spanish), medication refills, and database management. This may reduce the burden on the implementation team and staff, allowing them to focus on other duties (appendix 4; table 11).

Outer context

I recommend that the evaluation reports be presented to the clinic board, providers, community leaders, government officials, and potential granters. Process and outcome measures should be included in grant applications to increase the chance of continued funding. The evaluation reports should also be shared with the director of the neighboring free clinic and compared to that clinic's process and outcome measures (if known). They should also be shared with other potential supporters including community leaders and government officials. I recommend that the reports be presented at the clinic's annual fund raisers to raise earmarked funds for further improvement of the clinic infrastructure (e.g. an EMR). To facilitate the dissemination of the learnings from this research, the reports can be used to prepare manuscripts for submission to academic journals, and presentations for national free clinic conferences, such as the annual conference for the NAFCC -National Association of Free and Charitable Clinics (appendix 4; table 11).

APPENDIX 1: TABLES AND FIGURES FOR CHAPTER 1

TABLE 1: AGE-ADJUSTED PREVALENCE OF DIAGNOSED AND UNDIAGNOSED DIABETES AMONG ADULTS AGED ≥18 YEARS, UNITED STATES, 2011–2014. NHANES (NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY).[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)
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)

FIGURE 1: INCIDENCE OF TYPE 2 DIABETES IN CHILDREN (2011-2012).
NHW = non-Hispanic whites, NHB = non-Hispanic blacks, H = Hispanics, **API = ASIANS/PACIFIC ISLANDS, AI = AMERICAN INDIANS.**[1]

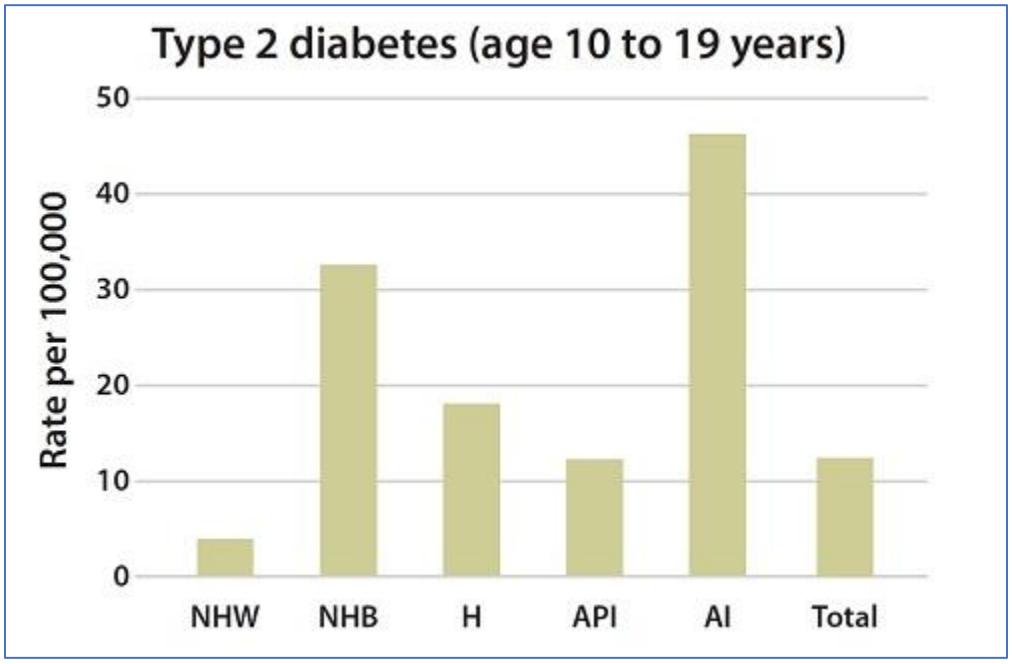


TABLE 2: TABLE MODIFIED FROM DARNELL: FREE CLINICS IN THE UNITED STATES: A NATIONWIDE SURVEY. ARCH INTERN MED. 2010;170(11):946-953. DOI:10.1001/ARCHINTERNMED.2010.107. COPYRIGHT © 2010 AMERICAN MEDICAL ASSOCIATION. ALL RIGHTS RESERVED.

Characteristic of free clinic/ free clinic clients	**Free Clinics**
Average hours open per week / Average wait time for appointments	18 hours / 12 days
Average operating budget per year	$288,000
% of clinics that got funds from private charitable donations	90.6%
% of clinics that got funds from civic groups / churches	66.8% / 66.3
% of clinics that got funds from corporations/ foundations	55% / 65%
% of clinics that got funds from government	41.3%
% of clinics that provided medications	86%
% that provided health education/ chronic disease management	77% / 73%
% that provided vision screening	53%
% that offered medications via a dispensary / via pharmaceutical samples	66%/ 87%
% that offered medications via a licensed pharmacy / outside pharmacy	25% / 52%
% that offered medications via corporate patient assistance programs	77%
Average fee charged to patients (as fees or donations) / % clinics that charged $0 for visits	$9 per visit/ 54%
% clinics that arranged for free lab/radiographic services	81% / 63%
% clinics that used volunteer physicians / nurses/ physician assistants/nurse practitioners	82% / 72% / 55%
% clinics that used volunteer social workers / psychologists	25% / 12%
% clinics that used full time/part-time paid staff	54% / 61%
% of patients who were uninsured	92%
% of patients who were female	58%
% of patients who are white	50%
% of patients who are Latino	25%
% of patients who are black	21%
% of patients who are American Indian, Alaska Native, Hawaiian or Pacific Islander	4%
% of patients who are at 200 or less % of the poverty level	97%
% of patients who are homeless	42%
% of patients who are immigrant	39%

TABLE 3: KEY POINTS FOR KEY STUDIES IN THE LITERATURE REVIEW

Source and year	Title	Setting/ length/ design	Intervention	# of pts intervention/ control/ % Latino	Statistically significant improved HBAIC	Limitations
Bluml et al. 2014[42]	Improving outcomes for diverse populations disproportionately affected by diabetes:	multiple/ 12 months/ retro-pre and post	pharmacists as health educators on site	1667/ 0/ 22%	YES	No control. Not specific to free clinics
Davidson et al. 2000[43]	Effect of a Pharmacist-Managed Diabetes Care Program in a Free Medical Clinic	free clinic/ ?/ retro-pre and post with control	pharmacists as health educators on site	50/ 27/ 64%	YES	Large % without repeat AIC, duration
Congdon et al. 2013[36]	Impact of Medication Therapy Management on Underserved, Primarily Hispanic Patients with Diabetes	safety-net clinic/ 3 months/ retro-pre and post	pharmacists as health educators on site	64/0/ 67%	NO	Not specific to free clinics, no control
Sease et al. 2013[51]	Pharmacist management of patients with diabetes mellitus enrolled in a rural free clinic	free clinic/ 24 months/ retro-pre and post	pharmacists as health educators on site	95/0/ 4%	YES	Limited # of Latinos, no control group
Shane-Mcwhorter et al. 2015[37]	Pharmacist-provided diabetes management and education via a tele-monitoring program	FHQC/ 6 months/ prospective with control	pharmacists as health educators via tele-monitoring	75/75/ 88%	YES	Not specific to free clinics
Schillinger et al. 2009[40]	Effects of self-management support on structure, process, and outcomes among vulnerable patients with diabetes	County run clinics/ 12 months/ RCT with 3 arms	Health Education- self management support via weekly phone or monthly physician group visits	112 /114/ 46%	NO	Not blinded, Not specific to free clinics.

