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Pharmacist collaborative practice and the development and implementation of team-based care in outpatient healthcare settings: A case study at El Rio Community Health Center

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PHARMACIST COLLABORATIVE PRACTICE AND THE DEVELOPMENT AND IMPLEMENTATION OF TEAM-BASED CARE IN OUTPATIENT HEALTHCARE SETTINGS: A CASE STUDY AT EL RIO COMMUNITY HEALTH CENTER

by

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"*Las paredes vueltas de lado son puentes*." (Walls turned on their sides are bridges). Spray-painted on the border wall between *Ambos Nogales* (both Nogales) Nogales, Sonora, México and Nogales, Arizona.

DEDICATION

To the many public health advocates who dedicate themselves to the well-being of those in the U.S.-Mexico border region.

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PHARMACIST COLLABORATIVE PRACTICE AND THE DEVELOPMENT AND IMPLEMENTATION OF TEAM-BASED CARE IN OUTPATIENT HEALTHCARE SETTINGS: A CASE STUDY AT EL RIO COMMUNITY HEALTH CENTER

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ABSTRACT

Background: The United States is experiencing a primary care physician shortage that will grow in the next decade as demand for primary care services is projected to increase. The growth in physician, Nurse Practitioner, and Physician Assistant supply alone will not be adequate to meet the demand for primary care services by 2020. Creating pharmacist-inclusive collaborative care teams for outpatient clinical care can help alleviate this health care delivery shortage.

Methods: A qualitative mixed-methods case study was conducted in Tucson, Arizona to determine the supports and structures behind the Pharmacy-Based Diabetes Management Program (PBDMP) at El Rio Community Health Center. Using key informant interviews from El Rio, other outpatient clinical pharmacy programs (OCPPs), and the Tucson Accountable Care Organization, coupled with Lean Management brainstorming group sessions, the study elicited information about how the experience of El Rio with the PBDMP can inform nationwide development and implementation guidelines for other OCPPs.

Results: The PBDMP at El Rio provides a blueprint for other programs interested in creating an OCPP. Key contributing factors to program success within El Rio and the other OCPPs interviewed included a focus on six key practices. Challenges inhibiting success were pharmacist provider status and reimbursement of clinical services provided.

Translation: Three public health practice products were developed as a framework to provide future OCPPs interested in implementing a pharmacist-inclusive practice model: 1) implementation guidelines, 2) a self-assessment outpatient clinical pharmacy program worksheet for clinics looking to create or expand an OCPP, and 3) a student management decision case study.

Conclusion: This study demonstrates the value of considering all potential members of a care team for diabetes care management. The decision by a clinic to create an OCPP should be based on team-based approaches to patient-centered chronic disease care management. Clinics looking to participate in a CDTM model OCPP need to identify if organizational transformation is needed for program buy-in and consider relational coordination between clinical roles as a major component of the coordinated work needed for a successful OCPP.

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LIST OF ABBREVIATIONS

AACP ..... American Association of Colleges of Pharmacy

AAMC ..... Association of American Medical Colleges

ACA ..... Patient Protection and Affordable Care Act

ACCP ..... American College of Clinical Pharmacy

AHRQ ..... Agency for Healthcare Research and Quality

AMCP ..... Academy for Managed Care Pharmacy

APhA ..... American Pharmacist Association

ASHP ..... American Society of Health-System Pharmacists

CAPE ..... Center for the Advancement of Pharmaceutical Education

CDTM ..... Collaborative Drug Therapy Management

CDC ..... Centers for Disease Control and Prevention

CPA ..... Collaborative Practice Agreement

DOL ..... U.S. Department of Labor

DSMT ..... Diabetes Self-Management Training

FQHC ..... Federally Qualified Health Center

FTE ..... Full-Time Equivalent

HRSA ..... Health Resources and Services Administration

IOM ..... Institute of Medicine

ISMP ..... Institute for Safe Medication Practices

MA ..... Medical Assistant

MHC ..... Marana Health Center

MPJE..... Multi-state Pharmacy Jurisprudence Exam

MTM..... Medication Therapy Management

NAPLEX..... North American Pharmacist Licensure Examination

NP ..... Nurse Practitioner

OCPP..... Outpatient Clinical Pharmacy Program

OTM..... Organizational Transformation Model

PA ..... Physician Assistant

PBDMP.....Pharmacy-Based Diabetes Management Program

PCMH ..... Patient-Centered Medical Homes

PDSA ..... Plan Do Study Act

PGY1..... Post Graduate Year 1

PGY2..... Post Graduate Year 2

RCA .....Root Cause Analysis

SSA .....Social Security Administration

T1DM.....Type 1 Diabetes Mellitus

T2DM.....Type 2 Diabetes Mellitus

CHAPTER ONE

Background and Significance

Introduction

Unfolding the layers of a program's development and implementation reveals the structures and supports in place leading to a program's successes and sustainability. These structures can prove beneficial for organizations looking to adopt a similar program. This dissertation seeks to identify and analyze the successes and barriers to the establishment of a pharmacist-inclusive outpatient clinical pharmacy program from the El Rio Community Health Center in Tucson, Arizona. The information collected can assist interested outpatient clinics in their development and implementation of their own collaborative pharmacy program.

This dissertation provides products that can inform future clinics to self-assess their barriers to collaborative practice models for pharmacist-inclusive primary care teams. Clinics interested in implementing and developing an outpatient clinical pharmacy program can apply the implementation guidelines and outpatient clinical pharmacy program worksheet generated from this research. A management case study applies the case facts from the El Rio Community Health Center (El Rio) for management education on decision-making for collaborative care teams. Ultimately, findings that emerge from this research can address the impending national primary care shortage in the coming decades by providing support and guidance for the inclusion of pharmacists in direct patient care.

The following eight chapters outline the background, setting, methods, findings, and discussion of the case study of the Pharmacy-Based Diabetes Management Program at El Rio. While El Rio is a good candidate for an in-depth case study, there are many options for a clinic to implement a pharmacist-inclusive care team to treat and manage chronic disease.

Problem Statement

In the mid-1960s, Physician Assistant (PA) and Nurse Practitioner (NP) education programs were established in part to address the primary care physician shortage identified at that time in the United States.(1) However, the demand for primary healthcare services continues to outpace the available supply of primary care providers.(2) Currently, it is estimated that over 56 million Americans lack adequate access to primary health care because of shortages of primary care physicians and allied health professionals in their communities.(3) Moreover, nearly half of all Americans—and over three-fourths of adults aged 65 and older—live with at least one chronic condition that requires prescription medication therapy.(4) There are serious shortcomings within our current healthcare system related to the provision and delivery of affordable, safe, and effective medication management in primary care services.(5) According to the American College of Clinical Pharmacology (ACCP), in 2000 the costs of drug-related illness and death in outpatient clinical care settings alone were estimated at more than $177 billion.(5) More recently, the persistent and critical unmet medication use support needs have been directly addressed through efforts led by the Institute for Safe Medication Practices (ISMP) among others.(5)

Many options exist for potentially addressing the healthcare system's current and future shortcomings in terms of access to primary care services. The need for expanded access to primary care may force the United States to look more broadly within the healthcare system to identify opportunities to expand capacity to provide quality primary and preventative care services, including the development of inter-professional teams to provide the highest quality of care to all patients.(5)(6)(7)(8)(9) In sum, with the expansion of health insurance and an aging U.S. population, more Americans than ever before will lack adequate primary care services in the future. This population will necessitate medication-based chronic disease care management in cooperation with all members of a primary care team including physicians, RNs, NPs, PAs and potentially the inclusion of pharmacists.(3)

Purpose Statement

The purpose of this study is to assess the viability and transferability of the Collaborative Drug Therapy Management (CDTM) program through a case study examination of the Pharmacy-Based Diabetes Management Program (PBDMP) at El Rio in Tucson, Arizona. The findings will be translated into immediately applicable public health practice products including implementation guidelines to create an outpatient clinical pharmacy program (OCPP), a self-assessment worksheet for clinics to evaluate their preparedness for an OCPP, and a management case study for educational purposes. The creation of intervention guidelines and a self-assessment outpatient clinical pharmacy program worksheet will assist willing and able clinics to engage pharmacists at the top of their educational level and involve them in outpatient primary care. The

management case study will outline the decision making processes taken by El Rio as an example case for future study in the development and implementation of OCPPs.

Research Questions

Central Question

How can the experience with the CDTM Pharmacy-Based Diabetes Management Program at El Rio inform nationwide development and implementation guidelines for other outpatient clinical pharmacy programs?

Sub-Questions

1. What led to the creation and implementation of the CDTM program at El Rio?
2. What were the major factors enabling or hindering the program's progress?
3. How transferable are these findings from El Rio to other settings?
4. How can theoretical constructs of the PRECEDE portion of the PRECEDE-PROCEED model and organizational transformation model be applied to the research to understand implementation actions taken or not taken?

Translation Question

How can the findings from this case study be translated into public health practice products to support successful implementation and maintenance of outpatient clinical pharmacy programs?

Background and Significance

Primary Care Shortage

According to the 2007 Institute of Medicine (IOM) report on Future of Health Care Workforce for Older Americans, primary care is the foundation and backbone of the U.S. healthcare system.(10)(5) The IOM defined primary care as: "the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community."(11) Primary care often serves as the point of entry to the health care system for patients who require medical care and attention. According to the ACCP, in addition to the diagnosis and treatment of acute and chronic illness, primary care practice encompasses activities such as health promotion, disease prevention, health maintenance, counseling and patient education.(5)

At the national level, both the supply and demand for primary care providers will grow over the next decade, due largely to aging and population growth.(12)(13) The U.S. population is increasing by one percent each year, with an aging baby boomer generation set to double the number of Americans 65 years and older by 2025.(10) Over 10,000 people of the baby boomer generation are qualifying for Medicare every day, further increasing the need for primary care services.(14) To a much lesser extent, the expanded insurance coverage implemented under the Patient Protection and Affordable Care Act (ACA) of 2010, includes a number of investments that strengthen the primary care workforce due to a projected increase in demand for primary care services. Given the

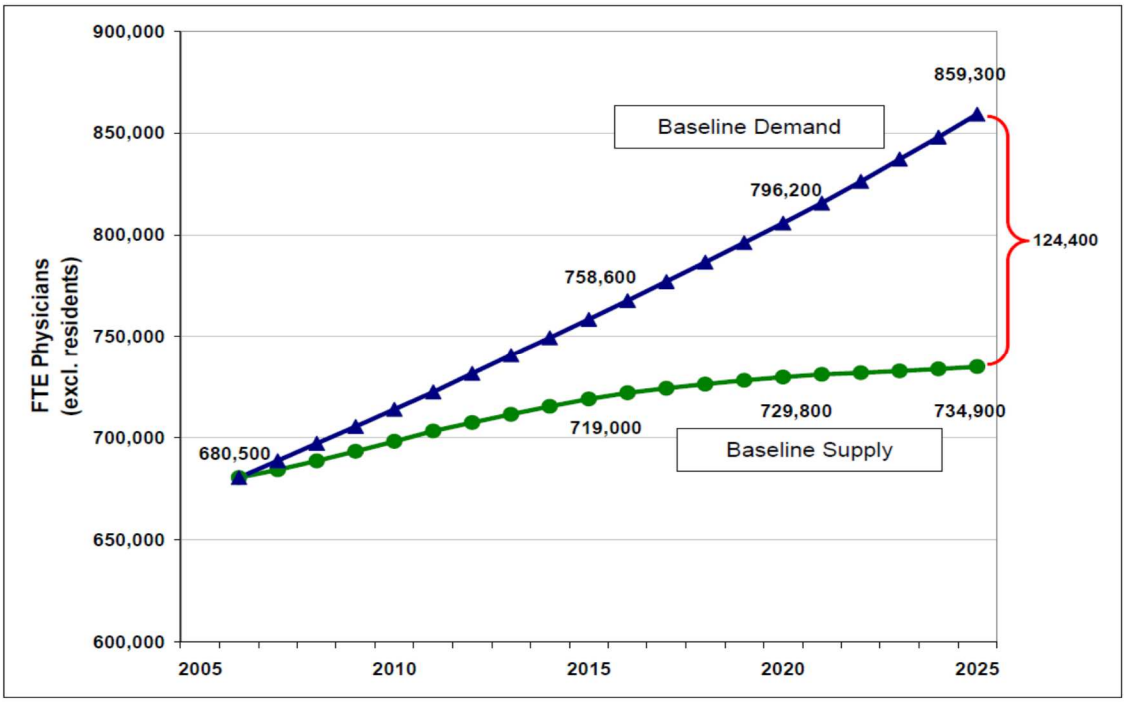
projected population growth trends, the shortage of primary care providers is even more critical and is projected to exceed 44,000 by 2025.(15)(16)

Primary Care Physician Shortage

The United States is likely to experience a shortage of physicians within the next decade which will also grow over the next decade.(16)(12) By 2025, a shortage of 124,000 physicians is projected in the United States.(16) Figure 1 describes this trend in supply and demand of physicians. According to the Association of American Medical Colleges (AAMC)'s Center for Workforce Studies, there will be a shortage of 45,000 primary care physicians in the next decade.(14) Physicians practicing in primary care comprise one-third of the U.S. physician workforce yet are responsible for more than half of all patient visits.(5)

Although the supply of physicians is anticipated to increase modestly between now and 2025, the demand for physicians in primary care is estimated to increase even more sharply.(16) The number of primary care physicians is projected to increase from 205,000 FTEs in 2010 to 220,800 in 2020, an eight percent increase.(12) However, the total demand for primary care physicians is projected to grow by 28,700, from 212,500 FTEs in 2010 to 241,200 FTEs in 2020, a 14-percent increase.(12) During the past decade, the number of generalist physician graduates fell by 22 percent and the number of newly graduated U.S. medical students who chose primary care as a career has declined by 50 percent since 1997.(5) The AAMC estimates that by 2020 the U.S. will face a serious shortage of both primary care and specialist physicians to care for an aging and growing population.

Figure 1. Baseline Physician FTE Supply and Demand Projections, 2006-2025 (16)



Source: Dill M. The Complexities of Physician Supply and Demand: Projections Through 2025. Assoc Am Med Coll Cent Work Stud. 2008

Nurse Practitioner and Physician Assistant Shortage

While physicians are considered the cornerstone of the primary health care system in the U.S., there is a wide array of allied primary care health care professionals in the workforce.(5) While many consider nurse practitioners and physician assistants primary care physician-extenders due to their limited licensure, they can have large impacts and a broad scope of practice. Over the past two decades the supply of PAs and NPs has grown faster than the supply of physicians.(16)

According to the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), the supply of primary care NPs is projected to increase by 30 percent, from 55,400 in 2010 to 72,100 in 2020.(12) The

supply of primary care PAs is projected to increase by 58 percent, from 27,700 to 43,900 over the same period.(12) This 17 percent combined increase in supply in 2020, could help mitigate the projected shortage of physicians if NPs and PAs continue to be effectively integrated into the primary care delivery system.(12) The efficient use of NPs and PAs will require patient and health system acceptance and the continued dissemination of more effective models of workforce deployment.(12)(16)

Future Shortages and Pharmacist-Inclusive Practice

Given the projected growth in the NP and PA primary care workforce, as well as ongoing efforts to effectively integrate these providers into the primary care delivery system, the physician shortage could be somewhat alleviated. Models that include patient-centered medical homes (PCMH)s and emphasize team-based care, have the potential to help address the projected shortage of primary care physicians.(12)(17) However, the growth in primary care physician, NP and PA supply alone will not be adequate to meet the demand projected for primary care services in 2020.(12)(18)

Other members of a team-based model for primary health care delivery can include clinical pharmacists in pharmacist-inclusive health care delivery models. Pharmacists represent the third largest health professional group in the U.S.(19) Although some pharmacists work in non-patient care settings (e.g. teaching, research, and administration), most work in a variety of patient care settings.(19)

In 2011, according to the Bureau of Labor Statistics, there were 272,320 working pharmacists and an estimated 343,550 pharmacy technicians in the U.S. workforce.(20)(19) This corresponds to a national average of 87 pharmacists and 108

pharmacy technicians per 100,000 population.(19) Table 1 shows the projected need for pharmacists from 2001 as compared to 2020.(20) The increase in pharmacist demand for secondary and tertiary services follows the increased need for medication therapy management and medication dispensing for chronic disease management. The Bureau of Labor Statistics estimates that the total number of pharmacists in the U.S. is expected to increase by 95,680 (35 percent) from 2020 to 2030.(19)

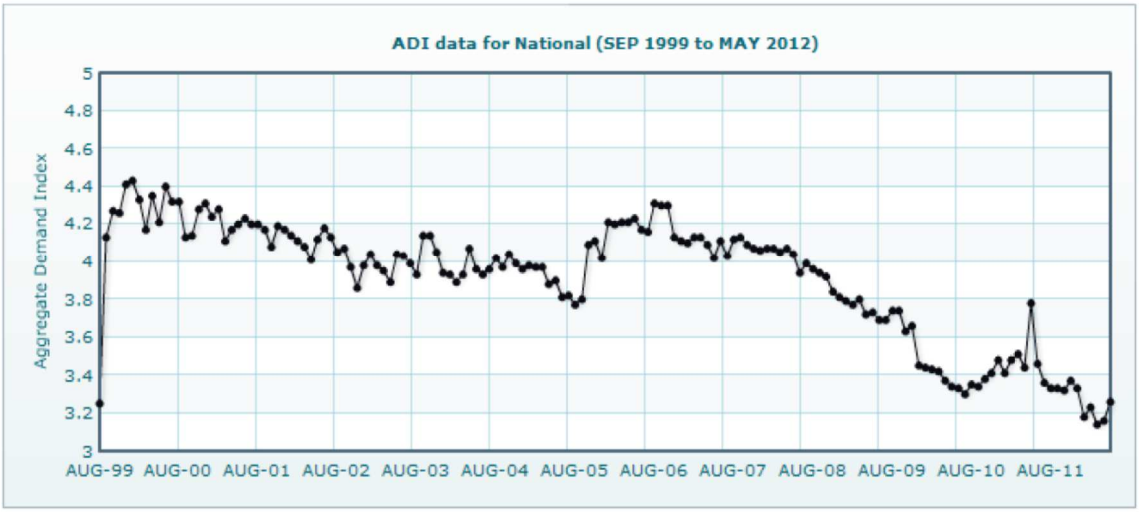
Table 1. Projected Need for Pharmacists(20)

Service Type	No. Pharmacists Employed in 2001	No. Pharmacists Needed in 2020
Order Fulfillment	136,400	100,000
Primary Services	30,000	165,000
Secondary and Tertiary Services	18,000	130,000
Indirect and other	12,300	22,000
Total	196,700	417,000
Source: Johnson TJ. Pharmacist work force in 2020: implications of requiring residency training for practice. Am J Health Syst Pharm [Internet]. 2008 Jan 15 [cited 2014 Nov 26];65(2):166–70. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18192265		

As of 2010, 62 percent of pharmacists worked in retail pharmacies that were either independently owned or part of a larger chain store.(21) About 23 percent worked in hospitals, while others worked in clinics, mail-order pharmacies, or the Federal government.(21) In 2013, the Aggregate Demand Index (ADI)—a monthly survey of unmet demand for pharmacists initiated in 1999 by the Pharmacy Manpower Project—showed a roughly balanced supply and demand of pharmacists across the country.(22)(19) Figure 2 shows the trend of the Pharmacist ADI mainly reaching a balance (in the range of 2.5 to 3.5) between 2009-2011.(22) To reach a balanced supply and demand of pharmacists in the U.S., a data point needs to fall within the 2.5 to 3.5

range in Figure 2. While the demand for pharmacists has decreased relative to supply in recent years, pharmacists still remain in high demand.

Figure 2. ADI Supply and Demand for Pharmacists, 1999-2011 (22)



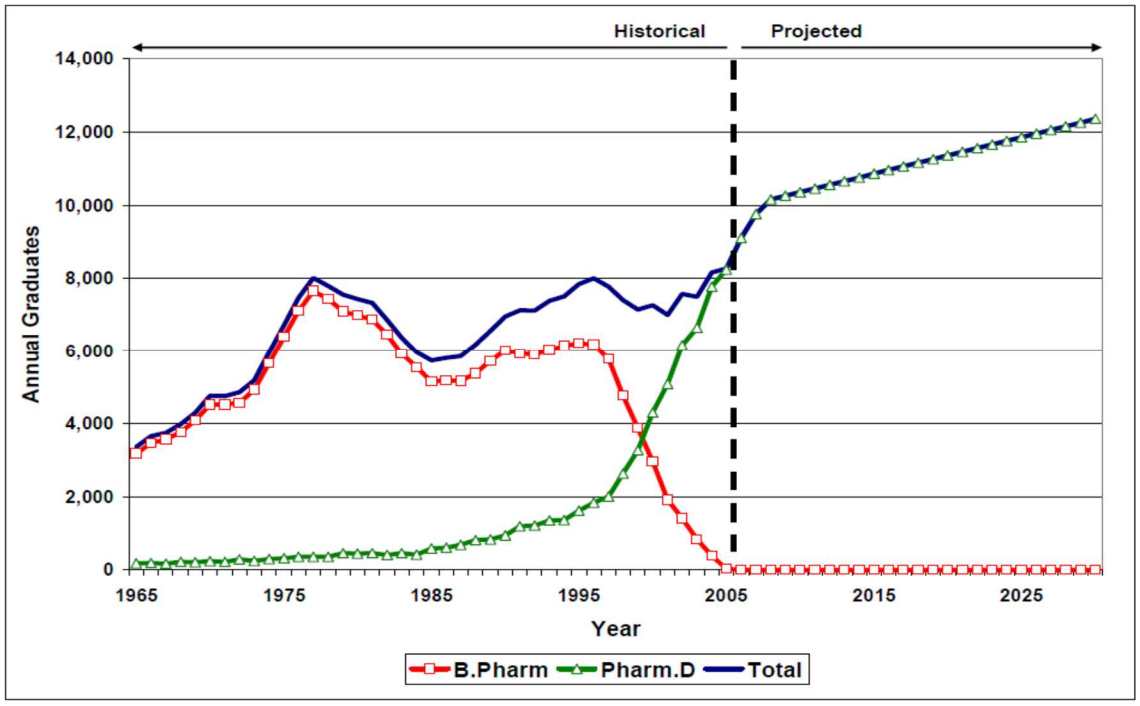
Source: ADI [Internet]. Pharmacy Manpower Project, "Aggregate Demand Index" National Pharmacist Demand. 2013 [cited 2014 Jun 23]. Available from: http://www.pharmacymanpower.com/index.jsp

The 2013 American Association of Health-System Pharmacists' annual survey found that pharmacists perceived a 33 percent shortage in clinical-specialty roles available for potential pharmacist job placement.(23) The survey concluded that a slightly higher number of pharmacists are seeking clinical non-medication dispensing roles from 2012 to 2013.(23)

Pharmacists, coupled with NPs and PAs among other allied health professionals, can help address the future need for integrated team-based approaches to primary care services. Solutions on how to address primary care shortages will require creative ways of looking at the healthcare system that are inclusive of all licensed primary care providers and focus on providing the highest quality of care to all patients.(5)

The rate of Doctors of Pharmacy (PharmD) training is expected to increase by over 12,000 by 2025.(13) Figure 3 represents the historical number of pharmacists from 1965 and projected number of pharmacists in 2025. National trends suggest that the supply of pharmacists is growing faster than previously projected primarily as a result of the recent rapid growth of pharmacy education programs and expansion of enrollment at existing schools across the country.(19)

Figure 3. Number of First-time Pharmacy Degrees Conferred, Historical and Projected 1965-2025 (13)



Source: Services H, Resources H. The Adequacy of Pharmacist Supply : 2004 to 2030. 2008;(December)

While the number and rate of pharmacists graduating annually is projected to grow through 2025, the number of clinical pharmacists is more difficult to estimate. Table 2 describes the practice site of pharmacists as of 2006. Mindy Smith, the Executive Director for the American Pharmacist Association (APhA) estimates that

nationally there are 8,500 clinical pharmacists practicing in outpatient settings with direct patient care.(24) Practice sites only represent part of the full picture for pharmacists and their employment. According to the ACCP, there are no data on residency-trained pharmacists practicing in other areas, such as managed care and community pharmacy.(20)

Chronic Disease and Medication Use

In 2005, 133 million Americans—almost one out of every two adults—were diagnosed with a least one chronic illness.(4) Moreover, nearly half of all Americans and over three-fourths of adults aged 65 and older, live with at least one chronic condition that requires medication therapy overseen by a medical professional.(4) As a result, 75 percent of our nation's $2 trillion in annual health expenditures are attributable to management of problems associated with chronic diseases.(4) While chronic diseases are common and costly, many are also preventable though strategies such as healthy eating, being physically active, and using medications safely and appropriately.(25)

Medications play a significant role in the management and prevention of chronic diseases in primary care, and are taken by a greater proportion of the population than ever before.(18)(5) Predictably, medication use among older adults is high—accounting for more than a third of all prescriptions.(5) In addition, 28 percent of patients aged 65 and older take five or more medications treating chronic conditions each month.(10) Two out of every three patients who visit a doctor leave with at least one prescription for medication, leading to a record volume of nearly 3.4 billion prescriptions dispensed in 2005.(26) This is an increase of prescriptions dispensed by nearly 60 percent since 1995.

According to the American Association of Colleges of Pharmacy (AACP), “there are serious shortcomings within our current healthcare system related to the provision of safe and effective medication management and primary care.”(5) In the past decade, the persistent and critical unmet need to address medication use was highlighted through efforts by the Institute for Safe Medication Practices (ISMP) and the IOM.(26) These primacy care medication management needs are expected to rise for patients of all ages over the coming decades.(18)(5)

According to research published by the California Board of Pharmacy, half of prescriptions taken each year in the United States are used improperly, and 96 percent of patients nationwide fail to ask questions about how to use their medications.(27) When patients do not take medication that has been prescribed, unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death can result.(28)(26) At least 1.5 million preventable adverse drug events occur in the United States each year; these costly and sometimes fatal incidents include cases of drug mix-ups and unintentional overdoses.(28)

The increasing complexity of patients, comorbidities, and their treatment regimens in primary care requires access to providers who can manage patient’s medication therapy, identify adverse events, and manage drug-related problems.(5) Factors such as increased outpatient surgery, shorter hospital stays and decreased recovery time have contributed to patients accessing the primary care system with more serious health care needs that require more immediate treatment resources and more complicated medication therapy.(5)(26) This demand for more intensive primary care,

combined with the role that medications play in quality prevention and primary care treatment, has created an increased demand for accessible healthcare professionals who can fill the needed primary emergent and longitudinal care roles. Doctors of Pharmacy (PharmD)s are trained and qualified to help fill these documented gaps in care around medication management in the primary care setting through both drug dispensing and patient care.(5) Table 2 describes the accreditations and possible educational paths for pharmacy-related fields and pharmacists.

Table 2. Pharmacy-Related Educational Paths

Terminal Degree	Education	U.S. Practice Purview
Bachelor of Pharmacy (BPharm)	-Pre-Pharmacy undergraduate program -60-90 semester credit hours -completion of a four-year program; 120-130 credit semester hours -does not qualify a recipient to sit for licensing exams to practice	-pharmaceutical research -usually obtained as a prerequisite to apply to pharmacy school -BPharm degrees are phasing out of popularity in the U.S. (now superseded by the PharmD degree)
Master of Pharmacy (MPharm)	-1-2 year post-graduate program -does not qualify a recipient to sit for licensing exams to practice	-pharmaceutical research
Doctor of Philosophy (PhD)	-2-5 (average) years of post-graduate education -does not qualify a recipient to sit for licensing exams to practice -research intensive degree usually focusing on pharmaceutical sciences	-pharmaceutical research -academic jobs; teaching and research
Doctor of Pharmacy (PharmD) (in some states referred to as a Registered Pharmacist (RPh))	-3-4 years of doctoral training -"educationally prepared for practice and should satisfy educational requirements for licensure."(29)	-After passing the licensure exam, pharmacists may then be designated "Pharmacist" or "Registered Pharmacist" (RPh) and practice (30) -Pharmacists can practice in a multitude of industries: research, teaching, clinical practice, industry, manufacturing, and judicial jobs
Clinical Residency Programs (for PGY1/ PGY2, PharmDs)	-residencies are 1-2 years in length and are necessary to practice clinical pharmacy -Most pharmacists participate during the first year after graduation	-During residency, pharmacists practice as a pharmacist, complete a resident project, and see clinical patients -There are 15 recognized specialties for clinical residencies (e.g. immunology,

	with a PharmD degree	transplantation, cardiology, pharmacotherapy)
Pharmacist Fellowship Programs	-fellowships train PharmDs and RPhs for careers in academic research, laboratories, clinical, and industry settings -fellowships range from 1-4 years	-fellowships exist in over 50 areas of study ranging from direct patient care (e.g. transplantation), to academic laboratory sciences and pharmacy/drug-specific topics (e.g. pharmacokinetics)(31)

Clinical Pharmacy/Pharmacology: Nationwide

The requirements to become a pharmacist in the United States include: 1) graduating from a Doctor of Pharmacy program at an Accreditation Council for Pharmacy Education (ACPE) accredited school, 2) conducting 1800 hours of internship under a licensed pharmacist, and 3) passing the North American Pharmacist Licensure Examination (NAPLEX) and a Multi-state Pharmacy Jurisprudence Exam (MPJE). While residencies are optional, they are necessary to practice clinical pharmacy.(29)

Clinical pharmacy is "a professional discipline that combines basic pharmacology and clinical medicine."(1) In 1965, most pharmacy graduates were entering a professional practice that had changed very little over the previous 50 years.(1)(32) This practice focused almost exclusively on the preparation and distribution of drug products.

The clinical pharmacy movement began at the University of Michigan in the early 1960s. Much of the pioneering work about the nascent field of clinical pharmacy was completed by David Burkholder, Paul Parker, and Charles Walton at the University of Kentucky in the latter part of the 1960s.(1) In the late 1960s, pharmacy students at the University of Kentucky created an institute to study pharmacists in the decision-making process of patient care. The institute encouraged the clinical pharmacy movement to

differentiate itself from the standard pharmacy education based only on drug information. The institute eventually led to the creation of a unique and separate entity and degree program, a Doctor of Pharmacy (PharmD). By the late 1960s, many other schools followed the University of Kentucky's lead and developed PharmD programs for training clinical pharmacists.(1)(32) The most important reason for the rapid growth of this almost entirely new profession probably was "the great dissatisfaction of pharmacists with old practice norms."(1) Pharmacists began to specialize in areas of medication use or disease pathways and were looking for ways to address a specific patient population through clinical practice.

Doctors of Pharmacy: Educational Path

In 2004, the American Association of Colleges of Pharmacy revised and released the Center for the Advancement of Pharmaceutical Education (CAPE) new educational outcomes which outlined target areas toward which the evolving pharmacy curriculum should be aimed at U.S. Schools of Pharmacy. These CAPE outcomes have since been incorporated into the accreditation standards for the Doctor of Pharmacy Degree. These educational outcomes include (5):

- "Provide pharmaceutical care in cooperation with patients, prescribers, and other members of an inter-professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving pharmaceutical, biomedical, socio-behavioral, and clinical sciences that may impact therapeutic outcomes."

- "Manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide access, and coordinate safe, accurate, and time-sensitive medication distribution and to improve therapeutic outcomes of medication use."
- "Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an inter-professional team of health care providers." (33)

Pharmacists in the U.S. are trained at the doctoral level and are educated in the following areas: pathophysiology, pharmacology, therapeutic, clinical problem solving, medication use, and laboratory monitoring.(5)(33) They are trained to become patient educators, patient coaches, with the most extensive knowledge and training in medication use, medication management, and problem-solving with any member of the healthcare team.(5) Furthermore, pharmacist experiential training is composed of significant practice experiences rooted in primary and ambulatory care, community health, different health care settings (rural and urban health challenges), and long-term care.(5)(34)

According to the ACPE's Accreditation Standards, PharmDs are trained and qualified to (5)(35):

- "Manage complex drug therapy and make recommendations for initiation, modification and termination of therapy
- Obtain medical histories
- Perform health screening and prevention assessments and evaluations

- Perform and interpret diagnostic and laboratory studies
- Counsel and teach health and nutrition
- Screen and refer patients to specialists and other health care providers
- Provide education to allow patients to make decisions about their own health
- Pharmacists are increasingly being integrated into these primary care teams, in family practice settings, ambulatory care clinics and community-based locations."(2)

There are many commonalities when the educational competencies of NPs, PAs, and PharmDs are compared. The educational path for PharmDs focuses more on therapeutics and medication pharmacology while NP and PA programs place more emphasis on patient diagnostic skills.(32) These overlaps—and slight but important differences in educational competencies—create a solid foundation for building integrated, team-oriented and collaborative approaches to patient care.(5)(32)

Clinical Pharmacy Residencies

After accreditation with a PharmD degree, a pharmacist can pursue a residency consisting of one or two years. The purpose of a postgraduate year one (PGY1) or postgraduate year two (PGY2) pharmacy residency is to prepare pharmacists for practice. Residency training is designed to provide residents experience working with a wide range of patients and in three types of residency settings—1) Pharmacy Practice (based in a hospital setting, 2) Community Pharmacy (based in a community pharmacy), and 3) Managed Care Pharmacy (based in managed care organizations such as health plans or

pharmacy benefit management companies.(36)

Residency training offers pharmacists advantages in the job market by making their training more highly specialized in a specific market, helps them network to expand their professional acquaintances, and further plan their careers. During residency most residents gain a clearer picture of what type of practice best suits them and the specific field where they want to work in the future. Currently, the American Society of Health-System Pharmacists (ASHP) recognizes fifteen specialized areas of practice.

Historically, pharmacy residencies date back to the early 1930s where the primary purpose of the residency was to train pharmacists in hospital pharmacy management. In 1948, the ASHP developed standards for pharmacy residencies in hospitals. During the early 1970s, residencies in clinical practice grew at a rapid rate, leading to the establishment of accreditation standards for clinical pharmacy and specialized residency training programs to ensure a quality training experience.(36) As of 2012, there were a total of 1,443 accredited programs participating in the resident matching program and a total of 2,594 residents were placed in these programs.(37) The supply of pharmacists and pharmacist demand for residency programs is growing significantly faster than was previously projected.(13)

ASHP is the sole accrediting body for pharmacy residencies in the United States. In 2007, approximately 1,600 PGY1 residency positions were available, and over 1,300 residency candidates obtained positions through the ASHP Resident Matching Program.(38) Table 3 describes pharmacist employment by sector in 2006. If all 1,600 PGY1 positions were ultimately filled, then 16 percent of the approximately 10,000

pharmacy graduates in 2007 entered residency training.(20) Outpatient clinical pharmacy requires residency training and disease-specific certifications.

Table 3. Pharmacist Employment in 2006 (20)

Practice Site	No. Pharmacists Employed
Community	155,010
Health Systems	63,190
Public Administration	7,450
Other	14,270
Total	239,920
Source: Johnson TJ. Pharmacist work force in 2020: implications of requiring residency training for practice. Am J Health Syst Pharm [Internet]. 2008 Jan 15 [cited 2014 Nov 26];65(2):166–70. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18192265	

There is a clear disconnect between the number of residency positions available and the number of residency-trained pharmacists likely to be needed in the future. Currently, most residency training programs are conducted in a health-system setting. Many pharmacists are entering residency training as a prerequisite for direct-care practice. While the majority of these residency-trained pharmacists will enter inpatient hospital clinical care, others are looking for outpatient clinical practice. Some describe this disconnect as a 'chicken and egg' problem—what comes first? Are there enough residency-trained pharmacists interested in outpatient clinical pharmacy to take a job in the community, or are there enough outpatient clinical care centers looking to hire outpatient clinical pharmacists?

This uncertainty carries through to the residency training programs—are there enough pharmacists looking for outpatient clinical pharmacy training for these roles upon graduation? Are potential pharmacy students looking for community–based jobs when they apply to pharmacy school? According to Mindy Smith at the APhA, the lack of

clinical pharmacy positions offered to PharmDs after residency is due directly to patient demand for medication disease state management clinical services.(24) Smith posits that patients are not referred to pharmacists for disease state management since pharmacists cannot bill for the claim of services rendered due to a lack of pharmacist provider status. This lack of patient supply leads to a decrease in demand for potentially beneficial clinical pharmacy services and therefore a lack of programs or jobs for pharmacists looking to provide clinical services. While there are no direct answers to these questions or ways to confirm or deny claims about clinical pharmacy supply or demands, chronic disease care management can most likely benefit from pharmacist-inclusive practice.

Pharmacist Compensation

In contrast to NPs and PAs, pharmacists do not have provider status as recognized by Title XVIII of the Social Security Administration (SSA). Consequently, pharmacists are not considered 'providers' according to the SSA and therefore cannot bill the government or private insurance plans for patient services rendered since they cannot submit a claim for clinical services provided. Without provider status, pharmacists do not have reimbursement eligibility under Medicare Part B. Funding received from a third party grant or award can be spent to reimburse pharmacist services, pay a pharmacist's salary, among other options. However, pharmacists are credentialed to submit claims through three mechanisms in Medicare—Part A, B and D. In Medicare Part B, pharmacists can bill for "Incident-to" billing for services rendered after a referral from another health care provider.(39)(40) The services provided through "Incident to" billing are defined as services or supplies furnished as an integral, although incidental, part of

the pharmacist's professional services.(41) For example, a pharmacist can bill through Medicare Part B if a physician sends a patient with high blood pressure to a pharmacist for medication follow-up education. If the clinic is accredited as a Diabetes Self-Management Training (DSMT) or Diabetes Self-Management Education (DSME) site, then a pharmacist can bill Medicare Part B for diabetes education or training by a pharmacist.

Medicare Part A has a facility-fee claim that a pharmacist can submit to Medicare for the use of the clinical or pharmacy location for patient education or management. Medicare Part A claims are usually submitted by a drug dispensing pharmacist within a pharmacy when the patient education itself occurs after a drug is dispensed and counseling services are provided. Medicare Part D is also associated with drug dispensation specifically for Medication Therapy Management (MTM). A pharmacist can bill for MTM services in a drug dispensing pharmacy or a clinical outpatient practice.

The reimbursements through Medicare Part A, B and D are not solely sustainable for a clinic to employ a full-time clinical pharmacist since the reimbursements for the services provided from Medicare are lower than the services themselves cost to the clinic. Moreover, pharmacist reimbursements through these mechanisms are not sufficient to sustain an individual pharmacist's salary based on the percent of the reimbursement that comes back to the pharmacy. Since pharmacists are not considered clinical services providers in terms of insurance compensation and cannot support their full salary from these claims, many pharmacists receive an annual salary from the clinic or outpatient facility.

Pharmacist's Role in Helping Solving the Primary Care Crisis

The public health problems caused by the expanding gap between the supply of primary care providers and the demand generated through unmet patient needs are formidable and will not be solved by a re-constituting or adapting a single profession.(5)(33) Since the issues are complex and will be compounded in the future with an aging population, collaborative efforts to identify solutions and provide high quality, team-delivered primary care are necessary. In assessing the functions and areas of deficiency in primary care practice, and thinking critically about untapped resources, pharmacists, among other clinicians, emerge as a potential resource to increase access to primary care and address one of the most challenging aspects of patient care—appropriate medication management. (5)(26)

Many pharmacists will be motivated to seek proficiency in the skills required to become a primary care provider, others may not choose to practice pharmacy clinically. Moreover, the health care system could not afford a global shift away from the role that many pharmacists play in the provision and delivery of medications.(43) However, some pharmacists will look to expand their care role, and their current educational background provides a strong foundation from which to build competence in physical assessment and diagnostic skills that will complement their expertise in managing complex medication therapies for their patients.(5)(44)(8)(6)

As of 2012, there were approximately 286,000 pharmacists and 353,000 pharmacy technicians practicing in the United States.(45) The average age for a pharmacist was 45 and 53.7 percent of pharmacists were women.(21) The national mean

annual earnings for a pharmacist were $116,670, with the lowest 10 percent earning on average $89,000 while the highest 10 percent earned $145,000.(21) Table 4 provides an overview of trends for of trends for pharmacist training and employment wages.

Table 4. Pharmacist Trends, 2012

Pharmacist Training and Prevalence	Employment Overview	Wages
-Since 2003, the number of pharmacists in the U.S. increased by 23 percent in 10 years.(21)	-As of 2010, 62 percent of pharmacists worked in retail pharmacies, 23 percent in hospitals, while others worked in clinics, mail-order pharmacies, wholesalers, some health care agencies or government.(45)	-Pharmacists experienced a 16 percent increase in real wages since 2003.(21)
-The U.S. Bureau of Labor Statistics projects faster than average growth for both pharmacist and pharmacy technicians from 2010-2020.(45)	-As of 2010, 73 percent of pharmacy technician and aide jobs were in retail pharmacies.(46)	-In 2012, median annual earnings for pharmacy technicians were $29,320, representing just a 3 percent increase in real wages since 2003.(45)
-In April 2013, the Aggregate Demand Index calculated by the Pharmacy Manpower Project was 3.21; indicating a roughly balanced supply and demand of pharmacists across the country.(22)	-As of 2010, about 21 percent of pharmacists worked part-time.(45)	-In 2012, reported earnings for pharmacists varied by industry, type of employment, and region.
-While reports once suggested demand for pharmacists would outpace the supply in the coming decade, trend data show that it has not been the case for the previous ten years.(22)(47)	-In 2012, Gallup Poll measured public perceptions of professional ethics and honesty. Respondents placed pharmacists second only to nurses—75 percent of respondents ranked pharmacists as "very high" professional ethical standards.(48)	-In 2012, health and personal care stores reported the highest concentration of pharmacist employment, while the highest average annual wages were in pharmaceutical and medicine manufacturing. (21)
-As of 2012, there were 61,275 students enrolled in 124 accredited programs.(49)	-In 2012, the pharmacist workforce was 6.8 percent African American, 18.5 percent Asian, and 5.1 percent Hispanic or Latino.(50)	

Source: AFL-CIO. Fact Sheet 2013: PHARMACISTS AND PHARMACY TECHNICIANS FACTS AND FIGURES. Dep Prof Employees [Internet]. 2013;1–7. Available from: http://dpeaflcio.org/wp-content/uploads/Pharmacists-and-Pharmacy-Technicians-2013.pdf (21)

Chapter One Summary

In summary, Chapter 1 outlined the research questions, propositions, and translation of this research. Chapter 1 also outlined the future of pharmacist-inclusive practice for primary care in the United States. The projected primary care shortage of physicians, Nurse Practitioners, Physician Assistants and other allied health professionals leaves a potential gap for pharmacists to fill for medication management of chronic disease. To understand how pharmacists can address this gap, Chapter 1 defined pharmacy education, residency and training in the United States.

To understand the Collaborative Drug Therapy Management program at El Rio, background knowledge about pharmacists and current supply and demand trends is paramount. The projected increase in future U.S. demand for primary care services and the potential benefit pharmacist integration into clinical outpatient care services, leaves a gap for pharmacist inclusion that could be addressed with CDTM models and theory. Chapter 2 describes the study setting and case study analysis employed by this research.

CHAPTER TWO

Literature Review

Introduction

Chapter 1 described the state of the pharmaceutical profession and the potential role pharmacist-inclusive practice can have in helping to address upcoming physician shortages. Chapter 2 describes the specific pharmacist-inclusive practices used for collaborative practice in patient care settings. The rationale behind this study, theoretical models and the gaps in current research are discussed in Chapter 2. The specific aims and models used to analyze the case study of El Rio are further developed as well.

Collaborative Practice

The IOM has called for "a new health system for the 21st century for primary health care teams to play a central role in the care of patients."(33) The leap in the complexity of patient care prevents physicians, NPs, or PAs from managing a patient's treatment plan alone.(51) Studies have demonstrated that in settings where physicians and non-physician professionals work together as teams, patients have improved health outcomes and lower hospital 30-day re-admission rates.(52)(53)(54)(6)(55)(56)(57)(25) According to the IOM, "all health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based practice quality improvement approaches and informatics."(10)(5) Each health care professional on the healthcare team brings a core set of skills and training to provide primary care services that directly impact quality care for patients and contain costs of

treatment. The highest quality healthcare is provided when all members of the healthcare team improve communication and collaboration between each other while treating a patient.