Willard-Grace et al. 2015[33]	Health Coaching by MAs to Improve Control of DM, HTN, & Hyperlipidemia in Low-Income Patients	Safety-net clinic/ 12 months/ RCT	Latina Health education coaches did monthly phone, q3m in person education	167/ 165/ 90%	YES	Not blinded, Not specific to free clinics
Gorrindo et al. 2014[44]	Med students as health educators at a student-run free clinic: improving the clinical outcomes of diabetic patients.	free clinic/ 12 months/ retro-pre and post	Health education via medical students	45/0/ 33%	YES	No control.
Kahn et al. 2012[34]	The impacts of "growing our own": A pilot project to address health disparities by training health professionals to become CDEs in safety net practices	safety- net clinic/ 12 months/ retro-pre and post	Health education: CDE doing classes or 1:1 visits	219/426/ 14%	YES	Unmatched controls, lower AIC at start, Not specific to free clinics
Khan et al. 2010[41]	Caring for uninsured patients with diabetes: Designing and evaluating a novel chronic care model for diabetes care	urgent care, safety-net/ 12 months/ prospective pre and post	Chronic Care Model (DM & nutrition classes, patient tracking, & dedicated staff)	1098/ 0/ 30%	YES	variable follow up period, Not specific to free clinics
Mayes et al. 2010[39]	New Direction for Enhancing Quality in Diabetes Care: Utilizing Tele-communications and Paraprofessional Outreach Workers Backed by an Expert Medical Team	primary care clinic/ 42 months/ prospective pre and post	PCP & endocrinology care via tele-health, promatoras, RNs, & CDEs	16/ 0/ 100%	YES	small sample size, Demographic data not presented, Not specific to free clinics

APPENDIX 2: TABLES AND FIGURES FOR CHAPTER 2

FIGURE 2: THE CFIR TO MODEL THE KEY VARIABLES AFFECTING PATIENT CARE AT AL-SHIFA FREE CLINIC.

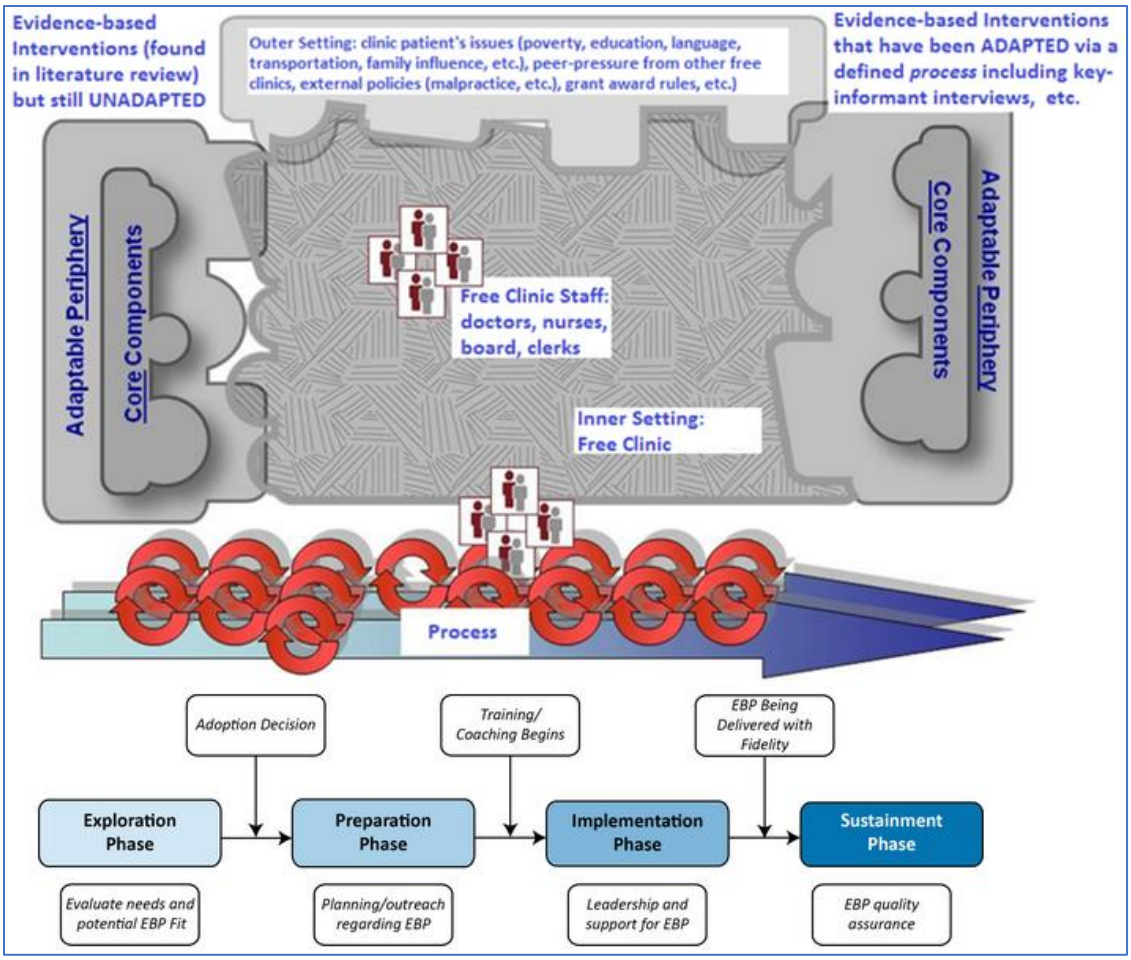


FIGURE 3: EPIS: CONCEPTUAL MODEL OF GLOBAL FACTORS AFFECTING IMPLEMENTATION IN PUBLIC SERVICE SECTORS (AARONS, 2011)[55]

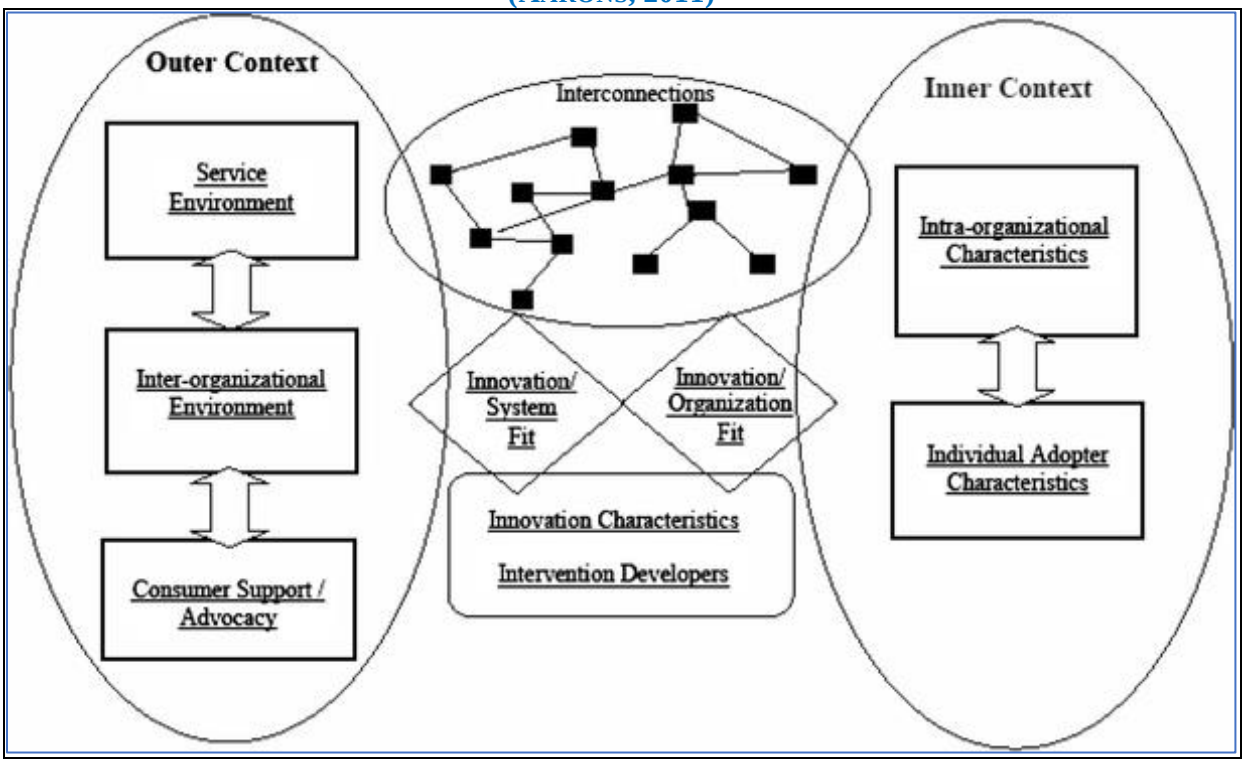


TABLE 4: CFIR DOMAINS, CONSTRUCTS, AND PARTICIPANTS; AND THEIR RELEVANCE TO THIS STUDY

Outer Setting	Short description	Relevance to this study	Participant/s	Relevant Questions
Patient Needs	The extent to which patient needs & determinants to meet those needs are known and prioritized by the organization	This study will seek to better understand patient needs and determinants as well as the clinic's understanding of those needs through patient and provider interviews	Patients, providers	See patient questions 1-6 (table 3)
Patient Resources	The extent that patients have resources (facilitators) or don't have resources (barriers) to implement an intervention			See patient questions 3-8 (table 3)
Cosmopolitanism	Degree that organization is networked with other external organizations	The clinic has a strong tie with a local HMO that both sends providers and grant money to care for patients at the clinic but may be lacking otherwise in networking	Donor; director of a neighboring free clinic; clinic board	See donor question 8 (table 6), director questions 1-2 (table 7), and board question 8 (table 5)
External Policy & Incentives	Includes government policies, regulations, guidelines, public reporting, etc. as well as the policies of granting organizations.	Regulations of donors/granters are important. (e.g. a grant giver may require proof of patient adherence to and results of an intervention and the creation of electronic databases)	Donor	See donor question 5,7 (table 6)
Peer Pressure	From competing organizations	There is competition for the grants that Al-Shifa has received in the past.	Donor; director of a neighboring free clinic	See donor question 6 (table 6), director questions 3-5 (table 7)

Intervention Characteristic	Short description	Relevance to this study	Participant/s	Relevant Questions
Evidence Strength & Quality	Perception by clinicians at clinic	Will only consider interventions that have been proven to improve diabetic care in safety-net clinic sites.	Donor, providers	See provider question 6 (table 4), donor question 1 (table 6)
Adaptability	Degree to which it can be adapted to meet the needs of the patients and clinic	The intervention/s will be adapted first to meet the needs based on the info gathered in the interviews with the stakeholders	Donor, providers	See donor question 1 (table 6)
Trialability	Can it be tested on a small scale and abandoned if necessary	The plan for change will include a preliminary testing phase followed by an evaluation before a full commitment is made to any intervention	Donor, providers	See donor question 1 (table 6)
Complexity	Perceived difficulty of implementation (duration, scope, disruptiveness, number of steps required)	An intervention/s that has the minimal complexity possible will be selected.	Donor, providers	See donor question 1 (table 6)
Design Quality & Packaging	Perceived excellence in packaging of the intervention	Will plan to package the intervention during the adaptability phase	Patients, providers, board	See patient question 9 (table 3)
Cost	Including investment, supply, and opportunity costs	Will select the most cost-effective option and one that is fundable by donors to the clinic.	Board, donor	See donor question 1 (table 6)
Inner Setting	**Short description**	**Relevance to this study**	**Participant/s**	**Relevant Questions**
Networks & communications	Quality of social networks & communication within an organization	Social networks and communication are lacking. The clinic manager sends a monthly email with the clinic schedule and major updates like when a fundraiser is scheduled, but otherwise there is scheduled regular communication between the clinic administration	Providers, board	See provider & board question 1, (tables 4 and 5)

		(board, director, manager) and the clinicians.		
Culture	Norms, values, and basic assumptions of the organization	The organization values volunteerism, altruism & the faith traditions. Clinicians are generally left to practice within their comfort level without oversight.	Providers, board	See provider & board question 2, (tables 4 and 5)
Implementation climate	1.Tension for change (among stakeholders that change is needed) 2.Compatibility of intervention with involved individuals 3.Incentives & rewards from implementation	For factors 1,2,3: information will be gathered via focus groups & interviews to get understand where staff are regarding these factors.	Providers, board	See provider & board questions 3-7, (tables 4 and 5)
Readiness for implementation	1.Leadership engagement with the intervention 2.Available resources for implementation ($, time, space, education, training)	1, 2: through interviews with the clinic administration, will ensure that they are fully engaged with the selected intervention/s; that they have allocated all the necessary resources for it	Providers, board	See provider & board questions 3-7, and board question 8 (tables 4 and 5)
Characteristics of individuals	**Short description**	**Relevance to this study**	**Participant/s**	**Relevant Questions**
Knowledge & beliefs about the intervention	By the staff. Beliefs include values and attitudes	Information will be gathered via focus groups and interviews with staff to understand these	Providers	See provider question 6 (table 4)
Process	**Short description**	**Relevance to this study**	**Participant/s**	
EPIS Stages	The process by which an intervention will be implemented and adapted to fit the site and the site adapted to fit the intervention	This is process is the 'plan for change'	Board, donor, director of a neighboring free clinic	See donor, board, & director questions (tables 5-7)

TABLE 5: FOCUS GROUP QUESTIONS FOR THE CLINIC PATIENTS & THEIR CORRESPONDING CFIR & EPIS CONSTRUCTS

Questions for patients	CFIR constructs (Outer Setting)	EPIS phase	EPIS context/ variables
Thank you for coming. We are here today to learn from you about your needs and priorities for improving your diabetes so as to enjoy greater health & wellbeing. In order for the clinic to best help you, we need to understand those needs & priorities so that we can best tailor care to you. Diabetes care includes everything you do to improve your blood sugar (avoiding high & low sugar) as well as improving your cholesterol, blood pressure, body weight, and energy level. It also involves getting periodic checkups on your eyes, feet, and blood testing. I will be asking you some general questions relating to your needs and to what you think Al-Shifa should provide to you. There is no wrong answer -this is not a test -this is for us to learn from you. If you don't feel comfortable discussing any question asked, you do not have to respond to it. It is also up to you how much and what information you share. You are not required to share any personal, private, or potentially embarrassing information. If you wish to add any information with us in private, outside of the focus group, we can arrange for that as well. To start, please introduce yourself and tell us a little bit about yourself and how many years you have had diabetes and how many years you have been coming to Al-Shifa.			
1. What are your most important needs to improve your diabetes?	Patient Needs,	1,2,4	Outer/ client advocacy, valuing multiple perspectives
2. What do you think Al-Shifa can do to best help you improve your diabetes?			
3. In what ways do you think having more medication education can meet your needs to improve diabetes? Do you have the ability/resources to benefit from such a program?			
4. In what ways do you think having more dietary, exercise, and stress relief education through an Al-Shifa program can meet your needs to improve diabetes? Do you have the ability/resources to benefit from such a program?			
5. In what ways do you think having a dedicated clerical and nursing staff through Al-Shifa can meet your needs to improve diabetes? Do you have the ability/resources to benefit from such a program?			
6. What do you think are potential barriers to you meeting those needs so that you can be healthy?			

7. What resources (knowledge, $, family or friend support) & available time do you have to meet those needs?			
8. What do you think other organizations in your community can do to best help you improve your diabetes (this may include organizations that you have been to or have heard about)?			
9. How would you like such a program delivered in terms of location (e.g. in the clinic or over the phone or at your home), and at what frequency (e.g. weekly, monthly, etc.) & why?	Intervention Characteristics		

TABLE 6: FOCUS GROUP & INTERVIEW QUESTIONS FOR THE CLINIC PROVIDERS & THEIR CORRESPONDING CFIR & EPIS CONSTRUCTS

Questions for providers	CFIR Constructs (Inner Setting)	EPIS phase	EPIS context/ variables
Introduction: Thank you for doing this! I know that you are dedicated to improving your patient's health as you volunteer your time here. We are here to learn your perspective on potential education interventions to improve diabetic care at Al-Shifa. While we aim to be on par with national expectations for diabetic care, we also have unique challenges & opportunities in being a free clinic. For an intervention to be implementable and sustainable for years to come at AL-Shifa, it should be evidence-based and fit our needs and resources as a provider. There is no wrong answer to the following questions, this is a chance for me to learn from you. Let's start by having you introduce yourself, how long you have been with AL-Shifa, and your current work with diabetics here.			
1. What are your feelings regarding the quality of social networks & communication within Al-Shifa?	Networks & communications	1,4	Inner/ social networks
2. What are your feelings regarding the norms, values, and basic assumptions of Al-Shifa?	Culture	1,2,3,4	Inner/ culture, leadership,
3. How do you feel about implementing a health education program (like a weekly class taught by a dietician) at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa? -what rewards may Al-Shifa reap from doing this? 4. What do you think about using a clinical pharmacist to educate patients at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa? -what rewards may Al-Shifa reap from doing this? 5. What do you think about using a dedicated multi-specialty team (with doctors, nurses, health-educators, case manager) to educate patients at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa? -what rewards may Al-Shifa reap from doing this?	Implementation climate	1,3	Inner/ knowledge, skills, priorities, attitudes toward EBP

6. What do you know about the outcomes of the following educational interventions to improve diabetic care in free clinics: -a clinical pharmacist to educate patients / manager their medications -a dedicated multi-specialty team (physician, nurse, case-manager, etc.) involved in patient education -a health education program (e.g. weekly, dietician-led class)	Knowledge & beliefs about the intervention	3	Inner/ attitudes toward EBP, EBP structural & ideological fit
7. What would you envision your role being if one of the following interventions were being implemented at Al-Shifa? -a clinical pharmacist at Al-Shifa? -a dedicated multi-specialty team -a health education program (e.g. weekly, dietician led class)	Self-efficacy/ Individual stage of change (also relevant to the Inner Setting Construct of "readiness for Implementation"	1,2,4	Inner/ readiness for change, perceived need for change, role specialization, championing adoption, staff selection criteria

TABLE 7: FOCUS GROUP & INTERVIEW QUESTIONS FOR THE CLINIC BOARD & MANAGER & THEIR CORRESPONDING CFIR CONSTRUCTS & EPIS PHASES/CONTEXTS/VARIABLES. FOR THE EPIS PHASE COLUMN: EXPLORATION PHASE =1; PREPARATION PHASE =2, IMPLEMENTATION PHASE =3; AND THE SUSTAINMENT PHASE =4.