The imperative of cost containment in health care leads provider organizations to favor hiring lower paid clinicians over physicians.(52) Moreover, the demand for quality patient care encourages primary care settings to add caregivers with skills that physicians may not possess.(5) PAs and NPs are formally recognized primary care providers with national provider status as defined by the Social Security Administration. These professionals have significantly expanded the primary care capacity, access, and availability in the U.S. over the past 40 years.(5) Although some are state-regulated—PAs practice in collaboration with and under physician supervision—many exercise autonomy in clinical decision making.(53) Nurse Practitioners also practice through collaborative practice agreements or under some level of physician supervision in most states.(5)(34) While healthcare settings differ in patient volume and complexity of care, in 22 percent of states in the U.S., NPs have authority to practice independent of physician involvement.(58)

States determine the laws regarding licensing of pharmacists. All states require, at minimum, both graduating from an accredited first professional degree program from a pharmacy college and passing of the North American Pharmacy Licensing Examination.(21) After licensure, pharmacists can work in many settings ranging from drug dispensing, administration, to outpatient clinical pharmacy.

Collaborative Practice Agreements (CPAs)

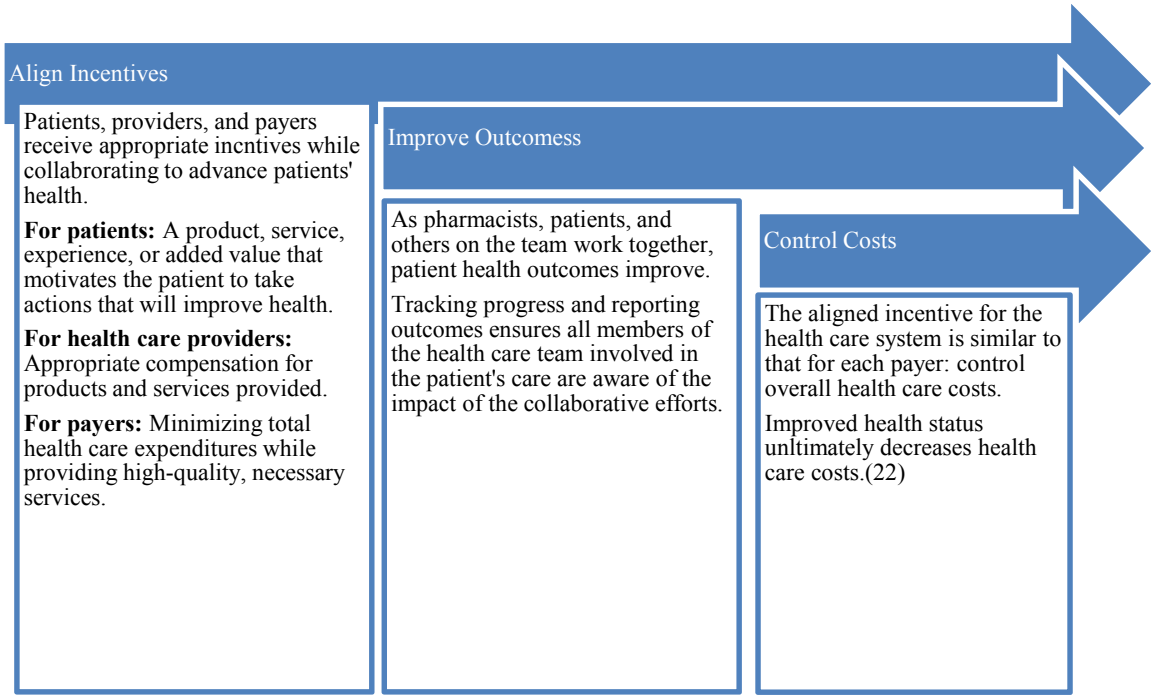
According to the Centers for Disease Control and Prevention (CDC), "a CPA is a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions."(59) CPAs can be arranged between any type of licensed health care provider in both inpatient and outpatient settings. CPAs define certain patient care functions that each care provider on a team can provide autonomously under specific situations and conditions.(60) While CPA's provide one option for increased collaboration, they are one of many tools used by hospital and clinical administrators to address a patient-centered team-based approach to care. The CDC collaborative practice framework is outlined in Figure 4.

CPAs are most common for NPs and PAs due to their direct involvement with patient care. In 21 states NPs must practice under a CPA with a physician.(58) The requisite level of specificity for a NP's clinical purview varies by state. Nationwide, CPAs and other types of binding contracts are in place for PAs as they must work under the auspices of a physician.

Research has shown that pharmacists can directly improve a patient's health and the health care delivery system only if they are a part of the patient's health care team.(17) As illustrated in Figure 4, one way to meet this goal of including a pharmacist on a care team is through pharmacist-inclusive CPAs between pharmacists and other health care providers.(59) Patient care services provided by a pharmacist-inclusive team can reduce fragmentation of care, lower health care costs, and improve health

outcomes.(59) A 2010 study found that patient health improves significantly when pharmacists work with doctors and other providers to manage patient care under CPAs.(61)

Figure 4. Framework for Successful Collaborative Practice Agreements.(59)



Adapted from: Centers for Disease Control and Prevention. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. Atlanta, GA: US Dept. of Health and Human Services, Centers for Disease Control and Prevention; 2013. (59)

Collaborative Drug Therapy Management (CDTM)

Many types of employment and practice agreements exist between NPs, MDs, and PAs, however, a Collaborative Drug Therapy Management (CDTM) Collaborative Practice Agreement is specific to pharmacists. The CDTM contract identifies and clarifies a pharmacist's clinical practice role when pharmacists are working with other clinicians in a collaborative manner. These pharmacist-specific CPAs are the foundation

of pharmacist-inclusive CDTM models that have been shown to reduce fragmentation of care, lower health care costs, and improve a patient's health outcomes.(34)(62)

According to the AACP, "CDTM is a team approach to healthcare delivery that seeks to maximize the expertise of the pharmacist and the physician in order to achieve optimal outcomes through appropriate medication use and enhanced patient-care services."(5) The Academy for Managed Care Pharmacy (AMCP) describes CDTM models as a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy autonomously.(63) The CDTM designation is used primarily because it is descriptive of the usual scope of practice between the physician and the pharmacist; e.g. drug therapy management.(63)

CDTM is most commonly provided under mutually agreed upon practice protocols and guidelines in both clinical inpatient and outpatient settings. The AACP defines CDTM activities that include, but are not limited to, the following pharmacist activities:

- "Initiating, modifying, and monitoring a patient's drug therapy
- Ordering a performing laboratory and related tests
- Assessing patient response to therapy
- Counseling and educating patients about their medications
- Administering medications"(2)

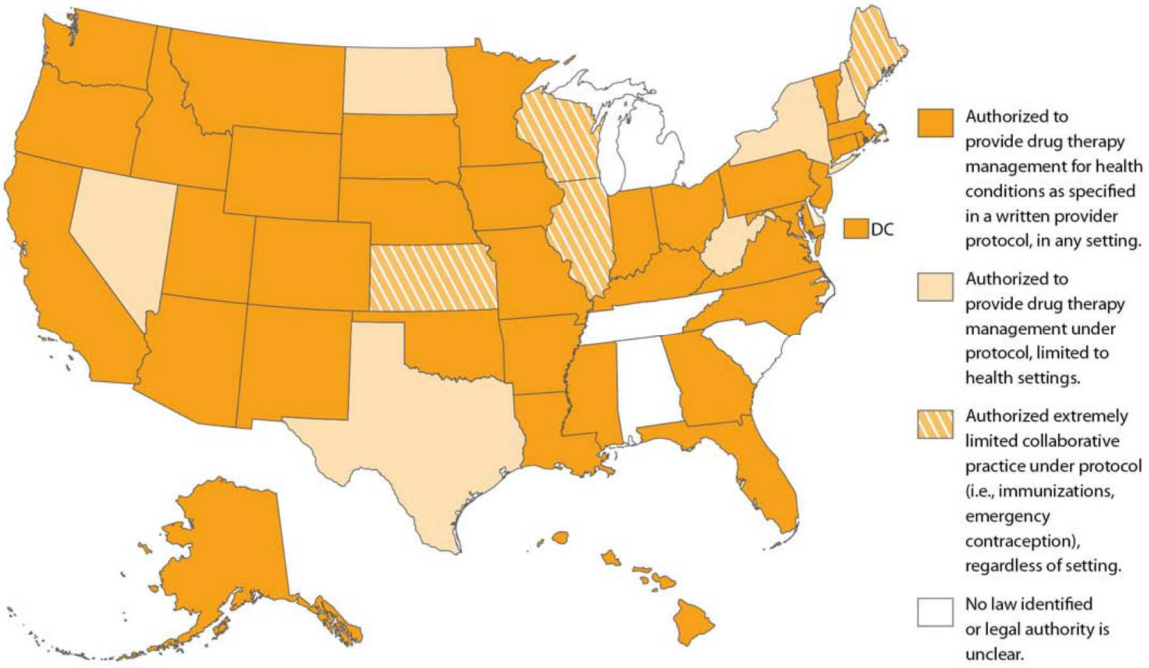
Pharmacists have varying degrees of prescriptive authority depending on state law. Because CDTM allows pharmacists to provide services that are typically outside

traditional pharmacy practice laws, authorization in each individual state is required to establish the laws governing the CDTM scope of practice for pharmacists.(63) A significant barrier to the ability to deliver this quality primary care is embedded in pharmacist practice laws and regulations.(5) In forty-seven states, the District of Columbia, the territory of Guam, the Department of Veterans Affairs, and the Indian Health Service, pharmacists are authorized to enter into collaborative drug therapy management (CDTM) agreements with physicians in clinical settings.(64)(40) In forty-six states and the territory of Guam, laws and regulations permitting pharmacists to authorize either a limited or broad scope of drug therapy management have been adopted.(34)(59). As of December 2013, only Tennessee, South Carolina, Michigan, and Alabama did not have a law or identified legal authority condoning or eliminating clinical pharmacy practice.(34) Figure 5 identifies state authorizations regarding drug therapy management by pharmacists. In many cases, CDTM acceptance and integration into current care models is more of a barrier than the legal obstacles approving pharmacist-inclusive team-based care models in outpatient care settings.

Due to their regular direct contact with patients, pharmacists are the most accessible and frequently visited members of the healthcare team.(5) Community pharmacists are among the most widely accessible healthcare professionals, and can be utilized not only as the traditional prescription medication dispensers, but also as disease state managers providing patient education, counseling, and monitoring of drug therapy.(26) Many pharmacists have established practices in primary and ambulatory care settings, working in teams to provide medication therapy management and (usually

disease-specific) chronic and preventative care to patients in disease specific models.(5)(65)(66)

Figure 5. Map of States with Laws Explicitly Authorizing Pharmacist Collaborative Practice Agreements, 2012 (59)



Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

CDTM models make drug therapy earlier, more efficient and convenient for the patient, pharmacist and physician. With a CDTM model in place, the health care team is able to expand the ability of health care professionals able to provide optimal care to their patients.(63) A CDTM model extends access to health education, health screening, vaccine administration, among other services for community health where physician access is limited.(67)

An example of a successful CDTM model is when a physician and pharmacist both see the same patient with diabetes. The visits are different—the clinician diagnosed the patient, and the pharmacist completed the follow-up tests and initial medication dosing. At a later check-up when the pharmacist observed that the patient's insulin dose needed to be increased or decreased by one small unit of measure, the pharmacist could prescribe and fill the new medication dosing. When a CDTM model is in place, a pharmacist does not need to run medication changes by the physician. Instead of having 'double work' by having the physician check the dosing change before approving and filling it, the pharmacist can change the medication dosing, write the prescription and note the change in the patient's chart without physician approval. Not only do CDTM models save patients time, they are cost effective for clinics as practitioners are not repeating work.

A successful example of how changes in scope of practice for pharmacists can impact the care of patients is the provision of immunizations. As of 2010, more than 40,000 pharmacists have received formal training and recognition as providers of a wide range of immunization services. This broad adoption of immunization training and services has resulted in millions of patients receiving pharmacist-delivered immunizations each year.(5) Due to this increase in vaccination coverage, the AACP believes that, "state-based scope of practice laws and regulations must be revisited and updated to allow CDTM and immunizations in all U.S. states and territories."(5)

Pharmacist's Role in Diabetes Care

One of the many chronic diseases that can be clinically and cost-effectively managed by pharmacists in collaborative practice is diabetes.(25)(65) Diabetes mellitus is one of the most prevalent chronic diseases in the United States and is also a leading cause of morbidity and mortality.(68) Diabetes is a group of metabolic diseases in which a person has abnormally elevated levels of blood sugar. Diabetes is the seventh leading cause of death in the United States and can cause serious health complications including heart disease, blindness, kidney failure, and a potential for lower-extremity amputations.(69) The symptoms of diabetes include: frequent urination, unexplained weight loss and extreme hunger among other symptoms.(70) There are two main types of diabetes—type 1 and type 2.

Diabetes type 1 (T1DM), historically referred to as juvenile diabetes or insulin-dependent diabetes mellitus (IDDM). T1DM accounts for five to ten percent of all diagnosed diabetes cases. Autoimmune, genetic and environmental risk factors are involved in the development of this type of diabetes. Treatment includes frequent insulin injections.(71)

Diabetes type 2 (T2DM), historically referred to as non-insulin dependent diabetes mellitus (NIDDM) or adult onset diabetes. T2DM accounts for 90 to 95 percent of all diagnosed cases of diabetes. Risk factors for type 2 diabetes include older age, obesity, physical inactivity, and ethnicity.(72) African Americans, Hispanic and Latino Americans, American Indians, and some Asian Americans are at particularly high risk for T2DM. Treatment typically includes diet control, home blood sugar testing and in some

cases oral insulin medications or insulin injections.(71)

According to the American Diabetes Association (ADA), the total estimated total cost of diagnosed diabetes in 2012 was $245 billion—a 41 percent increase from the previous estimate of $174 billion in 2007.(73) Of the $249 billion total costs, an estimated $175 billion were direct medical costs and an estimated $69 billion in reduced productivity.(73) The ADA estimates that care for people with diagnosed diabetes accounts for more than one in five health care dollars in the U.S., and more than half of that expenditure is directly attributable to diabetes.(73) While total diabetes-related costs are estimated to accurately represent the cost of diabetes, the burden of diabetes is imposed on all sectors of society through higher insurance premiums paid by employers and employees and reduced earnings from productivity losses.(68) In response to the growing health burden of diabetes, the public health community is working to prevent diabetes; cure diabetes; and take better care of people with diabetes to prevent devastating complications.(70)

El Rio: Historical and Current Context

El Rio Community Health Center was founded in the late 1960's by neighborhood activists and the University of Arizona. The clinic founders wanted to bring accessible and affordable health care to Tucsonans who were "being overlooked by traditional health care systems."(74) El Rio now consists of seventeen clinical sites and serves over 79,000 patients—almost 900 patients per day.(74)(75) Over 70 percent of the patient population self-identify as Hispanic or Mexican-American.(76) El Rio provides accessible and affordable health care primarily to underserved populations in the greater

Tucson area and southern Arizona. Of the patients served at El Rio, 76 percent report living at or below the federal poverty level.(74)

As one of the largest non-profit community health centers in the United States, El Rio has become a national model for pharmacy-based outpatient health care delivery.(76) As many patients who receive care at El Rio are pre-diabetic or have diabetes, the Pharmacy-Based Diabetes Management Program (PBDMP) began in 2001 and has served over 4,000 patients.(75) The program includes direct service and interventions for patients through disease state management including prescribing medications and in-depth educational consults empowering patients to proactively manage their health. This ongoing direct consultation integrates treatment of three related diseases: diabetes, hypercholesterolemia and hypertension. The program has been found to be cost effective and clinically effective in treating diabetes (T1DM and T2DM) and preventing hospital admissions.(76)(65)

In 2009, a team of researchers from the University of Arizona and El Rio developed and implemented an internal case study analysis of the El Rio patients who had participated in the PBDMP. The methodology included the identification of a few key indicators, development of an abstraction tool, and then data collection from the program's data base. The first deliverable of the project was to evaluate the program's effectiveness in terms of affecting utilization of emergency departments (ED) for diabetes and other indicated outcomes.(76) After the first phase of data was collected and analyzed, the second variable examined by the team was cost effectiveness data of the PBDMP in contrast to the diabetes-related ED visits.

The study team found that the El Rio measures were generally superior by a relatively large amount for tests and exams related to diabetes as compared to the ED. The trend data showed substantial improvements from 2000-2009 in El Rio performance of the diabetes tests and exams over time. This trend was accompanied by a shift from lower rates than the control group to higher rates, around 2003, and the maintenance of that superiority in all subsequent years between 2000 and 2009. While data related to total charges are a notoriously poor proxy for total costs, the analysis showed average total charges were substantially lower for El Rio. The team showed that there was substantial evidence to support a conclusion that the El Rio PBDMP is effective in improving the care and, within stated constraints, succeeds in reducing the health care costs of the patients that it treats.

Research Gaps

Patients with a broad range of diseases and conditions can be managed by pharmacists in conjunction with primary care clinicians. Many of these conditions are comorbid and thus require complicated medication therapy and sometimes may require other clinical interventions.(5) To effectively care for these complex patients and "take responsibility for achieving intended therapeutic outcomes through medication management," pharmacists rely on a strong clinical and pharmacological knowledge and experience base.(5)

Numerous scientific publications have conclusively demonstrated dramatic reductions in morbidity and mortality that pharmacists practicing in primary care can have on patient populations afflicted with chronic diseases such as asthma(77),

diabetes(6)(7), Hepatitis C(57), hyperlipidemia(6), hypertension(25), chronic kidney disease(66), and HIV(78), among others.(6,25,55–57,78,79) Many articles examine the perspective of family physicians and NPs with the inclusion of a pharmacist in their collaborative practice. Although operational and practice integration challenges are usually recognized, the clinical benefits of working collaboratively with a pharmacist include: "access to colleagues with reliable drug information, fresh perspectives, and increased security in medication prescribing".(80) Many of these articles focus on the clinical outcomes or cost-effectiveness of pharmacist-inclusive collaborative care while overlooking exactly *how* the model for pharmacist integration was initially formed. As it is difficult to rationalize clinical time spent describing best practices of a program or intervention, many clinics have not published what worked and why it worked for their specific patient population and the subsequent potential for larger dissemination and transferability to other clinical sites.

Study Purpose

The purpose of this dissertation is to study the process, successes, and challenges associated with the implementation of pharmacist-inclusive collaborative care models in outpatient clinical settings. The study will investigate the CDTM Pharmacy-Based Diabetes Management Program at the El Rio Community Health Center in Tucson, Arizona. An in-depth examination of the experience with CDTM implementation will be analyzed using the PRECEDE-PROCEED model (a cost-benefit evaluation framework) and the organizational transformation model (describing a model for moving

organizations from short-term, isolated performance improvements to sustain and organization-wide improvements in patient care) in order to identify factors influencing the improvement initiatives leading to organizational transformation in El Rio's CDTM Pharmacy-Based Diabetes Management Program.(81) Study findings will be used to create intervention guidelines for CDTM in public health practice by: a) developing practical outpatient clinical collaborative practice agreements for pharmacist-inclusive practices b) proposing mechanisms for more successful CDTM implementation, both in Arizona and in other locations considering similar CDTM models.

Specific Aims

The objectives of this dissertation are to address the current gap in knowledge of the ways in which CDTM models are implemented and adopted; to identify perceived and documented successes and challenges related to full implementation of the CDTM model at El Rio Community Health Center; and to develop practical tools for implementation, adoption, and monitoring for other outpatient clinical settings considering the development and implementation of a similar model. Study objectives are summarized in the following specific aims and sub-aims.

Specific Aim 1: To identify the ways in which the CDTM model became a: 1) clinically effective, 2) cost-effective, and 3) sustainable model at the El Rio Community Health Center.

Sub-aim 1a. Identify key aspects of the clinical management processes (through lean management brainstorming exercises and key informant interviews) that served as structure and support for the CDTM model at El Rio.

Sub-aim 1b: Apply the PRECEDE portion of the PRECEDE-PROCEED model and organizational transformation model to an analysis of the El Rio CDTM model implementation in order to identify the foundational aspects of the socio-ecological model that supported the program's inception.

Specific Aim 2: To translate findings from the implementation assessment into public health practice products that support successful implementation and maintenance of CDTM models throughout Arizona and nationwide.

Sub-aim 2a: To study the contextual information and literature to inform both the analysis of Arizona's experience and the development of CTDM implementation guidelines and resources.

Sub-aim 2b: Create CDTM model implementation guidelines for clinics and hospitals looking to implement a CDTM model in their health care setting.

Sub-aim 2c. Build a decision support tool—in the form of an embedded Google Forms document or worksheet—that will allow clinics to assess their capacity for

implementation of a CDTM model.

Sub-aim 2d: Develop and disseminate a management case study about the Pharmacy Based Diabetes Management Program at the El Rio Community Health Center. The management case study will focus on key administrative decisions made during program implementation used by the El Rio administration and other stakeholders.

Conceptual Frameworks

PRECEDE-PROCEED Model

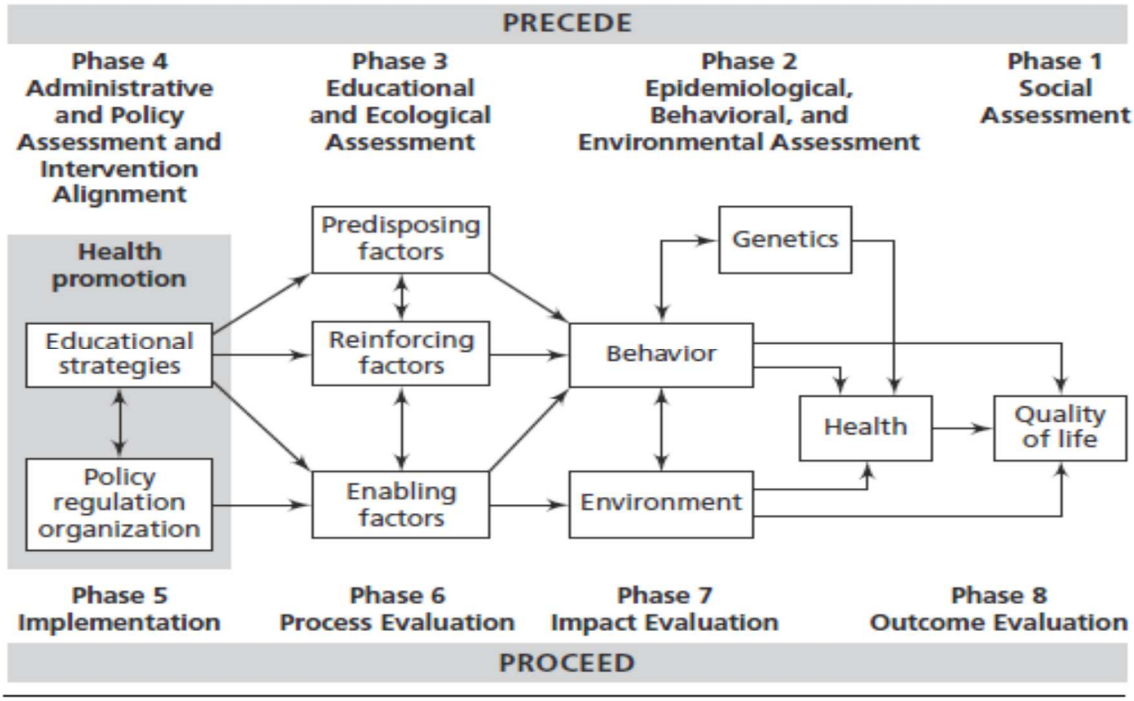
According to Andrea Gielen et al., "the Precede-Proceed model can be thought of as a road map and behavior change theories as the specific directions to a destination." (82) The road map presents all the possible avenues a health program can take, whereas the theory suggests certain avenues to follow. Gielen et al. argue that "the Precede-Proceed model does not predict or explain the relationship among factors thought to be associated with an outcome of interest, rather, its main purpose is to provide a structure for applying theories and concepts systematically for planning and evaluating health behavior change programs."(82)

The model is an example of a behavioral logic model, in that it links the causal assessment and the intervention planning and evaluation into one overarching planning framework from the beginning to the end of the intervention. Developed in the 1970s by Lawrence Green and colleagues, the acronym (PRECEDE) stands for: Predisposing,

Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation. Green described the framework, "PRECEDE is based on the premise that, just as medical diagnoses precedes a treatment plan, so should educational diagnosis precede an intervention plan."(82) In 1991, PROCEED (Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development) was added to the framework recognizing the importance of environmental factors as determinants of health.

There are eight phases of the PRECEDE-PROCEED model including: 1) Social Assessment, 2) Epidemiological, Behavioral, and Environmental Assessment, 3) Educational and Ecological Assessment, 4) Administrative and Policy Assessment and Intervention Alignment, 5) Implementation, 6) Process Evaluation, 7) Impact Evaluation, and 8) Outcome Evaluation. This study will utilize all eight phases as a roadmap, focusing on the first four phases of the PRECEDE framework. Figure 6 presents the PRECEDE-PROCEED model and describes determinants of each phase.

Figure 6. PRECEDE-PROCEED Planning Model



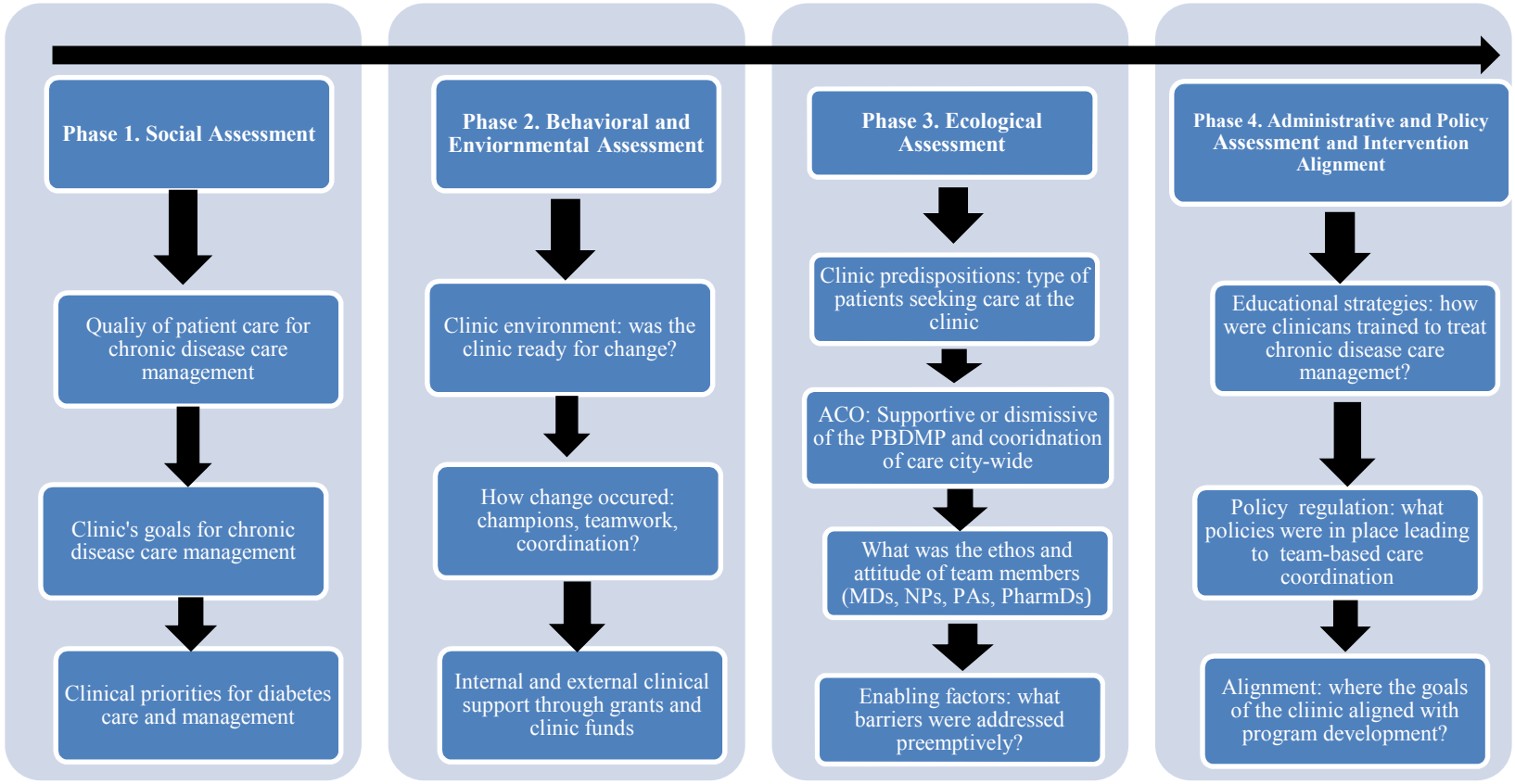
Source: Phillips JL, Rolley JX, Davidson PM. Developing Targeted Health Service Interventions Using the PRECEDE-PROCEED Model: Two Australian Case Studies. Nurs Res Pract [Internet]. 2012 Jan [cited 2014 Jan 28];2012:279431. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3407641&tool=pmcentrez&rendertype=abstract.(83)

While the PRECEDE-PROCEED framework typically addresses behavior change models applied to the public, this study applies the framework to a clinical model of practice in the context of the El Rio Pharmacy-Based Diabetes Management Program (PBDMP). The first four steps of the PRECEDE-PROCEED model, specifically the PRECEDE segment of the model, will provide a framework to outline the key administrative, ecological, environmental and social aspects of El Rio throughout the CDTM model. Steps five through eight of the PRECEDE-PROCEED model address the program's implementation and process evaluation through an outcome evaluation phase.

The PROCEED portion of the model covers the Administration, Educational and Ecological assessment, epidemiological and social assessment of the program design. The PROCEED segment of the model is important for the implementation, process evaluation, and outcome evaluation of a program.

The PRECEDE portion of the model is more applicable give the scope of the research questions. The PRECEDE portion of the model focuses on the structure of the environment and assessment leading up to an implementation. These key factors are exceedingly important to define and address to assist in the creation of the backbone of the PBDMP in order to ultimately create implementation guidelines on how the program was created. The research questions for this research focus on how these factors assisted with the structure and development of the program and not on the specific process or outcome evaluation of the program as a whole. Figure 7 describes the PRECEDE segment of the model as it applies to the research in more depth.

Figure 7. PRECEDE Model for CDTM Implementation Guidelines



Adapted from: Phillips JL, Rolley JX, Davidson PM. Developing Targeted Health Service Interventions Using the PRECEDE-PROCEED Model: Two Australian Case Studies. Nurs Res Pract [Internet]. 2012 Jan [cited 2014 Jan 28];2012:279431. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3407641&tool=pmcentrez&rendertype=abstract.(83)

The PRECEDE segment of the PRECEDE-PROCEED model will provide the socio-ecological framework to understand the backdrop and foundation where the PBDMP was created. The individual and environmental factors that influence the model will be defined and studied to gain and more complete picture of El Rio and Tucson as the program was founded. The factors that create the PRECEDE segment of the model are especially important to understand the organizational and management decisions as the program was created. This research is the first of its kind to apply the PRECEDE-PROCEED framework to an organization's behavior as a change model instead of an individual, study group, or community.

Organizational Transformation Model

Organizational Transformation Model offers a conceptual model for moving organizations from short-term, isolated performance improvements to sustained, reliable, organization-wide, and evidence-based improvements in patient care.(81) The model is based on the IOM's 2001 report *Crossing the Quality Chasm: A New Health System for the 21st Century,* arguing for a fundamental redesign of the U.S. healthcare system.(81) While many health care organizations have embraced the report's goals, few have succeeded in making the substantial transformations within their organizations needed to achieve those aims.(81)(84) Since transformation occurs over time with iterative changes being sustained and spread across the organization, organizational transformation takes leadership, dedication, and sustained support to succeed.(81)

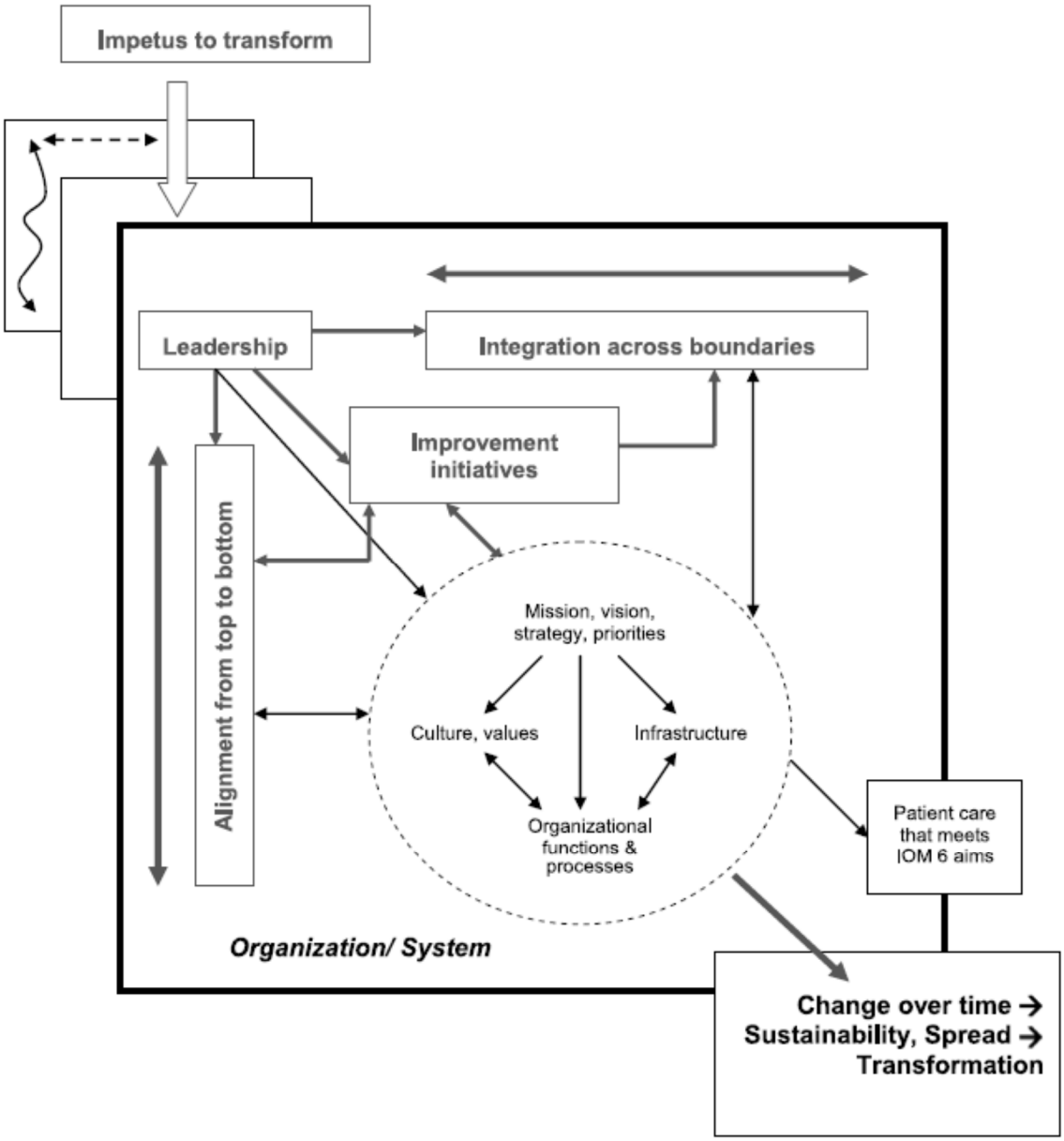
The model outlines five interactive elements critical to successful transformation of patient care: 1) Impetus to transform, 2) Leadership commitment to quality, 3) Improvement initiatives that actively engage staff in meaningful problem solving, 4) Alignment to achieve consistency of organization and goals with resource allocation and actions at all levels of the organization, and 5) Integration to bridge the traditional intra-organizational boundaries among individual components.(81) These elements drive change within an organization by affecting the components of the health care organization in which they operate including the: 1) Mission, 2) Culture, 3) Operational Functions and 4) Infrastructure.(81) These five elements interact within the organization to create change. The organizational transformation model identifies factors critical to successful redesign, transformation, and patient care. To achieve transformation through the OTM, the five drivers for change not only need to interact with each other, but also drive change through the organization's mission, culture, infrastructure and operations.(81)

The five critical elements of the model do not operate in isolation. Rather, the components of transformation occur in and through the context of complex dynamic health care organizations.(81) Figure 8 describes this model. When improvement initiatives are aligned with the organization's priorities and linked to the organization's administration, senior managers are more likely to provide the needed infrastructure to encourage the transformation. To achieve transformation, the five elements not only interact with each other, but also drive change through the organization's mission, culture, infrastructure and operations. While elements such as communication and

relational coordination are associated with aspects of successful transformation, the five critical elements of transformation are the most important for sustainability of change.(81)

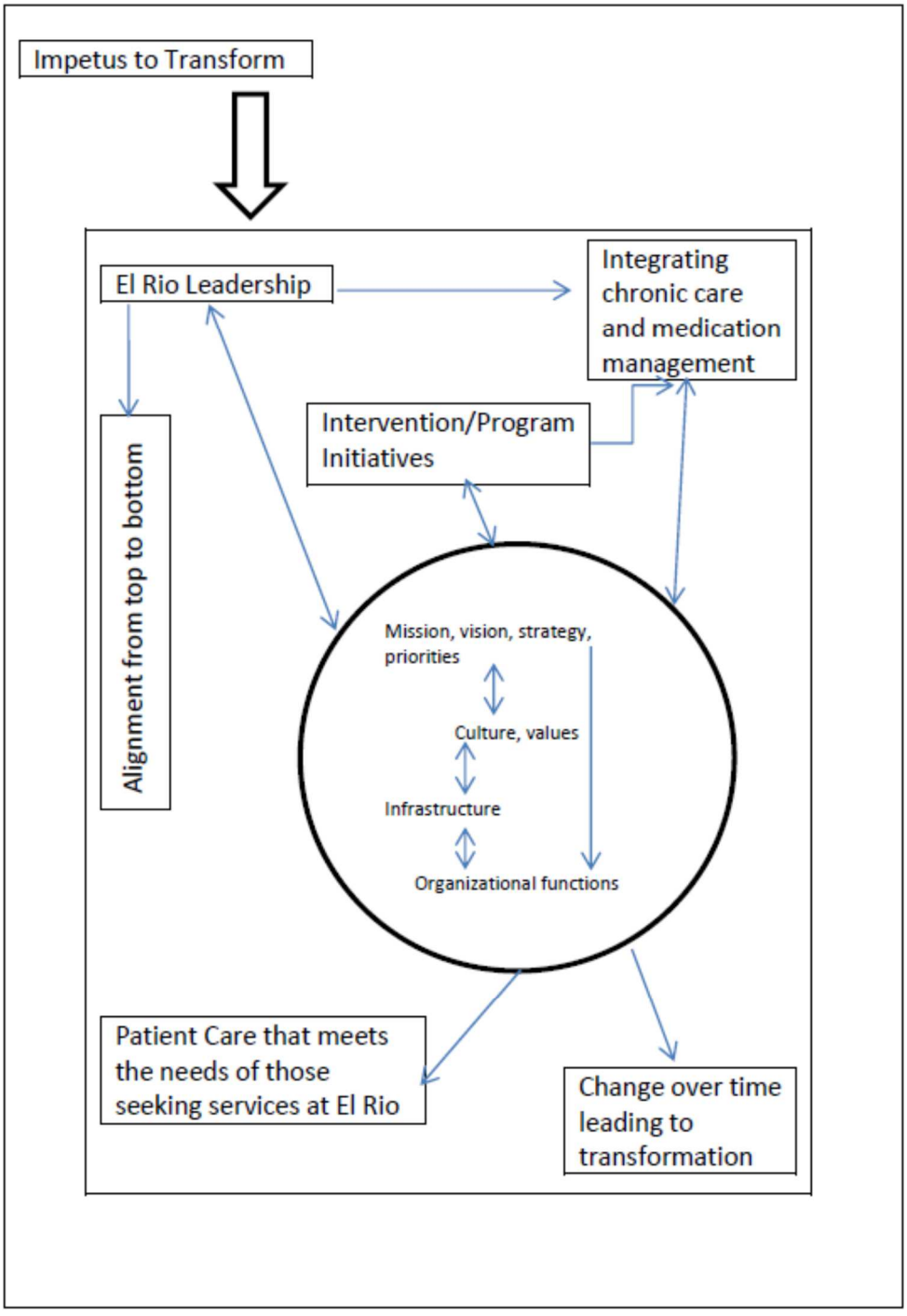
Transformation occurs when these five factors interact with each other over time and drive change through the larger organization. As described in Figure 9, the transformation to a CDTM model to address chronic disease care management at El Rio was innovative for the five factors integral for a successful intervention. Applying the five factors to the timeline and organizational change at El Rio will be helpful to understand how the changes occurred and the most important aspects of the model intervention. Looking at the complementary programs and systems in place at El Rio will also assist the study to highlight the most important factors necessary to be in place for intervention success.

Figure 8. Organizational Transformation Model (81)



Source: Lukas CV, Holmes SK, Cohen AB, Restuccia J, Cramer IE, Shwartz M, et al. Transformational change in health care systems: an organizational model. Health Care Manage Rev [Internet]. 2007;32(4):309–20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18075440

Figure 9. Organizational Transformation Model, El Rio(81)



Adapted from: Lukas CV, Holmes SK, Cohen AB, Restuccia J, Cramer IE, Shwartz M, et al. Transformational change in health care systems: an organizational model. Health Care Manage Rev [Internet]. 2007;32(4):309–20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18075440

Lean Management

According to Raymond Floyd, a developer of lean culture in the process industries, “lean manufacturing, lean management, lean enterprise, or lean production, often simply, ‘lean’ is a production practice that considers the expenditure of resources for any goal other than the creation of value for the end customer to be wasteful, and thus a target for elimination.”(85) Lean works from the perspective of the customer who consumes a product or service. “Value” is defined as any action or process that a customer would be willing to pay for in return for that service or product.(85)

Lean enterprise emerged from post-World War II Japanese automobile industry as a fundamentally more efficient system than mass production.(86) Lean thinking is the dynamic, knowledge-driven, and consumer-focused process through which all people in a defined enterprise continuously eliminate waste and create value.(86) In healthcare, lean is about shortening the time between the patient entering and leaving a care facility by eliminating all non-value added time, motion, and steps.(87) The value of lean is in the substance of improved performance that makes the lean form of operation more effective than traditional manufacturing practice.(85)

The assessment of staff support services and processes can be codified and measured using lean thinking by creating a process map of current or future workflow. Individuals or groups can map a system for a current state and extrapolate how the system currently functions or should function by identifying process steps integral to the program. The process steps are defined and placed in chronological order on the maps. Through this exercise, standardization of processes can be calculated or examined. By

decreasing variation and streamlining steps, ‘waste’ is eliminated and a process becomes more efficient.

Process maps will be used in this research as a tool to develop quantifiable visual representations of the PBDMP. The process maps help understand the efficiencies and inefficiencies in the PBDMP process. Process steps will be identified in the lean brainstorming groups and compared to each other to best understand the current state of the PBDMP at El Rio.

Lean Management Project Examples

Examples of the successful implementation of lean management to improve efficiency in clinical settings are relevant to understanding the potential benefit of applying lean thinking to the case study of El Rio.(88) Lean management and quality improvement techniques have been widely incorporated into multiple levels of health care systems to decrease variation and waste while increasing efficiency.(88) In 2013, at Virginia Mason Medical Center in Seattle, Washington, a series of lean interventions combined with direct observations were followed by a decrease in the number of medication administration errors from 10.3 errors/100 doses at baseline to 2.8 errors at final follow-up.(89) The study found that lean improvements coupled with direct observation can contribute to substantial decreases in errors in nursing medication administration and an increase in quality improvement.(89)

A collaborative quality improvement project was conducted from June 2011-January 2012 by the Veterans Health Administration to determine whether care to prevent postoperative respiratory failure could be improved through a Virtual

Breakthrough Series (a quality improvement technique).(90) The study showed that the project helped teams implement process changes that led to a reduction in Intensive Care Unit (ICU) readmissions for respiratory failure. This type of quality improvement model shows promise for knowledge sharing between multiple medical departments.(90) The Pharmacy-Based Diabetes Management Program at El Rio requires multiple medical departments to cooperate and align well to share patient data and create a sustainable treatment plan. Lessons learned from collaborative quality improvement projects can be applied to these patient care models at El Rio.

In 2008, the Greater New York Hospital Association launched a program for ICUs to complete Plan-Do-Study-Act (PDSA) cycles to decrease central line-associated blood stream infections.(62) A total of 36 hospitals participated in the quality improvement project for 33 months which showed a statistically significant decrease in infections by 58 percent during the intervention period as compared with the mean baseline rate. While lean management principles have been used effectively in manufacturing companies for decades, the lean principles can be—indeed, already are being—successfully applied to the delivery and provision of health care services.(91) El Rio completed PDSA cycles while studying the cost-effectiveness of the Pharmacy-Based Diabetes Management Program, however mapping the process of the program itself through PDSA cycles may be worthwhile for program staff.

This research applies lean management concepts to better understand the wastes, efficiencies, and inefficiencies during the implementation of the Pharmacy-Based Diabetes Management Program at El Rio. Using lean process maps, participants in the

study outlined processes before and after the El Rio CDTM intervention. Efficiencies and wastes were identified from this process and then extrapolated into intervention guideline recommendations for clinics nationwide.

Conceptual Frameworks and Clinical Pharmacy

The frameworks and theories utilized in this dissertation, the PRECEDE-PROCEED Model, Organizational Transformation model, and lean management have the potential to illustrate aspects of the CDTM model never previously addressed. These theories and frameworks help understand the areas of CDTM which are the most generalizable to multiple settings looking to create a CDTM-type model. The clinical and cost effectiveness of CDTM has been studied, but examining the structure and supports leading to a successful application of CDTM has not been addressed in current literature.(64)(65)

The PRECEDE-PROCEED model will provide a roadmap to understand the underlying behavior changes in management practices from the leadership at El Rio. The model will help analyze the social, ecological, policy and environmental rationale for adopting the CDTM model. The PRECEDE section of the PRECEDE-PROCEED model will be specifically applied to the key informant interviews and group sessions as to how the CDTM model was implemented.

The organizational transformation model will elucidate the relational dynamics of transforming work between departments participating in the CDTM model at El Rio. The theory will provide mechanisms to articulate and quantify these clinical relationships and understand how the burden of work is distributed between employees for program

coordination. The organizational transformation between employees is vital and will be extrapolated from the lean management brainstorming activity group sessions.

Chapter Two Summary

The genesis of this research stemmed from desire to examine an example of a pharmacist-inclusive chronic disease care management outpatient program. To study the El Rio Community Health Center's Pharmacy-Based Diabetes Management Program, the PRECEDE portion of the PRECEDE-PROCEED socio-ecological model, Organizational Transformation Model and lean management will be applied. Through a case study analysis focusing on the structures and supports in place fomenting the program's development, intervention guidelines, a self-assessment Outpatient Clinical Pharmacy Program Worksheet, and a management case study will be created.

The increasing numbers of people seeking primary care services, coupled with a physician primary care shortage will require solutions that require creative ways to look at the health care system and potential healthcare providers. An inter-professional team provides optimal performance of providers, patient outcomes and cost-effectiveness. The research presented in the following chapters provides the methodology and data to support the utility and applicability of a pharmacist-inclusive team for chronic care disease management. Since the theoretical application of behavior change models to a CDTM model has not been addressed in current literature, the methodology described in Chapter 3 details how this analysis was conducted.

CHAPTER THREE

Research and Design Methods

Introduction

This chapter will describe the research design and methods employed in the case study of the El Rio Pharmacy Based Diabetes Management Program (PBDMP). A case study analysis was chosen for the research in order to take advantage of the strengths of the case study method: to define topics broadly and not narrowly, to confer contextual conditions and not just the phenomenon of study, and to rely on multiple and not singular sources of evidence.(92) A case study methodology is applicable for this research since the phenomenon under study—the PBDMP—is not readily distinguishable from its context. The case identification and boundaries are defined and set in context given the rationale and study propositions. The depth of case studies makes generalizability for other settings more difficult. Due to this difficulty in generalizability, Chapter 5 discusses the importance of transferability for other outpatient clinical pharmacy settings.

Multiple sources of information were gathered for this research including key informant interviews, using tools such as root cause analysis diagrams, in the form of fishbone diagrams and process maps, using the lean management approach of identifying value. These data will inform the ecology of the clinic and community leading up to the program's development and through program implementation. Data will be analyzed through NVivo coding of key informant interviews, close examination of the process map diagrams and comparison among the root cause analyses.

Data Collection Summary

Building on the findings from the literature review in Chapter 2, the data collection activities for this research included a series of six key informant interviews and three lean management group brainstorming sessions. Three different types of data were collected over the course of this study: results of key informant interviews, and process maps and root cause diagrams developed from the brainstorming sessions. Table 5 outlines the method of data collection and key findings from the three data sets.

Table 5. Method of Data Collection and Key Findings

Method of Data Collection	Data Collection Subjects	Key Finding	Link to Specific Aim or Research Question
Key Informant Interviews	Completed interviews with: 1. Program Director, El Rio 2. Administrator, El Rio 3. Program Director, MHC 4. Program Director, UNC 5. Interviewee 1, ACO 6. Interviewee 2, ACO	• Successful CDTM model programs focused on teamwork as a key element to their program and model success.	• Supports Specific Aim 1, helping to identify ways in which a CDTM model became 1) clinically effective, 2) cost-effective, and 3) sustainable.
Process Maps	Completed lean brainstorming activity with: 1. Administrative Group 2. Pharmacist Group 3. Clinical Group	• Iterative and coordinated efforts of work in the PBDMP were identified as critical elements to success of the program.	• Supports Specific Aim 2, translating findings from the study to public health practice products. • Identifying the process steps supporting the structure and function of the program was integral for practice recommendations.
Root Cause Analyses	Completed lean brainstorming activity with: 1. Administrative Group 2. Pharmacist Group 3. Clinical Group	• The identification of overlapping major bones from the different brainstorming groups highlighted the elements of the PBDMP that were critical to its success. • Leadership and	• Supports Specific Aim 2, Sub-aim 2b; translating findings from the study to implementation guidelines for future OCPPs. • RCA diagrams specified strengths/weaknesses of program structure and

		Teamwork were identified as key elements for success in the PBDMP, overlapping in the major bone of "People" in the RCA diagrams.	support assisting in guideline development.

Research Design and Methods

Case Study Rationale and Overview

Case studies are used in studies of "systems, individuals, programs, and events."(93) According to Robert Yin, the case study research method is used to answer questions relating to "how" and "why" a change in practice may have occurred when the questions being asked are "about a contemporary set of events over which the investigator has little or no control."(94) The case study approach is a detailed examination of a phenomenon in its real-life context during which the researcher studies the "embeddedness,"(95) boundaries, and interactions between the event or activity and its contextual setting.(96) The method is particularly well-suited for studying phenomena for which "boundaries between phenomenon and context are not readily evident."(94)

The El Rio Health Community Health Center was chosen for a case study since it was a singular program bounded in a place and time. To prioritize and best represent the diversity of perspective about the CDTM model at El Rio, a case study was chosen to present the program's perception within El Rio and in the larger Tucson community. Due to the richness of the context and abundance of individuals to speak with, the study could not rely on a single data collection method, but needed to use multiple sources of

evidence. According to Creswell, "besides dialogue and understanding, a qualitative study may fill a void in existing literature, establish a new line of thinking, or assess an issue with and understudied group or population."(97) The qualitative data included in the case study further develops the depth of the perspectives and fully explores one program bounded in time.

Qualitative Research

According to Creswell, "the research design process in qualitative research begins with philosophical assumptions that the inquirers make in deciding to undertake a qualitative study. In many approaches to qualitative research, the researchers use interpretative and theoretical frameworks to further shape the study."(97) Creswell goes on to define that good research defines these assumptions with the awareness that they influence the research inquiry.(97)

The data collected for this study were best analyzed through a mixed methods design with a heavy reliance on qualitative research methods due to the lack of qualitative data on the current El Rio program. In addition, the data collected explored multiple perspectives about the program's relevance and importance. Data were then analyzed through NVivo coding to identify topics and phenomena that comprised and characterized the practices leading to successful program implementation.

Specifically, qualitative research methods were used to characterize the structures and supports behind the El Rio Pharmacy-Based Diabetes Management Program. The goal of this research was to determine whether the lessons learned from the El Rio experience could be applied to other community health centers. In this case study,

answers to closed-ended survey questions may have concealed a variety of meanings. For example, asking the questions of "how?" and "why?" through qualitative research was more effective in this research than collecting numeric responses during interview questions. To understand the structure of the program, "what?" was defined and then data was extrapolated through key informant interviews, root cause analysis diagrams, and process flow maps.

Case Study: El Rio Community Health Center, Tucson, Arizona

Background: Pharmacy-Based Diabetes Management Program

The Pharmacy-Based Diabetes Management Program (PBDMP) stemmed from a three year outpatient clinical pharmacy demonstration grant from the Office of Pharmacy Affairs under the U.S. Health Resources and Services Administration (HRSA)'s Healthcare Systems Bureau at the U.S. Department of Health and Human Services. The demonstration grant from HRSA identified Federally Qualified Health Centers to run an outpatient clinical pharmacy program within their clinic addressing disease state management for one chronic disease. El Rio was one of 17 grant recipients, and they began to develop a disease state management program for diabetes.

After three years, the program revealed progress when all clinical parameters monitored showed statistically significant improvements for diabetic patients enrolled in the pharmacist-based program as compared to a control group.(98) There was a decrease in negative drug interactions, lower A1C levels, more stable A1C levels for hard to manage patients. The initial demonstration project was a documented and validated

success in part due to the providers and patients alike recognizing the program's potential power and embracing it early on into the program. At the conclusion of the grant, El Rio created a formalized and clinic-wide PBDMP.(99)

Under the direction of Tony Felix, the El Rio Pharmacy Director, the PBDMP at El Rio officially began in August, 2004. The program developed slowly working to augment care provided by physicians. The program expanded over the following six years and the clinical roles of the pharmacists were defined over time.

Legislative Processes

In January of 2011, the initial law "SB 1298 Pharmacists; Drug Therapy Protocols" was introduced to the Arizona state senate.(100) The state bill described the State Board of Pharmacy's clinical practice purview for Doctors of Pharmacy. The bill defined the circumstances when a pharmacist could be "implementing, monitoring, and modifying drug therapy and use; conditions; definitions" in the state of Arizona.(100) From January to April, the bill was modified and the pharmacist community of Arizona worked to better define pharmacist's role in Arizona state law. On April 13, 2011, the bill was made into law defining pharmacists expanded roles in clinical patient care. Further legislation followed, including Arizona Revised Statute 32-1970 allowing qualified pharmacists in specified health care settings (such as a community health center) to implement, monitor, and modify drug therapy as described by written protocols in collaboration with physicians.(101)

Through these legislative processes and community advocacy, the practice model of Collaborative Drug Therapy Management (CDTM) was approved for use in Arizona.

The CDTM model, aspects of which were already in place at the El Rio Health Center in Tucson, Arizona, was quickly embraced. Originally funded as a Clinical Pharmacy Demonstration Project by the Office of Pharmacy Affairs under the U.S. Health Resources and Services Administration's Healthcare Systems Bureau, the El Rio Clinical Pharmacy Demonstration Project's main objective was to provide comprehensive pharmacy services to the medically underserved in Tucson, Arizona.(76)

The program included increasing access to affordable pharmaceuticals, promoting efficient management of these services, and focusing on improved patient outcomes. Specifically, the clinical pharmacists at El Rio and the medical and administrative team determined that a diabetes-focused disease state management clinic would serve the needs of its members.(65) The project initially hired one clinical pharmacist to begin the outpatient pharmacy program. The initial demonstration project was a documented and validated success in part due to the providers and patients alike recognizing the program's potential power and embraced it early on into the program.(9) After three years, the program revealed progress when all clinical parameters monitored showed statistically significant improvements for diabetic patients enrolled in the pharmacist-based program as compared to a control group of diabetic patients not enrolled in the program.(65)(101)

This single instrumental descriptive case study describes the implementation of the CDTM model at El Rio within the pre-existing PBDMP in the context of the Arizona Revised Statute 32-1970. Since Arizona is one of the oldest CDTM models in the U.S.,

the implementation of the El Rio program was selected as the study case for learning about the processes of CDTM model implementation and development.

Case Study Questions and Propositions

The study questions, presented in Section 4, include questions about "how" the CDTM model was developed and implemented, and "why" clinical activities and actions occurred or did not occur during policy implementation. Key informants recalled the program from memory and contemporaneous documents from this period were also reviewed. Issues and topics that were studied include the set of activities used to put the CDTM model into practice. Actions taken to implement and enforce specific aspects of the model on an individual patient basis and steps used to maintain changes made were addressed in the case study. Individuals and organizations involved in developing and completing these activities, barriers to action and the context of the El Rio experience were also studied. The study also looked to related policies and practices, larger public health frameworks, and trends in state clinical pharmacy initiatives in Arizona and throughout the U.S. to inform the larger context of the case study.

Case study propositions identify the factors, issues, and elements that were examined, displaying the underlying theory or theories guiding the inquiry. These theories provided direction in identifying evidence pertinent to the case.(94) The questions that guided the case study propositions and purpose are described below in Table 6.

Table 6. Case Study Proposition Questions

The case study was designed to examine the following questions:
• Who were the organizations or individuals that took responsibility for the CDTM model adherence and compliance during the demonstration phase of the project? • What implementation mechanisms were in place? • What cost and economic implications of model adherence and compliance were potentially minimized or otherwise addressed? • Was the CDTM model sustainable and have (long-term) relevance to stakeholders?

Next, the case study considered why simple implementation of the CDTM model was insufficient for statewide comprehensive implementation and adoption. It identified how contextual factors, most notably other hospitals and clinical policies, had a strong influence on the amount of adoption and implementation of CDTM practices. It studied characteristics of these policies and practices, such as setting, scope, timing, responsible parties, sustainability, and relevance that could have had an impact on program effectiveness. It highlighted situations where CDTM model compliance occurred despite limited knowledge of the practice's success in southern Arizona. Last, the study identified how multilevel influences and relationships affected the actions taken or not taken by organizations and individuals involved in or responsible for the CDTM model compliance and adoption.

Case Description

Case Identification

The sampling for the entire case study used the critical case approach, defined by Michael Patton as the selection of a small number of important cases that are anticipated

to "yield the most information and have the greatest impact on the development of knowledge."(102) As noted, El Rio runs the oldest and only disease-specific CDTM model in southern Arizona and one of only a handful of programs in the United States with the same program definitions. Studying the El Rio experience thus represents an opportunity to obtain detailed information about the processes of developing, implementing and adopting an innovative model for a specific sub-section of the population. Study findings hold promise for informing recommendations for policy development and implementation guidelines, in Arizona and elsewhere.

Case Boundaries

Pursuant to case study methodology, the case was be bounded by two dates: August 2001, when the original El Rio demonstration project was implemented; and August 2014, over thirteen years after the CDTM model first went into effect in El Rio. Documentation of the planning and development in the weeks or months leading up to the August 2001 implementation of the CDTM model at El Rio will also be analyzed.(94)

Identification of Key Informants

A stakeholder analysis is an approach, a tool or set of tools that generates information about a group of actors to help understand their behavior, intentions, and interrelation.(103) For this research, a stakeholder analysis was conducted to map the positions of the actors in relation to El Rio's implementation and current Pharmacy-Based Diabetes Management Program. The stakeholders identified had an active influence on the decision-making and implementation process of the program.(103) While the stakeholder analysis was not used to draw conclusions, it solidified the list of

key informant interviewees and participants for the lean management group sessions for the data collection.

The methods followed for the stakeholder analysis were in line with recommendations from stakeholder analysis resources and documents.(103)(104)(105) Individuals and organizations were recommended as stakeholders during initial data collection stages of the research. Stakeholders were identified though informal conversations with community and El Rio leaders. Potential stakeholders were also identified by using a controlled vocabulary search of research and grey literature databases (PubMed, Web of Science, LexisNexis, Google Scholar), search engines (Google), and individual websites (state websites, organizational websites).

From the brainstormed list of potential stakeholders, a chart was created for each stakeholder. The stakeholder's name was placed at the top of each sheet and two separated columns were drawn. One column listed the stakeholder's expectations of the organization, and the second column described how the stakeholder perceived the overall health of the organization. The researcher wrote down thoughts about the potential stakeholders and compared the columns. The responses were identified through color coding as they corresponded to the questions: good (green), fair (yellow) or poor (red). The data was color coded and the longer-term issues with each individual stakeholder and with stakeholders as a group were created in a separate column.(105)

The scope of the stakeholders chosen for the research was helpful for the stakeholder analysis since the analysis was directed specifically at the current El Rio program. The analysis showed that not all of the stakeholders knew about the Pharmacy-

Based Diabetes Management Program, but had different insights about CDTM, the Tucson diabetes advocacy community, and El Rio. The stakeholders were chosen to bring different perspectives to the study. This research and in-depth analysis sought to add value through obtaining and analyzing stakeholders' current perceptions of the "historical processes which have led to the present."(103) The stakeholder analysis was a critical tool in identifying interested parties that should be incorporated into the decision-making process, in addition to understanding the basis for their inclusion.(104) Other informal interviews with staff members of the PBDMP at El Rio were conducted to further inform the research. These interviews are cited throughout the research to support and augment a priori themes from the key informant interviews.

Working Definitions

Implementation

For this research, implementation describes the set of activities involved in applying a collaborative care model within the confines of a clinical practice. These activities include, but are not limited to:

1.1. dissemination of clinical regulations or policies;

1.2. development of formal practices and procedures to put the CDTM policies into operation;

1.3. allocation of funds and resources for implementation; and

1.4. state or county enforcement of the regulation.

Collaborative Drug Therapy Management (CDTM)

CDTM is a "team approach to healthcare delivery that seeks to maximize the expertise of the pharmacist and the physician in order to achieve optimal outcomes through appropriate medication use and enhanced patient-care services."(5) CDTM is most commonly provided under mutually agreed upon practice protocols and guidelines for health care teams. Health care programs administered by U.S. Public Health Services (such as the Indian Health Services and the Veterans Health Administration), as well as independent practice settings in over 40 states across the U.S., now support pharmacist participation in CDTM.(65) Most of these 40 states require drug-or disease-specific collaborative practice agreements or drug therapy management plans approved by physicians participating in and supervising programs. (65) The majority of these 40 states that allow pharmacist-inclusive Collaborative Practice Agreements utilize the CDTM model for medication therapy in tem-based care.(59) The CDTM Model at the El Rio Health Center limits the pharmacists' clinical activities to those found in the physician approved guidelines. CDTM activities include, but are not limited to, the following pharmacist activities:

- "Initiating, modifying, and monitoring a patient's drug therapy
- Ordering a performing laboratory and related tests
- Assessing patient response to therapy
- Counseling and educating patients about their medications
- Administering medications"(2)

Key Informant Interviews

The first key informant interview was conducted on July 29, 2014 and the last interview was completed on November 3, 2014. The data collected from the brainstorming activities at El Rio spanned from August 4, 2014 through August 6, 2014. A sample of key informants were identified using emergent or snowball sampling with knowledge of aspects relevant to the case.(106) Key informants were identified at the state, local, and clinical levels. All of the interviews were conducted in-person or by telephone to gather information about respondent experiences during the development, implementation, and adoption of the CDTM model at El Rio. The interviews included closed- and open-ended questions about the implementation of the model with no personal identifiers or questions of opinion. All questions were tailored to only ask factual and objective questions about the process behind the implementation of the CDTM model (e.g. based on clinical 30-day re-admission data, patient feedback, and satisfaction surveys, what were the successes and failures of the program within the first few years of implementation?) Introductory questions were identical between each interview, but questions were also tailored to the interviewee and focused on their area of expertise or employment. See Appendix A for the full interview guide.

Interview topics included the following:

- contextual conditions and factors relevant to a clinic's ability to make changes to comply with the model (implementation climate and resources),
- communication about the model and about strategies for compliance,
- El Rio implementation activities,

- potential programmatic supports for implementation and monitoring of the model.

Contextual conditions and factors of interest included the following:

- other state, county policies and practices relevant to the CDTM model in the community;
- organizational characteristics and priorities; and
- resources available for clinic's use in implementing changes to comply with the model, such as staff, technical assistance, or funding.

All of the key informant interviews were recorded and responses were transcribed into QSR NVivo Software. The key informant interviews were conducted with the following six individuals/organizational representatives described in Table 7:

Table 7. Key Informant Interviewees

Name	Degree	Position Title	Location	Interview Method	Interview Relevance
Program Director	PharmD, MPH, FAPhA, CDE	Clinical Director, Pharmacy-Based Diabetes Management Program (PBDMP), El Rio Community Health Center	Tucson, AZ	In-Person	El Rio Health Center currently runs the Pharmacy-Based Diabetes Clinic—a CDTM model program for patients with T2DM. Questions focused on how the clinic was created, current patient volume, future plans, how other clinics can make a clinical pharmacy program.(98)
Admini-strator	RN, PhD	Officer, El Rio Community Health Center	Tucson, AZ	In-Person	Questions about the clinic's priorities and perspective about the Pharmacy-Based Diabetes Management Program were addressed.(99)
Program Director	PharmD, RPh	Clinical Director, Marana Health Center, (MHC)	Marana, AZ	In-Person	Tucson-based community network of health clinics in southern Arizona. Marana Health Center recently created a CDTM model. Questions focused on

					their approaches to an outpatient clinical pharmacy program, what they have done to create the program, what they are looking to do, barriers/successes they faced in the process, and their future plans.(107)
Program Director	Pharm.D., CDE, CPP, BCACP, FASHP	Clinical Director, University of North Carolina, (UNC) Internal Medicine Enhanced Care Program	Chapel Hill, NC	By Tele-phone	Questions about the UNC Program and potential similarities and differences with El Rio were explored. Specifics about the development and implementation of the UNC program were also described.(108)
Inter-viewee 1	BS, Account-ing	Accountable Care Organization (ACO) of Tucson, Arizona	Tucson, AZ	In-Person	Oversight of the Accountable Care organization of Tucson, Arizona. Questions focused on the ACO, how it was formed, the impact (if any) of CDTM models and other collaborative practice agreements on the ACO, and how ACA will impact community health, and future plans.(109)
Inter-viewee 2	MD	Accountable Care Organization (ACO) of Tucson, Arizona	Tucson, AZ	In-Person	Questions about total costs of diabetes care management and community-wide chronic care disease management were discussed.(110)

Lean Management Brainstorming Activities

Structure

A series of three group meetings of El Rio employees occurred the week of August 4-7, 2014. Individuals were recruited to the three group sessions through e-mail inviting them to participate in the group brainstorming session to discuss the Pharmacy-Based Diabetes Management Program (PBDMP). The study participants were identified based on their role in managing the program (Administrative Group), working with or referring patients to the program (Clinical Group) or employed by the program itself

(Pharmacist Group). Names and e-mails were furnished by members of the PBDMP staff from El Rio internal list-serves.

All meetings were voluntary and occurred within a two-hour time frame. The Pharmacist and Clinical Group sessions took place at El Rio in a conference room near the PBDMP's main offices. The Administrative Group session took place in a conference room at the main El Rio administrative office building. All groups were read the IRB Research Consent Form before participating in the research and a verbal approval was recorded from each participant. The activity was twofold for all groups: 1) the group diagramed a process flow of how the CDTM model currently works at El Rio, and 2) as a group, the participants created two root cause analysis fishbone diagrams (Ishikawa Diagram) describing the main 'bones' that consisted of successes and barriers to the Pharmacy-Based Diabetes Management Program (PBDMP). The RCA diagrams were conducted to understand the depth of reason leading to a success or barrier of the PBDMP. The fishbone diagrams are presented in Appendix D.

Each session started with an introduction of the goals of the meeting, the study research and goals, and introductions from each participant. After introductions, and to emphasize the importance of process, a quote from W. Edwards Deming was read, "If you can't describe what you are doing as a process, you don't know what you're doing."(85) The concepts of a process and a process flow chats were described using an example process flow chart on how to diagram a complete cycle of laundry. The diagramming tools were posted on the wall of the conference room and printed in handouts for each participant. As the RCA diagrams were created I probed any vague

response with "5 Why's," asking the study participant "why" five times to best define the actual variable they were identifying. Asking "why" for responses that are not yet fully formed is helpful for the participant to specifically define the attributes of their comment before adding it to the diagram. Each session completed one process flow chart together except for the Pharmacist Group—where three process maps were created—due to the large size of the group. See Appendix C for the complete set of group process flow maps.

Study Groups

The three groups consisted of the following individuals:

a) Clinic Administrators: El Rio's Chief Operating Officer, Chief Clinical Officer, and the Executive Director of the El Rio Health Center Foundation.

b) Clinical Group: One Nutritionist, One Nurse Care Coordinator and Associate Health Manager, Two MDs—one Family Medicine practitioner and the Family Medicine Medical Director.

c) Pharmacy Group: Five Medical Assistants (MAs) for the PBDMP and six PharmDs—including the Pharmacy Director and Clinical Pharmacy Coordinator.

Process Maps

To begin the process mapping portion of the brainstorming sessions, each study participant was given a blank piece of white paper to map their personal perception of the current process flow of the PHBMP. After 10-15 minutes, group members were

encouraged to interact with their neighbors and compare and contrast their individual maps. After the individual mapping and initial discussion was complete, the group-wide process map was created.

To create the group map, one volunteer from the group came to the front of the conference room and scribed onto poster paper as the group discussed the flow of the PBDMP. Each group presented their findings independently of the other groups and no information was shared between the study groups. The volunteer added to the discussion and diagram along with the rest of the group, but only one individual wrote on the poster paper. If issues or confusion in the diagram occurred; the map was amended to fit the revision. The group physically re-created each process, decision point, start, and end of the process cycle of the CDTM model. These diagrams served as a visual representation of the current status of the program. After the group finished the process map, a different volunteer from the group—who did not scribe the process—stood in front of the group process map and verbally described the diagram to help understand the efficiencies and inefficiencies within the program. The rationale for having two separate volunteers to diagram and then describe the process aims to assure that the whole group understood what was interpreted and scribed by the volunteer drawing the diagram. While this measure does not ensure that all members of the group agree with each process described, it is one step that can be taken toward data validity. In all of the groups except the Administrative Group, the diagram was hand drawn on the poster paper. In the Administrative Group Post-its were used to define each process step and then each step was place in chronological order. After the second volunteer described the process and

worked through each step of the process map, there was a short break for study participants.

The first group meeting included the El Rio clinic administrators. The group included El Rio's Chief Operating Officer, Chief Clinical Officer, and the Executive Director of the El Rio Health Center Foundation. The Administrative group was the smallest of the brainstorming sessions. In the Administrative Group, participants wrote each step of the process map on Post-its and then placed the Post-its onto the poster board. While there was still one diagram scribe connecting the Post-its, this step was slightly different for the Administrative Group. This minor inconsistency in process most likely did not impact the process map or data gathering since the group size was much smaller than the other study groups. The fluidity between the Post-its and diagram drawing in other groups were almost identical.

In the Pharmacist Group, a total of 12 pharmacists, medical assistants, and pharmacy technicians participated in the group mapping session. In an effort to represent the medical assistant (MA)'s and pharmacy technicians' opinions along with the PharmD's, the larger group was split into three smaller groups. The Pharmacist Group was split equally—by degree type and number—into three smaller groups for the process mapping exercise so all group members could participate and provide input. Each group consisted of at least one pharmacist, medical assistant, and pharmacy technician. The decision to split the Pharmacist Group into three separate groups for the process mapping exercise was recommended by the group itself due to the different personalities and power dynamic between the MA's and the PharmDs. All of the MAs present during the

data collection, directly reported to the PharmDs in the room. While the methodology was the same for the Pharmacist Group as the other study groups, three smaller groups within the Pharmacist Group created process flow maps for a total of three maps—each of the three groups created one process map. At the end of the brainstorming session, the group re-convened and discussed the similarities and differences between each of the smaller group's maps.

The last group session was the Clinical Group, which was composed of four clinicians who all either referred patient into the program or worked directly in the PBDMP. There were two Family Medicine physicians, a Nutritionist and Registered Nurse who participated in the brainstorming sessions. The methodology followed for the clinical group was identical to the Pharmacist Group, however the group worked to create one process map together due to the manageable group size.

Root Cause Analysis Diagrams Using Fishbone Diagrams

After the break, about 20 Post-its were passed out to each study participant. A root cause analysis (RCA) diagram in the form of a fishbone diagram describing the success and barriers to completing a cycle of laundry posted on the wall was used as an example for each group. The RCA diagrams were conducted to understand the depth of the reasons for the efficiencies and inefficiencies within the program. After the discussion about why RCA diagrams matter and how to create them, a list of the 4P's (People, Products, Process, and Performance) and 5M's (Manpower, Machines, Methodologies, Measurements, and Materials) of lean management were posted on the wall and given to each study participant as a hand out. The study participants were then

given 10 minutes to brainstorm which P's and M's most closely described the barriers and successes of the PBDMP at El Rio.

Due to the small size of the group, the Administrative Group session held a discussion as to which P's and M's were most appropriate to be the 'bones' of the RCA diagrams. From the discussion, the bones of the RCA were defined and drawn onto the poster board. In both the Pharmacist and Clinical Group, all of the P's and M's were written out on separate sheets of paper and placed around the room. Individually, participants anonymously described their perceived barriers and successes of the PBDMP and wrote them onto Post-it notes. The participants then placed the specific Post-it note under the specific M or P that best described the barrier or success they identified on the Post-it. Study participants silently wrote and posted each of their Post-it notes for about 10-15 minutes under the appropriate M or P around the room. When a participant felt that they had completed the task, they sat back in their seat and waited for the rest of the group to complete the assignment.

After the exercise, participants discussed the experience in a group format. One participant volunteered to read all of the barrier Post-it notes and another volunteer read all of the success Post-it notes. After an initial discussion, the number of Post-it notes under a specific M or P barrier or success became the primary bones in the RCA diagram. As the bones of the diagram were identified, the group modified their elections to most accurately define the topic (e.g. Manpower may be re-envisioned as Clinicians). As a group, the fishbone RCA diagrams were created from the M's and P's previously identified with the most amounts of Post-its and then the minor bones were identified

from the main M or P. For example, the major bone, 'Price' was identified as a barrier due to the high number of Post-its under the Price sheet of paper. Under Price there were multiple Post-its that became the minor bones—lack of provider status for pharmacists, no insurance, etc.

As a group, the major and minor bones of the RCA were defined and drawn onto the respective poster boards—successes of the program and barriers to the program. Minor bones were read and transcribed onto the diagram, and minor bones that were not previously identified under the M's or P's around the room during the exercise were added to the final diagram as well. Some of the minor bone Post-its were re-envisioned or further described to fit within the constraints of the major bones selected. At the end of each session, after a complete process map and RCA diagram were created, an informal conversation ensued to identify aspects of the data collection methods that were successful or challenging to understand. Study participants discussed how the exercise made them feel about the PBDMP, the program's successes and failures, and their role in the program. A central aspect of the debriefing conversation after the mapping exercise was how the current system evolved from what was originally planned—given the importance of flexibility in sustaining a process during implementation.

During both the process mapping and the RCA analysis, the primary researcher took photos, video and notes describing the process and methods of the research. During the discussion, the primary researcher also noted key quotes and side bar conversations to follow-up on and mention during my analysis. After each of the sessions, the primary researcher took ten minutes to write down her thoughts and reflected on the group

dynamic, conversation and outputs. The interview data collected from each of the group sessions ended in six RCA success and barrier diagrams and five process maps as the physical representations of the data collected.

Analysis

The analytic strategy for Specific Aim 1, to identify the ways in which the CDTM model became and remains a clinically and cost-effective model at the El Rio Health Center, used a theoretically and empirically driven approach. Specifically, propositions (Table 8) were used to guide the data collection and analysis. Analyses focused on using data to prove or disprove the study propositions and to generate alternative explanations as needed. The study propositions in Table 8 were based on the literature review, preliminary informal interviews, and personal experience.

Table 8. Study Propositions

1. While El Rio did not base the CDTM program on the PRECEDE-PROCEED or organizational transformation theoretical frameworks, implementation and adoption of the CDTM model was effective when characteristics of these theories were present during their decision making management processes. Specifically, the PRECEDE segment of the model served as the foundation for organizational change.
2. While necessary for pharmacists to practice collaboratively with other health care providers, passage of a supportive state policy was insufficient for comprehensive implementation and adoption of the model for El Rio outpatient clinics.
3. Contextual factors, CDTM programs, and state support for a community-based chronic disease care management program, most likely a strong influence on the decision to implement a CDTM model at El Rio.
4. Simple passage of the CDTM model within El Rio was insufficient for comprehensive implementation and adoption of the program. Knowledge of the CPA agreements and potential benefits from the model increased employee willingness to embrace the program.
5. Multilevel influences from the Tucson ACO, the El Rio Finance and Operations Department, and other community relationships affected the actions taken (or not taken) by organizations and individuals involved in or responsible for CDTM implementation or adoption.

Specific Aims: Context for the El Rio Case Study

Case studies use multiple forms of evidence to provide a detailed and in-depth summary of case events, triangulate data, and develop themes.(94) Data used in this case study to provide case facts and context include key informant interviews and the lean management brainstorming activities. Based on the qualitative inquiry and research design methods outlined by Creswell, "evidence from prior implementation research and case study literature will inform data collection."(97) As described below, data collection followed an iterative process, where search terms and strategies and data collection procedures were adapted throughout the study to best address the study aims.(82) Three main sources of data were collected for the research: key informant interviews, process maps, and root cause analysis (RCA) diagrams in the form of a fishbone diagram from three groups affiliated with the PBDMP.

Specific Aim 1: To identify the ways in which the CDTM model became a: 1) clinically effective, 2) cost-effective, and 3) sustainable model at the El Rio Community Health Center.

Case Facts

In a case study, the primary analysis is, as Creswell describes, the development of a "detailed description of the case and its setting."(97) To identify the ways in which the CDTM model was implemented and adopted between August 2001 and August 2013, the analysis began with the development of a draft of what Ellinger et al. refer to as a "descriptive account of important components of the case" including case facts and context. (93) In the account, the following was documented:

- administrator, organizational, and clinical experiences, actions, and methods used implementing and enforcing the CDTM model at El Rio;
- state and community-level parties involved in adoption and implementation; and
- the context for implementation and adoption activities.

Sub-Aim 1a: Identify key aspects of the clinical management processes through lean management brainstorming exercises and key informant interviews that served as structure and support for the CDTM model at El Rio.

The key informant interviews were transcribed and coded using software to identify the key themes serving as structures and supports for the CDTM model at El Rio. The lean management brainstorming activities and products created from these activities were examined to define the process of the PBDMP at El Rio. Together these data offer a picture of the implementation and sustainability of the PBDMP at El Rio for analysis.

Pattern, Trend, and Theme Identification

In addition to a careful documentation of the facts, data analysis in case study research includes linking case information and elements to the study propositions or purposes. The overall analytic goal is to identify the linkage that best connects information from the case to a theoretical, chronological, or logical construct; and to reject alternative explanations.(94)

Leverage Points, Strategic Decisions, and Communication Techniques

The published reports documenting El Rio's experience developing and implementing the CDTM model were compared to the information from the key informant interviews, lean management brainstorming activity, and observational data. The information collected from the lean management activity and key informant interviews also informed the process information on how the CDTM model works in the clinic. As part of the analysis, individuals and groups who could have been involved in implementation and adoption will be identified and reasons for their lack of participation were documented. The factors that influenced the initiation, trajectory, and success of implementation and adoption processes and actions were also documented. Such factors may include the following:

- demographic and other characteristics of El Rio;
- knowledge of benefits from a collaborative practice model for outpatient clinical pharmacy such as CDTM;
- costs and savings associated with changes;
- availability of resources to complete implementation tasks; such resources may include staffing, funding, partnerships, or information on collaborative practice alternatives; and
- acceptability of the model.

Broadly, these actions, actors, and factors comprise the leverage points, strategic decisions, and implementation techniques that affected the success of the CDTM model's implementation and adoption. The theoretical constructs of the PRECEDE section of the

PRECEDE-PROCEED framework provided an understanding of case events and the actions taken or not taken by El Rio when implementing the CDTM model. Specifically, findings were compared from the descriptive accounts in the key informant interviews and lean management activities with the key aspects of the CPAs and dimensions of the CDTM and medication management framework.

> Sub-Aim 1b: Apply the PRECEDE portion of the PRECEDE-PROCEED model and organizational transformation model to an analysis of the El Rio CDTM model implementation in order to identify the supportive structures enabling the creation of the El Rio Pharmacy-Based Diabetes Management Program.

As noted, the key elements of the case context are other federal and state policies and practices that were in place in Arizona during the study period. These elements influenced or could have influenced the extent and content of the El Rio CDTM model and the promotion of clinical pharmacy programs. Information about the case context is summarized in a descriptive chronology of events as well as using other groupings, such as themes or characteristics using the PRECEDE section of the PRECEDE-PORCEED model. An example of a grouping and theme is: 1) Grouping—the CPAs in place throughout El Rio as part of the CDTM model implementation and, 2) Theme—how these agreements increase or decrease organizational transformation.

PRECEDE-PROCEED and Organizational Transformation Models in a CDTM Context

The data from the El Rio model and other CDTM models were applied to the theoretical constructs and frameworks of the PRECEDE-PROCEED and organizational transformation models. Using the PRECEDE section of the framework, a roadmap was created showing the sequence of El Rio's intervention. Identifying the aspects of successful implementation and failed implementation were also analyzed and studied.

Summary Themes and Case Contextualization

The findings were summarized by documenting patterns, identifying trends, and characterizing themes of the topics and phenomena that comprise and characterize the implementation and adoption experience of CDTM at El Rio. The relationships between groups of events and processes, patterns, trends, and/or themes were examined and summarized. This analysis includes an assessment of relationships between case events and themes and other contextual factors, such as the following:

- the history of CDTM;
- the public health policy setting in Arizona, specifically policies related to outpatient clinical pharmacy;
- collaborative practice agreements in Arizona and elsewhere; and
- local and national trends in CDTM models.

Summary findings include a description of needs for complete implementation and adoption of CDTM in the context of other related policies and practices. Needs may

include programmatic supports to help accomplish changes, information and/or awareness-building, and staffing and resources, among others.

Data Analysis

Iterative Cycle Approach

Analyses are drawn from all available data sources, including research and program literature, documents, interviews, and observations. The technique outlined by Ellinger et al. was used to identify pattern, trend, and theme identification. The "iterative cycles" of data collection and analysis described by Ellinger trim down the information to include facts and concepts that a) match or comprise the case story and b) relate to underlying theories that clarify or predict the associations between case components (phenomena).(93) The data and analysis evolved over time as data were analyzed and added and theories are confirmed or rejected. Specific analytic approaches used in these iterative cycles will include one or more of the following, selected based on availability of data and appropriateness to the analytic question of interest:

1. Pattern identification and matching, where the data was reviewed for a predicted pattern or patterns and for relationships between two or more categories of themes, issues, or meanings.(94,95) Patterns of interest will be drawn from the study propositions and initial analyses.(93)
2. Categorical aggregation, where a subset of the data was reviewed to identify possible themes, issues, or meanings related to the research questions and study propositions.(95)

3. Direct interpretation, where a single instance from the data was reviewed to identify possible themes, issues, or meanings related to the research questions and study propositions.(95)
4. Time-series analysis, where data points were organized chronologically and compared with a time-based theoretical explanation/study proposition.(94)
5. Logic models, where data are identified to support or rebut cause-effect patterns between specific events, actions, or decisions and implementation and adoption outcomes. Relevant events and actions include activities to put the CDTM model into operation and to ensure ongoing and consistent compliance with the core components of the model.(94)

Each iterative cycle included a review and incorporation of contextual and background information, to ensure the case study is as detailed and thorough as possible. Patterns and themes were identified by using qualitative content analysis.(94) This approach is a "data reduction and sense-making effort that takes a volume of qualitative material and attempts to identify core consistencies and meanings."(106)

Interview Data Coding and Theme Identification

Data Coding

Codes used in qualitative research are described as, "most often a word of short phrase that symbolically assigns a summative, salient, essence-capturing, and/or evocative attribute for a portion of language-based or visual data."(111) For this research, pre-specified codes using theoretical frameworks and a literature review were

identified, defined, and listed in a code book.(112) The pre-specified (a priori) codes were identified from the research questions, study propositions, and theoretical constructs assigned before data analysis began.(112) New codes were created during the coding process using open coding.(97) All of the code definitions were listed in a code book and refined over the course of the data analysis.

The a priori codes directly address focus areas for all of the key informant interviews. These focus areas were defined as: program successes and failures, processes, and teamwork. A priori code categories were created to characterize program supports and structures that lead to program impediments or successes. The process of identifying the codes was iterative with feedback from the dissertation committee. The code book was created and approved before text coding began. The coding categories added during the coding process related to program sustainability and maintenance. Secondary themes that became a coded category during the interview analysis were assertions and generalizations made by key informants during the interviews. These coding categories served as a conceptual coding practice when individuals spoke at length regarding a specific topic or concept.(97) See Appendix B for a complete description of each code.

Theme Identification

The content of textual data from the interview transcripts were analyzed manually through the qualitative data analysis software package NVivo 10 by QSR International. I used the software to code and analyze recurrent themes from each of the key informant interviews. NVivo allows the user to organize data into containers called "nodes." A

user may catalogue notes into a hierarchy with main categories—"Tree Nodes"—identifying the key themes of the interviews. The tree nodes are organized from the more general "Parent Nodes" groupings to the more specific "Child Nodes."

First, I listened to the audio recordings from each key informant interview. I then transcribed each of the six interviews by transferring the interview from an Olympus recording device onto my computer. I listened to the interviews and transcribed them into my computer. Each interview was transcribed once and re-visited twice for editing. After the interview transcriptions were complete, they were then uploaded into the QSR NVivo software for analysis.

For each key informant interview, major topic categories—Parent Nodes—and subcategories—Child Nodes—were created for analysis. These topic categories were created after each key informant interview was transcribed and before coding commenced on the transcripts. Tools within the NVivo software were then applied to code the texts further into organized nodes and transcription response attributes. The attributes were defined by the nodes and main themes were generated from the nodes for the attribution table. Collective responses to the same question presented evident patterns or trends, which translated well into the predefined nodes.

If one Parent node included a grouping of similar comments or theme, a subsequent Child node was created to better identify the classification within the Parent node. For example, the Parent node "Pharmacists" initially included only the Child node "scope of practice." As the coding progressed, the primary researcher noticed that comments regarding pharmacist provider status were commonly coupled with a

conversation about pharmacists' scope of practice. In response, a separate Child node of "provider status" was created and the comments were re-coded accordingly under one or both of the Child nodes: "scope of practice" and "provider status."

NVivo Analysis

The quantitative multivariate tables and graphs created from the NVivo software were applied to each key informant interview and between interviews. Word frequency queries and text searches were compiled and analyzed. Word clouds and computer-generated images were created for a visual representation of the qualitative data.