Questions for Board & Manager	CFIR Constructs (Inner Setting)	EPIS phase	EPIS context/ variables
Introduction: Thank you for doing this! I know that you are dedicated to this clinic's success as you volunteer your time here. We are here to learn your perspective on potential education interventions to improve diabetic care at Al-Shifa. While we aim to be on par with national expectations for diabetic care, we also have unique challenges & opportunities in being a free clinic. For an intervention to be implementable and sustainable for years to come at AL-Shifa, it should fit our needs and resources. There is no wrong answer to the following questions, this is a chance for me to learn from you. Let's start by having you introduce yourself, how long you have been with AL-Shifa, and your current roles & responsibilities here			
1. What are your feelings regarding the quality of social networks & communication within Al-Shifa?	Networks & communications	1,4	Inner/ social networks
2. What are your feelings regarding the norms, values, and basic assumptions of Al-Shifa?	Culture	1,2,3,4	Inner/ culture, leadership,
3. How do you feel about implementing a health education program (like a weekly class taught by a dietician) at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa? -what rewards may Al-Shifa reap from doing this? 4. What do you think about using a clinical pharmacist to educate patients at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa? -what rewards may Al-Shifa reap from doing this? 5. What do you think about using a dedicated multi-specialty team (with doctors, nurses, health-educators, case manager) to educate patients at Al-Shifa? -Do you feel it is urgent to do? -What factors make this compatible (or not) with Al-Shifa?	Implementation climate	1,3	Inner/ knowledge, skills, priorities, attitudes toward EBP

	-what rewards may Al-Shifa reap from doing this?			
	6. What type of role would you like to play in improving the health education at Al-Shifa? 7. To what extent are internal resources available to implement: -a clinical pharmacist at Al-Shifa? -a dedicated multi-specialty team -a health education program (e.g. weekly, dietician led class)	Readiness for implementation (also characteristics of individuals "self-efficacy"/ "stage of change"	1,2,3,4	Inner/ readiness & perceived need for change for change, leadership, championing adoption, EBP role clarity, support system/coaching, staff selection criteria
	8. To what extent are external resources (other local service providers that Al-Shifa can network with) to support the implementation of -a clinical pharmacist at Al-Shifa? -a dedicated multi-specialty team -a health education program (e.g. weekly, dietician led class)	Outer setting, Cosmopolitanism	1	Outer context, inter-organizational context.

TABLE 8: INTERVIEW QUESTIONS FOR THE CLINIC DONORS & THEIR CORRESPONDING CFIR & EPIS CONSTRUCTS

Question for potential donors	CFIR Construct (Intervention Characteristics)	EPIS phase	EPIS context/ variables
Thank you for coming. We want to learn from you about your priorities & expectations for funding education interventions to improve diabetes at Al-Shifa. I will tell you about 3 types of interventions that have been shown to work in free clinic settings for Latinos, but of course require sustained funding. To start, please tell us about yourself & your relationship with Al-Shifa.			
1. Of the following characteristics of an intervention, which do you feel are most important for you to consider as a donor? Why/ why not?	(see following below)	1,2,3,4	Outer/ funding/ service, research, & foundation grants; support tied to fed/state policies; contracting arrangements; fit with existing service funds
i. Intervention Source	Intervention Source		
ii. Evidence Strength & Quality	Evidence Quality		
iii. Adaptability	Adaptability		
iv. Trialability	Trialability		
v. Complexity	Complexity		
vi. Design Quality & Packaging	Design Quality		
vii. Cost	Cost		
2. What are the relative advantages (or disadvantages) of using clinical pharmacists for medication education & management (vs. other options?	Relative Advantage		
3. What are the relative advantages (or disadvantages) of implementing a health education program (e.g. weekly class with dietician)?			
4. What are the relative advantages (or disadvantages) of implementing a diabetes care team (e.g. with clinician, nurse, case manager, etc.)?			
5. What are your current policies that may affect funding a free clinic for diabetes-related interventions?	External Policy & Incentives		
6. What can you tell us about the competition for your funding of Al-Shifa's efforts to implement diabetes-related interventions?	Peer Pressure		
7. Would you like to see Al-Shifa collaborate with other organizations that provide service to the same population? If	External Policy & Incentives		Outer/ direct & indirect networking,

so, can you provide examples of the type of organizations/ type of collaboration?			organizational linkages
8. How well has Al-Shifa networked with your group/agency over the past 3 years? What could the clinic have better in this regard?	Cosmopolitanism		

TABLE 9: INTERVIEW QUESTIONS FOR THE DIRECTOR OF A NEIGHBORING FREE CLINIC & THEIR CORRESPONDING CFIR & EPIS CONSTRUCTS

Question for potential donors	**CFIR Construct (Intervention Characteristics)**	**EPIS phase**	**EPIS context/ variables**
I just wanted to let you know that I am a board member at Al-Shifa. I volunteer over there. The free clinic, I think, neighbors with you. I am doing my dissertation, doctoral research on how to improve patient care for Spanish speakers at the clinic. As part of that, I've been doing a series of interviews with different stakeholders, patients, providers, board members, and then donors. It was Martha from Kaiser, their outreach department, community benefits who connected me with you. What Martha has told me, at Al-Shifa, we are still maybe a little bit behind the curve in getting proper disease management for diabetes without outcomes, measurements, and patient education and all that. We are trying to develop it. She told me that there are a lot of community clinics that have already done that. They've found a way to do it, they've found a way to have resources to sustain these interventions. They have steady employees who they pay a living wage and so forth. That's an amazing accomplishment for a clinic that does not bill patients. The questions revolve around that, understanding what you may have done to take care of diabetic Spanish speakers, and see what we could learn from you.			
Questions for potential donors (continued)	**CFIR Construct (Outer Setting)**		
1. How well has Al-Shifa networked with your group/agency over the past 3 years? What could the clinic have better in this regard? 2. Would you like to see Al-Shifa collaborate with other organizations that provide service to the same population served by Al-Shifa (and what can Al-Shifa do to do that)?	Cosmopolitanism	1,2	Outer/ direct & indirect networking, organizational linkages
3. I wanted to get an idea maybe about what you've done in the past to help diabetes or in general for chronic disease management. 4. As a free clinic, what is/are your secret/s to preventing staff turnover and for sustaining your care with limited resources? 5. How do you manage Spanish translation?	Peer Pressure	1,2, 3, 4	Outer/ Funding/ service, research, & foundation grants; contracting arrangements; fit with existing service funds

APPENDIX 3: TABLES FOR CHAPTER 3

TABLE 10: CODING OF INTERVIEW & FOCUS GROUP DATA

Themes *& subthemes*	**CODE:** from CFIR	**EXAMPLES** (from the raw data)	**Memos**
OUTER SETTING			
Need for Knowledge Nutrition	Patient needs	"The Diet… very important that we have a nutritionist, especially in a group like this where we can receive information" "you could stop taking medication with diet." Wife: "nutrition class will be really beneficial because that will help him understand what he should and shouldn't be eating"	all interested in dietary info, especially in groups.
Need for Knowledge Medication		"Should teach the people what the side effects are specifically with each medication." "great if we have pharmacist here to explain the (Rx) information" "I would like to know…about medication like timing, specifically what time should I be taking the medication"	much interest in getting info about meds (side effects, proper usage)
Need for Knowledge Diabetes		"if I could know my values of blood sugars" "more education…about how blood sugar can affect…feelings" "…what's really important is that they inform us about the consequences…of diabetes if you don't care for yourself." "(teach us how to use glucometer) …we don't know how to use it." "to get education about neuropathy"	They wanted to know about diabetes & how it affects them
Need for Knowledge Stress Relief/ Exercise		"That would be very important (stress relief/exercise education)" "I need that relaxation" "…having a room where you come in exercise (to) motivate you." "Sewing... (for peace of mind)"	stress was the 2nd desire