The first analytic tool applied to the interviews was a word search. The frequency of words and terms used helped underscore the most important themes in the data. From the word frequency results, a text search was completed to understand where and how these terms were used. The query for in-text citations of the most frequently used words started to build the emergent themes discussed in the key informant interviews. The word frequency and text queries helped distill the substance of the interview texts to gain a better idea of word patters, frequencies and topic covered in the interviews. The word cloud in Appendix E shows the words most commonly used to describe a success and a barrier in all of the interviews combined.

Data Extraction from the Root Cause Analysis Diagrams and Process Maps

The root cause analysis (RCA) diagrams and process maps from each of the three group sessions with the Administrators, Clinicians and Pharmacists were transposed from the poster boards in each group session into Microsoft Visio Software to create computer-generated visual maps of the processes, RCA success and barriers. After the maps were

printed, the process maps and RCA diagrams were color coded with different color highlighters to determine similarities and differences between diagrams.

The process maps were examined for similarities and differences between the groups by identifying similarities with a yellow highlighter and circling differences with a blue highlighter. As the Pharmacist Group created three separate maps, these mas were compared to each other for examination as well. Each process was noted and analyzed with close scrutiny to show subtle differences between processes, decision points and start and end points. Close attention was paid to the specifics and timing of each process step. Comparisons between ordering, prioritization, and description were made. Specific words and phrases used to describe each process was also noted and studied.

The main bones of the RCA diagrams were coded with a yellow highlighter to find the overlaps between diagrams. The minor bones off of the major bones were color coded with a blue highlighter for similarity as well. Tables were created with similar theme identification and to further analyze the data. After similarities became clearer, the differences became more apparent. Employing these tools and methodologies, similarities and differences were studied and results were drawn. The variables that were identified on the RCA diagrams and process maps were also aggregated and compared to the key informant interviews.

Strategies to Ensure Validity and Reliability

Stake (1995) underscores the "importance of confirming the data collected in a case study and suggests the use of triangulation and member checking."(95)

Triangulation was achieved by using multiple sources of evidence to confirm facts.(113) To complete the member checking activities, only a few of the interviewees were consulted when the voice recording was not clear, or a segment of the transcript did not flow linearly in order to review drafts of case study text that contain their quotes and ideas.

Threats to construct validity were addressed by creating operational measures—how, when, why the CDTM program began and the current operational process of the program—for the constructs being studied. External validity, or generalizability, was addressed by using theory to guide the research design.(114) Threats to reliability were addressed by using a case study protocol and compiling a case study database with notes, documents, a data dictionary, and codebook. Following the recommendations of Yin, a case study protocol "was developed for internal use and includes objectives, field procedures, questions (data collection instruments), analysis plans, and a description of the final report format."(94)

Two key measures were taken to ensure reliability during data collection. As two of the key informants were also slated to participate in the group brainstorming sessions, their key informant interviews were conducted before their participation in the group lean management sessions. While their participation in the group brainstorming sessions could have been affected, the one-on-one interviews were prioritized for the higher likelihood of potential re-call bias. This decreased the probability of recall bias during their one-on-one interviews. Moreover, one of the transcribed interviews was checked by a second coder for interrater reliability by a fellow doctoral student in Global Health at

Harvard University, Julia Raifman. The code book descriptions from NVivo and a complete transcript were provided to Mrs. Raifman. Then, Mrs. Raifman re-coded one of the interviews for reliability and consistency. This re-coded interview was compared to an interview the primary researcher coded and it was concluded that the coding had a 92 percent overlap in codes—over 22 percent higher than the pre-identified goal of 70 percent overlap.

During the brainstorming sessions, a different volunteer scribed and explained the process maps from the lean management group sessions. By encouraging participation from more than one group member, the results from the session had a higher likelihood to represent the perspective of more than just one individual from each group. While not a perfect measure for participation or representation of multiple viewpoints, it was one small step taken to help with data collection reliability.

Interpretation and Reporting

Because case studies are analyses of a single event, condition, or group, they do not inherently produce statistical results that may be generalizable to other populations or settings.(94) However, conclusions from case studies can contribute to the development or modification of theories (or in this research, implementation guidelines) and to a deeper understanding of the underlying processes and themes and the individual components of the real-world topic under investigation.(94)

El Rio's experience implementing and adopting a CDTM model was summarized into three deliverables: 1) implementation guidelines for clinical administrators and

practitioners in other settings who are considering adopting the CDTM model, 2) a Google Forms Outpatient Clinical Pharmacy Program Worksheet for clinic self-assessment before CDTM adoption or implementation, and 3) an educational management case study. A single narrative was used to describe the case from El Rio and the management case study will follow a linear-analytic structure.(94)

Limitations

It is important to note the potential biases inherent in this type of single iterative case study research associated with historical document research within any given organization. The documents accessible for this research had a certain amount of "selective survival" bias since the available documents were more likely to have a positive and not a negative opinion of the CDTM model.(114) Since the CDTM model survived, so too did the positive feedback and argumentation supporting its implementation and existence. The selective survival bias of both documentation and memory of those interviews inevitably influenced the analysis. Many of the perspectives from the key informant interviews may have become more positive or remember the El Rio or clinical history in a more positive light since the program was set in place. Many of the counter arguments to the program's adoption or implementation may have been forgotten or overlooked. The limitation of positive recall bias is compounded by the fact that key informant interviews are focusing on memory of the program alone during the interviews.(114)

While all the key informant interview questions followed the same framework and line of questioning, pre-approved by the Boston University Institutional Review Board (IRB), the questions in each interview were different. The probe questions that followed each stem question were different per interview and may have shaped the interviewee's answers. Inherently, the probes and follow-up questions asked were included in the final transcript and coded for frequency values. Since each interview was different and all of the probes per interview were different, this may affect the frequency data analyzed in the results. Moreover, generalizability between interviews is also difficult to assess due to the lack of specific question uniformity among interviews.

Another limitation of the research were the personal biases of the primary researcher. Since the primary researcher volunteered as a Spanish-English medical interpreter in the Pediatrics department at El Rio during high school in Tucson, Arizona, she may have a slightly positive bias supporting El Rio and its endeavors. While first a researcher during this project and not an El Rio volunteer, the primary researcher made steps to ensure her own even reliability. Each question for the key informant interviews was written out as either a closed ended or open-ended question. The primary researcher administered each key informant interview using the same questionnaire and added probe questions from the question stem, but not any further questioning that could potentially confer bias during the interviews. Moreover, the primary researcher did not offer any personal identifiers about her connection to El Rio or past work experience before conducting any of the lean management brainstorming sessions or key informant interviews. While these steps cannot completely ensure unbiased questioning, the

primary researcher worked to gather and ensure the most unbiased qualitative information available.

Research Translation into Public Health Practice Products

Specific Aim 2: To translate findings from the implementation assessment into public health practice products that support successful implementation and maintenance of CDTM models throughout Arizona and nationwide.

The findings from research of the processes, successes, and challenges associated with the implementation of the CDTM model at El Rio is of interest because it can be translated into implementation guidelines for other outpatient clinical centers looking to create a CDTM model at their clinic or hospital. The implementation guidelines help improve and guide public health practice by a) developing practical model and policy implementation tools and b) assessing mechanisms for more successful CDTM model implementation and adoption.(40) Because El Rio has one of the oldest and still active CDTM models in an outpatient clinical care center in the nation, findings from this case study have policy implications of interest to health advocates and clinic administrators across the country.

Accordingly, the second aim of this study is to translate findings from the case study into public health practice products to support successful implementation and maintenance of CDTM models in clinics and hospitals. This section describes the methods that were used to create three products based on the information gathered in the case study. Products include implementation guidelines for clinics and hospitals, a

decision support tool or worksheet that will allow clinics to assess their capacity for implementation, and a teaching case.

CDTM Model Implementation Guidelines

Sub-aim 2a: To study the contextual information and literature to inform both the analysis of Arizona's experience and the development of CTDM implementation guidelines and resources.

Sub-aim 2b: Create CDTM model implementation guidelines for clinics and hospitals looking to implement a CDTM model in their health care setting.

Guidelines are commonly used as a way to compile a concise set of information and resources (tools) that help facilitate an implementation process for a specific initiative, for example, a new legislation, policy, program or regulation.(82) Most toolkit or guideline authors seek to provide users with clear and consistent information, including concrete examples of approaches used to put a regulation, research finding, or theoretical concept into practice.(115) The Agency for Healthcare Research and Quality (AHRQ) defines a toolkit as "an action-oriented compilation of related information, resources, or tools that can guide users to develop a plan or organize efforts to conform to evidence-based recommendations or meet evidence-based specific practice standards."(115) A planned approach to guideline development, dissemination, and adaptation can promote more successful adoption of the implementation guidelines and its components.(115)

The results from the case study were used to develop a proposal for CDTM model implementation guidelines. These guidelines were the starting point for many clinics in

the U.S. that would like to start an outpatient clinical pharmacy program, but do not know where to begin the process.

The implementation guidelines were modeled after existing resources from the CDC, including two toolkits addressing Collaborative Practice Agreements in health care settings.(59) Guidelines may include fact sheets, technical assistance resources, such as a budget planning tool, a step-by-step guide that clinics can use to identify what programs their patient population would most benefit from, or sample language to explain CDTM to a patient population.(40) The guidelines for this research incorporated selected existing tools of CDC's CPAs and will expand on CDTM-specific intervention tools adaptable for all settings. While the intervention guidelines were based on the El Rio experience, all interventions will be generalizable to other settings.

Guideline implementation recommendations may include the following:

- revisions to the current CPA to better address CDTM model implementation;
- specific adoption guidelines and methods, such as requiring new employees working with CPAs attend a CDTM education session;
- proposals for increasing the availability of resources to address at-risk patient populations through CDTM clinics; resources might include staff, funding, or technical assistance materials and sessions; and
- methods for regular evaluation of compliance and of implementation successes and challenges.

- consideration of how the lessons from the El Rio program which focused on diabetes management would apply to other chronic disease management.

The draft intervention guidelines were developed in collaboration with El Rio clinical pharmacy staff, El Rio administrators, and other local and national stakeholders identified during key informant interviews. Specifically, questions asked during the key informant interviews addressed intervention 'steps' translatable into guidelines. The "how" and the "process" behind the CDTM model were addressed and then translated into intervention guidelines. After drafting the first set of guidelines from important themes from the key informant interviews, a meeting of the clinical staff at El Rio was convened to discuss the initial implementation recommendations. After the El Rio team of clinical pharmacists approved the feasibility of the guidelines, further feedback was gathered from El Rio administration and community. All feedback was reviewed and summarized into edits of the guidelines or noted in a section of the guidelines addressing the limitations of the intervention guidelines themselves.

The final implementation guidelines will be provided to El Rio Health Center and Tucson stakeholders for use in state and local technical assistance activities. Draft guidelines will also be provided to national and state organizations working on outpatient clinical pharmacy, such as the ACCP. Local, state and national organizations may disseminate final versions of implementation guidelines via list-serves and websites, presentations at conferences, published reports, and technical assistance workshops.

Outpatient Clinical Pharmacy Program Worksheet

Sub-aim 2c. Build a worksheet that will allow clinics to assess their capacity for implementation of a CDTM model.

Regulations enabling new clinical practices frequently do not provide adequate information or advice for implementation or lack explicit guidance for model assurance or maintenance. Implementation guidelines published by the authorizing organization or agency help the entity responsible for implementation achieve the intended results. The primary technique used to ensure the implementation of the CDTM model was to outline explicit suggestions for the implementation, monitoring, and assessment of the regulation. Other mechanisms used to support clinical model implementation included evaluating existing materials and developing action based learning among other ideas.

The guidelines annotate a step-by-step process that clinics can use to identify if they are a good candidate for a clinical pharmacy program. The guidelines are distilled into a Google Forms worksheet that will allow clinics to assess their capacity for implementation. The worksheet will be accessed through Google so availability to technologic software is not a barrier for use in low resource settings. The worksheet will not be directive; it will identify areas the clinic may need to address to increase clarity before implementing a CDTM model.

The results from the key informant interviews and lean management brainstorming activity informed the self-assessment worksheet. Pathways and methods each individual and group used to support the success of the CDTM model were distilled into a data input in Google Forms. To develop the query inputs in Google Forms, the

themes and anecdotes from the case study were reviewed identifying potential needs for supports and resources that translate to clinic administration recommendations. After a set of draft Google Forms inputs are created, they were shared with El Rio stakeholders to address ease of use and utility. Feedback from El Rio was integrated and modified into the worksheet before final development.

Teaching Case

Sub-aim 2d: Develop and disseminate a management case study about the Pharmacy Based Diabetes Management Program at El Rio Health Center. The management case study will focus on key administrative decisions made during program implementation used by the El Rio administration and other stakeholders.

The public health practice component of public health education and training should address the "translation of public health science into policy action."(116) Case studies documenting program implementation experiences are useful teaching or action tools to a) facilitate replication of effective strategies and discourage replication of unsuccessful approaches and b) promote professional dialogue. Cases should be designed to illustrate specific policy theory, learning objectives, and skill sets. The case study or teaching case approach aligns well with adult learning principles, which underlie many professional education initiatives in public health.(116)

The written case study report was adopted into a teaching case with study guide to communicate lessons learned about El Rio's experience implementing and adopting the CDTM model. The target audience for the teaching case included public health students,

public health and clinical pharmacy professionals, and clinical administration in outpatient clinical care centers. The adaptation from case study to teaching case used established techniques to create a case suitable for use in a learning setting, including condensing and modifying text to include discussion questions and teaching points.(116) Following Yin's advice, the goal of the adaptation was to "establish a framework for discussion and debate among students." (94) The teaching case will be piloted in a Boston University public health course and written and verbal feedback from students and instructors will be gathered. All of the feedback will be reviewed and the case will be revised.

The teaching case will be made available for dissemination through national and state networks. It may be adapted further as a white paper or a research paper for dissemination through national and state organizations and/or publication in a peer-reviewed journal.

Chapter Three Summary

Chapter 3 described the research and design methods for the Case Study of El Rio and the Pharmacy-Based Diabetes Management Program. The background of clinical pharmacy in Arizona is described along with the case description and boundaries of the research. The definition of a case study was identified and described in depth to support this application to this research. Chapter 3 describes the methodology employed during the data collection for key informant interviews and group lean management sessions. The data analysis and tools used to code and extract data were also detailed in Chapter 3.

CHAPTER FOUR

Results: Shared Practices that Contribute to Program Development, Adoption, and Implementation

Introduction

As outlined in Chapter 3, multiple quantitative and qualitative tools were used to examine the development and implementation of the Pharmacy-Based Diabetes Management Program (PBDMP) at El Rio Community Health Center. This chapter highlights the results of this analysis, which point to a variety of conclusions and outputs that are discussed in further detail in Chapter 5. Chapter 4 first identifies the emergent themes from each of the data collection methods. The four themes defined were: teamwork, process, leadership, and challenges. These four themes are categorized by six key practices. The six practices that affect OCPP support and structure are: 1) Setting a vision and objectives, 2) Obtaining and using resources that support the objectives, 3) Defining the program structure of the PBDMP, 4) Leadership taking on roles in guiding the program development, 5) Collaboration and teamwork between program roles and individuals, and 6) Data and data analytics to inform decisions. The PRECEDE section of the PRECEDE-PROCEED model and the Organizational Transformation Model are applied to the practices to help identify the supports and structures of the PBDMP at El Rio to inform the implementation guidelines and study products.

Chapter 4 will provide an overview of the findings from all three data collection sources. The chapter will begin with a data collection summary, and then offer

benchmarks for comparison between the three OCPPs interviewed. The six practices are described in detail and then compared with each other. Chapter 4 concludes with similarities and differences between the programs.

Findings Overview

Table 9 describes the three clinical sites studied:

Table 9. Outpatient Clinical Pharmacy Program Sites

	El Rio Community Health Center (PBDMP)	**Marana Healthcare (MHC)**	**UNC Internal Medicine Enhanced Care Program**
Year of program foundation	August, 2001	January, 2014	July, 1999
Clinic Structure	Stand-alone program housed within larger clinic setting	Program based out of a drug-dispensing pharmacy within a clinic setting	Stand-alone program within an academic outpatient clinical setting
Clinical Focus	Diabetes-only focused	Diabetes-only focused	Program oversees medication management for diabetes, hyperlipidemia, and hypertension
Pharmacist FTEs	8 Pharmacists (5.6 FTEs)	3 Pharmacist FTEs	4 Pharmacists (2.25 FTEs)
Diabetic Patient Volume	275 to 350 individual patients per year, 4,500 unique patient visits in 2014	3 patients total	6-8 diabetes patients daily
Number of Visits per Year	4,000 to 5,000 diabetic patient visits per year	50 diabetic patient visits per year	800 diabetic patient visits per year

Benchmarks for Program Comparison

The El Rio Experience: Compared and Contrasted

To enhance the relevance of the case analysis, the Pharmacy-Based Diabetes Management Program (PBDMP) was compared to other settings with successful and failed program development and implementation. The case description of the PBDMP at El Rio has similar case boundaries and identification to the outpatient clinical pharmacy program at Marana Health Care (MHC), in Marana, Arizona and the University of North Carolina at Chapel Hill (UNC) Internal Medicine Enhanced Care Program. Incorporating benchmarking to compare the three programs is useful to examine the structures and supports in place assisting or hindering the CPA development and implementation. Moreover, a comparison of the results from the multiple lean brainstorming sessions and key informant interviews from within El Rio is useful to reflect on the current state and genesis of the PBDMP. Through this analysis, a comparison between these programs reveals the aspects of the PBDMP that could be applicable for alternative settings seeking to incorporate a collaborative practice model in an outpatient setting.

This analysis suggests the key benchmarks for comparing outpatient clinical pharmacy programs include:

- Patient volume utilizing the outpatient clinical pharmacy services;
- 30-day re-admission rates for patients within the program;
- Physical space dedicated to the program within the clinical/health system framework based on key informant interviews;

- Number of staff members (FTE) dedicated to the outpatient clinical pharmacy services;
- Amount of time the program has been open and working with patients' diabetes state management.

To best understand the context of the results, a snapshot of the individual clinics was created based on first-hand observation of the clinical facility supplemented by the content of the key informant interviewees. The three different clinical sites, Marana Health, UNC Internal Medicine Enhanced Care Program, and El Rio's Pharmacy-Based Diabetes Management Program are described below.

El Rio Pharmacy-Based Diabetes Management Program

The Pharmacy-Based Diabetes Program at El Rio began in August, 2001. After receiving a clinical pharmacy demonstration grant, El Rio was committed to hiring a clinical pharmacist and beginning a clinical pharmacy program. The program developed slowly by working to augment care given by physicians. The program expanded over the following six years and the clinical roles of the pharmacists were defined over time. The program currently has eight clinical pharmacists (5.6 FTE clinical pharmacists) on staff. The PBDMP sees about 4,000 to 5,000 unique patient visits annually.(98) In 2014, there were 4,500 unique patient visits.(98) Each pharmacist sees approximately 275 to 350 individual patients per year—approximately 2,400 unique patients each year. Most patients seek services at one specific clinical site and see the same clinical pharmacist on the clinic's staff for all of their care. A patient's frequency of visits depends on the

individual's diabetes control. Depending on a patient's control of their diabetes, a patient can see a clinical pharmacist between four visits a month and one visit every six months.

The PBDMP started recruiting patients by contacting the department heads of Internal Medicine and Family Practice encouraging them to send 10 of their most complicated patients to the program.(117) By working closely with these patients and providers, the pharmacists were able to document and show improvement with this initial group.(117) The department heads then became the champions for the pharmacist when recruiting other providers to start referring patients to the PBDMP.(117)

There is data to support a decrease in hospital 30-day readmission rate of patients participating in the El Rio PBDMP.(101) There are clinical pharmacists physically based in eight of the 17 clinical sites of El Rio although they are available for remote consultation with all sites. Each clinical site has at least one exam room and shared office space for the clinical pharmacists to work. While there is not clinical pharmacist coverage every day of the work week at each clinical site, usually four out of five days a week there is a clinical pharmacist on-hand at each clinic. At the main El Rio office of clinical pharmacy at the Congress Clinic there are three dedicated exam rooms and three offices for the PBDMP Director and nutritional counseling services. There is also a dedicated conference room for training and group classes of the PBDMP in the Congress Clinic.

The Case of El Rio

Shared Practices and Topics that Relate to Program Development, Adoption, and Implementation

The six themes or activities that were discovered in this investigation contain both external and internal activities carried out by outpatient clinical pharmacy programs. For this research, the clinical steps and actions taken by the OCPPs will be referred to as *practices*. These practices are activities carried out by the PBDMP as well as the other outpatient clinical pharmacy programs studied. The six practices examined do not represent all of the program activities, only those that had an impact on the program supports and structures leading to program success.

The four segments of the PRECEDE model and the six primary constructs of the Organizational Transformation Model were used as guidance to define the shared practices present in all of the data collection methods: key informant interviews, root cause analysis diagrams, and process flow maps.(82)(81) These practices are somewhat chronological in order, as activities and processes evolved throughout the planning stages of program development. Within the limited evidence available regarding the other outpatient clinical pharmacy programs, the same practices were observed in the primary case study of El Rio. Although most of the evidence is from El Rio, supporting evidence from other sites was included when available. This analysis will contain a description of the practice, the impact it had on program support, and examples of how the practice was identified in applicable case sites. A brief summary concludes each practice section. An overview of all the practices is provided in Table 10.

Table 10. Overview of Six Key Practices of Successful OCPPs

Name of Practice		Impact on Program Support and Structure	Example Impact
1.	Setting program objectives	Used to keep mission, vision, and priorities aligned through program development and implementation.	Setting the scope and vision of the program to include or exclude specific programs, e.g. the inclusion of 340B medication discounts.
2.	Obtaining and using resources that support the objectives	Determines the internal and external resources, and process of utilizing the resources efficiently and effectively.	Identifying current clinic resources, e.g., clinic office and conference space, available for program execution.
3.	Defining the program structure of the PBDMP	Sets the flow of the patient care services and pharmacist/clinician interaction.	Specifying the cycle of care within the program, e.g. a patient continues to regularly visit a pharmacist and clinician until their diabetes is stabilized.
4.	Leadership taking on roles in guiding the program development	Leaders guided and simplified the program's processes through a series of program definition and re-definition.	Strong leadership and vision was necessary during hiring practices, e.g. leaders understood the needs of the program and matched individual characteristics of new hires with those needs.
5.	Collaboration and teamwork between program roles and individuals	Formal and informal teamwork impacted work practices of the programs.	Defining formal roles for team members was integral for program success, e.g. CPAs outlining work relationships between employees.
6.	Data and data analytics to inform decisions	The integration of data from multiple sources assisted in individual patient and program-wide decision-making.	Data platforms allowed pharmacists to assess individual health on a population level, e.g. a query of NEXGEN identified patients with A1Cs over nine who needed more support.

PRACTICE ONE

Setting Program Objectives

In an organization it is critical that the vision, mission and organizational priorities are aligned for programmatic success.(81) When mission, vision, and priorities of an organization are further defined, the Organizational Transformation Model points to

the importance of these strategies for organizational direction and priority setting. The model framework shows priorities as integrated into the larger construct of mission and vision. Priorities are defined as the vehicle to employ an aligned mission and vision.

Mission

In the PBDMP, the clinic administration defined the mission and vision of the program within El Rio's purview. The El Rio Community Health Center's mission was "improving the health of our community through comprehensive, accessible, affordable, quality and compassionate care."(74) In line with the overall clinic's mission, the PBDMP was expressly created to address a high burden of uncontrolled diabetic patients: "In the Hispanic and American Indian population they (El Rio's leadership) were seeing a lot of people with uncontrolled diabetes. So they felt that there was a really important need to address diabetes just because of the high volume of patients that they were seeing needing help."(99) The PBDMP's Director defined the program vision as a collaborative drug therapy management program that "addresses diabetes self-management, education and training, and support."(98) The Director further elaborated on the vision by describing what was needed to overcome the clinical inertia to implement a program like the PBDMP: "we were able to sort of break that inertia and get people to activate sooner and then also in between visits with the providers, so you're not always doing things when you're seeing the patients—you're doing it more frequently and then in between the physician visits so it's a really nice relationship."(98)

The program's mission was first defined by the leaders who applied for the HRSA demonstration grant in 2000. They defined the initial goal of the program to integrate

clinical pharmacists into ambulatory care for diabetes. After a few years of existence, the program's priorities shifted to cover the continuum of diabetes care management, and not just individual diabetes care visits. The alignment of the vision, mission and priorities of the program assisted in patient retention and program success. For example, due to the increase in patient volume, pharmacists were no longer able to see patients with recommended frequency. In response, El Rio hired additional pharmacists and staff members for the PBDMP to serve the increased patient demand. By increasing the number of pharmacists the volume of patient visits and retention increased thereby leading to a higher number of patients with diabetes control.(98)

Vision

Vision was described throughout the interviews in terms of both leadership and individual foresight. In multiple brainstorming sessions the fact that the PBDMP was created as a free program within El Rio was seen as positive foresight from the clinic administrators. The Pharmacy Group noted that the "free status of the clinic" was a leading reason for program success, for building program volume and retention. The same group also noted that the "help with medications" that the clinic offered was integral for program use by the El Rio patient population. One of the perceived benefits of the program for the patients was the access to free or low-cost frequent visits to clinical pharmacists for patients with diabetes in highest need.

Due to the HRSA 340B Drug Pricing Program, under which individuals can receive medications for free or at a reduced rate, many of the diabetes medications prescribed form the clinic were offered for free or at a low cost.(42) Participants in the

brainstorming sessions discussed the high number of patients who did not take their medications as prescribed due to financial barriers. Not only did the free clinic status increase patient volume, it also enabled patients who would otherwise not be able to take their medication regimen correctly, take all of their medications as prescribed.

In other groups, vision was described as a perspective used when the clinic administrators hired staff for the program. By identifying pharmacists as potential integral members of the care team, clinic leadership was able to define the set of skills that pharmacists added to the patient diabetes care management. For example, in the Administrator Process Flow Map, a whole process step was identified to describe the skill set of the pharmacists: "assessment, learn needs, motivational interviewing, etc." This step shows that administrators had identified a set of skills that a pharmacist added to the program and validated the pharmacists as an important member of the diabetes team-based care.

In one of the Pharmacist group process flow maps, a process step was dedicated to the fact that "someone [clinician, pharmacist, or nutritionist] decides a patient needs the program." This step again describes programmatic vision of the PBDMP since an individual integrated in the program was able to and encouraged to make the decision if a patient entered the program. The same process flow map showed individual knowledge of program vision, since the employees embedded in the program were making decisions about which patients should or should not enroll in the PBDMP.

Administrators for the clinic and the PBDMP itself were also praised in the Clinical Group's RCA diagram of success for their hiring and management processes.

The "experience of managers" was seen as a bonus for the program, adding to the depth of understanding of the patients. The "management knowledge of staff" was also a success defined in the Pharmacy Group RCA diagram. Being able to "hire well" for the program was also seen as a success in this diagram. Similarly, in multiple diagrams the "motivated team" of the PBDMP was described in detail. Hiring a motivated team and knowing the clinic gaps and patient needs was repeatedly cited.

Therefore the depth of understanding of the clinical staff and their specific skills was seen as a key element to program success. This understanding was also confirmed in the key informant interview with the Clinical Director of the PBDMP in describing the hiring process: "But, they did do a good job recruiting, because they hired me! No, but, they were very thoughtful in how they recruited for the position. They were looking for residency-trained bilingual clinical pharmacist—that's me."(98) The importance of clinical administrative buy-in for the program was also highlighted in the interview: "Showing them the difference in outcomes that level of buy-in obviously helps, you can get there without that level of support, but it's much faster and more easy *[sic]* if you have that level of administrative support coming from the top."(98) Clear communication of the PBDMP's benefits between El Rio's clinical administration and the pharmacists working in the PBDMP was a key element to organizational transformation.

Priority Setting

The OTM defined strategies that set and directed priorities as a key element for priority setting.(81) For this research, the two key aspects of priority settings were: 1)

priority setting process on a clinic-wide level, and 2) priority setting within an outpatient clinical pharmacy program. The participants from the brainstorming sessions identified priorities that were both pre-identified from program formation as well as additional areas employees identified as important for program success.

Priority Setting: Clinic-Wide

When key informants discussed clinic-wide priorities, interviewees discussed the program's sustainability and maintenance or a specific patient population using clinical services. For example, the Program Director at UNC Chapel Hill Program noted that: "So we are really fulfilling the role of the provider. And so ordering meds that need to be ordered and ordering labs that need to be ordered. And, at the same time we're also doing multiple projects looking at population health and management in ways that we can all improve."(108) Clinical pharmacists at the UNC program were able to identify strategies that set the program's direction and priorities. The director described that the UNC program was founded based on two clinical pharmacist's vision and priorities, "So that's kind of what the physician's envisioned, and that was very different than what the two of us envisioned, and so we began drafting up a disease management work that we envisioned for diabetes specifically."

The key informant interview with the PBDMP Clinical Director described program priorities through strategies for addressing a high patient volume: "Now we have an abundance of referrals. That's not an issue about whether or not the physicians understand what we do. And, then also integration. Not just the patient care level, but the organization promoting it to more higher administrative responsibilities that really

sets the strategy. We're looking at ways as a whole as to how we can improve prescribing and how we integrate the pharmacy."(99)

Priority Setting: Program Specific

In the PBDMP, the results of the priority setting process from the Clinical Group RCA diagram map identified a "high quality of service" and "communication and affiliation" as important priorities and behaviors for employees. One of the Pharmacist Groups defined patient education as a process step in their process flow map. The step is a decision point asking if "patient knows their A1C?" This concern with patient knowledge and patient ownership of their own health is a key aspect of the program and its success. The Clinical Group described the "self-management" goals for the patients to understand their diabetes diagnosis and the prescribed treatment plan. The group noted that one of the successes of the program was the consistency in messaging of the various providers—"same message from multiple people." The medical assistants, pharmacists, and clinicians participating in patient management all shared a vision for "what" and "how" to treat patients enrolled in the program.

In addition, better "communication between patient expectation and providers" was identified as an issue between patients and providers. Identifying the priorities of the program and what a patient could expect from the PBDMP was important, but communicating those expectations clearly and effectively to the patients was paramount. While the priorities for the PBDMP were aligned with the vision and mission, the link between the providers and patients for program expectations was not as strongly communicated as necessary for program clarity.

Conclusion

The combination of mission, vision and priority setting is integral for an organization's success. Since each of the aspects of organizational change supported each other at El Rio, not one of the areas was considered more important or imperative for program success. The practice of identifying the vision, mission, and priorities at the PBDMP was a key element of organizational and programmatic success.

PRACTICE TWO

Obtaining and Using Resources that Support the Objectives

There were two consistent types of resources discussed in the key informant interviews and brainstorming sessions. In both of these data sources, resources were either described as internal or external support. The support received was usually financial, while other resources were described as physical support for the program itself including, staffing, office space, and administrative engagement. All types of resources and support that the PBDMP and other program sites received are important for considerations of transferability to other program settings.

Internal Resources

All of the outpatient clinical pharmacy programs received funding from line-item budgets internally from within their respective clinics. More importantly, this financial support was coupled with philosophical support from the clinic's administrative and clinical leadership. Key informants frequently noted that program finances provided by the clinic were concrete manifestations of the buy-in from clinic leadership. To secure

funding, program directors needed to provide evidence that an outpatient clinical pharmacy program would respond to the patient needs of the clinic, produce positive health outcomes for the patients enrolled in the program, and not serve as a financial burden to the overall clinic.

The Program Director at El Rio noted that the support from the clinic leadership was integral to program development and implementation: "It was all about showing improved outcomes. Solid, improved outcomes. Provider acceptance and provider satisfaction. Convincing our administrators we were a program that mattered."(98) To garner the support of the key leadership, the PBDMP not only produced a plan for program implementation, but in addition clear outcome data was shared with clinic leadership to encourage continued programmatic support. For example, patient outcome data was shared with El Rio leadership on a weekly and monthly basis. The administrators also articulated their "full full [*sic*] support" of the program in the RCA diagram. They went on to discuss their financial support for the program and the importance of providing funding for the PBDMP in the RCA diagram: "mobilizing funding: or helping to get enough for them." According to the Program Director at El Rio, funding creativity was also important for program sustainability, "We've created ways to fund our program."(98)

In line with the vision of the PBDMP, the "free status" of the program was identified as a major success in all of the data sources. The Pharmacy and Clinical Group both said that the fact that the program was "free to all patients" enabled clinicians to refer individuals into the program without a financial consideration. As noted in Practice

One, the pharmacists pointed out that the "needs exceed capacity" for the program explicitly since providers tended to refer patients to the program because it was free. This deluge of patients created a long wait time to see a pharmacist—almost three months—and major challenge for the PBDMP. In the RCA diagrams, there were over eight references describing the types of "free" services offered by the clinic. Notably, the Administrative Group was the only group to not mention the free status of the PBDMP.

It was considered a benefit for the clinic and the patients with diabetes at El Rio that a PBDMP existed. However, the pharmacists saw the program as potentially being 'over-used' by providers referring patients that do indeed have diabetes, but who may not need the individualized care that the program offers. Some of the groups argued that this increase in patient volume was beneficial for the patients at El Rio, while others noted that some patients "come to the appointment without the intention of participation" in the program. This lack of program engagement not only wasted pharmacists' time, it also drained the program's resources.

Many types of resources were also described in the data in terms of education and knowledge directly received by patients. In multiple RCA maps, "patient education" and knowledge of their current disease state was a positive outcome of the PBDMP. For example, the Clinical Group RCA diagram specifically identified "incorporates other quality services: eye/foot check, medical services" as a resource to patients. And finally, on multiple diagrams, the "ABI" (Ankle-Brachial Index Test) checking for peripheral arterial disease in the legs was mentioned as a service of the PBDMP for patients. The Clinical Group RCA diagram noted the "education in multiple formats" as a resource to

patients enrolled in the program. Many of these resources were explicitly purchased by the PBDMP to use with patients enrolled in the program.

Other educational resources for clinician interactions with PBDMP patients were identified by the brainstorming sessions as priorities of the El Rio leadership. The Pharmacist Group RCA diagram reflected "health education" as a major aspect of direct patient care. Training providers on "patient education" and "motivational interviewing" were also specifically identified as skills clinicians were taught at El Rio. In addition, the UNC Program Director described patient education as a type of resource: "I think the other thing is that we do an education session every time a new group of medical residents come in and we educate them about any health care programs and what resources we provide to them."(108) Training the PBDMP staff on how to effectively use program resources to educate and benefit patients within the program, was identified as a success on multiple RCA diagrams.

Physical space, materials, and tools were also described as PBDMP resources in the brainstorming sessions. The Pharmacist Group RCA diagram specified the "eye machine" and "exam rooms to see patients" as resources. The Clinical Group noted the "help getting supplies/medications" as a success of the program and its potential for providing resources to patients. The Clinical Group also said that the physical setting of the PBDMP within El Rio was a success of the program. The group identified that: "services delivered in multiple venues" and "co-location on site with PCP" were benefits of the program. Finally, the PBDMP and MHC program both identified as resources a dedicated conference room in the clinic for group education. While the conference rooms

were used for large patient group education settings or clinic staff meetings, there were not seen as necessary for program success.

Staff and personnel working in the program were described as program resources throughout the data. The Program Director of UNC described that the individuals on staff for the program were shared with other departments within the academic setting: "I mean, there's technically 4 of us, but we are faculty and other responsibilities so if you factor in the amount of time we are funded by the clinic to do clinical work it's about 2 to 2.25 or something like that."(108) The number of FTE staff equated financially to the program's bottom line since the staff services were reimbursed. UNC capitalized on their academic setting to create flexible part-time employees. Similarly, many of the pharmacists on staff at the PBDMP and MHC program were part time drug dispensing pharmacists as well as employees of the outpatient clinical pharmacy program.

External Resources

In response to the question of buy-in from the clinic's leadership, the Program Director at the Marana Health Center said: "So, those barriers have been overcome. We have the full support of the health center to do this. Basically, right now, it is just the financial impediment to get reimbursed."(107) The MHC Program Director continued to describe that the main financial impediment for the program was not internal, but external through medical insurance reimbursements: "So, that's our stumbling block right now, because to really just to place one or two or three pharmacists into this position, to do what we want to do—develop this program—that costs money. Because you're pulling someone away from where our real income source is, which is still filling prescriptions,

and counseling."(107) External insurance reimbursement was a key factor for all of the outpatient clinic pharmacy programs, and a difficult impediment to overcome. All of the programs placed the clinical pharmacists on an annual salary from their respective clinics and filed insurance reimbursements for services rendered.

This external issue of reimbursement was reiterated in multiple data sources. The Director of the UNC program commented, "But, it is frustrating that pharmacists are not providers, but we all know that. And, that it's hard to figure out the financials of the pharmacists in those particular models. So, yes, we can show that we decreased hospital readmissions with our model, but pharmacists are expensive [and] they can't technically charge for those visits, so how do we show the financials that are positive feedback to the hospital [or clinic]?"(108) This cycle of care and lack of insurance reimbursement for pharmacists was discussed during the brainstorming sessions as well as in multiple key informant interviews. The cycle of insurance reimbursement represents a barrier to obtaining further resources for the clinics. In some cases, this barrier represents a need to obtain more resources to offset the costs due to the lack of insurance reimbursement for clinical pharmacists.

One major barrier noted in the Pharmacy Group RCA diagram was the fact that patients have "no insurance" and "no money for medication" for medical services. While the PBDMP was free, referrals outside of the program and some medications prescribed from pharmacists within the PBDMP were still too expensive for some patients. The Administrative Group RCA diagram described these issues "social determinants" that highlight the "patient's complicated patient history" making positive health impacts even

more convoluted and difficult in the long term.

External support also came in the form of community engagement. The Program Director at El Rio noted that "getting buy-in from the community" helped galvanize support in terms of payment reform and pharmacist provider status on a city and state-wide level.(98) The community advocates supported the PBDMP both financially and politically in community forums. The Program Director for El Rio noted: "we had a lot of donors from the community who supported the program because they believed in what we were doing. And they personally had family members who they sent here who had success that hadn't had success and they tried different programs around the city and different things like that. So, initially it was a lot of that and now we became an accredited diabetes site and so we can bill for the program..."(98) While many of these supporters provided some financial assistance, their support mostly came in the form of community engagement for the PBDMP.

The PBDMP received a HRSA demonstration grant in the initial stages of the program development and implementation. The Program Director at El Rio noted that the administrators: "sort of had written for the money, but they didn't know what they were going to implement. Or, what it really meant or how it was going to work."(98) The process of developing the grant helped clarify the current and future needs of the patients and the program structure. Payment for pharmacists was first discussed during the HRSA demonstration grant: "since clinical pharmacists don't get paid for their health care services in general they get paid for dispensing product I mean, pharmacists. It is very hard to start a program."(98) The Program Director went on to note that: "You almost

need like seed money, or you just need somebody who can say, we're just going to eat the cost of paying the salary."(98) The grant allowed the leaders of the PBDMP to implement the type of program they thought best addressed the needs of their patient population without directly tackling the issues of pharmacist salary head-on. At MHC and UNC, the outpatient clinical pharmacy programs were created without federal external grants.

Conclusion

The outpatient clinical pharmacy programs obtained resources through multiple sources both internally and externally. The support for the programs from within the clinics was through leadership buy-in and financial line-items. External resources tended to be from of external grants and support from the community. Together, these various resources supported the creation, implementation, and execution of the programs.

PRACTICE THREE

Defining the Program Structure of the PBDMP

The structure of the PBDMP and other outpatient clinical pharmacy programs studied were discussed and defined in the brainstorming sessions and by interviewees in three distinct categories: 1) Clinic-Wide Program Structure, 2) Referral Process, and 3) Program Structure of the PBDMP. Through a process of program definition and re-definition, these categories help describe the function of the OCPP and how the services offered by the programs fit into the larger landscape of the clinic. Together, these

categories identify the form of collaborative drug therapy management and CPA in place at each clinic.

Clinic-Wide Program Structure

Program design and implementation differed among the clinic sites. In the case of the UNC program, the Director described the brainstorming process leading to program creation as straightforward and methodical: "And so that's kind of what the physicians envisioned, and that was very different than what the two of us envisioned, and so we began drafting up a disease management work [*sic*] that we envisioned for diabetes specifically, because they [the UNC clinic itself] did have data showing the huge amount of expenditure in meds and just care of our diabetes' populations that were Medicaid." According to the MHC Program Director, their program started, "Ad hoc and through my own brain." MHC focused on training the pharmacists on staff in diabetes disease state management. The Program Director of MHC noted that, "The number one thing that I thought we had to do was, we had to be trained in these key areas because we needed the certification in order to prove that we had the skills to do these kind of things." The cycle of defining and re-defining the program and program structure evolved over time for all the clinics. Many of the decisions made in the process of these cycles incorporated various practices supporting program efficiency and coordination. The importance of constant re-definition and flexibility within each program was a common theme in the data underlining the critical step of program development and structure.

In the initial stages of the PBDMP, clinic leadership looked into the possibility of a pharmacist-inclusive model after a recommendation from the University of Arizona.

Since the El Rio leadership at that time did not have a pharmacy background, El Rio applied for a HRSA grant to start their program. The instructions to the PBDMP Program Director were cursory, "When I started here, they had given me no parameters. No direction. They just said, "Start a diabetes program!" The Director drew from past work experience to design and implement a clinic pharmacy program addressing the community of diabetes patients at El Rio. In addition, the Director also compared the programs that addressed diabetes in use at El Rio to the future plans for the PBDMP, "So you could see how it [*the past program*] could be a burden on the clinic. Versus if you just implement a very similar practice to any other one. It's seamless, and it's accepted, and that's what it is and sort of people get comfortable with that. So, anyway, that's how we started it."

The landscape of the clinics and states where the outpatient clinical pharmacy programs were created was an important element to program development and implementation. The Director of the UNC Program mentioned that a familiarity with clinical pharmacists was a benefit for the program, "So, I would say that back in like 1999 when we first started, most people were just familiar with the concept of clinical pharmacists on rounds within the hospital on the inpatient side, so they were familiar with what pharmacists could do as part of that team…they weren't, in our clinic, as knowledgeable about what the pharmacists could do in an outpatient setting." A supportive medical community that understood the intent of an outpatient clinical pharmacy program was important for program awareness.

The ability for pharmacists to practice under a Collaborative Practice Agreement

(CPA) in a given state is integral to program formation. The PBDMP Program Director noted that, "I would say 47 out of 50 states allow some form of collaborative practice. But, you have to understand the scope of practice you're allowed to do in each state and what the requirements are. When I first started, there was no legislation for that." Identifying if a state can house a pharmacist-inclusive CPA is paramount for program development. Specifically, researching if a CDTM model is permitted within the state helped the programs plan for service delivery within a pharmacist-inclusive team. It is critical for a program to link practice with the legal realities within a state to ensure the feasibility of the proposed program structure and process. Appendix C includes a process flow map from Pharmacist Group 1 depicting the structure of the current PBDMP.

Referral Process

Patients were referred to the outpatient clinical pharmacy programs through the family and internal medicine departments. At MHC and the PBDMP patients were also recommended to the programs through the pharmacy. In the case of the PBDMP, the Administrative Group process map identified nine separate points of entry to the program. Some of these referral systems included, self-referrals, Missed Opportunity Reports, and Community Health Advisors. The Pharmacy Group RCA diagram noted the "provider referrals" as a success of the program. The Administrative Group RCA diagram also mentioned that "11 years ago: DO/MD could not opt out of PBDMP—now no opt out." This identified success of the program referral structure ensured that all clinicians were able to refer patients to the program.

The Program Director of the PBDMP described the referral process as diverse,

"Referrals come from many many [*sic*] places. I mean, the physicians refer—if they have people who are out of control or need help. But, we also have other staff that refers. We have our behavioral health counselors that refer. We have a pharmacy that refers if they see somebody who needs help. We have self-referral, family referral, we have other people in the community that have either read or heard about our program." There was not a one-size-fits-all method for successful patient referral for the programs. However, the Clinical Group RCA diagram reflected that they thought there was much "confusion over referrals" and that there was "no easy way to enter the program." While the referral process was considered robust with a wide reach for patients at El Rio, the clinicians believed the process to be somewhat unclear. The existence of multiple forms of referrals to the PBDMP was highlighted by the administrators; the referral process itself was not discussed in the brainstorming session. The managerial tradeoff made by the administrators to cover the breadth of potential referrals to the PBDMP, may have come at a cost in terms of convenience of referrals by clinicians.

The referral process itself was defined and then re-defined over time by El Rio's administrative and clinical leadership. The first type of referrals to the PBDMP came from clinicians: physicians, nutritionists, social workers, and nurses. Referrals from missed opportunity reports and i2i queries were introduced into the referral process after El Rio migrated to an electronic medical record system. Over time, the referral process was refined and expanded to try and reach the highest potential number of patients at El Rio. The El Rio Administrator noted that the more referral pathways into the PBDMP, the higher the number of patients ultimately referred and enrolled in program services.

Program Structure of the PBDMP

While each process flow map highlighted different aspects of the program in more detail, all of the basic steps and processes were identical. Once a patient was referred and enrolled in the program, a medical assistant followed up with the patient to schedule an initial visit with the clinical pharmacist. At the initial visit, the pharmacist conducted a patient intake and assessed the needs of the individual. Medication reconciliation, baseline measures, and A1C levels were checked and documented. Referrals for a patient to visit a dietician, behavioral health counselor, or ophthalmologist were made at the first visit or during future visits. Goals were established with input from the patients and a follow-up appointment was made. A patient continued to visit a clinical pharmacist in the program until they were in control of their diabetes care. The Administrative Group RCA diagram noted these "Iterative process of [*the*] program" as a success in structure.

Not all of the data about the program structure and flow were positive. The Pharmacy Group noted "clinic consistency" and "lack of understanding about the program" as major barriers to program coordination. This was identified as a barrier due to the potential difference in care or services offered to patients, depending on which clinic site they frequented. The brainstorming group discussed the differences in care between the seven El Rio clinical sites due to personnel, resources, and program inconsistencies. Monthly meetings of whole PBDMP team were held to address clinic consistency, difficult cases, and program current events. Informal meetings or conference calls were held on an as needed basis for specific cases or issues that arose. However, the lack of one central site was felt to be both an advantage for patient services

and an impediment to equal care across clinic sites. Importantly, this perceived difference between program sites did not create a noticeable impact on programmatic success.

Another barrier described in the Pharmacy Group's RCA Diagram included "wait times" for patients to see a pharmacist. Steps to decrease patient wait times were taken over multiple years by hiring more pharmacists, expanding the services offered by the clinic, and addressing scheduling head-on. As in Practice One and Two, wait time was a consistent complaint of program process—"needs exceeding capacity." The brainstorming groups discussed how long wait times tended to decrease the volume of referrals from clinicians to the PBDMP and lowered the likelihood of the patients wanting to enter the program. Data confirming this trend was also provided during the key informant interviews.

A final barrier identified during the discussion of program structure in the brainstorming groups was "Provider Status." The groups noted that provider status was a key element for reimbursement of medical care as well as pharmacist inclusion in clinical services. The lack of insurance reimbursement for clinical pharmacists due to the absence of provider status affected how the program was designed. Visits and group sessions were planned around the potential for clinical pharmacists to code for aspects of the patient visit combined with other clinicians with provider status.

Provider status for pharmacists differs by state and a national decision about provider status would address health insurance reimbursements among other potential issues. The ACA described integrated models of care utilizing pharmacists, medication

therapy management grants, and reimbursement tied to quality measures. However, the ACA did not address pharmacist provider status and pharmacist reimbursement for services. The Director of the PBDMP described the importance of provider status during the key informant interview, "Not having it [*provider status*] has been a barrier—absolutely. Having it will be very helpful. I think there's a double edged sword, though. And I always am very conscientious of this. If we get paid, we will have to have this high volume [*of patients*] like the physicians have done in order to be sustainable. So, I hope that doesn't happen because then you would lose, you know, the benefit of provider status." While a national decision may complicate patient volumes for clinic sustainability, it is a discussion that has reached the national stage. Provider status will be discussed in further detail in Chapter 5.

The data also pointed to the "lack of perceived benefits (on the part of) the providers" as a major barrier to the program. The diagram also noted that patients "do not receive all of the benefit" of the program. The Pharmacy brainstorming group discussed the fact that there were so many potential resources available to the patients enrolled in the PBDMP, that many patients do not receive all of the program benefits.

In terms of patient outcomes, the Clinical Group RCA diagram noted the "lower admissions due to complications" and the "high quality of service" for patients enrolled in the program. The Pharmacy Group RCA diagram also described the "patient outcomes" as a success of the PBDMP. The product and output of the PBDMP service is a key element to the current and future success of any outpatient clinical pharmacy program.

Conclusion

The data describing the program development of the PBDMP and other outpatient clinical pharmacy programs focused on multiple important categories. The clinics all discussed the community and state where the program was developed as well as the specific processes within the program itself. There were multiple ways to develop and implement a program from the cases studied. Notably, at the PBDMP, basic process steps did not markedly differ between brainstorming groups. Moreover, the internal environment of an outpatient clinical pharmacy program must also be willing to change and transform as a result of the addition of the new program.

PRACTICE FOUR

Leadership Taking on Roles in Guiding the Program Development

Multiple types of leadership in the PBDMP guided the administration's program development. Institutionally, El Rio administrators and top clinic leadership were supportive of the project goals throughout the lifecycle of the program—from initiation to present day. Departmentally, clinicians from the family and internal medicine departments were supportive of the program and took on leadership roles for care coordination for patients.

Institutional Leadership

The concept of leadership was discussed in multiple forms. Influential individual leaders were specified and teams of leaders were also discussed. The leadership choices that were made institutionally in support of the creation of an outpatient clinical

pharmacy program, were also described in many of the interviews. The Program Director of El Rio mentioned the founder of the PBDMP, "And, so, I think he saw a need from the pharmacy director's perspective, I think he really, like just understood the value pharmacists could bring in this type of model. Moving away from the dispensing role and actually making clinical interventions." These types of decisions made at a high level to direct the focus of the future PBDMP were a key element for program formation.

A key factor identified in the El Rio key informant interviews was the El Rio leadership creating an institutional culture of openness and experimentation. The Administrator from El Rio discussed the culture of El Rio, "I mean there's obviously entry barriers whether you need may resources or money or whatever you might need. But, from an organizational culture, perspective, nobody says, no, Julia, we don't want to talk about that or we don't want to do that. So, any idea that's presented, I find people are willing to talk about it and examine it and […] entertain it." This open attitude from the top leaders at El Rio instilled a culture of innovation throughout the clinic.

Moreover, innovation was reflected during the Pharmacist Group brainstorming session about pharmacist education and best practices. The El Rio Program Director created an internal website for pharmacists, RxPrescribingPearls, to share their best practices and innovations about drug therapy and patient care delivery. The website innovation served as a tool for "Pearls" of information to be shared between PBDMP pharmacists. As discussed in Practice Three, the freedom for the pharmacists at the UNC program to innovate and create the current UNC Enhanced Care Program was another example of the culture of support for new ideas.

The "Administrative support" was mentioned as a success of the program in multiple data sources and specifically identified in the Pharmacist Group RCA diagram. This support pointed to both financial and ideological support throughout program creation and implementation. The Program Director of UNC noted that after receiving the buy-in from clinic leadership, they understood what pharmacists could offer to clinical services, "And so they're very very [*sic*] receptive to what we can do and I think they've also shown other clinics the impacts that pharmacists can have and what they can do for them." The support from management was both a resource and a key element of leadership for the clinic as well as the outpatient clinical pharmacy program itself.

Departmental Leadership

From a program standpoint, the strong leadership in the PBDMP was described through hiring practices that sought specific individual personality traits for program employees. The administrators discussed the personality traits that were most desirable with the PBDMP staff for future employees and sought individuals to join the team that were most in line with these characteristics. However, the identification and weight given to each of these specific skills in potential employees were less tangible from the data. For example, the Pharmacist Group RCA diagram described the "motivated team" that was hired and mentioned that the leadership "hired well: [*employees have*] thick skins." Clinicians, administrators and pharmacists themselves described the PBDMP staff as "friendly/accessible," "accountable," and "highly qualified." These characteristics of individuals hired for the PBDMP team pointed directly to the clear vision and leadership of program directors in addressing personality matches within

program staff themselves. The brainstorming group also directly credited the "management's knowledge of staff" praising the program leaders' involvement and familiarity with the PBDMP employees.

The Administrator at El Rio pointed to the specific involvement of the PBDMP Program Director's leadership as a key driving force behind the program's creation and implementation, "I seriously have to go back to [*PBDMP Director*]'s leadership…if [*PBDMP Director*] wouldn't have shown up here, I don't think that would have happened. Because, you know, [*PBDMP Director*] was focused on that population. Very interested in connecting other resources around it, so I really think that would be the key driver." The PBDMP Program Director had experience working at the Veterans Administration and in the Kaiser Hospital system in anticoagulation and blood pressure clinics addressing chronic disease state management.

Through these past work experiences, the Director was able to shape the current and future state of the PBDMP, "I was able to take a lot of the things I really loved about other practices that were successful and not in diabetes necessarily…there were elements of the care that the pharmacists were providing there that I really liked, that brought those in, and then there were things I didn't like. And, I didn't include those. And, then I made sure that we had things like, well, things that I saw that were deficient in other sites. Like, having a nurse, like a medical assistant assigned to the pharmacist. Which in other practices, that's not usual. We make that the standard here." This vision and leadership combined with the experience of past working experiences shaped the PBDMP.

Program Leadership

There was not one definite way to begin or develop a successful outpatient clinical pharmacy program. However, clear vision and leadership were present in all of the clinics studied. Program leaders creatively shared patient outcomes with clinic leadership reinforcing the importance of the program. For example, systematically documenting positive impacts on a patient population and reporting those successes through a third-party reviewer in an objective format was imperative for administrative and clinical buy-in. The Director of the PBDMP explains that, "We did a lot of objective third-party evaluations…so that they could give us objective feedback, so that they could say, hey, yeah-this has, you know—it works! So that was it. And then we did a lot of things, publications, PR, we won awards that showed us to be exceptional like as compared to other practices in the country." Other programs, like the MHC just started the program and brought in the administrators after full program implementation, "So, I kind of know what I want to do as a Pharmacy Director. And, I just pursue it. I don't really wait for anyone's approval to do what I want to do. I know it, it makes sense and it's logical and then I present it to like my CEO—like, a year ago. I think this is the way I think we should go—I think this is the direction things are moving." Strong vision and leadership were key drivers for program creation.

The data showed that the individual "[*PBDMP Director*]" and the "Recruits from [PBDMP Director]" were major successes of the PBDMP. The Administrative Group's RCA diagram further identified the "PharmDs themselves" serving as leaders for the program. Another outcome identified by the Clinical Group's RCA diagram was positive

leadership and participation in the program "PCPs learn from PharmDs" which in turn "improves PCP [patient] management." The brainstorming group identified that the product of good leadership and communication between program employees led to "lower [hospital] admissions due to complications." These positive externalities of the PBDMP were attributable to the strong vision and leadership shown by the PBDMP Director.

One of the barriers to successful implementation of the PBDMP was the inundation of work that fell to the pharmacists. The Administrative Group RCA diagram identified that the program leadership needed to "streamline process by clinical pharmacists to not do all the work." In addition, the group identified that "using the team well" and "pharmacists not working at the top of licensure" were major concerns for program leadership. The administrators stressed that the program leadership needed to find ways to use all of the skills of each employee. While the group reflected on how they had utilized the skills of their employees, they pointed out that improvement was still needed. The Program Director at UNC noted that, "In the beginning, our manager in chief wasn't as interested in pharmacy services, and so, wasn't as big of an advocate within leadership and then that changed and luckily for us it became a physician that very much wanted to promote what pharmacists could do and utilize them to the top of their degree." Finding the management support necessary to empower pharmacists to work at the top of their level was important for program success. While empowering employees to work to the top of their degree is still a barrier at many of the clinics, identifying the need for the delegation of work and beginning to seek solutions for these issues was a

component of active leadership from program and clinic leaders.

Conclusion

There were multiple types of leadership that actively guided the development of the PBDMP as well as in the outpatient clinical pharmacy programs. Leadership that actively guided the development of the PBDMP was identified at all levels of the clinics from the institutional, departmental, and programmatic level. Leaders worked to include all employees and key stakeholders during program creation and implementation. The culture of support and innovation at the PBDMP pointed to the clinic leadership's and program staff's willingness to change. The types of leadership models these activities described will also be discussed further in Chapter 5.

PRACTICE FIVE

Collaboration and Teamwork Between Program Roles and Individuals

Teamwork at El Rio: Formal and Informal

Teamwork was described as both formal and informal in the PBDMP at El Rio. *Formal teamwork* (e.g. CPAs) was described as containing a structured team created for a specific purpose. The formal working relationships identified by the upper level management, were defined by job description and patient care coordination. *Informal teamwork* (e.g. informal check-ins about individual patients and their needs) did not include a set structure and tasks were interoperable between staff members. Informal teamwork described communication between employees of the PBDMP and the

relational coordination between work practices.

Formal Teamwork

At the PBDMP, formal teamwork was identified in the CPA signed by the participating physicians, pharmacists and clinical team members. The CPA outlined the formal working agreement behind the program and specific function of the clinical pharmacist. Setting a CPA for structured work outlined the working relationships between key PBDMP staff members. Clinical pharmacists' patient care services, including those provided through CPAs, can reduce fragmentation of care and improve health outcomes.(59) Moreover, job descriptions and divisions of labor regarding patient care were identified in work contracts and departmental agreements within El Rio. The CDTM was pre-identified by El Rio leadership before hiring a team of clinical pharmacists. Importantly, all participating clinicians contributed to the CDTM model before implementation. El Rio management tailored the CPAs and CDTM model to foster an environment of collaborative and functional teamwork under the auspices of mutual agreed upon contracts.

Formal teamwork was most articulately described in the brainstorming group diagrams as "cycles of care coordination." For example, teamwork was noted as the set of "cycles" taken by a patient as they progressed through the different areas of the PBDMP. An example cycle of care was described in the data: after a patient was seen by the pharmacist, the patient entered into a state of care with referrals to specialists, the primary care physician, and then back to the pharmacist. This formal cycle of teamwork identified in detail in the Pharmacist Group 3 Map, addressed the needs of the patient at

all stages of care identified the coordination necessary for program success. This formal cycle of care was developed over time and through active reflection in the PBDMP through direct oversight by the El Rio Program Director. The PBDMP arrived at the current structure after a series of trials and changes to the program's teamwork structure.

Another example of this formal cyclic care was described in the Pharmacist Group 1 process map, described in detail in Appendix D. As presented in the diagram, the medical assistants checked the patient's blood sugar levels, took vitals, completed a foot exam, and then sent the patient to the primary care provider. The primary care provider then sent the patient back to the pharmacist or to other clinical referrals leading the patient back into the program cycle. While each brainstorming session perceived the order of the teamwork process steps somewhat differently, the formal work cycles remained consistent. Data presented in the key informant interviews described how this type of patient hand-off and teamwork directly correlated to improved patient outcomes in the PBDMP.

Interviewee 2 from the Tucson, Arizona ACO described the importance of formal teamwork during the key informant interview, "care coordination is either an embedded component, like at El Rio for example, has embedded care coordinators [*sic*] they hire their own people to help identify high-risk people. Folks that are either at high risk for readmission, or admission in the first place, we can also call people on, you know, train wrecks, people that you know that something's going to happen." Interviewee 2 pointed out the utility of the formal job descriptions that the El Rio leadership had created—Registered Nurse Care Coordinators (RNCC)s—specifically for patient continuity and

team coordination. This foresight on the part of El Rio to identify a need within the PBDMP directly addressing coordination and teamwork was notable.

The Administrative Group RCA diagram described the formal teamwork of CPAs during the brainstorming session. The group noted that the "pharmacist-inclusive practice: CPAs" was a success of the PBDMP. This recognition of the existence of CPAs within the structure of the program pointed to both the leadership's deep knowledge of the inner workings of the program, but also to the success of the formal CPAs themselves.

Informal Teamwork

Formal teamwork identified each individual team members' role and function. In contrast, informal teamwork was not formulated or codified by clinic leadership. The ways that employees related to each other informally to understand each other's skills was reflected in multiple data sources. The key informal teamwork practices included team communication and affiliation to identify the best individuals for a specific task. Allowing health care providers to interpret details of the CPA to best fit the group dynamic was also an important feature of informal teamwork at the PBDMP.(59)

The Program Director of the UNC program described this informal understanding between pharmacists and physicians, "I think our physicians have always felt like we have functioned very much as a team, so, we're helping. They recognize us as part of that team and they recognize how we can contribute to the goals of an ACO and so we're very team-based. And, so if the patient is seeing me and I can address some of those issues then I should be held accountable to try to meet some of those while the physician

if they are meeting with the patient then they should be responsible." This collaboration surpassed typical clinical roles and expectations by arriving at a place of mutual respect between physicians and pharmacists. In many cases, identifying a team leader at the outpatient clinical pharmacy programs was a simple process due to the small number of team members and division of labor. Data showed that delineating formal team responsibilities was identified upon team formation, and informal working relationships developed over time.

The UNC Program Director identified coordinated care through informal teamwork as the preferred model for outpatient clinical pharmacy, "I think that's the best model—to have coordinated care. Because everybody brings their strength to the table." The Clinical Group RCA diagram described "communication and affiliation" as a success of the PBDMP reflecting this coordination of care between employees. In addition, the Pharmacist Group RCA diagram specified "team-approach" and "group dynamic" as a success of program delivery. This group dynamic was reflected in the group's identification of the fact that "everyone is included in different projects." During the brainstorming sessions, these self-identified groups and affiliations were described as informal teamwork, pointing to the importance of program communication to achieve a common goal.

While the data described the positive attributes informal team dynamics brought to the PBDMP, there were barriers identified relating to program consistency and expectations between employees. The Pharmacist Group RCA diagram reflected both the necessity for better provider-to-provider communication as well as patient to provider

communication. The data reflected that the need for "more communication between providers." The lack of this communication between providers described a potential breakdown in some team communication.

Culture of Teamwork

Creating a team-driven environment with mutual understanding took time for the outpatient clinical pharmacy programs. The Program Director at MHC reflected on the struggle to create shared work practices between clinicians, "For us, I really believe it is still really a work in progress. We're always talking about it in senior staff meetings. We talk about it between me and my medical director and other providers. And, part of my goal, I'm not getting ahead of myself, is the development of our clinical pharmacy practice to coincide with the medical group so that we can work as a cohesive unit—pharmacy to medical and back and forth and share the same stories and report data that we collect in pharmacy back to medical through our EMR system. So, it's still in development. There's a lot more to put together." The goal to achieve collective work between practitioners at MHC showed a desire for a culture of teamwork and cooperation.

Work culture as it related to teamwork was described by a respondent from the Tucson, Arizona ACO as fiefdoms, "But, medicine tends to be a bunch of tribes. And, so if they practice tribal medicine, in isolation, what I call—a consensus of one—then that isn't going to work." The ACO Interviewee 2 noted the importance of teamwork, both formal and informal, since a consensus of one does not create the best patient outcomes. The respondent continued to describe the types of work cultures present within a clinic

and how teamwork reflected the organization's attitude toward inclusion, "This is all important when it comes to team-care. And, so, I think El Rio does [team-care] so don't be afraid to interview or start to interview all the members of a team because I think you miss some of the sub-culture stuff that goes on there." These fiefdoms were not as present in the key informant interview with the Program Director at UNC, "…and it [the UNC program] really is to enhance the care of patients in a team-based approach. So, we're not here to take the care away from the physicians, we're here to augment that care." The augmentation rather than the replacement of care was a common theme throughout the interviews with outpatient clinical pharmacy programs.

Clear communication leading to positive teamwork was discussed in multiple brainstorming sessions. The data pointed to bilingualism as a key element of teamwork throughout the brainstorming sessions. Importantly, lack of complete bilingualism among staff members could hinder patient visits.

The presence of bilingual staff who could communicate with Spanish-speaking patients was highlighted as a strong and positive characteristic of the employees in the PBDMP. The independent characteristic of bilingualism itself did not lead to successful teamwork, but the clear communication between patients and providers and also from providers to other providers led to better teamwork. However, the lack of bilingual staff was also specified as a barrier to program success in the Clinical Group's and Administrative Group's RCA Diagrams. While a number of reasons could lead to this dissonance in the data, it is noteworthy that the vast majority of the PBDMP staff was bilingual.

Conclusion

Teamwork took two main forms informal and formal in the PBDMP and other outpatient clinical pharmacy programs. Cohesive health care teams not only have clear and measurable outcomes, but also have successful division of labor and effective communication.(52) The El Rio leadership created the PBDMP with clinical teams and measurable goals. Together, the formal and informal teams created by BDMP leadership contributed to the success of the program. The communication between team members supported collaboration and positive patient health outcomes. Teamwork was repeatedly cited as the backbone of the program structure which directly led to the successful implementation of the PBDMP and the other outpatient clinical pharmacy programs.

PRACTICE SIX

Data and Data Analytics to Inform Decisions

Data that Informed Decision Making

The clinics collected data (biometric markers, medication lists, and behaviors among others) based on disease profiles for a given patient population. These profiles were then described within the larger disease burden framework for the clinic and community. The data on patient profiles and burdens were collected using technology and specific forms of documentation. Together, these data collected served as background for informed decision-making by clinic and program leadership.

Disease Profile of Patient Population

Key informants reflected on the difficulty in understanding the needs of their patient populations seeking services at their clinics. The El Rio Administrator described what led to the creation of the PBDMP from the patient population at El Rio, "A large population of unmanaged diabetics who didn't have resources. So, most of them, you know, uninsured, or on ACCESS/Medicaid, so, a population in need and also, the other piece about the El Rio population would be majority Hispanic." The Administrator also highlighted that the PBDMP offered an opportunity to really look at culture within the Hispanic population to learn lessons for diabetes and other chronic disease. Identifying a specific patient population with a matching disease profile in need led to the creation of the PBDMP.

Multiple data platforms and tools were in use at the PBDMP showing clinic leadership a snapshot of the program's patient population. For example, NEXGEN, was the medical record software used by El Rio clinic-wide. El Rio bought and installed an i2i Track system within the PBDMP to monitor the pre-diabetic and high risk diabetes patients. The i2i system could query the patient database and produce a list of patients who had an A1C level over nine or another specific cut-off point. This tool enabled the pharmacists and leadership in the PBDMP to specifically identify the patients in highest need through the NEXGEN technology.

While tools like i2i Track and NEXGEN are modern systems assisting clinic leadership to track disease within the El Rio patient population, "common sense" was used in 2001 when the PBDMP was created. The El Rio Administrator described the

disease burden when the program began, "And, then you know once again, 2001, all the focus around diabetes, looking at the cost, recognizing what a serious disease it is, and the burden on everybody, you would have had to have been deaf blind and dumb not to go…problem!" The Administrator specified that the only method for large data analysis before the introduction of the electronic health record was chart review. In 2001, the diabetes problem was so pervasive, that the Administrator noted that all of the leadership, "saw [*diabetes*] as a problem" as well as identifying it through chart review.

A needs assessment was the tool employed by the UNC program to describe the issues facing the patient population during their program creation in 1998-1999. The Program Director at UNC noted, "So, in any effort in starting new programs, you have to do a needs assessment and so we always look at basically the data. So, if you go back to '99 that's how they came up with diabetes, and so we looked at the top ten health issues with our patient population and then looked at calls and then looked at ways that we could implement new programs and that's how we came to diabetes." Multiple key informants incorporated a full needs assessment or aspects of a needs assessment to determine population needs. Prioritization was determined through visioning meetings where data about the patient population was analyzed. This analysis was then compared to the program mission, objectives, and clinic goals. A prioritization decision was made ensuring alignment between the data presented and program goals.

Disease Burden

At El Rio, pharmacists were seen as population health managers. The pharmacists were responsible for not only the diabetes care of their patients, but also to

keep the patients from using emergency services as a source of primary care. The El Rio Administrator described this job as, "So, they're [*pharmacists*] population health managers in that regard and analyzing the patients that are assigned to them, keeping the needed team members engaged as to who needs to interact with this patient." The Administrator pointed to the PBDMP as a platform for the pharmacists to engage with other clinicians at El Rio working to keep their patient population healthy. As population health managers, clinical pharmacists employed techniques to identify the disease burden within their patient populations to drive decisions about treating diabetes within a specific community.

The El Rio Program Director described the clinic leadership in 2001 when the decision was made to create an outpatient clinical pharmacy program. The PBDMP Director discussed the past program director, "Although, he wasn't gung ho when we first met. I think what drove it was…definitely some of the audits… like I was going through my files when we moved and we had some of the audits, some of the insurance plans were getting back to our medical plans and administrators saying, here's the areas you're deficient in, and here's your HEDIS scores, and here's the benchmarks that you have to get to. So they already saw a need there because they weren't scoring as high as they needed to for some of these elements. So, that I think that drove some of our medical director—who was very data driven. I mean, this guy was like, you know, here's where we need to improve, here's the accountability for that. And, so, I think he saw a need from the pharmacy director's perspective, I think he really, like just understood the value pharmacists could bring in this type of model. Moving away from the dispensing

role and actually making clinical interventions." In former roles, El Rio's previous medical director had exposure working with pharmacists in team-based settings. It was this experience and understanding of pharmacist potential that contributed to the creation and development of the PBDMP. Moreover, leadership used data to identify disease burdens and the highest cost centers of the patient population and this led directly to PBDMP formation at El Rio.

Technology

The importance for a pharmacist to appropriately code and notate a visit with a patient in the PBDMP was discussed both from a financial reimbursement and data standpoint. The Clinical Group noted that "PharmDs have good codes" and an excellent use of "hierarchy of codes." The clinicians described that pharmacists were both able to specify exactly what was covered during their visit, and code accurately in a patient scenario.

Al El Rio, pharmacists were able to code the patients more precisely with a hierarchy of CPT codes that gave more clarity regarding a specific diagnosis than clinicians. More specific codes by pharmacists contributed to payers' understanding of the complexity of the population. The fact that the clinicians also pointed to pharmacists' expertise in coding expressly described the pharmacists' command of the coding hierarchy. The clinicians commended pharmacists' precision in coding as a clinical issue contributing to a 'warm hand-off' of patients between their departments.

Similar to i2i Track but at a larger scale, the ACO of Tucson, Arizona queried their databases to look for disease trends. Interviewee 1 for the ACO noted that, "Well,

when we go—into it we use OptumInsight. It identifies the high-risk patients and actually scores them…it's predictive software that tells you next year's predicted costs. It's not 100% accurate, but it's probably at least 50% accurate. It gives you a place on where to start. If the ACO defined a potential issue for a clinic under their purview of the potential for a high-cost event that may occur, the ACO contacts the clinic for a heads-up." Interviewee 1 further described the success the ACO has had from the use of OptumInsight, "And, so our readmit rate in an 18 month period of time went in half. It went from 18% down to 9%." While it is unclear if these readmit outcomes were solely due to the software, Interviewee 1 believed that OptumInsight was integral to their success.

Interviewee 2 from the ACO of Tucson mentioned issues with care coordination and technology. The collaborative effort of patient care coordination was described in detail, "Just to care coordination, I would say [*a barrier is*] the lack of interoperability, technology, communication, said differently: having full access to people's EHRs and being able to communicate through EHRs would just be phenomenal." This lack of electronic medical record interoperability within one community could lead to continuity of care issues if a patient sought services at multiple medical facilities in Tucson. In many cases at El Rio patients had a break in care services at El Rio and collecting medical records and information on a patient was challenging. However, even with imperfect data, care decisions still had to be made by the pharmacists at the PBDMP.

Electronic Health Record (EHR) Documentation as a Data Source

Documentation was also identified in all of the process flow maps from the brainstorming groups. In most of the process flow maps, a documentation process step was added after patient contact. The Administrative Group identified the highest number of documentation steps, while the Clinical Group did not specify any documentation steps. The Administrative Group was also the only brainstorming group that recognized both medical records and computer programs in the process map. In fact, the process map's documentation steps were so thorough that the computer system where the documentation occurred was identified. For example, after medical reconciliation occurred, "Document action in EHR" was identified. In addition, if PharmD patient contact was not made, a "referral in the MRS system" was specified. This attention to detail for the systems in place clinic-wide reflected a wide range of knowledge of clinical documentation data sources. The information generated ranging from missed opportunity reports to referrals within the clinic, assisted with the data analytics to form conclusions about the PBDMP patient experience.

Many of the brainstorming groups also identified issues in terms of the EHR reporting system. The Clinical Group RCA diagram discussed "EMR upgrades" that had a "lack of effectiveness" for patient care. In addition, the Pharmacist Group noted the "EHR reporting problems" over five times within the same diagram. The group also identified that "Man power for IT support" was lacking. These perceived frustrations on behalf of the PBDMP staff were an impediment to successful information gathering using all of the EHR tools available. These obstructions to effective data necessary to drive

decision-making were clear in both the Clinical and Pharmacist Groups.

The key informant interview with the Program Director for MHC discussed the future of pharmacy and clinical pharmacists. In the Program Director's mind, the need for clinical pharmacy will increase in coming years, "Eventually it's going to go to an ATM machine and you're going to walk in and pick up your med by putting in an access code. That's where it's really going. So, pharmacy is going to stay alive and vibrant but it has to get into another mode which is going to be more of what we were trained to do anyway which is intense counseling, more monitoring and follow-up."

The Administrative Group's RCA diagram went into depth on program promotion and data. The group mentioned the "National info and data," "longitudinal data," and "Not just A1C: longitudinal data" available to document the work of the program as successes. The Clinical Group RCA diagram reflected the "Documentation" and "Award-winning program" as indicators of success of the PBDMP.

Specifically, "Documentation" was also noted twice on the Pharmacist Group RCA diagram as a major success of the program. Documentation was turned into action steps for the PBDMP development by creating a public record of the program processes and activities, further contributing to the potential data that could be used for future publication. The "data base for outcomes" and "internal list serves" were also described as resources for the program. The brainstorming group commented that the program "works up to that, not below that" in terms of "Data standardization." Documentation was discussed in all of the brainstorming groups and was highlighted as a key factor in determining program outcomes.

Conclusion

The data collected from the outpatient clinical pharmacy programs was important through all key informant interviews and brainstorming sessions. There was a clear connection between the power of data to inform decision making at the PBDMP and the utility of software used to support the program. The disease profile of the patient population was the first step in defining diabetes as an interest area for programmatic intervention for the outpatient clinical pharmacy programs. The next step the clinics took was to identify the disease burden of the specific patient population, e.g. diabetes within a specific age group of patients at the PBDMP. Within the programs, the technology and documentation used to streamline the work was defined in detail in the data collected. Many participants in the brainstorming sessions aggregated technology and documentation to show the potential of data gathered from the program to affect future reports and publications. While some headaches were described relating to technology in the PBDMP, the data generated from the program was seen as immensely powerful to show the success of the program.

Similarities and Differences Between Programs

While the El Rio PBDMP is the largest of the three programs—both in unique patient visits and staff—there are many more similarities between all three of the programs than differences. The goal of each program is to provide disease state management for diabetes. While the UNC and MHC programs are more fully integrated with multiple chronic disease state management, the main reason all three program were

formed was based on diabetes education and management. Each program is downstream treatment-based and not focused merely on a prevention-based model since all of the programs treat patients who are already diagnosed with diabetes, not those at risk for developing diabetes. However, the main similarity throughout all of the programs was the barriers for their development and implementation due directly to billing and reimbursement.(39) As of April, 2014, pharmacists in Arizona have provider status in title only. Pharmacists in Arizona are not listed in the health insurance code for clinical payment or reimbursement.

The UNC program began in 1999, and by 2000 the clinical pharmacists received state-recognized provider status and could bill for patient services within a set scope of medication therapy management. Accordingly, upon program inception, each clinic found creative ways to pay for the pharmacists working with the clinical pharmacy programs. While each program envisioned their clinical pharmacists' roles and responsibilities differently, the impediments to their growth and future stability are the same for all clinics. While provider status in North Carolina most likely positively affected the rate of program growth at UNC, the program began with the same obstacles as El Rio and MHC.

The major differences, other than size and longevity of the programs, are the payment and reimbursement systems in each program. At the MHC, pharmacists are paid on salary from the drug dispensing pharmacy. MHC does not have dedicated staff that work on the diabetes management program team—the pharmacists are primarily drug dispensing with credentials to work clinically. In contrast, the UNC model and the

El Rio model have clinical pharmacists working only for the disease state management programs. These clinical sites also have specific drug dispensing pharmacists and clinical pharmacists on staff. The pharmacists from UNC and El Rio are placed on salary from the clinic or medical system and are not primarily paid for drug dispensing. Moreover, many of the staff members from the UNC and El Rio programs also have academic appointments, and a portion of their salaries are paid for by outside entities. The patient volume at El Rio and UNC allows for a larger and more developed program.

Furthermore, both the UNC and El Rio programs began with seed money from federal or state partners assisting with the creation of the program. The MHC program began from the ground-up from within the clinic itself under the direct influence and guidance of the MHC Pharmacy Director. While MHC does not consider the program in its current form to be a complete success, the barriers the program has overcome came from the internal supporters from the clinic and the program itself without any external financial support.(107) These similarities and differences between the programs as it relates to transferability for future program implementation will be further explored in Chapter 5.

Marana Health Center (MHC)

Marana Health Center, a Federally Qualified Health Center (FQHC), provides integrated team-based care to patients in Marana, Arizona (about an hour drive from downtown Tucson) and the surrounding communities. MHC was incorporated in 1957 and is the oldest continuously operating community health center in Arizona. There are three full-time pharmacists and five pharmacy technicians on the MHC staff. In January,

2014, with guidance from El Rio, the clinical pharmacy program at MHC officially began by supporting clinical pharmacists to receive training and certifications for diabetes education and management. Over the past five years, the MHC clinical pharmacy program tried to get off the ground and only in 2014 has the program succeeded in securing space and staff for the program.

There are three patients receiving 'complete' care through the clinical pharmacy program, and the patient volume is not expected to increase rapidly in the coming months.(107) Many other patients with diabetes receive counseling through the program, their medication management is not under the auspices of the pharmacists at MHC. There is not data to support a change in 30-day readmission data based on the small sample size of patients utilizing services at the clinic. The clinical pharmacy program is run out of the MHC dispensing pharmacy. There is a conference room for patient consults next door to the pharmacy and a smaller space cordoned off from the pharmacy itself for medication management and consults.

UNC Internal Medicine Enhanced Care Program

The information about the University of North Carolina at Chapel Hill program was gathered from an interview with the Clinical Director of the UNC program. The clinical pharmacy program at UNC began in 1999 based on a grant from the North Carolina State Medicaid program encouraging better and more frequent patient interaction. The initial program was designed by physicians and was started with two pharmacists on staff to address disease state management through chart reviews and medication reconciliation with patients. Within a few years after the program started, the

two pharmacists working in the program drafted a new disease state management plan specific for diabetes and presented the plan to the physicians running the clinic. They believed the program they created would better address clinic goals and patient needs. The pharmacist's disease-specific plan became the UNC Internal Medicine Enhanced Care Program that focuses on disease state management for over fifteen conditions through team-based care. There are four clinical pharmacists (2.25 FTE clinical pharmacists) on staff.

Within the first three years of existence between 2001 and 2003, the UNC program met and exceeded their goals for care improvement. They improved A1C levels by one percentage point and blood pressure by almost 10mmHg, compared with usual care.(118) Recently, there is data to support a decrease in 30-day readmission rate of patients participating in the UNC diabetes state management program.(108)

Today in the UNC program, pharmacists see between six to eight diabetes patients daily and over 800 patient visits per year.(108) In conjunction with hypertension, hypothyroidism, and diabetes, among other chronic diseases, the program also focuses on transitions of care for patients in and out of a hospital setting. The program has consult rooms shared with the Internal Medicine Department for use by program staff within the UNC Internal Medicine Enhanced Care Program.

As the program is based within a university setting, the UNC program is the most different of the three clinical sites. There is more leeway and potential for reimbursements for pharmacists due to their academic standing. Provider status and reimbursement for clinical services is approached differently under the auspices of a

learning or teaching hospital or clinic. Hospital-based clinics are not as limited for reimbursements as Federally Qualified Health Centers due to the "core provider" regulation mandating clinicians oversee the medication prescribing.(119) Moreover, as of July 1, 2000, clinical pharmacists in North Carolina received provider recognition under state law and can be reimbursed for direct patient care to implement predetermined drug therapies as outlined by a drug therapy management program.(120)

Chapter 4 Summary

Chapter 4 highlighted the results of the analysis, by identifying six practices consistent across multiple data sources and settings. The six practices that affect OCPP support and structure are: 1) Setting a vision and objectives, 2) Obtaining and using resources that support the objectives, 3) Defining the program structure of the PBDMP, 4) Leadership taking on roles in guiding the program development, 5) Collaboration and teamwork between program roles and individuals, and 6) Data and data analytics to inform decisions.

The practices are organized chronologically based on recommended steps for action on behalf of program leadership. Chapter 5 will continue to refine guidance for the creation and expansion of OCPPs. These key practices identified the actions, strategies, behaviors and steps program leaders and advocates employed to create and sustain their OCPP. While many key informants mentioned persistent barriers to program execution, the practices categorized the steps taken to overcome impediments and create 'best practices' for program implementation. The key practices also point to

the areas of the PBDMP that were the most applicable to assist other settings interested in creating or expanding an OCPP.

Chapter 5 identifies two analytic frames to understand the six practices identified by Chapter 4. The categories include: 1) Organizational and Strategic Alignment and 2) Program Execution. The six practices are examined together under the two categories to highlight the most common actions and behaviors taken by successful OCPPs. Chapter 5 continues the discussion of the data collected and interpretation of the findings. Further lines of research and conclusions based from this research will also be provided in Chapter 5.

CHAPTER FIVE

Discussion

Introduction

Chapter 5 focuses on the discussion and interpretation of the findings presented in Chapter 4. The key findings—organized by the six key practices—and their potential application to the implementation guidelines, self-assessment Outpatient Clinical Pharmacy Program Worksheet, and management case study will be addressed. The six practices are organized into two categories for further clarity: 1) Organizational and Strategic Alignment and 2) Program Execution.

Recommendations for the field of clinical pharmacy will be made in Chapter 5 as well as potential barriers to the outpatient clinical pharmacy program's potential success in the future. Future lines of research and persistent gaps in knowledge will also be identified and described. Chapter 5 summarizes the research and key findings from the study and their potential application to other settings. The chapter will conclude by identifying study strengths and limitations, and positing final conclusions.

Study Overview

The growth in physician, nurse practitioner, and physician assistant supply alone will not be adequate to meet the demand for primary care services by 2020.(12) Without a rapid growth in these clinical specialties, other members of a team-based model for primary health care delivery will be needed. Creating pharmacist-inclusive collaborative care teams for outpatient care is a potential solution to alleviate this health care workforce

shortage. The purpose of this study is to assess the viability and transferability of the Collaborative Drug Therapy Management (CDTM) program through a case study examination of the Pharmacy-Based Diabetes Management Program (PBDMP) at El Rio Community Health Center (El Rio) in Tucson, Arizona.

A quantitative-qualitative mixed-methods investigation was conducted in Tucson, Arizona to determine the supports and structures behind the PBDMP. Using literature and document reviews, key informant interviews from El Rio, other outpatient clinical pharmacy programs, and the Tucson Accountable Care Organization, coupled with usage of tools from lean management brainstorming group sessions, the study elicited information about how the experience of El Rio with the PBDMP can inform nationwide development and implementation guidelines for the creation of an outpatient clinical pharmacy program (OCPP).

The findings identified ways that the PBDMP at El Rio can inform other programs interested in creating an OCPP. Key contributing factors to success were the inclusion and identification of organizational strategic alignment and program execution in the development, adoption and implementation, phases of the PBDMP. Challenges inhibiting success were pharmacist provider status and reimbursement of clinical services provided.

Discussion of Results

Through careful analysis, the results from the brainstorming sessions with the PBDMP pharmacists and administrators and key informant interviews led to the identification of six common practices among the OCPPs. The six practices identified in

the data were: 1) Setting a vision and objectives, 2) Obtaining and using resources that support the objectives, 3) Defining the program structure of the PBDMP, 4) Leadership taking on roles in guiding the program development, 5) Collaboration and teamwork between program roles and individuals, and 6) Data and data analytics to inform decisions. Chapter 4 discussed how these practices were identified coupled with specific examples of each practice.

For the purposes of simplifying and streamlining the discussion, the data from the six shared practices will be discussed and compared through two larger categories—organizational leadership and program execution. While the categories offer further insight into the specific areas of data differentiation, the overarching themes of organizational leadership and program execution were present in almost all of the sub-categories defined. The different types of organizational leadership and program execution present in the data will be reflected in the discussion as well.

Category One: Organizational Strategic Alignment: This category is comprised of Practice One: Setting a vision and objectives, Practice Four: Leadership taking on roles in guiding the program development, and Practice Six: Data and data analytics to inform decisions.

Category Two: Program Execution: This category is comprised of Practice Two: Obtaining and using resources that support the objectives, Practice Three: Defining the program structure of the PBDMP and Practice Five: Collaboration and teamwork between program roles and individuals.

Category One: Organizational Leadership

How Leadership Affected Program Adoption and Implementation

As noted, this category is comprised of three shared practices: Practice One: Setting a vision and objectives; Practice Four: Leadership taking on roles in guiding the program development; and Practice Six: Data and data analytics to inform decisions. Many of the shared practices were managed or influenced by organizational leadership, which in turn, directly affected program adoption and implementation. Through culture, direct action, and guidance, leaders were able to support and encourage aspects of the PBDMP and other OCPPs during program creation and adoption.

The clinic leadership had the skills and experience to manage a diverse, and geographically dispersed group of clinicians, pharmacists, and program staff. Specifically, the clinic leaders had skills that related to multi-cultural staff integration, managing complex group dynamics, overseeing collaborative work under a CPA, and building understanding and trust between staff members. Most importantly, these clinic leaders excelled in shared decision-making. According to the CDC, the infrastructure and process changes that are necessary to implement a pharmacist-inclusive CPA model include: patient education, practice models, and business models.(59) Leaders must keep well-informed medical and pharmacy teams, create an expectation for collaboration of the health care teams, and ensure the business model is scalable, sustainable, and profitable.(59) These leadership skills, among others, outlined by the CDC are necessary to develop and implement a successful CPA agreement. The consensus building and shared decision-making skills of the leaders studied in this research was also noteworthy.

In each of the three programs studied, the clinic leadership either identified an individual to run the proposed OCPP or to assist in identification of clinic needs. These program directors were influential in developing a specific program with seamless pharmacist integration. The preferred model by all program directors was a centralized model with comprehensive collaboration among all clinic departments. However, this complex integration of multiple departments within a clinic required clear communication of the benefits the potential program would bring, and how the program worked directly impact other areas of the clinic. For example, at El Rio, the director of the PBDMP met with heads of the Family Medicine and Internal Medicine Departments to describe the program, benefits to the patients and providers enrolled in the program, and how the PBDMP would contribute to patients' control of their diabetes. Initially, it was optional for practitioners to refer patients to the program. However after a few years of the program's existence, with data showing improved outcomes for patients enrolled in the program, clinicians could no longer opt-out of referring to the PBDMP.