		"a therapist… (because we have so many emotions)"	
Need for Convenience Appointments / Medication		"It was really convenient (to) get blood test & see the doctor at same time." "It'd be really good to have an ophthalmologist… they referred me to a different location a month ago. They haven't responded yet" "(great)…if I could get my appointments a few days before the date so I can request time off work… Sometimes they'll call and just be like, can you come right now because the doctor is here" "(great) if the medication could be also given here." "yes… (would pay more to get meds at clinic) …the convenience and the time and getting it one place is very important."	Convenience seemed a big need, more important than money
Need for Support 1.Family 2.Community		"It is more helpful…if everybody is together, they know what's going on and if they're not connected then it is all over the place." "yes, would like (multi-disciplinary group)"	
Need for Preserving Dignity 1.Self-Sufficiency 2. Self-Efficacy		Patient: "why are you giving me money… I came with my mother…" "I want to give this money back as a donation to Al-Shifa…" "…must focus on oneself… "I'll do whatever possible and necessary." Daughter: "(my mother) has difficulty telling me, "Oh, I need (help)" she (says), "Oh, I am being a financial burden. You have your two kids." "I don't have economic problems …" "I have time to take care of myself"	Little interest in free meds. No blame put on others for their illness or problems
Disconnect Between Doctors		**Attending 2:** "pt.'s motivation is most important… **people need gift cards as a**	Patients didn't ask for $… despite

Perception of Patient Needs Vs. Actual Needs		**reward** to improve health…financial incentive ($10)" **Attending 3:** "**an app** that somehow collected data and there was a place where they could record data, it might help you more…" **PGY2 resident:** "have them checking their blood sugar (many) times a day (and) writing it down on a log…you can adjust their meds… have a system in place that tracked (lab tests) so you had a flag when they needed to get their labs done…some Excel file that tracks the patient population here to determine trends…"	admitting poverty. Some doctors not in touch with this
Knowledge Barrier/ Facilitators 1. Nutrition 2. Medication	Patient resources: Barriers/ Facilitators	"the first time I fell into a hospital… they gave me a lot of (do's &) don'ts (regarding food) …(but) I would feel that, everything would be shaking…Now, I just eat everything…don't eat too much sweet, but I still have a little bit in moderation". "My wife helps me a little, but I would like for her to have more knowledge." "… I study a lot … try to learn daily" "… have read in the internet… (helped her massage herself and improve symptoms"	
Time Barrier		Patient: "lack of time…to make the meal that's going to be good for me so end up eating fast food" "…long (work) commute. I'd love to go to the gym (but) I am just too tired, and I don't have the time." "I live in Hesperia. It is far (from clinic)"	
Bad Habit Barriers		Family: "He always want to eat something sweet" …Patient: "sweet food" "Money IS NOT necessarily the barrier, what makes it difficult is our habits, our custom, our culture." "You don't want to dedicate time until you are not feeling good"	

Financial Barriers Lack of $ Lack of Health Insurance		"One has a big family…we can't put a whole lot of money into resources…sometimes we can't eat what we want to eat that's healthy..." "Not having insurance, because if I had (it) I wouldn't leave the doctor." "having all those medications could be really expensive…"	
Support Barriers/ Facilitators Family		"…seems like (my family) don't really care because everybody has diabetes" "My wife helps me a little … (but)… she doesn't always have time to come to these meetings." "The support is the most important thing… once he didn't have her (wife) support, his health declined again" "I do have the support of my family (x 6 or more) especially my wife helping me with, telling me I need to go walk more, and I need to eat healthier." Patient: "What stresses me out is my wife, she's running out of time…with all these group activities at church (like marriage counseling they go to) ...takes us away from childcare…& when (she) says, "We need more money..." Wife: "(we) participate in the marriage group… offered at our church (they have) helped a lot…. with the communication between us, so I can understand what's going on with him"	Most think that they can come to classes ≥1 x month & find resources to comply with education. one couple was at odds- she saw marriage counseling as a facilitator; patient saw it as a barrier.
Support Barriers/ Facilitators Clinic		"(sometimes) you go to the pharmacy, and they say, "…this doesn't have refills…the doctor is not available… I go for two weeks without medication" "…greatest barriers…sorting all my medications out, because sometimes when I come in, it is a different doctor… I don't know the days and times in which I could speak to my doctor regarding the medications."	

		"I am really grateful for all the services they have here (Al-Shifa)" "She loves the care (at Al-Shifa)"	
Language Barrier		"I am not that good at reading things" Family "…she doesn't know how to read English… Sometimes I'll write (instructions) in Spanish on the bottles. She takes different medications…so that's really important." Daughter: "I don't have a lot of the resource… I can't come to all her appointments… Sometimes she doesn't know what the doctor told her"	
Trust Barrier		Patient: "I (don't trust) … the (glucometer) each gives different readings"	
Pain Barrier		"pain… 10/10… preventing exercise"	
Al-Shifa has not been as involved with the community or with granters as it should be and has not utilized freely available patient management resources in the community.	Cosmopol-itanism	Donor: "... I haven't seen the new (Al-Shifa) administrator in any coalitions, collaboration meetings, partnership meetings, but prior to a year ago, Al-Shifa had a presence in the community. They had good partnerships. So, I really don't know where that is (now)." Donor: "this past year (al-Shifa) did not apply (for a grant) because they missed a deadline… Al-Shifa did receive a grant each one of the two (previous) years… some of the feedback that I gave to them was to get their board involved in developing a strategic plan. I haven't seen much follow up on that (and) to communicate the impact of Al-Shifa over 10 years… and I haven't seen it… There was no follow up with me… So, the level of engagement from their end to us hasn't been very proactive or pursued. It is very reactive… I imagine that the challenge is… staff turnover. So, there's kind of a cycle of missed opportunities…" Donor: "(would be a plus for Shifa to) demonstrate by actually being involved and having a presence but really seeing some of those collaboration and partnerships actually become fruitful… something that I have strongly encouraged is board involvement and strategic planning.	The Donor represents the Kaiser Permanente Southern California Medical Group, a large donor to Al-Shifa with both money and staff. The director refers to the executive director of a free clinic system in Southern California that has 14 locations including one very close to Al-Shifa free clinic.

		Director of a free neighboring clinic (director): "We share the (Saint Bernadine) building with their health educators. We have full access to their health education. If you want to utilize Dignity Health's health education, we can coordinate that taking place so they can offer admittance to the (diabetic) classes…you put this software in and there's a spot in the software for referrals, you put health education, diabetes, and that referral goes to them. They'll contact the patients and set up an appointment. it is called CRN, Community Referral Network… we developed CRN…For clinics like Al-Shifa…there's a stand-alone software that you can use." Director: "In our system too, we also have specialty care, which I rarely ever see a referral from you guys (Al-Shifa) … We could do retinopathy exams on them, so you don't have to incur the cost of doing it. We have a grant that pays to do it, so let me use my grant to help your patients. ... we also have e-consult… upload any documents that that doctor needs to see… ask whatever question you want to ask. Then, that doctor will respond." Director: "We have (tried to reach out to Al-Shifa to collaborate) … part of my main problem with the Community Clinic Association in San Bernardino, is that they want (to work like independent states) ... in order for a coalition to succeed…We've got to work collaboratively… The only other thing I would recommend…is to ask them to join the (national) Free Clinic Association…"	
Al-Shifa has a financial incentive to follow the donors instructions	External Policy & Incentives	Donor: "When submitting a grant… have a team to help develop the grant… to really understand what the grant is asking for and determine what is the best proposal and…connect it to the individuals from the clinic that are running the program or delivering the services, to connect the dots…, if we have funded something in the past… and if we haven't seen progress or … the final report is not kind of what was proposed than that would	