One of the first activities that the clinic leadership accomplished was to establish a long-term vision with broad objectives. While this is a typical task for clinical programs under development, the leaders from the clinical sites studied leveraged these opportunities to include stakeholders from the community and at all levels of the clinic to support the goals of the OCPP. The leaders continued to keep the clinic administrators in-the-loop (formally and informally) with program changes so that the buy-in the leaders garnered from the administrators was sustained throughout program adoption and implementation.(121) The leaders of each OCPP were able to apply a CDTM model to

their respective clinics while also engaging all members of their team for their buy-in before a decision was made.

The Asheville Project is a widely known example of a successful pharmacist-delivered patient care in the non-federal sector.(122) It began in 1995 as a result of a strategic planning committee meeting held by state pharmacy leaders.(122) The Asheville Project utilized advanced practice pharmacists in North Carolina to coordinate diabetes state management services to people with diabetes.(34) Similar to the findings from El Rio, it demonstrated that patients, providers, and managers believed aligned incentives and pharmacists providing health care services to patients offered a practical, patient-empowering and cost-effective solution to escalating health care costs.(34) Due to the lessons learned from the Asheville Project, the long-term vision and objectives identified by El Rio were similar to the Asheville Project's strategic visioning meeting before program implementation. Alignment between the leadership's goals and mission are critical for program success.(81)

Throughout the program planning stages in all the clinic sites, clinic leadership and program directors were mindful of their role in facilitating and enabling information gathering for decision-making processes. They understood that to keep program employees engaged they needed to share information, weigh the options, and engage program employees about intervention options. The CDC recommends interactive discussions within a CPA to determine the appropriate incentives for practitioners that lead to meaningful process measures and outcomes for all providers involved in patient care.(59) This active engagement allowed program practitioners, employees and

stakeholders to contribute their ideas for problem solving, while keeping the program vision, mission, and objectives on track. The high degree of trust and respect among colleagues in each clinical site, demonstrated by clear communication between practitioners, contributed to the success of this management process.

Organizational leadership directly impacting decision-making was present in each case site. In the case of El Rio, organizational leadership recognized the benefit of sophisticated methods of information and data collection. The clinic's electronic medical records were queried to gather program statistics for high-level decision-making. The clinic directors of the UNC program tasked two pharmacists in the clinic to design what would eventually become the UNC Internal Medicine Enhanced Care Program. This shared tasking in a CPA within a set objective had positive outcomes on program development and creation. Not only were the two pharmacists tasked with the program design engaged in the success of the program itself, they were given the option to rise to the leadership challenge within the UNC clinical setting. Other studies on organizational leadership have found that ownership is a critical factor in ensuring sustained support during program development.(123) The MHC clinic approached program engagement and leadership from a bottom-up perspective where the pharmacists from the MHC program taught the clinic administrators about the potential benefits of the proposed program.

With the support of the top leadership and continual information sharing between clinic and program leadership about the progress of the program development, the program produced positive outcomes for enrolled patients. All of the programs benefited

from increased information sharing, buy-in from clinic administrators to support the programs, and clear clinic and program objectives.

Category One Summary

Leadership was an important element of programmatic approval in all OCPPs studied. In the case of El Rio, the clinic leadership engaged directly with program directors to actively reform and change the PBDMP. The buy-in from El Rio administrators was integral at each stage of the PBDMP. The data collected from the program outcomes at El Rio further supported the program's effectiveness and potential. The data and information sharing process between program directors and clinic directors was used to make decisions, rather than personal opinion or experience alone.

Category Two: Program Execution

How the Program was Planned, Adopted, and Implemented through Shared Practices

Category two is comprised of three shared practices: 1) Practice Two: Obtaining and using resources that support the objectives; 2) Practice Three: Defining the program structure of the PBDMP; and 3) Practice Five: Collaboration and teamwork between program roles and individuals. All of these practices directly identified the PBDMP and other OCPPs' execution and sustainability. Funding coupled with effective teamwork helped guide program creation and development.

As hypothesized, the PBDMP development and execution was effective when certain aspects of the "Impetus to Transform" and "Leadership" dimensions from the OTM were present.(81) Specifically when clinic and program leadership were in line

with the program transformation goals, the PBDMP was more likely to achieve successful program adoption and implementation than without the OTM dimensions present. While progress for program roll-out was initially slow, the buy-in and engagement from all levels of the clinic structure assisted in programmatic success.

Program success was directly tied to support, both financial and non-financial from the clinic leadership. The implications from obtaining financial stability were posited as a major barrier to program creation, expansion, and sustainability. Clinics that looked to make changes in diabetes care management considered multiple chronic disease care management models before settling on a pharmacist-inclusive program. After deciding on a pharmacist-inclusive CPA model, the clinics decided they would take on the financial burden of pharmacist salaries or a combination of program staff salaries with hope that the pharmacist-led initiatives would be self-sustainable in the future.

In 2011, a collaborative project through the Connecticut Medicaid tested a pharmacy practice model in patients with chronic conditions.(124) The program was a demonstration project where nine pharmacists worked closely with 88 Medicaid patients. The pharmacists identified drug therapy problems within the population totaling an estimated $1,123 per patient on medication claims in addition to departmental savings to emergency departments at the case study hospitals.(124) The project recommended that future projects study pharmacist medication management services in primary care medical homes and explore how to expand team-based care.(124) The case study of El Rio adds to the lessons learned from the Connecticut case by exploring a potential response to pharmacist-inclusion in team-based care. Program execution and

development was a critical element for the demonstration project in Connecticut to ensure the data captured all of the potential drug interactions with Medicaid patients. The six practices identified as the conditions present during El Rio program development and implementation support the recommendations made from the Medicaid Connecticut demonstration project.

A common theme from the interviews regarded the clinic administrators and funding of a CDTM program. It was not only buy-in from the administrators that led to success—there had to be money, a line item, or actual dollars spent to create a program. Three of the interviews discussed a cycle of trying to prove the worth of the CDTM program without funding or initially securing funding from an outside source to prove program success with the hope for the program to eventually be internally funded. While not unique to this case, it was not only difficult to show success without the financial support of the clinic, it was then difficult to convince administrators that dedicated funds from the clinic would lead to similar program outcomes.(122)

The UNC and El Rio programs both received direct seed funding or demonstration grants to show how an OCPP could positively affect the clinic's diabetic patient population. From funding secured externally to the clinic, they were able to prove their current and potential future success to subsequently garner financial support from the clinic administrators. MHC received financial support through a clinic-wide HRSA grant to track diabetic patients. While this patient identification ultimately turned into the MHC clinical pharmacy program, they never received direct funds to start an OCPP. MHC directly addressed this lack of seed funding as a major barrier to program execution

since the program had the administrative buy-in for the program, but they did not have enough funding to make a program sustainable. Clinic-wide administrative support was important to create a sustainable OCPP, however, administrative or external financial support was also as important for the success of a program.

Addressing sustainability of OCPPs is important for generalizability and transferability of findings from the case study at El Rio. While lack of funding and financial support was identified as a major factor that could impede future program creation, leadership buy-in from all levels of a clinic was the most important factor for sustainability. Literature suggests that collaborative meetings and information sharing techniques between clinic leadership and program coordinators improves the likelihood of a more successful program implementation.(62) It was necessary for program creators to share the future vision and objective of the OCPP for diabetes care management, to the clinic leadership, department heads, and pharmacists. Without this understanding of the potential benefit an OCPP could bring the clinic, the program would never have been prioritized or supported clinic-wide.

The attitudes and knowledge of the pharmacists who lead OCPP development were perceived to be key characteristics of program implementation and policy transformation clinic-wide. There is agreement in the literature that engaging all members of the CPA is an important factor to sustain the health care delivery offered.(5)(59)(120)(125) It is also suggested that pharmacist-inclusive team-based care models can have larger impacts on chronic disease care management in a specific population than traditional programs that do not include pharmacists.(3)

The view of health care and the active participation of pharmacists in outpatient ambulatory care are evolving. The value of team-based care models documented in the literature has increased recognition among regulators and payers.(64)(126)(17) The ACCP suggests that pharmacists working in an inter-disciplinary setting with practitioners and other health care providers, have demonstrated that they can improve the effectiveness, efficacy, and safety of drug therapy by providing CDTM.(64) Supporting creativity and innovation through formal and informal teamwork and open communication during program development, created an environment of inclusion and transformation at El Rio.

Category Two Summary

The data gathered regarding program execution revolved around financial viability, program structure, and effective teamwork. Engaging clinic leadership in the active transformation of a clinic to an OCPP was the key variable for all of the program directors. Even though El Rio benefited from an administrative culture of innovation, the program success was hard fought by program employees and leaders. Program execution was as much political capital and buy-in from likely leadership as it was an effective and well thought-out program.

Overall Summary of Results

Multidisciplinary models of pharmacists working in community pharmacies, VA medical centers, and managed care settings have been previously described in the literature and have documented teamwork, directed ambulatory care services and

increased data on outcomes as being essential to success.(122)(2)(5)(6) This literature includes longitudinal projects, such as the Asheville Project, to smaller research studies showing clinical effectiveness of team-based care with pharmacists in HIV primary care and pharmacist inclusion in urban private physician practices.(122)(78)(55) The Ashville Project was a leader in the clinical pharmacy field pointing to collaboration between providers and employers as an important element in the success of a community-based project. Disease-specific pharmacist models such as an HIV primary care, pointed to pharmacists assisting in drug adherence and continuity of care for a disease-specific regimen.(78)

This case study produced an in-depth examination of one community health center addressing diabetes chronic care management through pharmacist inclusion. The methodologies utilized in the study helped unearth the supports and structures present in the program leading to long-term sustainability and success. Unlike earlier studies which focused on outcomes, this case study addressed *how* and *why* an outpatient clinical pharmacy program showed success and identified key practices for other programs looking to develop or expand a pharmacist-inclusive model of chronic disease care management. As El Rio previously published multiple studies citing the effectiveness of pharmacists in point of care testing, diabetes care, and chronic kidney disease, this research explores the implementation and management process through a description of the environment and variables present within the clinic supporting these improvements in disease outcomes.(7)(65)(66)

Translating Findings into Practice: Relational Coordination, Organizational Transformation, and Dynamics of Work

It is important to consider the relational dynamics of work while interpreting the findings from Chapter 4. Each of the groups were separated out into their own peer-based group—an Administrative, Pharmacist, and Clinical Group—yet each group stressed the significance of interconnected work from each segment of El Rio for a successful PBDMP. One theory that successfully incorporated coordination between roles in a relational process is the Relational Coordination Theory.

Relational Coordination Theory

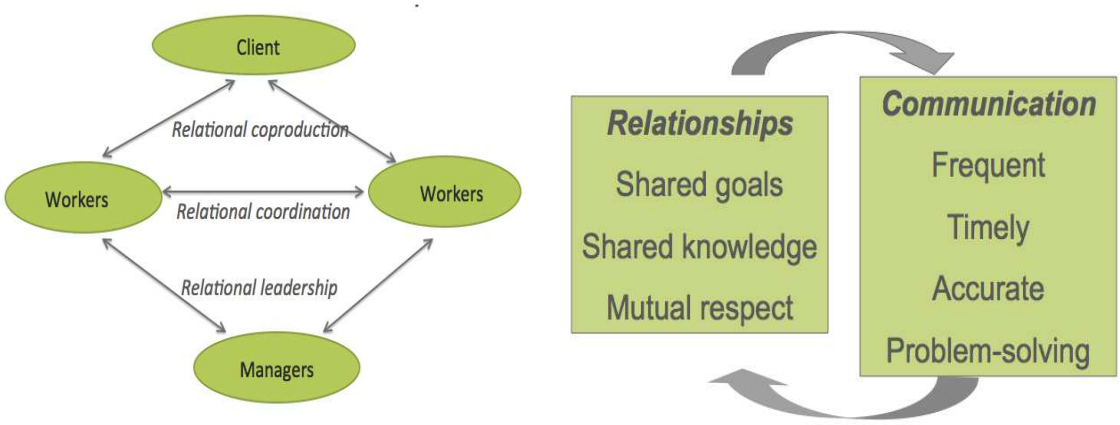
According to the pioneer of the theory, Jody Gitell, "relational coordination is a theory for understanding the relational dynamics of coordinating work."(121) Gitell et al. (2011) base the theory on James D. Thompson's seminal work on organizations from 1967.(127) Thompson argued that "effective coordination in highly interdependent task settings is characterized by "mutual adjustment" among participants, as outcomes from one task creates new information for participants performing related tasks."(121)

In the context of this larger body of work, the theory of relational coordination offers a unique way to conceptualize and apply the relational dynamics of coordination. Relational coordination is defined as "a mutually reinforcing process of interaction between communication and relationships carried out for the purpose of task integration."(51) The theory of relational coordination differentiated itself among other organizational research by arguing that shared knowledge or shared understandings are necessary but not sufficient for successful completion of a work task.(9)

According to Gitell, the relational dimensions form the basis for coordinated collective action for participants. The participants must: 1) be connected by relationships, 2) have shared goals, and 3) have mutual respect.(8) Together these three relational dimensions form the basis for coordinated collective action.(128) Fundamentally, relational coordination differs from other relationship-based approaches to coordination since relational coordination focuses on relationships between roles rather than on relationships between unique individuals. Gitell argues that the "coordination of these work relationships is the management of task interdependence and is therefore a fundamentally relational process."(51)

Relational Coordination theory assists in describing the organizational changes occurring between individuals and job positions when a new program or specific task is introduced. Work relationships are key factors addressing the generalizability of the El Rio model to other clinical settings nationwide. Figure 10 presents the key aspects of the relational coordination theory.(128)

Figure 10. Relational Coordination Theory (121)(51)



Source: Gittell JH. Relational Coordination : Guidelines for Theory , Measurement and Analysis Relational Coordination : Guidelines for Theory , Measurement and Analysis. 2011.

The PBDMP and Relational Coordination

Relational Coordination offers insights into the results from the lean brainstorming sessions to understand the nature of work dynamics within the PBDMP. Since the tasks performed in the PBDMP are completed through team-based CDTM, these efforts to care for a patient require a relational process. When the PBDMP was defined through the process mapping and RCA diagramming exercises, it became clear that there was "mutual adjustment" between process steps for effective patient coordination. Relational coordination theories are applicable for the care providers partaking and coordinating work system dynamics during these processes.

In the case of El Rio, coordinating mechanisms described in each of the group process maps highlighted this mutual adjustment to best coordinate their work processes. For example, the referral process was a cycle between three independent clinical roles (a medical assistant, clinician, and pharmacist) that adjusted when a patient entered a different disease state. The timing and cycle of care differed depending on a patient's A1C control. The RCA diagrams confirmed this cycle of patient care and identified the care team's roles during each step of the program. The relationships between the departments and individuals with different work functions were clear through the interconnected process of how a patient flows through the PBDMP. Each cycle or step reinforced what the process or step previously identified.

It is this shared knowledge and shared understanding of the PBDMP process that was necessary for the successful completion of a work task between each component of the organization. While aspects of the program were defined differently either through

immediate steps or iterative loops, it was the mutual understanding of each participant's role in the process that led to success. The shared goals and knowledge of the program and process defined how the individuals communicated between different roles to problem-solve together.

El Rio practiced decentralized decision-making and allowed the managers of the PBDMP a creative license to create a program within certain parameters. The Administrators did not micro-manage the program's day-to-day functions and instead focused on the big picture framework and how the PBDMP fit into the clinic's larger goals. Importantly, relational coordination focuses on relationships between roles rather than on relationships between unique individuals. For example, after a referral to a specialist, a patient was cycled back into the PBDMP from the specialist to the pharmacist if their A1C levels were not under control. The RCA diagrams and process maps clearly identified the coordinated nature of the different clinical roles cooperating to reach the goals for collective action of the PBDMP.

The process maps created from the Pharmacist Group were an excellent example of positive relational coordination. The understanding, respect, and task interdependence between the clinical roles was clearly delineated in the map and discussed during the brainstorming session. (Appendix C) For example, one of the medical assistants identified a process step (e.g. a patient no-show) and then continued to move on in the process mapping exercise showing how it affected the pharmacist's schedule and future scheduling. A pharmacist interrupted the conversation to explain why this patient no-show not only affected the pharmacist's schedule but the medical assistant as well. The

pharmacist explained that if there was a patient no-show, the medical assistant would then follow-up with the patient by sending a written letter and placing a phone call. The pharmacist suggested that these steps, along with the pharmacist's steps after a no-show, also be reflected in the group's map. This example of interconnected work and mutual understanding of how one action sets into motion multiple reactions within one process is not unique to this study, but is still important to identify in this setting.

Creating a culture of mutual respect and understanding where all individuals involved in a process rely on each other for shared success is necessary for an OCPP. Coordinating work efforts while keeping in mind that the dynamics for these tasks may change depending on the setting is important when clinics are thinking about adopting a CDTM model for an OCPP. Adopting a culture of interaction for communication and relationships to succeed in task integration is important for the implementation of a team-based OCPP model.

An essential element to understanding the PBDMP's success is based in El Rio's innovative culture and trust. Literature points to health care organizations that encourage a culture of safety leading to high-reliability between employees.(129) High reliability in a health care setting focuses on three central attributes: trust, report, and improve.(129) In 2001, after a series of failed programs directed at serving the high burden of diabetic patients at El Rio, the administration agreed to take a chance with the Pharmacy Department and let them create a pharmacist-based solution to the high burden of diabetes at the clinic. This leap of faith and trust was part of a larger organizational transformation for El Rio as they shifted into an era of embracing alternative solutions

and open-mindedness for patient-centered solutions. The new perspective was brought on due to a high number of diabetic patients seeking services at El Rio coupled with instrumental leadership guiding grant applications and program development. The Administrator at El Rio described this transformation in the early 2000s as part of the new ecology of El Rio: "You know if you think about the ecology of El Rio, as a general rule, is that it is an organization and culture of innovation. Let's try new things, you know, as far as that kind of gathering. There aren't barriers in this organization to try new things."

Study Findings and the Connection to Existing Theory

Relational coordination identifies the work between individuals in the PBDMP, while the organizational transformation model offers insight into the transition of El Rio to the adoption of the PBDMP. While it is important to understand the factors that led to the successful creation of the PBDMP, it is also important to recognize the interconnectedness of the work between those involved in the PBDMP.

The Organizational Transformation Model assists in the identification of the major stakeholders, barriers, successes, and extrapolates these findings on a macro-level for overall clinic or organizational transformation. These major leadership shifts in direction and alignment for a program are necessary for its success. Transformation occurs over time with iterative changes being sustained and spread across the organization, organizational transformation takes leadership, dedication, and sustained support to succeed.(81) At El Rio, successful transformation occurred with the inception

of the PBDMP. Successful application of relational coordination was also present between the participants within the program.

During the conversations with both key informants from the PBDMP, they mentioned the existing culture of innovation present in the late 1990s into the early 2000s. New Pharmacy Directors and Medical Directors joined El Rio and made creative patient-centered programs their mission. Around this same time, there was a critical mass of Administrators able to influence decision making in favor of innovative projects utilizing current staff to the top of their licensure. When the current Administrator at El Rio joined the team in 2009, the PBDMP was in already place. The PBDMP was an original project identified by the Administration since it reinforced employee interactions between task integration, relationships, and communication within the program.(121) Importantly, this study connects Relational Coordination Theories to the Organizational Transformation Model by revealing interconnected work between roles in one system within the larger clinical landscape of innovation.(81)(121)

Clinics looking to participate in a CDTM model OCPP need to identify if organizational transformation is needed, or if the clinic administrative and leadership environment would be responsive to the addition of a new clinical program. Interested parties should also consider relational coordination as a major aspect of the coordinated work needed for a successful OCPP. Both organizational transformation and relational coordination theories are applicable for all settings independent of financing, patient volume, or potential workforce.(81)

Limitations of the Study

Case Study

While it is important to understand the key similarities and differences among other CDTM programs studied for this analysis, this research is a case study of El Rio and its PBDMP. Since case studies are naturally difficult to generalize for other settings, the data collected in this mixed methods study combine both findings from a specific El Rio case study—the process mapping and RCA diagrams of the PBDMP—with key informant interview transcripts from multiple study sites. An important limitation for generalizability for this research is due to the imbalance between the amount of information gathered from one clinic site, El Rio, and the other sites.

The three clinic leaders interviewed not only have different structures, patient volumes, and clinical staff—they are difficult to compare to each other at any one time, let alone over time. While the diversity of clinical sites adds further dimension and strength to the study findings, it can also be considered a variable difficult to interpret for study generalizability. The patient volume of the PBDMP at El Rio is almost ten times the size at MHC. The study sites and key informants interviewed were chosen specifically for their perceived 'success' in settings that were different than El Rio. Since this research is not a multi-site case study, comparing these disparate programs to each other was not a reasonable research methodology.

While the triangulation of the data was hindered by the lack of primary documents from El Rio's PBDMP creation, the convergence of multiple data sources, use of multiple data collection methods, and literature describing pharmacist team-based care, increases

the credibility of the results. While the sample size for this research was small, the findings are valid. The El Rio case study of the PBDMP was limited to the examination of the seven outpatient clinics within El Rio. Moreover, the findings reported may be unique only to El Rio—it has yet to be applied to other settings using the implementation guidelines as a blueprint for the creation of an outpatient clinical pharmacy program.

The study's timetable may have impacted the outcomes of the lean management brainstorming activities. As previously noted, The El Rio Program Director and Administrator participated in a key informant interview before the group brainstorming sessions. Previous exposure to the study questions may have biased their participation in the lean management data collection.

Practical Implications and Recommendations

There are multiple practical implications that can be gleaned from this research for practice and research in the field of clinical pharmacy.

Implications for Practice

1. Team-based care and leadership are necessary features for an OCPP to possess in order to address the development, adoption, and maintenance of a program.

2. Strong support in the form of non-financial buy-in is integral for clinics looking to implement an OCPP program. Support can also be in the form of financial support, but the non-financial support from the internal management of the clinic is most

important. Strategic buy-in and engagement from clinic leaders is integral for program success.

3. Provider status through the Social Security Administration is an issue for current and future CDTM model OCPPs. The data pointed to impediments such as the lack of reimbursement for pharmacists affecting their engagement in clinical practice and future program sustainability. Multiple RCA diagrams from the brainstorming sessions also cited a lack of pharmacist provider status itself as the major impediment to development and implementation of more outpatient clinical pharmacy programs.

4. Empowering a team with members from all educational backgrounds can be a challenge in group dynamics. Pharmacist-inclusive OCPP teams allow for all members of a group to feel comfortable to express their opinions and strive to work at the top of their education level.

Key Findings and Additions to the Field

This research unearths important truths about the creation and implementation of OCPPs. Prior research has consistently shown that "health care organizations should now be working toward facilitating an interdisciplinary team approach to address the needs of their patients."(81)(51)(5)(65) Multiple national associations of pharmacists have printed guides for pharmacist to pharmacist program development. What was missing from the literature was a clinic-wide guide for multiple audiences—specifically

clinic leadership and administration. In the 2009 ACCP report, the implications, questions and conclusions from their research pointed to State and Federal legislators, examination boards, and the healthcare system to make changes in current practice to support pharmacist-inclusive teams.(130) This case study adds to the literature to describe the inner workings of an effective team-based care model of chronic disease state management. In addition, the products and findings from this research are written for the lay user to address patient-centered primary care in outpatient practice.

The CDC's Action Steps outlined in the 2013 report on CPA agreements, points to setting up inter-professional teams and "showing relevant stakeholders the value of aligning incentives."(59) This case study directly addresses this action step producing results on how to support the structure and function of OCPPs. The key drivers for transformation at El Rio were identified through the six practices. These practices coupled with recommendations for the field of clinical pharmacy in this chapter will hopefully guide behaviors and attitudes of administrators and policy makers when considering whether or not to move into the field of clinical pharmacy.

Applicability to Other Outpatient Clinical Pharmacy Programs

The findings from this investigation that are most applicable to other settings include the application of the six key practices reflected in this case study. The practices identify attitudes, behaviors, and factors influencing the PBDMP during formative program creation and implementation. The practices attempted to determine the type of information or processes that would best support decision-making and the maintenance or

creation of OCPPs.

One of the strengths of the PBDMP is the focus on relationships between roles rather than on relationships between unique individuals. The trust in the program to create iterative cycles of program referrals, specific physician or clinician visits, and pharmacist check-ups ensures the continual checks and balances of the program from within the PBDMP itself, but most importantly clinic-wide for diabetic patients.

The buy-in of the administrators and managers of the clinic is necessary for program development as well. The PBDMP was created under the guidance of El Rio leadership ensuring their support from the beginning of the project. An OCPP needs to continue to remind the Administration of its value, reach, and patient impact to confirm its continued existence. The El Rio Program Director pointed to the importance of this Administrative buy-in: "We [*pharmacists*] are with patients, but not with administrators or the business office or all of these other things that you really have to become very astute at being able to do so and do it effectively."

While a business manager can assist or replace a clinician-led OCPP, those clinicians interested in creating an OCPP need to learn how to wear two hats: 1) as a business manager identifying why an OCPP makes financial sense for the clinical setting and 2) as a clinician caring for patients and their medication therapy management. While these recommendations may not be limited to a clinical setting, they are applicable to OCPP development and implementation.

Using a PRECEDE roadmap to cover the Social, Epidemiological, Behavioral, and Ecological Assessment of the program's clinic and patient population is helpful to

identify potential barriers to program adoption and implementation. The PRECEDE framework points to the key elements of leadership and teamwork as the most important factors for program success. OCPPs can create a planning PRECEDE roadmap, or another theoretical framework that fits their clinic site, to map their program like a behavioral intervention for an individual, but in the case of CDTM—a cultural clinic-wide behavioral shift for a large population of uncontrolled diabetic patients.

Based on the six practices, Table 11 describes the actionable steps program directors and clinic administrators can take to replicate the successes of the El Rio PBDMP.

Table 11. Actionable Steps for Program Directors

Practice	Actionable Step for Program Development/Maintenance	Importance for Clinical Pharmacy
Practice One: Setting a vision and objectives	• Set clear priorities, a vision statement and mission for the program.	• The combination of these steps is integral for an organization's success. • The alignment and specificity of mission, vision and priority setting is important to support pharmacist inclusion in team-based care.
Practice Two: Obtaining and using resources that support the objectives	• Consider all potential avenues for support—both internal and external • Do not overlook current staff, physical space and current infrastructure as potential program supports. • Work to secure the non-financial support of clinic leadership and practitioners.	• The most likely barrier for sustainability in most outpatient clinical pharmacy program (OCPP)s is funding. • Consider all current clinical supports and how they can be leveraged for external or internal financial support.
Practice Three: Defining the program structure of PBDMP	• Create a Collaborative Practice Agreement for formal pharmacist inclusion in team-based care. • Make sure the program vision and leadership are in line for program sustainability.	• The specific number of OCPP patients is less important than the overall attitudes and behaviors around the program's structure. It is important that clinicians and employees support the program process flow.

Practice Four: Leadership taking on roles in guiding the program development	• Clinic and program leaders need to include all employees and key stakeholders during program creation and implementation. • Support innovation and foster a culture of openness within the program to support staff creativity and problem solving.	• Identifying the administrative support from the clinic leadership is essential for clinic-wide program buy-in and acceptance. • The more buy-in and support the program receives from all sectors of a clinic the higher the likelihood of program success.
Practice Five: Collaboration and teamwork between program roles and individuals	• Identify formal and informal teamwork within OCPP staff to support program collaboration. • The culture of teamwork and work practices were defined both through formal agreements, but also through information working relationships.	• Clear communication between employees leads to better collaboration in formal and informal working relationships. • Supporting the informal networks of team-based work strengthens program collaboration.
Practice Six: Data and data analytics to inform decisions	• Data collected from the OCPP is important for decision-making. • Technology and documentation assist in data collection.	• Data platforms through the use of electronic medical records, among others, assist pharmacists in the assessment of a patient population and specific health needs.

Implications for Research

1. Utilizing a theoretical road-map like the PRECEDE portion of the PRECEDE-PROCEED model allows researchers to uncover the layers of program development present in an OCPP. Applying theoretical frameworks to work practices and program structures can help identify supports and structures leading to a program's successes or impediments.

2. Theoretical frameworks identifying the type of transformation that occurs at clinics when an OCPP is adopted, like the organizational transformation model, is helpful for identification of current processes and future recommendations.

Limitations for Future Lines of Research

Benchmarks and Analytics Needed

Examining the PBDMP and other OCPPs in the future may require new and different approaches to data collection and analysis. No benchmark data presently exist for assessing an OCPP like the El Rio PBDMP. Future studies should explore how to codify and assess an OCPP given the variation of size and patient outcomes in the field.

To examine patterns, structures, and support mechanisms for OCPP success, researchers need to expand and crystalize their definitions of success for an OCPP to best identify the overarching themes and aspects that make a pharmacist-inclusive program function well. Clinics should create benchmarks for themselves identifying when they have completed a task or reached a goal. These benchmarks should be shared through pharmacist trade organizations and used nationwide. Importantly, benchmarks along with the most important recommendations for OCPPs are integrated into Intervention Guidelines in Chapter 6. The Implementation Guidelines focus on eight key areas: 1) People and Human Capital, 2) Political Environment, Legislation, and Rules Regarding Collaborative Drug Therapy Management (CDTM) and Collaborative Practice Agreements (CPAs), 3) Place, Environment, Setting for a CDTM model, 4) Patients, 5) Benchmarking, 6) Time, 7) Support, and 8) Finances.

Gaps in Knowledge

In addition to better benchmarking for the field of OCPPs, it is important that each clinic and program decide what is most important for the patient population, and work to address that clinical gap in patient needs. Disaggregating outcomes from social

determinants is especially difficult in a low-income patient population. The measure of success and prioritization for specific programs may differ depending on the metric used. Higher-income patient populations may experience a difference in patient outcomes when compared to a lower-income population. Incorporating these potential nuances from social determents in the study population is important to note in the initial needs assessment. From the needs assessment, the projected patient demand and volume can be determined. Social determinants may also need to be accounted for in the calculation used to identify patient needs and potential solutions.(114) The lack of research on OCPPs and longitudinal effects of patient enrollment in pharmacist-inclusive collaborative practice is necessary to address the current gaps in knowledge about what OCPPs are able to achieve.

Field of Clinical Pharmacy

The lack of a solid identification of the number of clinical pharmacists practicing nationwide is a major limitation in the field of clinical pharmacy, impacting the potential scalability and feasibility of OCPPs nationwide. It is helpful to know the number of pharmacists interested in practicing clinical pharmacy and not solely drug dispensing. By identifying the number of individuals practicing in the outpatient field, it is easier to advocate for other pharmacists to join the CDTM practice in other clinical settings. At the same time, the opportunities available for these pharmacists to practice clinically is difficult to assess.

While the Executive Director of the APhA Foundation, Mindy Smith was able to estimate the number of clinical pharmacists practicing nationwide, this estimation does

not include the number of OCPPs nationwide.(24) These disparate estimations make extrapolation challenging for this research since it is not inclusive of all the OCPP-type clinics or programs nationwide. Moreover, this investigation can only estimate the number of pharmacists interested in practicing clinically, but cannot identify if any of them are already working in a semi-OCPP type or full OCPP practice.

Recommendations for Clinical Pharmacy

The field of clinical pharmacy has many hurdles ahead since there is a dearth of literature, statistics, and knowledge of their existence or workforce. There are multiple recommendations for the field of clinical pharmacy to gain momentum and a higher profile.

Workforce Estimation Issues

The annual American Society of Health-System Pharmacists national survey includes multiple choice options for pharmacists to identify their scope of practice.(23) The areas identified for current employment include the following sections: Community, Health Systems, Public Administration, and Other. All drug dispensing pharmacists and pharmacists working in an inpatient setting are able to identify the most appropriate response given these options on the survey form. One recommendation would be to disaggregate the "Other" field so pharmacists working in outpatient clinical pharmacy would be able to identify themselves more readily. Codes could also be added specifically for "Clinical Pharmacy" and "Academic" to the survey as well.(23) Moreover, pharmacists splitting their time between academic positions and clinical

pharmacy are unable to identify either of their roles accurately given the current options. The survey needs to allow pharmacists to identify the number of hours dedicated to each role so that the number of FTE hours of clinical pharmacy can be accurately calculated. The practice sites should be more detailed and offer specific work sites to best address current pharmacist workforce numbers.

The APhA and ACCP should work with the U.S. Department of Labor (DOL) to identify key differences in pharmacy practice. While the DOL estimated pharmacy supply based on licensure, the number of pharmacists with multiple licenses in different states and how they are counted in their statistics is unclear.(50) Since ACCP defines the potential for a pharmacist to work in a state by the number of licenses they hold, the DOL estimated the number of pharmacists by their licensure number. Reconciling these numbers and how pharmacists are counted for workforce estimations are paramount and especially important for the future of clinical pharmacy. The statistics used to estimate the number of pharmacist are only as good as the data collected from the annual surveys and number of licensures used by APhA and the DOL.

Patient Demand

To identifying potential patients for an OCPP, clinics need to assess the burden of pre-diabetics and current diabetics. Conducting a database query on the electronic medical record software or through a chart review, will usually allow a clinic to see which of their patients with diabetes have an A1C level over 9 indicating the number of uncontrolled diabetic patients enrolled at the clinic. One approach would be to include an EMR dashboard notifying caregivers if a patient's biometric markers or A1C levels reach

a certain level. Estimating the need for a diabetes management program as a CDTM or MTM model is directly linked to the number of pre-diabetics, diabetics, and projected diabetics seeking services at a clinic. The threshold level of demand to begin a program is site specific, but creating a baseline for comparison is important for the field of clinical pharmacy. The determination of the patient demand threshold would be a major contribution to the field of clinical pharmacy.

El Rio was able to estimate the projected demand for patient services based on current numbers of patients with diabetes. El Rio was then able to show that diabetes was a major burden for primary care clinical services and create a program for patients and providers. El Rio identified that the burden of diabetes was high enough to create a program specifically targeting all aspects of diabetes itself during one visit and not as a comorbid or underlying disease while seeking other services. After trying to use physicians for diabetes management and then nurse case managers during "Diabetes Day," El Rio was open to pharmacist-inclusive programming suggestions. These steps are important to identify since estimating patient demand and appropriate program development can be complex depending on the patient population.

Moreover, clinics and hospitals looking to implement an outpatient clinical pharmacy model need to also make estimations for the potential future demand of outpatient clinical pharmacy services based on chronic disease medication use and not only on the number of patients enrolled in a program. The likelihood that a patient will develop diabetes if they have a specific disease profile may increase and impact future demand projections. Creating an algorithm or mechanism to determine a clinic's current

and future diabetes burden would be a recommendation for the field of clinical pharmacy to create through future research. In 2008, Thomas Johnson published a paper estimating the pharmacist workforce in 2020.(20)(38) While it would be feasible to use a similar systematic review to estimate patient demand, this calculation, research, and discussion will hopefully be addressed in future publications by Johnson and other researchers.

When potential OCPPs are thinking creatively about patient demand and potential patient volume, it may be worthwhile to consider combining an OCPP within a pre-existing outpatient clinical model. Integrating an OCPP within a physician, NP or PA clinic where patients make appointments when they are sick, or even during their weekly, monthly, or annual check-ups, it is conceivable that a pharmacist could be on the clinic's staff to run an OCPP as part of the outpatient model. Instead of creating a whole independent program as a separate entity to the clinic, one option would be to integrate it into outpatient family practice like at the UNC program. For example, the key informant from the Tucson ACO cited an ophthalmology practice where a successful program was in place. The practice offered routine ophthalmologic visits and additional services, within a formal program for specific disease states, were offered when needed. Not only did the program save the overall practice money, the patient outcomes were successful. This type of program would increase patient volume for an OCPP almost immediately due to the high number of patients who would be able to seek their diabetes check-ups at the same time as their primary care clinical visits. Since potential OCPP participant clinics already have a high volume of diabetic patients in their clinical care practice, adding a pharmacist to the team-based care may work well for specific clinics.

Future Lines of Research

This study uncovered multiple gaps that can be addressed with future research. While conducting the case study research within El Rio, numerous future potential studies became apparent within El Rio itself. Addressing collaborative practice agreements in OCPPs may also add to the current literature especially due to the future expansion and necessary cooperation of primary caregivers in the next decade.

El Rio

Research participants readily suggested that this type of program analysis should be conducted in multiple El Rio clinical sites to see the differences among the El Rio program itself. Without even comparing the PBDMP to other national programs, there was enough data to support a case study within a case study of the differences between how the PBDMP functions at the eight different El Rio locations participating in the PBDMP in Tucson.

Conducting an analysis comparing the nurse care coordinator system at El Rio with the pharmacists working with the PBDMP may uncover areas of synergy between the nurses and pharmacists at El Rio. There could be more collaboration between the primary care nursing staff and the pharmacists at the PBDMP to treat patients as a primary care team. Adding more people to the PBDMP may not seem like a typical solution, but there may be an area where nurses and pharmacists could work together to address a patient enrolled in the PBDMP.

Following-up with the other 16 grantees of the HRSA demonstration project would provide even further insight into supports and structures of OCPPs. Comparing El

Rio to the other 2001 HRSA study sites could potentially add a new perspective to the literature of federal seed grants and OCPPs. Identifying OCPP development within the clinics from other demonstration grant recipients would also be worthy of future study and add to the gaps in current knowledge.

Collaborative Practice Agreements (CPAs)

Studying an outpatient clinical pharmacy program through Collaborative Practice Agreements as a methodology would address a gap in the literature: comparing similar programs utilizing different types of licensed health care professionals. For example, a study comparing a CPA agreement utilizing Nurse Practitioners as compared to a CPA with a pharmacist-inclusive practice would be beneficial to the field of applied team-based care for chronic disease state management. Studying programs based on the type of licenses of employees may not be as beneficial as the mechanism and methodology of the program itself.

Provider Status

A study directed at comparing all the professions without provider status that practice clinically would inform pharmacist provider status. Researching clinical and cost-effectiveness with Naturopaths and other allied health professionals without provider status would address current gaps in knowledge, especially when compared to a pharmacist-inclusive outpatient practice model. Conversely, studying the previous passage of provider status with health professionals as it relates to pharmacist provider status, may also be worthy of study.

A complete case study of the most restrictive states for pharmacist collaborative

practice models would add to the current gaps in literature in the field of clinical pharmacy. In addition, interviewing pharmacists and state legislators in Alabama and Delaware where the scope of practice governing pharmacists is the most restrictive may help define key issue areas facing pharmacists nationwide.(120) A socio-ecological study addressing provider status at all layers of policy, community, and pharmacy would help identify the potential impediments to the passage of pharmacist provider status and consequences of not allowing CDTM models.

Creating a research project that followed the path of drug dispensing pharmacists joining an OCPP would add a first-hand report to the literature. A follow-up study could also research how to potentially combine drug-dispensing pharmacy into a pre-existing OCPP. Looking to drug dispensing pharmacists for more active engagement in OCPPs is important for MTM and the future of chronic disease state management. Studying the incorporation of drug dispensing pharmacy into an OCPP is most applicable and important in rural or hard to access communities where there are few pharmacists who cover the spectrum of disease state management.

Patient Protection and Affordable Care Act (ACA) and Current Legislation

The overall goal of the ACA is for health care reform to improve patient care, quality and outcomes while reducing cost. The ACA health care reform implementation process at the state and federal levels will continue for years to come along with ongoing Congressional discussions about different provisions and aspects of the law. The APhA is advocating for the inclusion of pharmacist-provider patient care services throughout this process.(131) Numerous provisions within the law either impact directly or could impact

pharmacists. The provisions directly addressing CDTM, MTM and OCPPs include integrated care models, transitional care models, and Accountable Care Organizations (ACOs). Notably, patient-centered medical homes (PCMH) are expected to increase care coordination and communication that will hopefully transform primary care in the coming decades.(132) CDTM models are an excellent response to ACOs seeking PCMH options for outpatient practice.(5)

Importantly, the creation of nationwide ACOs that address wellness at a community and not at an individual level will hopefully look to CDTM models to address chronic disease care management. The ACOs interviewed for this research were very supportive of the PBDMP but knew that the program was not financially independent and received funds from the El Rio administration. If an OCPP were able to show clinical and cost effectiveness, more ACOs may be more willing to look to alternative community-based long-term care management programs. Future lines of research could focus on the potential of ACOs to fund CDTM models to address chronic disease care management at a population level.

In January 2015, two bills, H.R. 592 and S.314, were introduced in the U.S. House of Representatives enabling Medicare patients in medically underserved communities to better access health care through state licensed pharmacists. These bills directly address pharmacists serving in a medication dispensing and counseling role similar to MTM. Both bills could have a large potential impact for CDTM, MTM, and OCPP awareness and legal status nationwide. As of July 2015, both bills are still active and adding co-sponsors. While the likelihood of these bills passing both the House of

Representatives and Senate may be low, H.R. 592 currently has 166 co-sponsors and S.314 has 24 co-sponsors.(133)(134) Moreover, while the feasibility of these bills serving as actual solutions may be low, it is important to recognize that language and bill creation around the issue of pharmacists practicing clinically is currently being debated.

Transferability

There are many factors that influence an OCPP in their nascent stages including; funding, non-financial buy-in and support, establishment of a vision and mission, and a clinic's impetus to transform, among others. There were many unique contextual factors in each of the case sites. As the case study methodology allows for isolation of a phenomenon of interest, in this investigation, the existence of clinical management processes served as structure and support for the CDTM model at El Rio. Through the application of the PRECEDE section of the PRECEDE-PROCEED model and OTM, the identification of the foundational aspects of the El Rio program inception were defined.

The question of transferability and application to other settings was addressed through the identification of six common practices used across the clinical sites to support program execution and function. The inclusion of multiple methodologies to define, adopt, and sustain an OCPP can be used in future settings seeking to expand or create a pharmacist-inclusive practice.

There are potentially multiple issues regarding transferability for this research. Since the patient volume of each of the three CDTM programs studied were drastically different, it is difficult to assess if comparing them between each other will lead to any

larger transferability or generalizability for future OCPPs. While the case study methodology can provide a framework to study multiple organizations, groups, or structures, the scope of this research was to study just one case: El Rio.

To increase potential transferability for other settings, all three data sets (the process mapping and RCA diagrams of the PBDMP and key informant interviews) were combined and analyzed together. The question of this research was to identify the supports and structures of each program—the genesis of the program, impediments, successes, etc., and extrapolate implementation guidelines for a broader audience from the research. While the programs are undeniably different, they shared similar barriers and successes to program adoption.

The pharmacy at MHC worked to prove that there was a patient population in need of a long-term chronic disease management program to receive clinical funding, while El Rio's administrators identified that a pharmacist-inclusive demonstration grant would address the burden of diabetes among their patient population. The fact that both clinics felt there was a need for a team-based OCPP is the key factor for transferability. If data is gathered and analyzed to address the question of a pharmacist-inclusive team-based care model, it would be possible to potentially identify the benefits of pharmacists working with chronic disease state management.

Perhaps the biggest challenge for OCPPs is that most clinics nationwide likely do not know they exist—or are even a potential solution for their chronic disease care management. OCPP program adoption can be more of a question of promotion rather

than an issue of fit for clinics since an obstacle to program adoption is promoting OCPPs even as a potential clinical solution.

Transferability of leadership characteristics is the hardest piece of the OCPP model to explain and encourage in potential clinical adopters, outside of senior officials in clinic leadership. Identifying leaders within an institution for day-to-day program execution is difficult, and then promoting OCPPs as a potential clinical option is even more difficult. All of the clinics identified have undeniably charismatic leaders who spearheaded the entire CDTM models at their clinics. Bottling up this leadership is impossible, but creating awareness about OCPPs and hoping it reaches similar leaders in other organizations is a potential solution.

This case study struggles with attributing success due to the environment in which the PBDMP at El Rio flourished or program structure itself. Specifying the conditions and critical pathways present during the PBDMP creation and implementation were integral to the identification of the six practices in Chapter 4. Disaggregating the presence of a supportive environment from a well-thought out program is difficult to analyze. Together, these critical elements within the El Rio community coupled with a unique staff supported PBDMP core development. Literature supports the idea that "the ability of an organization to innovate or adopt new programs will vary based on context."(123) All three case sites presented a supportive environment and staff, while the outcomes of each program were drastically different. Addressing which characteristics are sufficient versus necessary for successful program development and maintenance is an area for future study.

Conclusions

Thinking ahead to 2020, the need for expanded access to primary care forces us to look more broadly within the healthcare system to identify opportunities to expand capacity to provide quality primary and preventative care services especially related to chronic disease care management.(5) In response to the serious projected shortcomings in primary care, the U.S. can benefit from considering pharmacists as a potential source of support for primary care delivery and medication management. This case study of the Pharmacy-Based Diabetes Management Program at El Rio Health Center contributes to our understanding of team-based and pharmacist-inclusive collaborative care model research by proposing methods for adapting the implementation and adoption of a collaborative drug therapy model at El Rio for nationwide guidelines. By utilizing a mixed-method research approach, this study also advances the position of pharmacists within a clinical setting where an outpatient clinical pharmacy program is a potential clinical program addition.

The key practices and conditions that were present in all of the OCPPs studied included: 1) Setting a vision and objectives, 2) Obtaining and using resources that support the objectives, 3) Defining the program structure of the PBDMP, 4) Leadership taking on roles in guiding the program development, 5) Collaboration and teamwork between program roles and individuals, and 6) Data and data analytics to inform decisions. The six key practices were best characterized by two categories of qualitative findings: 1) Organizational strategic alignment and 2) Program execution. These two categories described how the practices interfaced with the clinics and outlined the set of behaviors

and actions taken to support OCPPs.

This study is part of a growing effort to understand how to explore pharmacist-inclusive practices in outpatient care settings. Derived from the PBDMP and other clinical sites, six practices detail the development and implementation of an outpatient clinical pharmacy program. El Rio's vision of a pharmacist-inclusive team-based care model from chronic disease care management provided the inspiration for this investigation. Hopefully the practices can be adopted and used by other OCPPs working to reduce the burden of diabetes or other chronic conditions in their communities. These findings point to practical implications and recommendations for how clinics can utilize the Intervention Guidelines and Outpatient Clinical Pharmacy Worksheet to improve pharmacist engagement.

CHAPTER SIX

Implementation Guidelines

The Implementation Guidelines for Outpatient Clinical Settings Assessing the Potential Integration of Pharmacist-inclusive Collaborative Drug Therapy Management (CDTM) are described below. The document includes four sections: 1) Purpose of this document, 2) Definitions of collaborative care, 3) Responsible organizational decision making, and 4) Implementation guidelines.

Purpose

The Implementation Guidelines for Outpatient Clinical Settings Assessing the Potential Integration of Pharmacist-inclusive Collaborative Drug Therapy Management (the "principles") have been created to provide direction and guidance to outpatient health care providers and administrators in identifying and advancing the potential role of pharmacist-inclusive chronic disease care management teams.

These implementation guidelines provide further details on how participating outpatient clinical pharmacy settings will put the principles into practice. The purpose of this document is to:

- Describe a set of actions that applies and adopts the principles.
- Provide direction for clinics on how to implement the principles.

The principles consider the development of different versions of the implementation guidelines that may be tailored to specific regions or sectors.

Importantly, the implementation guidelines are intended to direct practitioners and administrators through the initial stages of development or expansion of an outpatient clinical pharmacy program. The information provided in the guidelines is an overview of the initial requirements of an outpatient clinical pharmacy program coupled with sets of generalized recommendations for each category. Table 12 elaborates on the recommendations by providing primary sources (books, websites, and forms) dedicated to specific subject areas.

Table 12. Sources for Further Research on Outpatient Clinical Pharmacy Programs

	Organization/Division	Resource Description	Accessing the Resource
Federal Resources			
	Centers for Disease Control and Prevention (CDC)	Collaborative Practice Agreements and Pharmacists' Patent Care Services: A Resource for Pharmacists	http://www.cdc.gov/dhdsp/pubs/docs/Translational_Tools_Pharmacists.pdf
	Veterans Administration (VA)	Veterans Administration Handbook for Patient Aligned Health Care Team (PACT)	http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2977
	Health Resources and Services Administration (HRSA)	340b Pricing Programs: The 340b pricing programs refer to entities that participate in HRSA's drug discount program. Certain federal grantees, federally qualified health centers, and qualified disproportionate share hospitals can participate in this program for affordable medication for patients.	http://www.hrsa.gov/opa/introduction.htm
	Centers for Medicare and Medicaid Services (CMS)	More information on SWOT (Strengths, Weaknesses, and Opportunities and Threats) analyses is provided.	https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/LTSS-Roadmap/Step-4.html
	Medicare	This website describes information on Medicare Part B and the potential for pharmacist reimbursements.	http://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html

		Medicaid	This Medicaid website provides information on State Reimbursement Programs and State Prescriptions Drug Resources.	http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/state-prescription-drug-resources.html
National Associations				
	Association of Health-System Pharmacists (AHSP)		ASHP provides sample business plans, profit and loss statements, among other templates for participating clinics.	Building a Successful Ambulatory Care Practice, A Complete Guide for Pharmacists
	American Pharmacy Association (APhA)		For more information on creating a CPA agreement visit the American Pharmacist Association for directions on how to include key aspects of a pharmacist-inclusive CPA.	http://www.pharmacist.com/collaborative-practice-agreements-stimulating-increased-integration
	American College of Clinical Pharmacy (ACCP)		More information is provided regarding state policy and pharmacist scope of practice.	http://www.accp.com/govt/positionPapers.aspx

Definitions of Collaborative Care

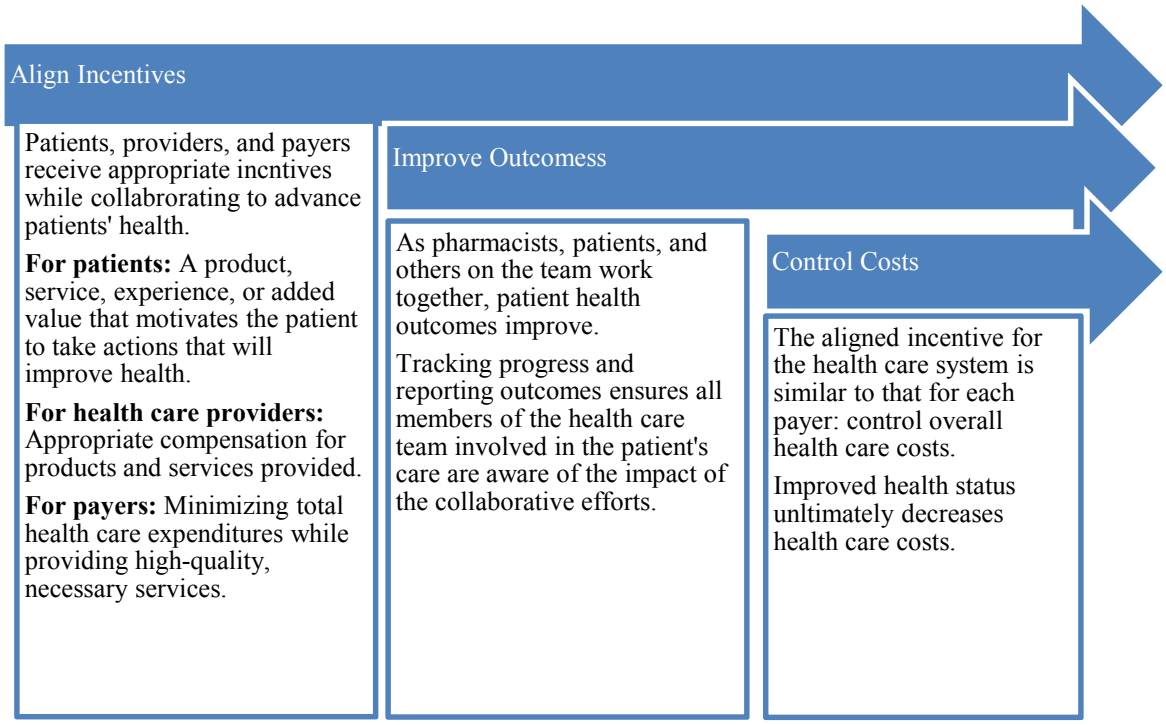
According to the Centers for Disease Control and Prevention (CDC), "a CPA is a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions."[1] CPAs can be arranged between any type of licensed health care provider in both inpatient and outpatient settings. CPAs define certain patient care functions that each care provider on a team can provide autonomously under specific situations and conditions.[2] While CPAs provide one option for increased collaboration, they are one of many tools used by hospital and clinical administrators to address a

[1] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

[2] Lisa Zubkoff. Using a Virtual Breakthrough Series Collaborative to Reduce Postoperative Respiratory Failure in 16 Veterans Health Administration Hospitals. Jt Comm J Qual Patient Saf. 2014;40(1).

patient-centered team-based approach to care. The CDC collaborative practice framework is outlined in Figure 11.

Figure 11. Framework for Successful Collaborative Practice Agreements.[3]



Adapted from: Centers for Disease Control and Prevention. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. Atlanta, GA: US Dept. of Health and Human Services, Centers for Disease Control and Prevention; 2013.

Many types of employment and practice agreements exist between NPs, MDs, and PAs, however, a Collaborative Drug Therapy Management (CDTM) Collaborative Practice Agreement is specific to pharmacists. The CDTM contract identifies and clarifies a pharmacist's clinical practice role when pharmacists are working with other clinicians in a collaborative manner. These pharmacist-specific CPAs are the foundation

[3] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

of pharmacist-inclusive CDTM models that have been shown to reduce fragmentation of care[4], lower health care costs, and improve a patient's health outcomes.[5]

According to the AACP, "CDTM is a team approach to healthcare delivery that seeks to maximize the expertise of the pharmacist and the physician in order to achieve optimal outcomes through appropriate medication use and enhanced patient-care services."[6] The Academy for Managed Care Pharmacy (AMCP) describes CDTM models as a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy autonomously.[7] The CDTM designation is used primarily because it is descriptive of the usual scope of practice between the physician and the pharmacist; e.g. drug therapy management.[8]

Practice Setting

In 2010, the American Society of Health-System Pharmacists (ASHP) Section of Ambulatory Care Practitioners conducted a survey of ambulatory care pharmacies. Of the respondents, 70 percent reported their ambulatory practice was associated with a hospital or health system, and 22 percent stated they practiced within a medical

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[4] Koll BS. A Collaborative to Reduce Central Line Infections The CLABs Collaborative : A Regionwide Effort to Improve the Quality of Care in Hospitals. Jt Comm J Qual Patient Saf. 2008;34(12):713–23.
[5] Giberson S, Yoder S LM. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice A Report to the U . S . Surgeon General 2011 [Internet]. Washington, DC; 2011 p. 95. Available from: http://www.accp.com/docs/positions/misc/Improving_Patient_and_Health_System_Outcomes.pdf
[6] Manolakis PG, Skelton JB. AACP REPORTS Pharmacists ' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs : The Emerging Role for Pharmacists to Address the Shortage of Primary Care Providers. 2010;74(10).
[7] AMCP. Practice Advisory on Collaborative Drug Therapy Management: Academy of Managed Care Pharmacy. 2012. p. 1–7.
[8] Ibid.

office/clinic or community health clinic.[9] The most common clinics with pharmacist-provided services identified at each practice site included, but was not limited to, anticoagulation (73 percent), diabetes (68 percent), hypertension (67 percent), hyperlipidemia (61 percent), and smoking cessation (45 percent).[10]

Many of the practice sites held clinical days for disease state management while others identified multiple health issues and risks during one visit. Each of the ambulatory practice settings brings with it particular strengths and weaknesses. Conducting a strengths, weaknesses, opportunities, and threats (SWOT) analysis as you choose what practice model to adopt will better prepare the program for the implementation stage.

Responsible Organizational Decision Making

Implementation guidelines for Outpatient Clinical Settings Assessing the Potential Integration of Pharmacist-inclusive Collaborative Drug Therapy Management may be a beneficial clinical direction for outpatient settings looking to address a high burden population of chronic disease management. However, the adoption of pharmacist-inclusive practice may not be the best solution for all clinics looking to increase their scope, depth, or breadth of chronic disease management programming.

Since it is difficult to assess if a CDTM-type program may work for a specific setting, evidence has shown that implementation guidelines can be adopted in individual

[9] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[10] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

segments.[11] While integrating all aspects of the CDTM model may have the highest likelihood of programmatic success, there is no restriction in applying the implementation guidelines in parts or as a whole.

Clinics need to be responsible and realistic with what they think is feasible within a specific time frame, political environment, and financial constraints to adopt the implementation guidelines. Nurse care coordination programs and physician-based collaborative team practices are just two of the many examples of integrated care management for disease state specific patients. It is important to consider all clinical options before prioritizing a pharmacist-inclusive practice. Pharmacist-inclusive CDTM models are one of several potentially successful programs from which a program can prioritize and assess programmatic fit.

Prioritization of which implementation guidelines to adopt, when to integrate them, and in what order, are decisions for each specific clinic and team. Adding locally relevant programmatic 'weights' to assist in the prioritization process may benefit the decision making process. A weight could be added to a specific set or individual guideline if a clinic identifies it as a priority area. There are currently no weights attached to any of the implementation guidelines or the worksheet. It is recommended that if a clinic wants to add weights and prioritize specific aspects of the principles that the outpatient clinical pharmacy program worksheet—attached to these guidelines—can assist in identifying the areas of greatest need and highest priority.

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[11] Cranor CW, Bunting B a, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash) [Internet]. 2003;43(2):173–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12688435.

The intervention guidelines outline a CDTM model of patients with uncontrolled diabetes somewhat case specific to El Rio Health Center in Tucson, Arizona. The model and guidelines can be applied to any number of chronic disease states such as cardiovascular or endocrine disease.

Implementation Guidelines

1. People and Human Capital

    - Participating clinics need to gather information about the local health care labor market in their community. It will be easier to make clinic-specific inferences of the People and Human Capital section if the data is previously collected.
    - Conduct a needs assessment or market analysis to understand the gaps between the current level of care and the level of care that is desired.
    - Personnel needs depend on the practice model, setting, and the services the clinic provides, but most typically the needs are represented by direct-care providers (i.e. pharmacists), support staff (i.e. pharmacy technicians, clerical staff), and administrative support.
    - Clinics need to consider the nonproductive time (e.g. such as vacation and education leave) by adding a 10 percent to 20 percent correction time to the current staffing needs estimate.[12]
    - Table 13 describes the Minimum Standards of Care for an Ambulatory Care Practice through the seven standards of ambulatory patient care.

[12] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

Table 13. Minimum standards of Care for a Pharmacist-Inclusive Ambulatory Care Practice[13]

1. Interviewing patients and caregivers to gather pertinent information for patient care
2. Assessing the legal and clinical appropriateness of medication regimen
3. Identifying, resolving and preventing medication-related problems
4. Participating in pharmacotherapy decision making
5. Educating patients and caregivers on disease, pharmacotherapy, adherence, and preventative health
6. Monitoring the medication effects and patient's health outcomes
7. Maintaining medication profiles and other documentations
Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

1.1. Pharmacists: Total Number of Pharmacists and total Pharmacist Full-Time Equivalent (FTE)

- The total number of pharmacist FTE workforce in the clinic currently is important to assess the staffing of an outpatient clinical pharmacy program.
- There are no minimum FTE hours that need to be spent on the program, since a pharmacist can be on an as-needed basis for difficult or uncontrolled patients with diabetes while working in a drug-dispensing capacity.
- Participating clinics and outpatient settings need to identify the total number of registered and licensed pharmacists on their staff. The total number of pharmacists and the FTE workforce may be different. Keep in mind a pharmacists may be splitting their time between a drug dispensing, academic, or policy role.

[13] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

- At minimum, one pharmacist is needed to support the program.
- Understand your state's current scope of practice and payment for pharmacists as they are continuously changing.
- According to the Veterans Administration Handbook for Patient Aligned Health Care Team (PACT), 1 clinical pharmacist is recommended per 3 providers.[14] The guidelines also recommend 1 anticoagulation clinical pharmacist for every 5 clinicians.[15]

1.2. Primary Care Providers: Physicians, PAs and NPs.

- At minimum, one physician (or individual with provider status who is considered the primary care giver or medical home of a patient)—PA, NP, or physician—is needed to support the program. This individual is necessary for patient continuity, diagnosis, treatment, and prescribing.
- Under a collaborative practice agreement in many states a pharmacist can change medication doses of pre-prescribed medications and prescribe new medications, within a CPA in collaboration with a provider.
- Providers need to be willing and able to refer patients to the CDTM program. Discussing potential referral strategy with physicians and care providers before rolling-out a program is imperative.
- The minimum number of primary care providers willing and able to participate and refer to the program: 1.

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[14] VHA Handbook 1101.10 [Internet]. [cited 2015 Mar 21]. Available from: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2977
[15] Ibid.

- The VA PACT guidelines recommend 3.0 FTE staff for 1 primary care physician per "teamlet" (provider, RN, LPN, and clerk). Patient referrals stem from clinician patient visits among other referral pathways.[16]

1.3. Care Team: Total Number of Pharmacy Technicians, Nutritionists, Social Workers, RNs, and Clinical Care Coordinators

- The total number of clinical FTE workforce that could support the program is important to assess the staffing of an outpatient clinical pharmacy program.
- There are no minimum FTE hours that need to be spent on the program, since a team member can be on an as-needed basis for uncontrolled diabetic patients.
- Participating clinics and outpatient settings need to identify the total number of potential team members whom could be listed on the CPA.
- The total number of care team members and their total FTE equivalent status will be different in every clinical setting. Keep in mind that the clinical team can split their time between primary care and care coordination roles.
- There is no minimum requirement for the care team—a CDTM model can function with only one provider and one pharmacist.
- It is recommended that there is at least 1 clinical care team staff member per area (e.g. social work, nutrition, etc.).

[16] VHA Handbook 1101.10 [Internet]. [cited 2015 Mar 21]. Available from: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2977

- VA PACT guidelines recommended one registered dietitian for approximately 6,000 patients. The guidelines also recommend 1 social worker for every 2 clinicians.[17]
- Participating sites should work with the clinical staff to see if there are nutritionists, social workers, RNs, etc. who are willing to work in the clinic at least part-time, if not full-time. If the program has sufficient funding, hiring at least one medical assistant to assist with the patient volume is recommended.

2. Political Environment, Legislation, and Rules Regarding Collaborative Drug Therapy Management (CDTM) and Collaborative Practice Agreements (CPAs)

- Evaluating the political and legal environment of the state where a participating clinic is looking to implement the principles is necessary.
- At minimum, one CPA needs to be in place legally supporting and defining the relationship between pharmacists and clinicians in the CDTM program.
- There are no specific recommendations for the number of CPAs as they are clinic specific due to number of providers and pharmacists.
- The CPA guidelines can be service line or disease state specific.[18]

[17] VHA Handbook 1101.10 [Internet]. [cited 2015 Mar 21]. Available from: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2977
[18] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

2.1. Legality of CDTM

- In forty-seven states in the U.S. and the territory of Guam, pharmacists are authorized to enter into collaborative drug therapy management agreements with physicians in clinical settings.
- In forty-seven states, the District of Columbia and the territory of Guam, pharmacists are authorized to enter into collaborative drug therapy management (CDTM) agreements with physicians in clinical settings.[19] Laws and regulations permitting pharmacists to authorize either a limited or broad scope of drug therapy management have been adopted. [20, 21]
- As of December 2013, only Tennessee, South Carolina, Michigan, and Alabama did not have a law or identified legal authority condoning or eliminating clinical pharmacy practice.[22]
- Participating clinics should reference Figure 12 which identifies state authorizations regarding drug therapy management by pharmacists. For

[19] Manolakis PG, Skelton JB. AACP REPORTS Pharmacists ' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs : The Emerging Role for Pharmacists to Address the Shortage of Primary Care Providers *. 2010;74(10).
[20] Giberson S, Yoder S LM. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice A Report to the U . S . Surgeon General 2011 [Internet]. Washington, DC; 2011 p. 95. Available from: http://www.accp.com/docs/positions/misc/Improving_Patient_and_Health_System_Outcomes.pdf
[21] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.
[22] Giberson S, Yoder S LM. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice A Report to the U . S . Surgeon General 2011 [Internet]. Washington, DC; 2011 p. 95. Available from: http://www.accp.com/docs/positions/misc/Improving_Patient_and_Health_System_Outcomes.pdf
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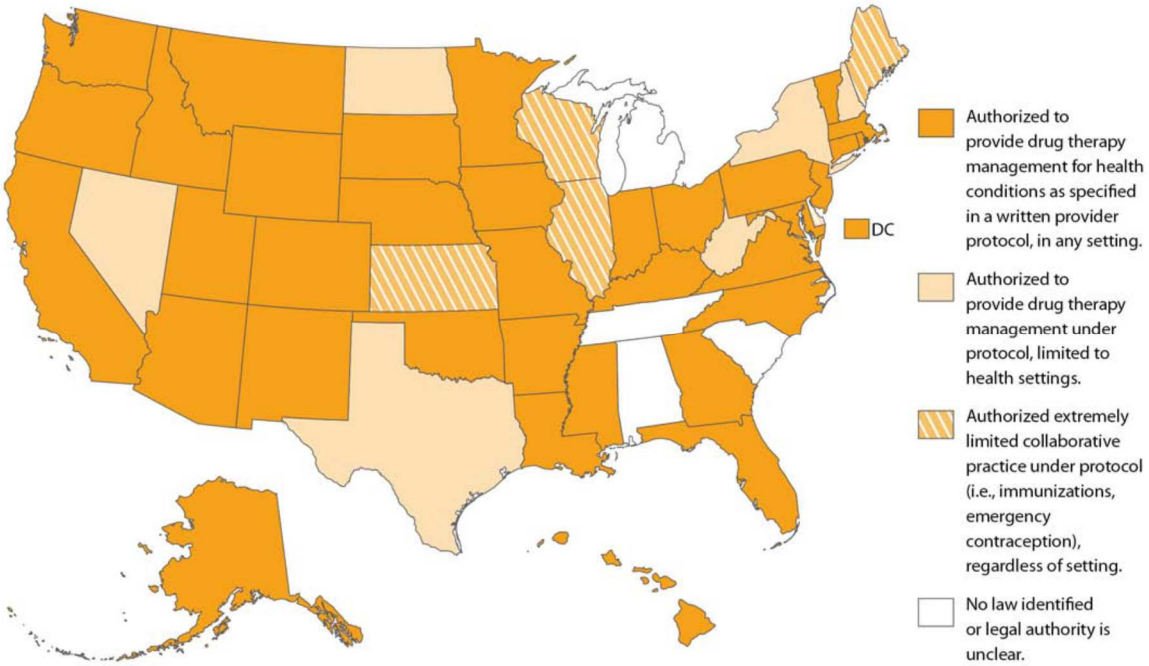
updated listings of regulations visit the CDC:

http://www.cdc.gov/pcd/issues/2015/14_0504.htm

Figure 12. Map of States with Laws Explicitly Authorizing Pharmacist Collaborative Practice Agreements, 2012[23]



Source: Pharmacists. C for DC and PCPA and PPCSAR for. Agreements and Pharmacists'. Atlanta, GA US Dept Heal Hum Serv Centers Dis Control Prev 2013.

2.2. Creating (CPAs) in clinical settings

- Participating clinics interested in creating a team-based care model will need to create formal CPAs between clinicians and departments to engage in CDTM.
- Every clinic and CPA will include different provisions, but the formal team-based care model necessitates departmental agreement as to which

[23] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

aspects of patient care will be addressed as a team.

- If CPA agreements already exist in participating clinics, amending the CPAs to include pharmacists as part of the clinical care team is necessary.

3. Place, Environment, Setting for a CDTM model

- A program needs to be housed within a physical space and organization.
- Creating a mission or vision statement for the program is important to determine the optimal desired future state of the program.
- The mission and vision of the program help identify the program so departmentspecific co-location can be established.[24]
- At minimum, one clinical space (exam room, conference room, drug dispensing pharmacy private alcove or area, etc.) is needed to support the program.
- While there is not specific algorithm recommended, based on the case study of El Rio, the recommended number of clinical exam spaces is: 2-6, depending on the clinical staff size, patient volume, and need.

3.1. Clinical Program Location

- Outpatient clinical settings include, but are not limited to: FQHCs, outpatient clinics within a hospital setting, public and private clinics.
- One key aspect of a CDTM is the support structure of a larger organization. The CDTM model should serve as an additional service for

[24] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

patients who may need more support than what they receive with their primary care provider.

- To protect patient privacy, finding a space away from other patients, health care providers, and the public is imperative.[25]
- In the case of El Rio, a CDTM model under the auspices of a larger organization not only increased potential patient volume, and referring providers, it allowed patients to visit one clinical site for all of their appointments.

3.2. Office Space

- Participating clinics need to have a programmatic home.
- The program can be run from one department (e.g. Family Practice, Internal Medicine, etc.), but it is ideal to have a separate office space for the program administrator.
- Physical space needs to include all the square footage a program may need to conduct their services: patient care areas, waiting rooms, storage areas, conference and meeting rooms, restrooms, etc.
- According to a 2009 report, the average cost for medical office space was $23.90 per square foot per year (or $2 per square foot per month).[26] Due to this program expense, it is wise to make use of any available resources that may be at a program's disposal in the current clinical environment:

[25] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[26] Ibid.

personnel, equipment, physical space, and supplies.[27]

3.3. Conference room for education

- Conference rooms are recommended, but not necessary to hold group patient education sessions.
- Conference rooms for the program can be shared space within a clinic as well.

3.4. Clinical services/exam rooms

- Exam rooms are recommended and not necessary for program success.
- Exam rooms are used for patient eye exams, diabetic foot checks, checking A1C levels, and consultation, among other uses.
- An exam room can also be considered a segment of the drug dispensing pharmacy that is private and set apart from the line of patients filling or picking-up prescriptions. The exam room or consultation area needs to be secluded and big enough for both a patient and a pharmacist to converse with HIPAA compliance.
- Medical supplies needed for the program should be considered as well: blood pressure cuffs, stethoscopes, thermometers, and weight scales among others. Point-of-care testing devices should also be considered: INR, blood glucose, lipids, sharps waste containers, among other items.
- Office furniture and supplies recommended include: computers, printers, a fax machine, exam tables, lighting, file cabinets, etc.

[27] Ibid.

4. Patients

- For program success, identifying the patient demand a patient volume is important to evaluate if the CDTM model program will satisfy the community's needs.
- At minimum, there needs to be at least one patient enrolled in the CDTM model and one pharmacist caring for that patient to constitute a program.
- The 2010 ASHP survey found that more than half the clinics reported having 3,000 or fewer documented patient encounters per year, yet 23 percent reported having more than 9,000 patient encounters per year.[28] The results demonstrate a variety of clinic types that are wide-ranging.
- According to the VA Handbook, the recommended number of patients to pharmacist ratio is about 1 pharmacist per 2,000 patients. The target patient volume is: 4,000-5,000 unique patient visits a year in the CDTM model.[29]
- For an accurate estimation of patient volume and time involved in providing direct care clinics need to determine: 1) the number of potential candidates for the service, 2) the frequency and duration of visits, and 3) the visit completion rates.
- Estimate that in a standard 8-hour work day pharmacists can generally accommodate 8-12 patients in disease management-style services and 15-

[28] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[29] VHA Handbook 1101.10 [Internet]. [cited 2015 Mar 21]. Available from: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2977.

20 patients in services with more focused care (e.g. anticoagulation and diabetes).[30]

- Table 14 describes an example direct-care pharmacist staffing needs for the clinical services.

Table 14. Determining Number of Patient Monthly Visits[31]

Total: 60 patients with uncontrolled diabetes	
• 80 percent will have routine visits every 12 weeks=48 patients every 12 weeks, or an average of 16 patient visits per 4-week intervals (roughly 12/mo)	• 20 percent will need more frequent visits every 4 weeks=12 patient visits every 4 weeks (roughly 13/mo)
Total: 35 patients on Warfarin (Anticoagulation medication)	
• 80 percent will have routine visits every 4 weeks=28 patient visits per 4 weeks (roughly 30/mo)	• 20 percent will need more frequent visits: 1 visit every 2 weeks=14 visits per 4 weeks (roughly 16/mo)
Total percentages of visit frequency:	
• 48 patients (50 percent) will visit every 12 weeks	
• 40 patients (42 percent) will visit every 4 weeks	
• 7 patients (8 percent) will visit every 2 weeks	
Total monthly visits= 76 (30 for diabetes and 46 for anticoagulation)	
Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.	

4.1. Patient Demand

- Evaluate factors that may impact the patient demand estimate such as changes in the local health care market or organizational emphasis on areas of care and government policy shifts in insurance coverage in the service area.[32]

[30] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[31] Ibid.
[32] Ibid.

- Clinics can use chart review or electronic medical records to query their database and see which patients have an uncontrolled A1C level over 9, have indicators for pre-diabetes, or are at high risk for developing diabetes.
- When thinking about patient demand, it is important to consider staffing needs of the pharmacist care provider's time related to activities and possible responsibilities such as: performing prescription refill authorization, reviewing laboratory results, consulting with providers, addressing external inquiries, precepting students, academic appointments, and research.[33]

4.2. Patient Referrals

- Consider whether the program service will be a mandatory referral system (i.e., automatic transfer of care for anticoagulation services for all identified patients) or referral based on physician or patient discretion (i.e. diabetic patients determined to be in poor control).[34]
- Participating clinics need to visit with providers and clinicians within their clinical setting to explain how the program functions and why patient referrals are important to create a patient-centered medical home.
- Describing the potential points of entry into the program is important for buy-in at all levels of the clinic.

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[33] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[34] Ibid.

4.3. Patient Volume

- Frequencies of patient visits are also important indicators for program planning. Identifying how often a specific patient population visits the clinic is key data to figure out how and when patients may be able to seek services at the CDTM program.
- Collect billing and financial data tied to ambulatory care visits, on the patient diagnoses (ICD codes), services provided, insurance/payer codes, and basic demographic information from the financial office in the clinic.[35] This information is valuable for helping determine patient and visit volumes, but also for evaluating other aspects of the program's services.
- Consider the clinic's 'show' rate for patient visits. According to ASHP, this number can vary as widely as 40 percent to 75 percent depending on the population served.[36]
- It is recommended for participating clinics to identify if diabetes is a major disease burden (defined as a disability-adjusted life year (DALY)[37], that quantify the number of years lost due to disease) within the patient population seeking services.[38] If diabetes is found to not be a major

[35] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[36] Ibid.
[37] A disease burden can be identified in multiple formats—a DALY is one option for this calculation.
[38] Yang W, Dall TM, Halder P, Gallo P, Kowal SL, Hogan PF, et al. Economic costs of diabetes in the U.S. in 2012. Diabetes Care. 2013;36:1033–46.

burden of disease, then the next step would be to analyze the data to see what other disease profile is more applicable: e.g. cardiovascular or endocrine health.

- One DALY can be thought of as one year of healthy life lost, and the overall disease burden can measured as the gap between current health status and the ideal health status of a patient.
- Patient volumes will ultimately determine the total time needed to provide direct patient care. To connect these pieces, a clinic will need to determine the expected duration and frequency of visits which depends on the patient treatment severity and complexity as well as efficiency of the pharmacist provider.
- Table 15 describes an example template for the duration of pharmacy visits.

Table 15. Example Template: Duration of Pharmacy Visits[39]

Appointment Type	**Length of Visit**
New Referral	30 minutes
Initial Visit	30 minutes
Regular Office Visit	20 minutes
Phone Visit	15 minutes
Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.	

5. Benchmarking

- Each clinic individually needs to create benchmarks for their own perceived success. Demonstrating the program's impact is an important

[39] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

component for stakeholder support financially and administratively within a clinic and with external granting institutions.

- The supporting evidence for pharmacy services will also provide examples of possible metrics for tracking value.[40]
- At minimum, data needs to be collected at baseline from enrolling patients in the CDTM model, and from each patient encounter.
- There are no specific recommendations for benchmarks a clinic adopts for the program, however, all of the benchmarking tools are recommended for the clinic to collect to identify areas of strengths and weaknesses of their program.
- Benchmarking data is needed for future quality improvement projects and recommended changes to the program.

5.1. Tracking hospital 30 day re-admission rate to the Emergency Department (ED)

- ED re-admission rates for diabetic patients enrolled in the program due to diabetic complications are important to track, since lowering the rate of ED admissionsbrings down total costs for patients and clinics. ED visits are often used a metric to identify the poorest performers within a health care system. As most ambulatory care centers do not have an ED, these visits are an indicator of the patients most at-risk for illness and negative health outcomes.
- For outpatient clinical settings, these statistics are not a financing model likemany hospital systems.

[40] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

5.2. Lower A1C levels

- Tracking patients with uncontrolled and unmanaged diabetes before the program implementation is important.
- Use A1C levels as an indicator of program efficacy and success.

5.3. Clinical Benchmarks Specific to Participant's clinics

- Each clinic needs to identify what they perceive as success data. This could be a range of indicators including but not limited to: increase in patient volume, increase in patient demand, increase in number of clinical referrals, number of program staff, increased funding from the clinic, grants from external sources, publicity, etc.
- This benchmarking data will be important to collect for discussions of program success and future funding both internally within the clinic and for external funders.
- Regardless of which benchmarks a program selects, it is important to proactively determine the comparator data (baseline data) to demonstrate the program's impact on patient services.

6. Time

- Time is usually not considered a financial consideration in program development, but is important for a CDTM model due to lengthy program implementation that can take up to a few years for complete program development.
- At minimum, one pharmacist or FTE program manager needs to be

identified to be the point-person for the program internally within the clinic.

- There are no specific recommendations for the number of hours or years that a CDTM model program should take to create and implement. In the case of El Rio, program implementation spanned three years, while other programs are created in 6 months or 7 years.

6.1. Project Management

- Identifying one programmatic head (1 FTE) per clinic that is able to liaise between the administrative staff and clinical staff is mandatory for program implementation.
- Conducting monthly meetings where all the participants in the program meet face-to-face are important for program morale and program efficiency.
- A collaborative team should be involved in the establishment of project and program aims so that the influence of the various program aspects is optimally considered.

6.2. Programmatic Bandwidth of Program Participants

- Each clinic should decide how to assess each individual participant's work projects by assigning their work and projects times or weights. Assessing what is on each team member's work 'plate' allows program tasks to be spread evenly among peers participating in the program.

- Assigning projects and tasks evenly within a program is important so that everyone feels invested in the program and is tasked to the fullest ability (and top of their educational level).

6.3. Staff time for education

- Integrating professional development into the program for the clinicians and support staff in the program is recommended.
- Encouraging staff to teach group education sessions for patients (e.g. healthy eating, healthy lifestyles, etc.) are also encouraged.
- Training staff to identify the patient population's specific health literacy needs and maintain educational materials in the office space and exam room is an optional educational outlet for program staff and patients.

7. Support

- Programmatic support is defined by both financial and non-financial support.
- At minimum, the political and bureaucratic support of the administrators is necessary for CDTM creation and implementation.
- It is recommended for the program to gain administrative and financial support before program implementation.
- There are three major steps to successfully marketing the ambulatory care clinic: 1) basic understanding of the customer's behavior and their connection to the services offered, 2) conducting marker research to understand the target group's wants and needs from the program, and 3)

crafting a message that will convey the value of the CDTM model program.[41]

- Consider clinic Administrators as program customers in that a program needs to demonstrate that the pharmacy services fit as the best provider for a set of services provided by the organization.
- CDTM program leaders need to identify, communicate, and empower the stakeholders internally within the program (e.g. pharmacists and clerical staff) and from all levels of the clinic administration.

7.1. Clinical Support: Internal

- Internal clinical support is categorized by: 1) financial support from within a participating clinic's budget, and 2) political/ bureaucratic support within the clinic to increase the program profile within the clinic.
- Financial Support:
    - Financial support: In the case of El Rio, the program received funding directly from the clinic administrators for the explicit purpose of funding an outpatient clinical pharmacy model.
    - Financial support can also come from within another department's budget to assist in the creation of the program (e.g. Family Medicine Department pays for a diabetes program out of their annual departmental funding).

[41] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

- Bureaucratic Support:
    - This refers to support offered by administrators to fight internally for the program's creation or existence. This is most likely an administrator who is a CDTM model 'champion' who is persuasive and effective within the clinic administration.
    - Assessing which administrator to target within the clinic is important as well. Find the leader with the most in common with the mission and vision of the program and most to gain from a successful implementation of the program.
    - It is necessary that clinical managers and administrators are in support of the program's creation, adoption, and implementation.
    - Collect medical literature supporting CDTM models; obtain health plan information (e.g. covered lives in the plan, number of members with high-cost chronic diseases), payer mix, average health care costs per member per year, and average health care costs per member per year for patients with certain high-cost chronic diseases.
    - Discussion of these costs with the Administrative team allows them to estimate how much the clinic could save by implementing a CDTM model program. Table 16 describes The Asheville Project

in North Carolina as an example of how program leaders can advocate for a CDTM model programs with Administrators.[42]

Table 16. Approaching Potential Decision-Makers: The Asheville Project

The Asheville Project, one of the most widely recognized and replicated models of CDTM models published outcomes data on diabetes, asthma, hypertension, and dyslipidemia management, all demonstrating the ability of pharmacists to decrease health care costs. Program leaders need to be well versed in medical literature supporting the creation of a CDTM model program.[43]
o The Asheville Project showed a mean direct medical cost decrease of $1,200-$1,872 per member per year.[44]
o If a given clinic had 100 members with diabetes and each member had an average of $5,000 in mean direct medical costs per year (total costs = $500,000), then implementation of the pharmacist CDTM program could decrease clinic mean direct medical cost to $3,128-$3,800 per member per year for patients with diabetes (total cost = $312,800-$380,000).[45]
o This would demonstrate a potential cost savings on average of $120,000-$187,200 in direct medical costs per year for patients with diabetes if all members participated in the CDTM program.[46]
Source: Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

- It is also important to consider the program from the patient's perspective to ensure that the program will be perceived as value-added from the patient's perspective.
- Patient Support:
    - Participating clinics need to ensure that spending the clinical and staff time to implement these principles will be well received not

[42] Cranor CW, Bunting B a, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash) [Internet]. 2003;43(2):173–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12688435.
[43] Ibid.
[44] Ibid.
[45] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.
[46] Ibid.

only from within the clinic's administration but also from patients interested in enrolling in the program.

7.2. Clinical Support: External

- External program support mainly includes funding from outside the clinical settings. These can include grants, contracts, etc. that can fund the program directly.
- Clinics and pharmacists can apply for HRSA's 340 B Drug Pricing Program that delivers medications to qualified clinics at a reduced cost for low-income patients.
- Clinic Foundations can also be an excellent source of fundraising in the community.
- In the case of El Rio, a relationship was built between the Pascua Yaqui Native American Tribe to fund one pharmacist FTE and one medical assistant FTE stationed within the reservation to serve the patients with uncontrolled diabetes within their population. This innovative model is similar to a self-insured group or employer-based insurance model for outpatient clinical pharmacy services.
- Publications, outspoken members of the community and high-profile individuals can also constitute external support for the program by publically and/or financially supporting the creation of the program.

8. Finances

- Funding a CDTM program is challenging—likely the most challenging

aspect of the principles for implementation guidelines. A CDTM model can be financed through multiple options: internally within a clinic, from outside organizations, grants, among others.

- There are no recommendations for the minimum amount of funding a program needs for clinical development and adoption.
- It is recommended that the program become a line-item budget within either a specific medical department's budget, or receive direct financing from the clinic's managers. As a line item, the program can be assured financing, clinical support, and a higher likelihood of sustainability.

8.1. Internal Finances

- Internally, a CDTM model program can receive line-items funding for its development and implementation.
- Clinic departments can identify funds specifically awarded to the program.
- The program can cite specific aspects of focus areas that are in line with a federal or large grant currently in place at the clinic and try and receive part of the funding for the development and implementation of the program.
- Estimating Program Expenses:
    - It is important to consider all of the program's expenses: 1) implementation costs (big budget, long-lasting goods), remodeling the physical space costs, and necessary supplies, and 2) expected operating expenses (labor, office, rent, and overhead).

    - After recording the estimated total expenses for the program, matching the expenses with the value of the program's service is the next challenge.

- CDTM program business plans should include: a start-up expense budget, staffing budget, projected payer mix, a 3-5 year profit and loss statement showing volumes, expenses and revenues.

8.2. External Finances

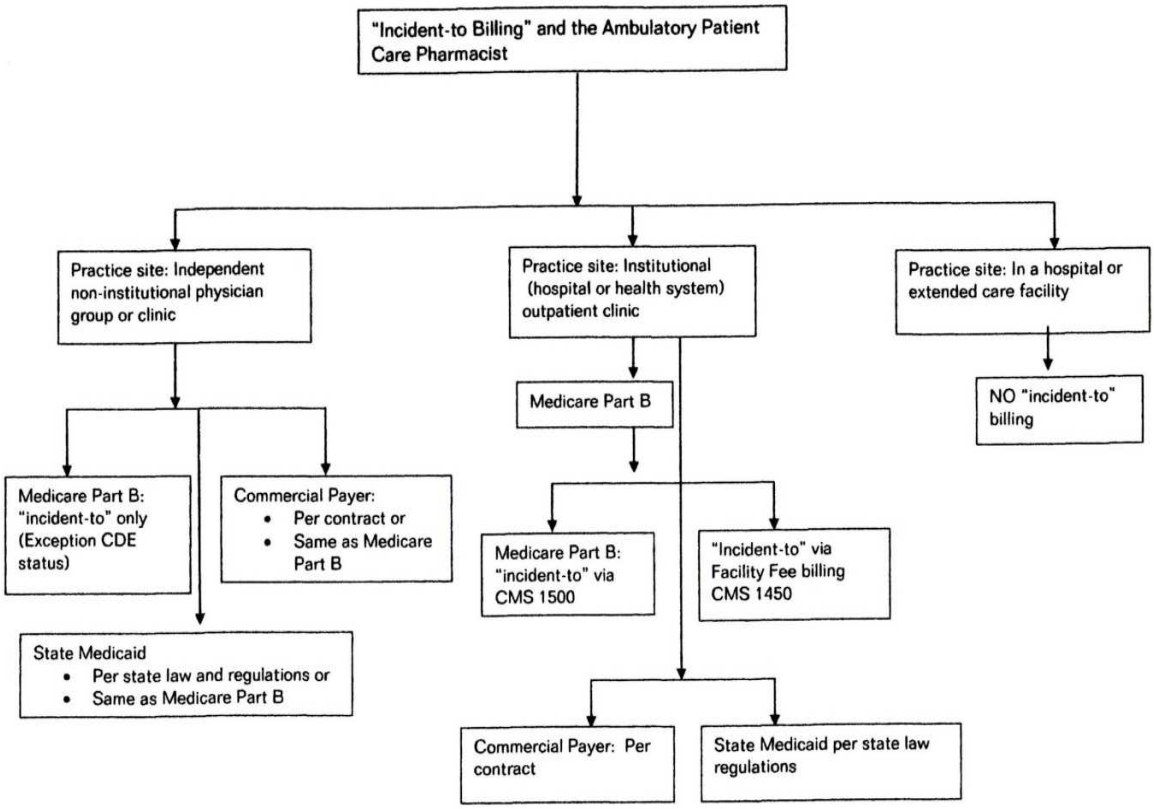
- The program can apply for a grant from a large or small institution to receive funding to either create, start, and/or maintain the program.
- The clinic or the program can apply for specific demonstration grants to showcase the potential power of the program.
- The clinic can also ask for community donations to fund the program.

8.3. Insurance

- Since pharmacists do not have provider status, they cannot be reimbursed for patient services rendered in the program.
- Pharmacists can bill for "incident-to" billing in Medicare Part B but not in a FQHCs since incident to visits are already part of the all-inclusive payment rate in that setting. This process is described in Figure 13.
- There are other loopholes that are state and health plan dependent and programs need to identify potential areas to potential reimbursement of services.