		affect funding… it is difficult to continue to fund … something that you don't really see the impact or …there's no sustainability plan… , if (we give) unrestricted grant funding… Part of it is to give the clinic some time to develop its capacity to become stronger but also … so that ultimately they're not relying on grant funding …"	
Al-Shifa is behind other free clinics in chronic disease management despite having similar opportunities	Peer Pressure	Donor: "we are seeing less requests for grants from community clinics because over the 10 years, community clinics have made tremendous progress in their chronic disease management... they have support, they have active chronic disease management. So, they're not looking for funding because that's covered now by their core operations and it is just part of regular patient care management… it is very competitive but what community clinics are asking for now is for support to cover a navigator or a case manager for mental health services… mental health is one of our priorities access to care and economic opportunity" Donor: "the other free clinic in San Bernardino… They're very successful in their fund development. So, they have core operating funds to hire people so that they are full-time permanent. They still use volunteer physicians, but they have a core team and I believe that because of that they can afford to pay livable wages to employees, and they have regular hours." Director: "we have 330 doctors that volunteer… We have 14 locations… from Compton to San Bernardino… we see 30,000 visits a year … We're a free clinic system… we're not an FQHC… (we don't bill people) …" Director: "I don't know that we pay that great. I think $14.50 an hour is what we start them out at… we have three staff members (at one clinic) ... All are …all MAs. Some days they're working up front, some days they're working in the back…we have 35 paid staff (overall)… not all 14 locations are open (daily)…. A lot of the	

		staff will be in Compton today and tomorrow they're in Norwalk…. they move around… we have an RN volunteer that annually does all the foot exams and then does their chart review to make sure that all of our diabetic patients are getting their annual stuff" Director: "They've all been with me for six years. I've never had any turnover… (our secret for retention is) Be nice to (staff). We give them no benefits… we make sure that the atmosphere at the clinic is happy… make time to take the doctors and my staff maybe once every three or four months out to dinner to say thank you for what you do… and just letting them know their worth to us and to the organization." Director: "(medical assistants) go in the rooms to translate (Spanish) when needed… We've been lucky enough to get some doctors that speak Spanish. Anytime we have three doctors or more than two doctors, only one of those doctors can't speak Spanish, who otherwise we're bottlenecked…We've also reached out to the local schools, UCR, Loma-Linda, Cal-state, San Bernardino … and get a lot of volunteer pre-med students., and we teach them how to translate in a room for us… (they) love it because it is like shadowing the doctor. Well, here, you can go translate in the room for the doctor. That way you can shadow them at the same time… We have … over 1000 student volunteers." Director: "We're also going to have the (school of) pharmacy (students) do med refills (with an overseeing physician). Too much time is spent by my staff doing all these call ins for med refills."	
INTERVENTION CHARACTERISTICS			
Most Patients prefer groups	Design Quality & Packaging	Patient: "it is really important to know the right information as well as to be in a group, so we can guide (and help) each other." Patients: "(prefer classes) in the evening" (or) "monthly" (or) "weekly" (or) "biweekly"	Most patients wanted the education "packaging" as recurring classes. 2 people

		Patients: (prefer class) "with wife & husband" Patient: "(prefer class) It'd be beneficial to have your children here- my daughter is 9…always ask me why are you poking yourself all the time?" Patient "…an actual care team that would include the doctors and nurses that would care for you - would be magnificent" "prefer… pamphlet, because … with my work schedule, I can't just come in…a pamphlet would be much easier." "prefer 1:1"	preferred 1:10
Doctors preferred non-group formats		**Attending 2:** "nice to get informational classes but 1:1 better" **Attending 3:** "…we **should have the brochures**, some of which we have here from Kaiser. But also, that **one-on-one** talking about what diabetes is and what it means to have a diabetic and all the risks associated with diabetes… "**Al-Shifa teleconference**…People could call in and participate. A moderator who's teaching and moderating." **PGY2 resident:** "implement something (like) social media…Facebook page with Q & A where you didn't have patient names (to answer) commonly-asked questions that people have in Spanish…patients could write things if they wanted to share with the group…"	Again, some disconnect: patient vs. provider priorities
Donor prefers a less formal, socially supportive group format.		**Donor: "**(prefer) less formal, more like in the form of a talk where individuals can focus on diabetes but also make it an opportunity for socioemotional kind of wellness. Sometimes people are looking social support. So, all that to say is something a bit less formal kind of that bridges the gap between the formal and the non-formal."	
Evidence strength & quality, adaptability,	Evidence Strength & Quality	**Donor: "(**evidence, strength, and quality, for example, an intervention that's been in published papers et cetera would be...a strong factor to consider) Absolutely"	

lack of complexity, and a less formal design packaging are the most important things to the donor. Trialability and cost-effectiveness are also important.	Adaptab-ility	**Donor: "…**would be a plus and part of the adaptability is keeping in mind the end user and getting some feedback from the actual users. That's a component of adaptability."	
	Trialability	**Donor: "Yes of course (trialability would** be looked on favorably)"	
	Complex-ity	**Donor: "**Less complex (preferred). I think part of getting patients to benefit from an intervention sometimes are the barriers that can make it complex. So, if it is too complex I think it becomes an inherent barrier to already basic normal barriers like timing, transportation, length of time. So, I think more simple interventions would be useful."	
	Cost	**Donor: "**I think thinking about community health and community clinics who usually serve lower income, I would say cost effective is better"	
INNER SETTING			
Inadequate communicati on network.	Networks & Commun-ications	**Board members**: "I don't think we have (a communication network) We would have to have an email chain that contains the on-call, the clinicians. I don't think we currently have one designed for outreach like this, but we can do it" … "it shouldn't be hard (to set up)." **Doctor 1**: "as communication from the administrators, it is pretty easy (but) I don't know that there's any easy way to communicate with other providers" **Resident doctor**: "I don't think we have that much said in terms of the communication with the Board…(but)… there's good communication between the staff… front desk people… always willing to provide information that is requested of them…" **Pharmacist:** "(communication) trickles down… would it be possible to have a website that's accessible by providers?" **PGY2:** if you had a newsletter… that (we) could subscribe to … for updates… would be	Board & provider consensus: we must design a networking process -we do not have it in place.

		helpful… because I don't know anything about the clinic… need more tight communication to have hand-offs" **Attending 3**: (the way communication works now without doing anything might interfere with proper implementation) **PGY1**: "(the clinic manager) here, and she's very knowledgeable about what's going on…she's my go-to person for finding out what's changed" **PGY1:** "I can't imagine being where we need to be without some type of electronic records"	
Limited time of volunteers makes it harder. **Paid staff & motivation of volunteers make it easier**	Culture	**Board member asked about culture affecting an intervention:** "It is tougher because you don't have a captive audience because it is volunteer-based … despite that, it wouldn't be difficult (to implement). We have our clinical manager… & our clinicians, and a good education of what the program is. "… (an intervention) will be well-received". **Doctor 1** asked about culture affecting an intervention: "…could vary…overall, everyone wants to provide the best care for the patient to take control of their health and diabetes (but) it could be challenging to get everybody on board with new programs … they may not have the time or energy to dedicate to making that program successful." **Attending:** "Culturally the best thing you have is dedicated people. If you didn't have that, you wouldn't have anything here" **Pharmacist:** "I think the culture here is pretty positive. I mean everybody here works collaboratively pretty well." **Attending 2, 3:** "no bearing on diabetic care"; "don't see a problem"	
Health education is	Implemen-tation Climate:	**Board members** in response to *what could clinic do to improve DM*:	Board consensus: health Ed

the board's top priority. **Providers prioritize clinic infrastructure & organization** **The Donor preferred lifestyle & diabetes management education as a top priority.**	Tension for Change & relative priority	"Health nutritionists ... top (priority) … exercise" "dental education" "better follow up of patients" … "(outcomes) data collection" "marketing…in the places of worship (get more patients to come)" **Board members:** "(pharmacist) would be nice… (but it is) less priority now" **Board members (& resident):** (multi-specialty team a priority only) if we had (resources)" **Attending, med student**: "health ed (is a priority) …I don't think (a pharmacist is) as necessary… having a dispensary on hand…would help" **Pharmacist:** "(pharmacist a priority to teach) how to use their supplies, for example, glucometers … insulin, using injections…" **Attending:** "…people don't realize that you can take medicines to keep you from getting sick… it is a priority to have health education, pharmacy, & support staff & if you can do it best with dedicated team, do it." **Doctor 1:** "(there is a need for) education …community health aid, physician extender, or diabetic nurses … (clinical pharmacists) could be beneficial to reinforce what the physician is explaining in more depth…(but) trying to stabilize the clinic … higher priority" because of the recent (admin) changes" **IMG:** "Coordinating management of diabetes (is the first priority)" **PGY2:** "getting more information to understand population better (EMR, with all the data capability is) the primary goal" **Attending 2**: "(health ed) not a priority…I don't think pharmacists would make a difference… (specialty team) not a priority"	program is highest priority. Providers discussed many priorities and were not decided. health ed; pharmacists; stabilizing the clinic; data collection; having a medication dispensary.

		Donor: "So, the basic nutrition, stress related class, I think is kind of basic. I think it would work to get individuals to be interested and you can build off that… (learning about) checking your sugar when you have to, eating when you have to, taking your insulin and Metformin when you have to and kind of tracking it… The clinical pharmacy, I think if you just focus on meds, I think that's very limited in focus… "	
Health Ed classes more compatible as per board but less compatible as per providers.	Implementation Climate: compatibility	**Board members:** (health education) "certainly compatible" (with Al-Shifa) **Doctor 1**: "the previous fellow started a class... (but) attendance (was low) … If all they were coming from was just the class, the attendance was low… could make it difficult to implement a class" **Resident:** "if there could be coordination when they have (lab) testing - they could have education classes running the same time?" **PGY2:** "might be hard for everyone to get transportation to come to group (need) way to (educate them) while they're here (for something else)" **Attending:** "Most of our patients...are going to have cultural issues" **Attending 3:** "Just a question of space /availability/accessibility (for classes)" **Attending 2:** "(health ed) would be ok…" **PGY3:** "I don't think there would be a conflict (with health ed)"	Board consensus: health Ed program is very compatible. Other things relatively less so. Providers mostly skeptical about compatibility
Pharmacists mostly not compatible as per board & most providers		**Board members:** (clinical pharmacist compatible) "(only if) free" **Doctor 1:** "(pharmacist) recommendations may not be feasible for the patient… due to the patient's financial limitations"	

		Attending 2: I don't think patients would be interested in (pharmacist) education (not compatible)" **PGY3:** "(pharmacist is) kind of a luxury item … one of the last things that we've actually added to our programs (outside Shifa)" **Attending & med student** (pharmacist compatible?): "yes"	
Team-based approach not compatible as per board & providers		**Doctor 1** (specialty team compatible?): "not as compatible for the clinic because people are volunteering, so their time is limited." **Attending 3:** (for team-based approach) "more complicated-don't know if possible." **Attending 2:** (for team-based approach) "patients may not consistently come…"	
All educational interventions would lead to rewards for Al-Shifa & patients	Implementation Climate: organizational incentives & rewards	**Board members** response to 'will health education benefit Al-Shifa?' "That's our mission". "Yes." "It will actually advertise us… Marketing (for the clinic) … "to bring people and educate them… So that way, they come". **Doctor 1:** (health education at Al-Shifa) "could definitely be beneficial ... if offered to the community…by bringing in more patients to the clinic." **PGY2**: "if the patient knows something about their illness when they come into the room (it) kind of facilitates a better discussion" **Doctor 1** (pharmacist will benefit by helping to reduce drug errors and dangerous side effects) **Doctor 1** (specialty team beneficial) "(yes) because it would give the opportunity for all the different components of the team that are impacting the patient to be in this room at the same time… being on the same page as far as what we're instructing the patient to do… maybe attract more patients to the clinic… may even attract other physicians (or specialists) to volunteer"	Board & providers felt that health ed programs will benefit the clinic & patients (Better patient health, safety, & positive advertising for the clinic).

		Medical student "Thinking of the bigger goal of clinics like this isn't to be busy. The goal is to provide care for patients when they need the care, but ideally, what you want is to not see patients because they're healthy and they don't have to come to the clinic. I think seeing fewer patients in that regard would be a huge benefit, not just to the clinic, but to the community"	
No interest amongst board or providers to lead implementation.	Readiness for Implementation: leadership engagement & available resources	**Board member:** "I'll be happy to help you, but **you** will have to take the lead because you will be the one making decisions, classes, scheduling, (etc.). But I'll be glad to help you at any level I can" **Doctor 1:** "If it is…clinical pharmacist or the health education, my role would be to refer my patients to whichever program it is, and also to follow up that they are being seen by that specialist…(for) multidisciplinary team, I would…be part of some meetings..." **Attending:** "… We can lead (the program) while we're here, but there are things that we don't have time to do." **Attending 3**: "I could see committing to doing an educational part".	Other board members preferred that I take the lead
Board confident but providers skeptical about implementing an educational program.		**Board members:** "I don't think we currently have a health nutritionist...not a dedicated person. We do have resources through Kaiser, which is very good about patient education. If we approach them, that would be our number one resource, to actually have them send somebody (dietician)". "Physical structure, we have"	

Board concerned about saving money		"I mean, depends on the budget size... It doesn't sound like it would be too expensive. But we'd need to know the budget." "I think we should (get) volunteers first. The nutritionist, the dietician... (should be volunteers)" "If we find someone (dietician who needs $) … we might be able to compensate a little bit. Not at full, but some compensation for their gas or to give them appreciation that way" **Doctor 1:** "it is beneficial if we have someone who is able to translate for us and (maybe a health educator who speaks Spanish) … it is almost a bottleneck having (only) one (translator) available…" **Attending:** "…you don't have (EMR)… it is going to be more of a challenge (to implement an intervention)"	
CHARACTERISTICS OF INDIVIDUALS			
Providers believe interventions to be beneficial but do not know the evidence.	Knowledge & beliefs about the interven-tion	**Doctor 1:** "I could (not) give you statistics and percentages (regarding outcomes of studies of educational interventions to improve diabetic care) … I know that (health education/diet/exercise) can lead to overall control of diabetes." **Attending:** "I don't know these studies, but I know in implementation science what works the best is what springs out of your culture." **PGY2:** "studies that have looked at diabetic case managers involved in following up with diabetic patients. That has been shown to be effective."	Beliefs about interventions are also well described in the previous sections regarding the implementati on climate.

APPENDIX 4: TABLES AND CHARTS FOR CHAPTER 5

TABLE 11: RECOMMENDATIONS, SUPPORTING RESULTS, AND IMPLEMENTATION STEPS FOR THE PLAN FOR CHANGE

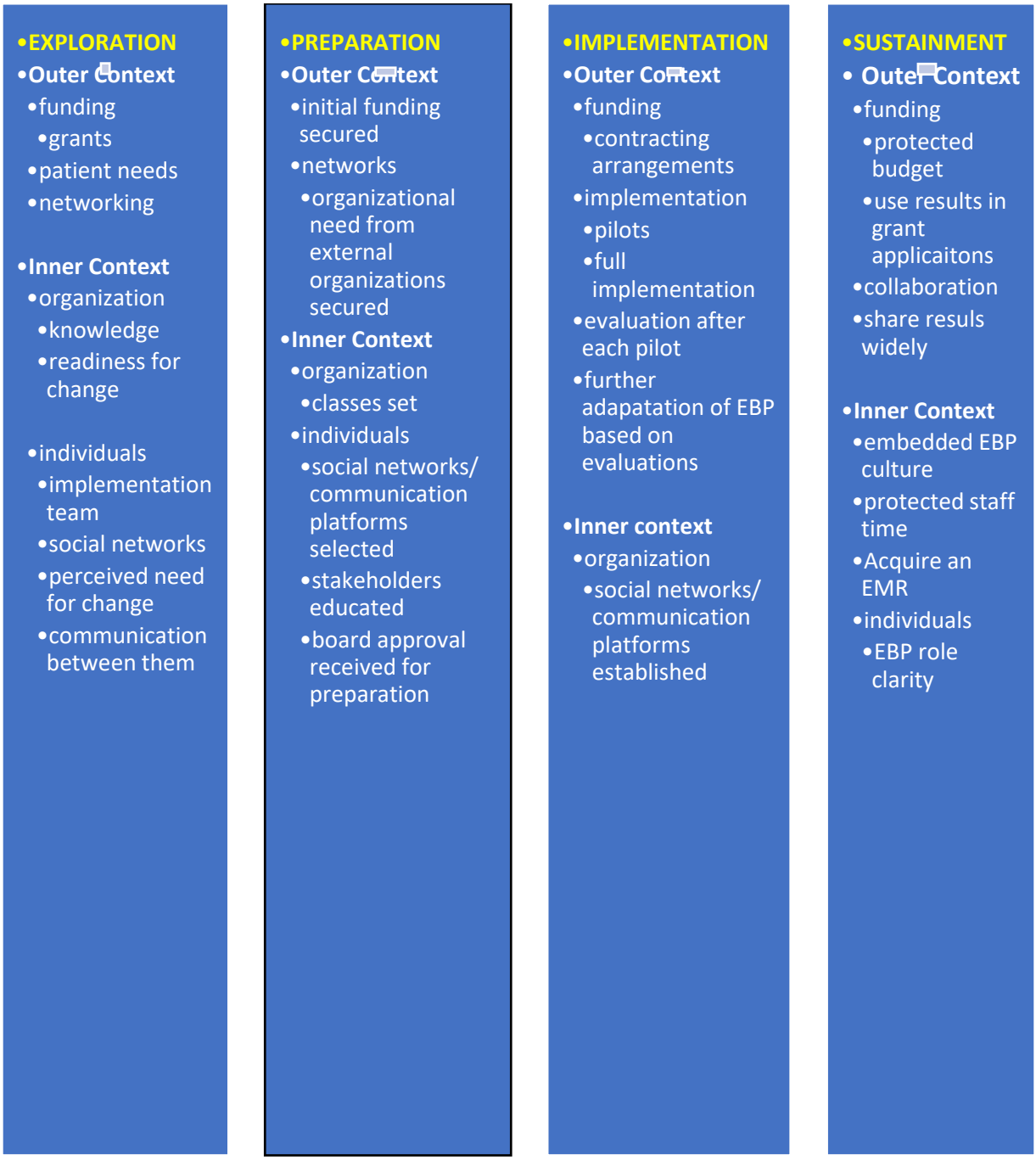
Recommendation	Support sections (from chapter 3: Results)	Steps to implement and sustain these recommendation
Form/ implementation team	Inner Setting Domain, Construct: Implementation Climate	Designate a board member to partner with the clinic manager as the implementation team
Improve communication between board & providers	Inner Setting Domain, Constructs: Networks & Communications and Culture	That set up a network that includes reliable and timely two-way communication between the clinic board and providers The clinic manager should be the liaison between the two groups as the manager sends a monthly schedule to the providers and is in contact with the board members weekly. Communication from the board to the clinic should be with a regular electronic newsletter with updates to the clinics long-term implementation plans; the needed steps from the providers to support it; any funding issues; etc. The providers should also be able to contact the clinic board/ clinic manager with regular feedback regarding what is going well or not well at the clinic. There should be options to use email/text/social networking platforms between the groups. Prior to implementing the intervention, the providers should be educated about the rationale for this intervention through one of the newsletters (should include a summary of this study's findings including an explanation of patient needs for dignity, self-efficacy, group education, and convenience as well as a summary for this plan for change)
Improve communication between patients and Al-Shifa Staff	Outer Setting Domain, Construct: Patient Needs & patient resources	Make a policy that all front and back office staff be fluent in conversational Spanish. Patients should have a reliable way to leave messages for staff after hours via a phone, text, or email
Revise medication refill workflow (to allow for timely refills of medications)	Outer Setting Domain, Construct: Patient Needs & patient resources	Designate a provider weekly to manage refills. The clinic manager should be responsible for communicating refill requests with this provider on a weekly basis.
Create/ update a patient registry	Outer Setting Domain, Constructs: Cosmopolitanism & External Policy	Should be used to keep track of the patients, their lab test results, appointments, and attendance of educational classes.

	& Incentives, & Peer Pressure	Other aspects of diabetic care may also be added over time, including performance of retinal eye screening tests and completion of annual foot exams. This should be managed by a designated individual (e.g. the clinic manager). The EMR should be used to update lab results and appointment components of the database. Use database to improve care (e.g. reaching out to patients to complete care gaps) & to show the outcomes of the program to potential granters in the future for sustained funding. The cost of sustaining the database should be minimal and be part of the clinic's budget. Grants should be sought to fund a more robust EMR in the future, but this is not a patient or board priority.
Offer educational classes to diabetic patients at Al-Shifa	Outer Setting Domain; Construct: Patient Needs & Patient Resources, Cosmopolitanism, External Policy & Incentives, & Peer Pressure	Establish a relationship between Al-Shifa and both Dignity Health and KPSC where Al-Shifa will be able to refer patients to these programs to attend their comprehensive diabetic classes at no cost to the patients or the clinic. Educate providers at Al-Shifa of the importance of referring patients to these classes. Keep track of the patients who attend these classes and their glycemic outcomes via the patient database registry.
Implementation pilots	Outer Setting Domain; Construct: External Policy & Incentives and Peer Pressure. Intervention Characteristics: Design Quality & Packaging.	Start with a pilot involving about twenty patients who would receive a referral to the Dignity Health classes and another twenty who would receive a referral to the KPSC classes. A subsequent pilot will include up to fifty patients who will be given the choice of which class to attend (Dignity or KPSC). Full implementation (referring all patients to the class with a goal to get 50% of diabetics at Al-Shifa to attend the classes) with clinic-wide marketing should start within one year of the initial pilot.
Implementation team duties	Inner Setting Domain, Construct: Implementation Climate	I recommend the implementation team meet every two weeks during the pilots to monitor all aspects of implementation including ensuring that the database of patients in the pilot is regularly updated by the front office staff. They should contact the providers and other staff to make sure they are referring patients as agreed to in the pilots. They should send updates to the board every 2 weeks and to the providers every month with the progress of the program in the monthly newsletter and via an email update.

		They should check their email regularly for feedback from the clinic board and providers. Designate the clinic manager to receive patient questions and medication refill requests by having the manager carry an Al-Shifa cell phone during daytime hours. I also recommend that a schedule of covering providers be set up so that every week, a provider is on call to manage refill requests and any clinical questions. Ensure that the clinic manager has protected time for implementation of the intervention as well as protected time to manager patient refill requests.
Implementation team sustainment	Inner Setting Domain, Construct: Implementation Climate	I recommend that the board commit to funding for the protected staff time needed to sustain the intervention from Al-Shifa's core-operations budget and that efforts be made to reduce staff turnover, especially of the implementation team. The database should include other components related to diabetes care (e.g. annual eye exams) and be used to reach out to patients to complete any care gaps. The clinic should work towards acquiring an EMR as soon as it can sustain one. Mandate a warm handoff describing all aspects of implementation and sustainment for this intervention between outgoing/incoming team members (in case of turnover) Discuss with students from local medical and nursing schools (who have rotations at Al-Shifa) about taking on enhanced roles with regards to translation (for those who speak Spanish), medication refills, and database management. Evaluation reports be presented to the clinic board, providers, community leaders, government officials and potential granters. Process and outcome measures should be included in grant applications to increase the chance of continued funding. The evaluation reports should also be shared with the director of the neighboring free clinic and compared to that clinic's process and outcome measures (if known). Present the reports at the clinic's annual fund raisers to raise earmarked funds for further improvement of the clinic infrastructure (e.g. an EMR).

		Prepare manuscripts for submission to academic journals, and presentations for national free clinic conferences, such as the annual conference for the NAFCC.
Process and outcomes evaluation		The initial trial should be followed by a formal evaluation of each component of the process and the outcomes (a comparison between Dignity Health & KPSC for all measures will be done). One month should be given to complete evaluations. The process outcomes should include • Number of patients referred to the classes • Number of patients who attended at least one class • Number of patients who completed all the classes • Whether the classes were accommodating to their friends or families • How convenient patients felt the classes were (class booking, timing, duration) • How comprehensive patients felt the classes were (did they feel they adequately covered nutrition, exercise, stress relief, general diabetes, proper use of diabetic equipment, and medication management). • How easy it was for staff to refer patients to the classes The outcome measures should include • Pre-class and 3 months post class HBAIC comparisons • Overall wellbeing felt by patients • Overall confidence/empowerment in self-management of their diabetes felt by patients and their families who attended. A budget analysis should be done at the end of the pilots and 3 months after full implementation with comparison between the budgeted and actual expenses.

FIGURE 4: MODIFICATION OF THE EPIS PHASES, THEIR CONTEXTS, AND VARIABLES FOR THE PLAN FOR CHANGE FOR AL-SHIFA FREE CLINIC (AARONS, 2011); EBP = EVIDENCE BASED PRACTICE[55]



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