- The potential for and degree of reimbursement for pharmacist's clinical services will depend to a significant degree on the insurers and payers in the practice setting. In the case of El Rio, a common range for rate of reimbursement for services rendered is 50 percent to 60 percent.
- Clinicians participating in the program are able to be reimbursed for their clinical time through insurance plans and third party payers.

Figure 13. "Incident-to Billing" and the Ambulatory Patient Care Pharmacist[47]



Source: Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

[47] Kliethermes M. Building a Successful Ambulatory Care Practice. A Complete Guide to Pharmacists. Bethesda, Maryland: American Society of Health-System Pharmacists; 2012.

8.4. Opportunity Costs

- The amount of staff time and energy to create, adopt, and implement a CDTM model program is an opportunity cost for the clinicians, administrators, and pharmacists.
- Opportunity costs are an important consideration if the program implementation is a protracted adoption and continues over multiple years.

CHAPTER SEVEN

Outpatient Clinical Pharmacy Program Worksheet to Assess the Potential Development or Expansion of Pharmacist-Inclusive Collaborative Drug Therapy Management (CDTM)

The following worksheet enables clinics to identify their access to key resources and self-assess their perceived barriers when considering whether or not to implement or expand an outpatient clinical pharmacy program. The potential audiences for the worksheet are the administrators at a clinic, hospital, or other facility looking to develop and adopt a pharmacist-inclusive practice. The worksheet is a Google Form survey that allows the user to answer a series of closed-and-open-ended questions that ultimately provide a self-assessment of readiness and willingness for a pharmacist-inclusive practice. The goal of the worksheet is to help clinics read what they perceive *their own* barriers are to implementation. The worksheet output is a summary table of the user's answers that corresponds to the implementation guidelines for generalizability and practice.(135) The survey can also be printed and administered as a physical worksheet. The Implementation Guidelines then delineate more of the recommendations for specific actions to consider when implementing a CDTM model program.

While it is feasible to add weighted values to each entry based on the perceived importance of each area, one should be careful not to project what is most important in every setting. The user must determine the critical areas of importance for their setting and add weighted values to the key outputs for program consideration. In the future, the

worksheet could enable an overlay option for users to choose their weighted values per area or use the recommended weights for the analysis tool. The output of the worksheet should be a general recommendation of where to best spend time, energy and funds to fully develop a collaborative pharmacist-inclusive practice.

The worksheet will include a description explaining how to use the tool itself and how to interpret the findings. This document will accompany the worksheet for user reference. An example of the description is below.

Worksheet Description

The worksheet enables clinics to identify their access to key resources and self-assess their perceived barriers when considering whether or not to implement or expand an outpatient clinical pharmacy program. The worksheet can be used as a directive device or to develop a general recommendation of areas to address for future reference. The goal of the worksheet is to help you assess and evaluate the benefit and resources needs associated with a pharmacist-inclusive collaborative practice. The worksheet will ask you a series of questions in eight categories in a survey format. Most every question is close-ended with multiple choice responses. The worksheet output is a summary of your responses and a corresponding set of Implementation Guidelines for generalizability and application to your work site. The summary table created at the end of the worksheet, shows projected successes of the current state of your clinic and the potential barriers you may encounter.

Open the link e-mailed to you, and begin the survey. A link to the survey is also available here. At the conclusion of the survey, your results will be sent to your e-mail

address provided. Alternatively, you may print the survey and administer the worksheet as a physical questionnaire. Compare the results output against the Implementation Guidelines for program creation, adoption, creation and maintenance. For a more accurate summary output, you will need basic descriptive data regarding patient volume, clinic budgets and workforce. Enjoy the worksheet, and we hope it is helpful for you and your clinic's pharmacist-inclusive practice evaluation.

Worksheet Summary Outline

1. People and Human Capital: Participating clinics need to gather information about their community to evaluate factors that may impact the patient demand estimate such as changes in the local health care market or organizational emphasis on areas of care and government policy shifts in insurance coverage in the service area. It will be easier to make clinic-specific inferences of the People and Human Capital section if the data is previously collected.
    1.1. Pharmacists at the Clinic: Total Number of Pharmacists and total Pharmacist FTE (Clinical and Dispensing Pharmacists)
    1.2. Primary Care Providers at the Clinic: Physicians, PAs and NPs.
    1.3. Clinical Care Team: Total Number of Medical Assistants, Nutritionists, Social Workers, RNs, and Clinical Care Coordinators
2. Political Environment, Legislation, and Rules Regarding Collaborative Drug Therapy Management (CDTM) and Collaborative Practice Agreements (CPAs): Evaluating the political and legal environment of the state where a participating clinic is looking to implement the implementation guidelines is necessary.

2.1. Legality of CDTM (For more information regarding state policy and pharmacist scope of practice visit the National Alliance of State Pharmacy Associations, NASPA: (http://www.naspa.us/).

2.2. Creating (CPAs) in clinical settings

3. Place, Environment, Setting for a CDTM model: A program needs to be housed within a physical space and organization.

   3.1. Clinical Program Location (e.g. hospital or clinical setting)

   3.2. Office Space

   3.3. Conference room for education

   3.4. Clinical services/exam rooms

4. Patients: For program success, identifying the patent demand a patient volume is important to evaluate if the CDTM model program will satisfy the community's needs.

   4.1. Patient Demand

   4.2. Patient Referrals

   4.3. Patient Volume

5. Benchmarking: Each clinic individually needs to create benchmarks for their own perceived success. Data on successes and failures will assist in garnering support financially and administratively within a clinic and with external granting institutions.

   5.1. Tracking 30 day re-admission rate to the Emergency Department (ED)

   5.2. Lower A1C levels for patients with diabetes enrolled in the program

   5.3. Clinical Benchmarks Specific to a Clinic's pre-identified Goals

6. Time: A key element to successful program adoption and implementation is time. Time is required by those administering the program, and for the clinicians and staff involved directly in the program.
    6.1. Project Management and Program Leadership
    6.2. Programmatic Participation of Employees
    6.3. Staff Time for Education
7. Support: Programmatic support is defined by both financial and non-financial support.
    7.1. Clinical Support: Internal
    7.2. Clinical Support: External
8. Finances: Funding a CDTM program is challenging—likely the most challenging aspect of the principles for implementation guidelines. A CDTM model can be financed through multiple options.
    8.1. Internal Finances
    8.2. External Finances
    8.3. Insurance (payer mix, contracting options, shared savings contracts, among others)
    8.4. Opportunity Costs

Outpatient Clinical Pharmacy Program Worksheet

Outpatient Clinical Pharmacy Program Worksheet

This worksheet excise will walk you through questions that you should be assessing when trying to start or expand services. If you have difficulty answering any questions or need further clarification, please refer to the Implementation Guidelines to determine the potential impact on your program development.

This worksheet and connected Intervention Guidelines outline an example CDTM model of uncontrolled diabetic patients. The worksheet and guidelines can be applied to any number of chronic disease states such as cardiovascular or endocrine disease. It is estimated that the worksheet will take approximately 20 minutes to complete.

There are eight sections included in the worksheet:

1. People and Human Capital
2. Environment
3. Place
4. Patients
5. Benchmarking
6. Time
7. Support
8. Finances

Please answer all of the questions to the best of your ability. The required questions are identified with an asterisk. Your summary data will be sent to the e-mail address you supplied upon signing-in to this survey. Lastly, please do not enter any information in this form that is not HIPAA compliant. Your responses may be used for research purposes in the future.

Thank you for your participation.

* Required

1. **To receive your responses from the worksheet, please enter your e-mail address below.**
   Your responses to this survey will be sent directly to your e-mail address. These responses can be compared to the Intervention Guidelines to assist you in further program development.

   _____

   _____

   _____

   _____

   _____

Survey Goals

What is your goal for taking this survey and using the tool outputs?

2. **Please check all that apply** *
   Check all that apply.

   - [ ] Learn more about outpatient clinic pharmacy programs
   - [ ] Identify our organization's areas of strengths
   - [ ] Identify our organization's areas of weakness
   - [ ] Other: _____

Section 1: People and Human Capital

The first section of this tool asks you a series of questions about yourself and your clinical facility.

Individual Characteristics

3. **How do you identify yourself within your clinical setting?** *
   Your educational or clinical certifications. (*This data will be used for study purposes only).
   Mark only one oval.

   - ◯ Administrator (BA, MBA, MA, PhD, DrPH)
   - ◯ Pharmacist (PharmD, RPh)
   - ◯ Physician (MD, DO)
   - ◯ Registered Nurse (RN)
   - ◯ Nurse Practitioner (NP)
   - ◯ Physician Assistant (PA)
   - ◯ Pharm Tech (MA)
   - ◯ Nutritionist (RD)
   - ◯ Social Worker (LCSW)
   - ◯ Other: _____

4. **Please define your clinical title**
   (e.g. Medical Director)

   _____

   _____

   _____

   _____

   _____

Number of Referring Staff Members

How many physicians, nutritionists, social workers, etc. are on staff at your clinic?

5. **How many pharmacists work in your organization?** *
   This includes drug-dispensing, academic, administrative and clinical pharmacists

   _____

6. **How many physicians work in the clinic?** *
   This includes all physicians who could potentially refer patients to the program

   _____

7. **How many Nurse Practitioners work in the clinic?** *
   This includes all NPs who could potentially refer patients to the program

   _____

8. **How many Physician Assistants work in the clinic?** *
   This includes all PAs who could potentially refer patients to the program

   _____

9. **How many Registered Dietitians work in the clinic?** *
   This includes all RDs who could potentially refer patients to the program

   _____

10. **How many Licensed Clinical Social Workers work in the clinic?** *
    This includes all LCSWs who could potentially refer patients to the program

    _____

11. **How many Registered Nurses work in the clinic?** *
    This includes all RNs and nurse care coordinators who could potentially refer patients to the program

    _____

Referral Projections

Do you think clinicians will be willing to refer patients to the CDTM model program?

12. *

On a scale of "Very likely to Refer" to "Not likely to Refer," how likely are clinicians willing to refer to the program?
Mark only one oval per row.

	Very Likely	Somewhat Likely	Likely	Somewhat Not Likely	Not Likely	N/A
Drug-Dispensing Pharmacists						
Clinical Pharmacists						
MAs						
RNs						
NPs						
PAs						
Physicians						
Administrators						
Dieticians						
Social Workers						
Other						

Perceptions of Pre-identified Champions

Do you think there are CDTM model champions within your organization? If so, who have you identified as a supporter of this proposed program?

13. Check all boxes that apply
Check all that apply.

- [ ] Clinic Administration
- [ ] Clinical Pharmacists
- [ ] Drug-Dispending Pharmacists
- [ ] Physicians
- [ ] Nurse Practitioners
- [ ] Physician Assistants
- [ ] Pharm Techs
- [ ] Nutritionists
- [ ] Social Workers
- [ ] Other: _____

Section 2: Environment

The second section asks you to identify the feasibility of a CDTM model program in your state.

Geographic Location

Where is your organization physically located?

14. **Please identify the State where your clinic/facility/organization is located** *

_____

_____

_____

_____

_____

Proposed CDTM Model Location

Where do you work? How would you best describe the organization?

15. **Please check all of the boxes that apply:** *

Check all that apply.

- [ ] In-patient Hospital
- [ ] Outpatient Hospital
- [ ] Outpatient Clinical
- [ ] Academic
- [ ] Non-clinical Organization
- [ ] Pharmacy
- [ ] Other: _____

Collaborative Practice Agreements (CPA)s

16. **Does your organization have a CPA in place for team-based care?**

Mark only one oval.

- ◯ Yes
- ◯ No *Skip to question 18.*
- ◯ Not sure *Skip to "Section 3: Place."*
- ◯ Other: _____

Skip to "Section 3: Place."

Yes, there is a CPA in place.

Please describe the CPA is place at your organization.

17. **Who does the CPA include?**

_____

No, there is not a CPA in place.

Please describe the reason for the lack of CPA. Does your clinic not recognize team-based care initiatives? Has the concept of a CPA ever been introduced?

18. _____

_____

_____

_____

_____

Section 3: Place

Section 3 describes the environment, setting, and physical place of the proposed program.

Clinical Program Location

19. **Do you have a physical space for a CDTM model program?** *

Mark only one oval.

- ◯ Yes *Skip to question 20.*
- ◯ No *Skip to question 21.*
- ◯ Other: _____ *Skip to question 22.*

Yes, you have a space for the CDTM model program.

20. **What type of room is it?** *

Mark only one oval.

- ◯ Conference room
- ◯ Exam room
- ◯ Drug-dispensing Pharmacy
- ◯ Office Space
- ◯ Other
- ◯

No, you do not have a CDTM model program.

21. **Why do you not have a CDTM model program? Do you have an alternative program?**
Please describe.

_____

_____

_____

_____

_____

Clinical Services

What types of clinical services are you planning on offering in the CDTM model clinic?

22. Check all boxes that apply
Check all that apply.

- [ ] A1C Blood Checks
- [ ] Eye Exams
- [ ] Diabetic Foot Checks
- [ ] Nutritional Counseling
- [ ] Medication Management
- [ ] Other: _____

Section 4: Patients

This section will identify projected patient demand, referrals and volume. Section 4 estimates the number of potential individuals who could benefit from the program.

Patients with Diabetes Mellitus Type 1 and 2

Identifying the patient demand begins with disease burden estimates.

23. **How many patients are currently diagnosed with Diabetes Type 1** *

_____

24. **How many patients are currently diagnosed with Diabetes Type 2** *

_____

25. **How many patients are taking chronic disease medications?** *

_____

26. **How many patients are identified as pre-diabetic?** *

_____

Patient Points of Entry to the CDTM model

This question identifies a patient's referral or entry to the program. A point of entry could include a physician referral, to a electronic medical record notification when a patient's A1C level is >9.

27. **Please check all of the applicable boxes.** *

Check all that apply.

- [ ] Clinician (MD, DO, NP, RN, PA, LCSW, or RD)
- [ ] Pharmacist (PharmD, RPh)
- [ ] Electronic Medical Record System
- [ ] Hospital Discharge
- [ ] Self-referral
- [ ] Community Health Advisor
- [ ] Behavioral Health Clinician
- [ ] Missed Opportunity Report
- [ ] N/A
- [ ] Other: _____

Patient Volume

Patient visit frequency data is an important indicator of potential patients who could enroll in the program.

28. **On average, how often does a diabetic patient visit your clinic?**

Mark only one oval.

- ◯ 0-3 visits per year
- ◯ 4-10 visits per year
- ◯ 11-20 visits per year
- ◯ Over 21 visits per year
- ◯ N/A
- ◯ Other: _____

Section 5. Benchmarking

Each clinic individually needs to create benchmarks for their own perceived success and failures. Section 5 identifies many of these benchmarks and data to track to show program successes and weaknesses for future planning.

Benchmarking Data

29. **What data is collected for diabetic patients in your clinic?**
Please check all boxes that apply
Check all that apply.

- [ ] 30-day Hospital Emergency Department Re-admission rates
- [ ] A1C level
- [ ] Weight or BMI calculations
- [ ] Clinical visits
- [ ] Eye Exams
- [ ] Foot Checks
- [ ] Retention Rates
- [ ] Other: _____

30. **How does your clinic or organization constitute success?** *
Please describe these benchmarks or success data collected (e.g. HEDIS Measures)

_____

_____

_____

_____

_____

31. **Do you perceive these benchmarks as adequate patient data to inform clinical services?**
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Other: _____

Section 6. Time

A key element to successful program adoption and implementation is time. Section 6 addresses the time individuals may have to dedicate to the program creation, adoption, and implementation.

Programmatic Bandwidth of Program Participants

32. **Please check all of the boxes of current projects you are involved in within your clinic.**
Check all that apply.

- [ ] Quality Improvement Projects
- [ ] Specific Process Improvements
- [ ] New Electronic Medical Record System
- [ ] N/A
- [ ] Other: _____

33. **How would you rate your work 'bandwidth'? Do you have more time to dedicate to a program implementation project?**
Mark only one oval.

- ◯ I do not have any current work projects
- ◯ I have some work projects
- ◯ I am inundated with projects from work
- ◯ N/A

34. **Rate your coworkers/potential program partners on their free work time.** *
Mark only one oval per row.

	Very Free	Somewhat Free	Free	Somewhat Not Free	Not Free	N/A
Clinical Pharmacists	◯	◯	◯	◯	◯	◯
Drug-Dispensing Pharmacists	◯	◯	◯	◯	◯	◯
MAs	◯	◯	◯	◯	◯	◯
RNs	◯	◯	◯	◯	◯	◯
NPs	◯	◯	◯	◯	◯	◯
PAs	◯	◯	◯	◯	◯	◯
Physicians	◯	◯	◯	◯	◯	◯
Administrators	◯	◯	◯	◯	◯	◯
Dieticians	◯	◯	◯	◯	◯	◯
Social Workers	◯	◯	◯	◯	◯	◯
Other	◯	◯	◯	◯	◯	◯

Section 7. Programmatic Support

Programmatic support is defined by both financial and non-financial support. Section 7 seeks to define the supports both internally and externally within your clinical setting.

Internal Clinical Support

What types of clinical support would the program have during the creation, adoption and implementation stages?

35. **Please check all boxes that apply regarding political/bureaucratic support** *
Check all that apply.

- ☐ Administrative
- ☐ Pharmacists
- ☐ Clinicians
- ☐ Specific Clinical Departments
- ☐ Other: _____

36. **Please check all boxes that apply regarding financial support** *
Check all that apply.

- [ ] Administrative
- [ ] Pharmacists
- [ ] Clinicians
- [ ] Specific Clinical Departments
- [ ] Discretionary Funds
- [ ] Other: _____

37. **How would you identify your clinic's support for innovation?**
Mark only one oval.

- ◯ Very supportive
- ◯ Somewhat supportive
- ◯ Neutral
- ◯ Somewhat un-supportive
- ◯ Very un-supportive
- ◯ Other

External Clinical Support

What types of support would the program have during the creation, adoption and implementation stages?

38. **Which groups support the clinic or program ideologically? Check all that apply.** *
Check all that apply.

- [ ] Outside Granting Institutions
- [ ] Politicians
- [ ] Community Organizers
- [ ] Pharmacists
- [ ] Clinicians
- [ ] Other: _____

39. **Which groups support the clinic or program financially? Check all that apply.** *
Check all that apply.

- [ ] Outside Granting Institutions
- [ ] Politicians
- [ ] Community Organizers
- [ ] Pharmacists
- [ ] Clinicians
- [ ] Other: _____

Patient Support

Do you perceive that the patient population frequenting your clinic would want to participate in this CDTM model program?

40. **Please rate your perception of patient support** *

Mark only one oval per row.

	Very Interested	Somewhat Interested	Interested	Somewhat Uninterested	Very Uninterested	N/A
Patient's Program Interest	◯	◯	◯	◯	◯	◯

41. **What do you perceive would be the barriers to entry for patients interested in this program?**

Please check all that apply
Check all that apply.

- [ ] Transportation
- [ ] Language
- [ ] Child Care
- [ ] Time off work to come to the visit
- [ ] Fear
- [ ] Illiteracy
- [ ] Misinformation/Misunderstandings
- [ ] Trouble paying for Medicaitons
- [ ] Other: _____

Section 8. Finances

A CDTM model can be financed through multiple options. This section identifies multiple methods for financial program support.

Internal Finances

Please identify the potential internal funding sources.

42. **Please check all the boxes that apply** *

Check all that apply.

- [ ] Drug-dispensing Pharmacy
- [ ] Internal Medicine Department
- [ ] Family Medicine Department
- [ ] Other Clinical Department
- [ ] Administration
- [ ] Larger clinic-wide federal grant that can be applied to the CDTM model
- [ ] Other: _____

External Finances

Please identify the potential external funding sources.

43. **Please check all the boxes that apply** *
Check all that apply.

- [ ] Demonstration Grant
- [ ] General Clinical Grant
- [ ] Seed Funding
- [ ] Funding dedicated to Program Sustainability
- [ ] Donations
- [ ] Other: _____

Reimbursement for Clinical Services

What are the ways your clinic reimburses for services?

44. *Check all that apply.*

- [ ] Pharmacy Drug-Dispensing
- [ ] Medicaid
- [ ] Medicare (specifically Medicare Part B funding)
- [ ] Third Party Payers
- [ ] Other: _____

45. **What do you perceive as the opportunity cost for creating a CDTM model for your clinic? What program/initiative will your clinic not develop while the CDTM model is being implemented?**

_____

_____

_____

_____

_____

Thank you!

This marks the end of the worksheet. Please check your inbox for your summary answers, or use the printed sheet to help guide your program development or expansion. Also, remember to compare your responses to the Implementation Guidelines.

CHAPTER EIGHT

Teaching Case: La Esperanza Community Health Center:

The Challenges of Disease Burden and Programmatic Planning

Introduction

It was August, 8, 2001. Tony Galeano, Pharmacy Director of the La Esperanza Community Health Center in Phoenix, Arizona breathed a sigh of relief as he set down the monthly pharmacy reports. His concern for the increasing number of patients with Type II diabetes at La Esperanza led him to compare two groups of patients who had uncontrolled and elevated blood sugar levels in a six-month trial program.

The study consisted of one control group receiving regular clinical care and another given the program intervention. The program intervention placed clinical pharmacists as the main interface with the patient, facilitating the patient visit to monitor and control the patient's diabetes. According to the American College of Clinical Pharmacy, a clinical pharmacist provides patient care that optimizes the use of medication and promotes health, wellness, and disease prevention.[48] Galeano noted that the blood sugar levels of the patients enrolled in the intervention group were more controlled after participating in the study as compared to the control group. While La Esperanza clinic leadership supported this project, Galeano's program was self-motivated. Moreover, Galeano was not convinced his trial program was making a big enough impact. He needed to replicate the outcome of the study and look at other options

[48] ACCP - Directory of Residencies, Fellowships, and Graduate Programs [Internet]. [cited 2015 Feb 19]. Available from: http://www.accp.com/resandfel/index.aspx

to treat the patient population to make sure he had thoroughly evaluated the best way to treat the high number of diabetic patients in the most effective way possible.

Galeano was not sure this trial study would ever come to fruition let alone show positive clinical results in six months. As he shuffled through the paperwork, he could not pinpoint what aspect of the program had worked most effectively. Once patients were diagnosed with diabetes, they were given the choice to opt into a program where they received face-to-face meetings with a clinical pharmacist who treated and educated them about their current disease state. The program was working as Galeano's statistics showed that more patients had more control of their diabetes. The Emergency Department reported lower admissions due to complications with diabetes, however Tony did not know why. After informally speaking with patients to better understand their preferences, Tony's hypothesis was that patients simply enjoyed and preferred talking with pharmacists directly about medication management. Professionally, he felt that he had to answer this question.

A clinic in northwest Phoenix, serving a similar patient population, had created a nurse case management program for patients diagnosed with diabetes. By all accounts the northwest Phoenix program was successful and Galeano wondered if the structure of his trial program should change in some way to provide increased benefits for La Esperanza patients. Galeano considered the other options for medication management for the patient population with diabetes at La Esperanza. Could there be a nurse case manager component to treat these patients at La Esperanza? Should nurse case managers be the primary point of contact for chronic disease care management? Galeano needed to

resolve how to most effectively and efficiently serve his growing population of diabetic patients. What type of outpatient clinical program would best address diabetes care management? Should La Esperanza expand the existing clinical pharmacist program, or try a new type of provider like nurse case management to address the patient population with diabetes? It would not be until almost eight years later under the direction of his successor, Camila Anzaldua, that the future of the program would be decided.

Background

A 1977 graduate of the University of Arizona College of Pharmacy, Galeano sought to provide quality practice and service to the Phoenix community and profession. He deeply believed in the potential of pharmacy and pharmacists to impact community and ambulatory services and felt that equal access to medications and healthcare were inalienable rights for all Phoenicians. After working as a drug-dispensing pharmacist at multiple pharmacies in the Phoenix community for over a decade, Galeano became the Director of the La Esperanza Community Health Center Pharmacies in January of 1998.

As Pharmacy Director, Galeano dedicated his time and efforts to providing the patients of La Esperanza quality care from the pharmacists on staff and dispensing low or no cost medications for those patients who could not afford them. In 1999 Galeano began to work with the Arizona Board of Pharmacy on a new system for remote pharmacy services called ScriptPro. This telepharmacy system provided remote pharmacy services to the La Aldea clinical site, one of La Esperanza's satellite clinics outside of Phoenix. La Aldea mainly served hard-to-reach populations that were either uninsured or on Medicaid. The ScriptPro system used a robot to pre-package tablets and

capsules into barcoded containers, which were then sent to the La Aldea clinic for filling prescriptions. The clinic would electronically transmit prescription orders to Health Center pharmacists who screened, approved, and released them back to the clinic for filling. Galeano and his team identified how the last step of the process would work. He was deciding whether pharmacy technicians would use scanning stations for prescription refills, or simply receive the prefilled containers labeled with instructions for patient use.

Galeano reveled in questions like: how do we make our patient populations healthier and have better access to quality services and low or no cost of medications? Over the next few months, Galeano built a team at La Esperanza of likeminded pharmacists and pharmacy technicians. He challenged his staff to be both creative and find solutions to daily problems facing their clientele. He focused on the elderly and on young families with linguistic, cultural, economic, and transportation-based barriers that hindered their access to health and pharmaceutical care. Galeano wanted the patients to obtain their medications on site at a La Esperanza clinic so that a pharmacist could provide counseling services. He believed that enabling patients to leave the clinic with prescriptions in hand would increase prescription pickup compliance and hopefully address underlying medical conditions.

It was from the ScriptPro effort that Galeano realized that pharmacists had more to contribute to patient care than just medication dispensation. Once it was documented that there was an increase in medication fulfillment and the patient population had more controlled diabetes using ScriptPro, Galeano worked to expand the ScriptPro program for a wider patient base. To lower the cost of medications for the patient population even

further, Galeano applied for a low-cost medication grant from Pfizer. By the end of 2000, after receiving the grant from Pfizer, La Esperanza's ScriptPro program became one of the largest national recipients of free pharmaceuticals from Pfizer. Galeano estimated that La Esperanza annually received about a quarter of a million dollars in free medications from Pfizer, which was only offered to a select few community health centers nationally. After implementing the ScriptPro program at all of the La Esperanza clinical sites, the number of prescriptions filled in the La Esperanza pharmacies increased over 30 percent from 1998 to 2001. A total of about 302,000 prescriptions were filled using the ScriptPro program and patient meetings with pharmacists increased sixteen fold. Galeano encouraged his staff of pharmacists, medical assistants, and nurses to think creatively about potential patient care solutions—including prescribing practices.

Galeano's leadership style and superior pharmacy management attracted pharmacy students from all over the Phoenix region and beyond. For experience, the University of Arizona College of Pharmacy conducted senior rotations in La Esperanza pharmacies. Pharmacy technicians from Pima Community College, Apollo College and Pima Medical Institute also chose to do rotations at La Esperanza where students received on-site experience. This influx of students and trainees bred a culture of innovation and learning.

La Esperanza Health Center

La Esperanza Community Health Center was founded in the late 1960's by Arizona State University and neighborhood activists. The clinic founders wanted to bring accessible and affordable health care to Phoenicians who were "being overlooked

by traditional health care systems."[49] By 2001, La Esperanza consisted of three clinical sites and served over 20,000 unique patient visits annually—almost 54 patients per day.[50,51,52] Over 70 percent of the patient population self-identified as Hispanic or Mexican-American.[53] La Esperanza provided accessible and affordable health care primarily to underserved populations in the greater Phoenix area and southern Arizona. Of the patients served at La Esperanza, 76 percent reported living at or below the federal poverty level.[54] Figure 14 describes the clinic's organizational make-up.

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[49] About El Rio [Internet]. [cited 2014 Jan 24]. Available from: http://www.aphafoundation.org/sites/default/files/ckeditor/files/El Rio - Community Fact Sheet(1).pdf

[50] Visits with clinical pharmacists could run between 15-60 minutes depending on the needs of the patient.

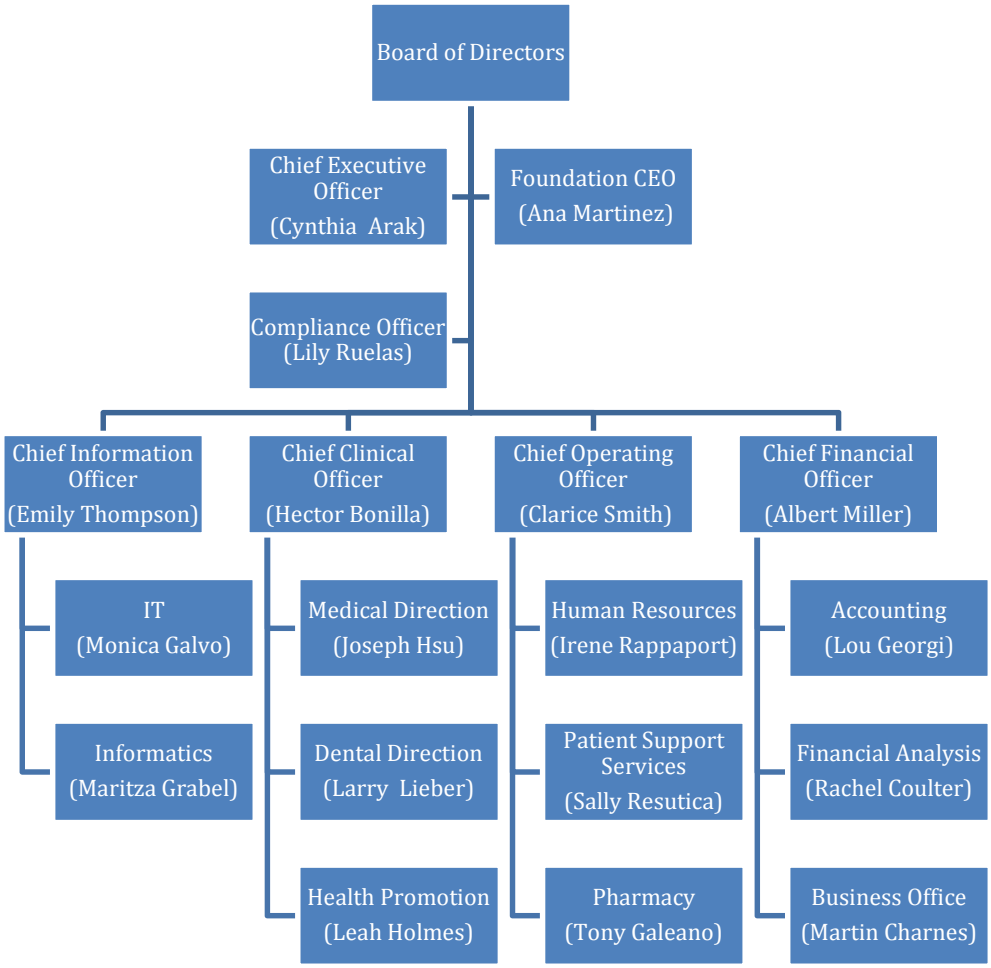
[51] Leal S, Soto M. Pharmacists disease state management through a collaborative practice model. J Health Care Poor Underserved [Internet]. 2005 May [cited 2013 Dec 17];16(2):220–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15937384

[52] Leal S, Soto M. Chronic kidney disease risk reduction in a Hispanic population through pharmacist-based disease-state management. Adv Chronic Kidney Dis [Internet]. 2008 Apr [cited 2013 Dec 17];15(2):162–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18334241

[53] Johnson, William et. al. Evaluation of El Rio Community Health Center ' s Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

[54] Our Story | El Rio COMMUNITY HEALTH CENTER [Internet]. El Rio Community Health Center. 2013 [cited 2014 Jun 23]. Available from: http://www.elrio.org/about-us/our-story/

Figure 14. La Esperanza Community Health Center Organizational Chart



Development of the Collaborative Drug Therapy Management (CDTM) Project

At the core of Galeano's goals for the patients at La Esperanza and for Phoenix, was a desire to address not only the cost of medications, but also the quality of the interactions between pharmacists and patients with prescription education and patient care. After his six month study was completed, Galeano knew that he needed to replicate his findings in an organized and longitudinal research project. He had already applied for

a Clinical Pharmacy Demonstration Project Grant from the Office of Pharmacy Affairs under the U.S. Health Resources and Services Administration (HRSA)'s Healthcare Systems Bureau at the U.S. Department of Health and Human Services. The demonstration grant from HRSA identified Federally Qualified Health Centers to run an outpatient clinical pharmacy program within their clinic addressing disease state management for one chronic disease.

What is Diabetes?

According to the Arizona Department of Health Services, diabetes mellitus is a group of chronic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Without insulin, or if it is ineffective in the body, glucose builds up in the bloodstream leading to diabetes. The concentration of blood glucose in the blood stream is most often measured in milligrams/deciliter (mg/dl) and the fasting test reports normal range is 60-100 mg/dl. The two preeminent risk factors associated with diabetes are obesity and physical inactivity. Diabetes is largely a preventable and manageable chronic disease. People with well-managed diabetes have better clinical outcomes and reduced medical costs. A patient's A1C level (a maker for average blood glucose levels) is the primary marker for diabetes control. *Citation: Montiel M. Arizona Diabetes Burden Report: 2011 Arizona Department of Health Services. 2011.*

The demonstration grant's specific objective was to provide comprehensive pharmacy services to the medically underserved in Phoenix, Arizona.[55] Galeano specified La Esperanza's diabetic patient population in the grant application since diabetes was the highest burden of chronic disease within the patient population at La Esperanza at that time. More than one third of La Esperanza's patient population had diabetes, and almost another third were pre-diabetic. Table 17 describes some of the patient disease profiles as of 2010.

[55] Johnson, William et. al. Evaluation of El Rio Community Health Center ' s Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

Table 17. La Esperanza Patient Disease Profiles, 2010

Disease	Total Number of Identified Patients	Total Estimated Number of Patients Undiagnosed[56]
Diabetes Mellitus, Total	8,629	1,350
-Pre-Diabetes	3,597	460
-Diabetes	5,032	890
Hypertension	15,842	3,500
Hypercholesterolemia	26,672	12,400

Since 1995, Arizonans were increasingly feeling the effects of diabetes, and the patient populations at La Esperanza were no exception. As of 2010, one in thirteen adults living in Arizona had diabetes—nearly 500,000.[57] The estimates of the total cost of diabetes on Arizona totaled $3.3 billion including $2.3 billion in medical bills and more than $1 billion in indirect costs.[58] There was an 80 percent increase in people diagnosed with diabetes from 1995 to 2010.[59] In Arizona, African-Americans, Hispanics, American Indians and Asian-Americans are twice as likely to have Type 2 diabetes as non-Hispanic Whites.[60]

Once Galeano received one of the 17 start-up grants from HRSA, he was off and running. Galeano and his team set-up the HRSA grant in the same way he had organized his previous small sized research project at La Esperanza. For the three year study, he added more patients and pharmacists to the study groups and organized the first outpatient clinical pharmacy program. The program had a group of patients with diabetes

[56] Figures estimated from 2010 data describing the current patient population seeking services at El Rio.
[57] Montiel M. Arizona Diabetes Burden Report: 2011 Arizona Department of Health Services. 2011.
[58] Ibid.
[59] Ibid.
[60] Philanthropies HF, Information H. Evaluation of El Rio Community Health Center's Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

who were referred to a pharmacist-overseen program. The program monitored, tested, and evaluated A1C levels, foot checks, eye exams, and medication management in the patient population. The program included four pharmacists with 400 diabetic patients seeking services. The patients visited with the pharmacist directly before filling their prescriptions at the pharmacy. Every few weeks, patients had their A1C levels checked by the pharmacists in a private exam room in the Internal Medicine Department.

Operation and Management of the Program

Patients were referred to La Esperanza's diabetes management program by their physician when they had newly diagnosed or uncontrolled diabetes. The collaborative practice agreements in place at La Esperanza allowed pharmacists to manage the patient's medication therapy within a pre-identified scope. During the patient visit, pharmacists used their understanding of medication therapy, including formulary guidelines and drug protocols, to make recommendations and changes in patient's therapy regimens.[61] The pharmacist was responsible for monitoring a patient's medication therapy and making modifications as they were needed. The pharmacist's role was to provide continuous monitoring, patient education, identification and resolution of adherence and therapy related concerns, as well as monitoring for actual or potential adverse drug interactions.[62] As identified during the pharmacy visits, a pharmacist could refer patients to other providers in the areas of ophthalmology, podiatry, nutrition or behavioral health.

After three years, the program had made progress reducing emergency room visits

[61] Project IMPACT: Diabetes | APhA Foundation [Internet]. [cited 2015 Mar 23]. Available from: http://www.aphafoundation.org/project-impact-diabetes/communities/el-rio-health-center
[62] Ibid.

for complications due to diabetes and increasing the number of patients with controlled diabetes. All of the clinical parameters (e.g. blood pressure, A1C levels, and BMI) that had been monitored showed statistically significant improvements for diabetic patients enrolled in the pharmacist-based program as compared to a control group of diabetic patients not enrolled in the program.[63, 64] For example, there was a decrease in negative drug interactions by 34 percent for patients enrolled in the program. Data showed that hard to manage patients experienced lower and more stable A1C levels. Most importantly, pharmacist providers included diabetes patient education during their office visits. The initial demonstration project was a documented and validated success due in part to the providers and patients alike recognizing the program's potential power and embracing it early on into the program.[65]

Galeano and his team were ecstatic with the results. The La Esperanza's administrative team encouraged Galeano to develop a sustainable model program for patient continuity for those patients already seeking services through this grant. Galeano ruminated on how he would integrate his findings from his first study and the results from the HRSA grant to come up with a more all-encompassing, effective, and sustainable program. How could Galeano harness the effectiveness from ScriptPro, and

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[63] Leal S, Soto M. Pharmacists disease state management through a collaborative practice model. J Health Care Poor Underserved [Internet]. 2005 May [cited 2013 Dec 17];16(2):220–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15937384

[64] Philanthropies HF, Information H. Evaluation of El Rio Community Health Center's Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

[65] Leal S, Soto M. Pharmacists disease state management through a collaborative practice model. J Health Care Poor Underserved [Internet]. 2005 May [cited 2013 Dec 17];16(2):220–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15937384

direct patient care to a larger audience? What other options did he need to consider to ensure that he covered his bases?

In the Beginning: Pharmacy-Based Diabetes Management Program (PBDMP)

Under the direction of Tony Galeano, the Pharmacy-Based Diabetes Program (PBDMP) at La Esperanza officially began in August, 2004. The HRSA-sponsored clinical pharmacy demonstration grant clearly showed the effectiveness of a clinical pharmacist working with direct patient consultations. La Esperanza was now committed to hiring a clinical pharmacist and beginning a formal clinical pharmacy program. The program developed slowly, initially working to augment care already provided by physicians. The program expanded over the following six years and the clinical roles of the pharmacists were defined over time. Clinical pharmacy roles became more defined regarding the patient encounter and interaction. Pharmacists began to develop niche areas—bilingual pharmacists saw many of the Spanish-only speaking patients, while other pharmacists specialized in Native American populations seeking services at La Esperanza.

The program included direct service and interventions for patients through disease state management including prescribing medications and in-depth educational consults empowering

What is Hypercholesterolemia?
Hypercholesterolemia is the presence of high levels of cholesterol in the blood stream. It is typically due to a combination of genetic and environmental factors. Lifestyle choices including diet, exercise, and tobacco smoking strongly influence the amount of cholesterol in a patient's blood. Patients diagnosed with hypercholesterolemia are recommended to make diet modifications, and in specific cases, medication is prescribed to lover cholesterol levels. *Citation: Health NI of. Hypercholesterolemia. US National Library of Medicine, National Institutes of Health, Department of Health & Human Services; 2015 Mar 16 [cited 2015 Mar 23]; Available from: http://ghr.nlm.nih.gov/condition/hypercholesterolemia*

patients to proactively manage their health. This ongoing direct consultation integrated treatment of three related diseases: diabetes, hypercholesterolemia and hypertension. In 2006, after two years of existence, the program was found to be cost effective and clinically effective in treating diabetes (Type 1 and Type 2) and preventing hospital admissions.[66, 67]

The leadership of La Esperanza noted that most of the decrease in total costs of patients was accounted for by a shift from insurance claims for the emergency department, inpatient and physician office visits to prescription claims. In a comparable setting, mean costs for insurance claims decreased by $2,704 per patient per year in 2002 and by $6,502 per patient per year in 2003.[68] During the same period, payers realized decreases in total direct medical costs that ranged from $1,622 to $3,356 per patient per year.[69]

The program included increased access to affordable pharmaceuticals, efficient program management, and a focus on improved patient outcomes. Specifically, the clinical pharmacists at La Esperanza as well as the medical and administrative team determined that a diabetes-focused disease state management clinic would serve the

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[66] Johnson, William et. al. Evaluation of El Rio Community Health Center ' s Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

[67] Leal S, Soto M. Pharmacists disease state management through a collaborative practice model. J Health Care Poor Underserved [Internet]. 2005 May [cited 2013 Dec 17];16(2):220–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15937384

[68] Cranor CW, Bunting B a, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash) [Internet]. 2003;43(2):173–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12688435

[69] Cranor CW, Bunting B a, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash) [Internet]. 2003;43(2):173–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12688435

needs of its members.[70] In 2007, the project initially hired one clinical pharmacist to begin the outpatient pharmacy program—Camila Anzaldua. While Anzaldua was a recent clinical pharmacy graduate of the University of Arizona School of Pharmacy, she was committed to working with underserved Hispanic communities. As a bilingual Mexican-American, Anzaldua connected well with the patient population at La Esperanza.

By 2009, after five years running the PBDMP, Tony Galeano officially stepped down and promoted Camila Anzaldua, PharmD, into his role as Pharmacy Director. Galeano thought Camila was a perfect fit for the role. She was passionate about medication management and diabetes patient care and took the helm of the program seamlessly.

Further Development and Research on the Pharmacy-Based Diabetes Management Program

In 2009, a team of researchers from Arizona State University and La Esperanza developed and implemented an internal case study analysis of the La Esperanza patients who had participated in the PBDMP. The methodology included the identification of a few key indicators,

What is Hypertension?
Hypertension is a condition where high blood pressure forces blood against a patient's artery walls at a high enough rates that it may eventually cause health problems, such as heart disease. It is estimated that 1 in 3 U.S. adults have high blood pressure. Lifestyle changes are recommended to decrease blood pressure, and medications are also available to treat the condition. *Citation: High Blood Pressure (Hypertension) Information | cdc.gov [Internet]. [cited 2015 Mar 23]. Available from: http://www.cdc.gov/bloodpressure/*

[70] Leal S, Soto M. Pharmacists disease state management through a collaborative practice model. J Health Care Poor Underserved [Internet]. 2005 May [cited 2013 Dec 17];16(2):220–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15937384

development of an abstraction tool, and then data collection from the program's data base.

The first deliverable of the project was to evaluate the program's effectiveness in terms of affecting utilization of emergency departments (ED) for diabetes and other indicated outcomes.[71] After the first phase of data was collected and analyzed, the second variable examined by the team was cost effectiveness data of the PBDMP in contrast to patients diagnosed with diabetes seeking regular care at La Esperanza.

The study team found that the La Esperanza measures of the program were generally superior by a relatively large amount for test and exams related to diabetes as compared to the ED. The trend data showed substantial improvements in outcome measures in La Esperanza performance of the diabetes tests and exams over the study period. This trend was accompanied by a shift from lower rates than the control group (regular care at La Esperanza) to higher rates and the maintenance of that superiority in all subsequent months of the study.

The analysis showed average total charges were substantially lower for La Esperanza during the PBDMP as compared to the years prior to the program implementation. The team showed that there was substantial evidence to support a conclusion that the La Esperanza PBDMP was effective in improving the care and, within stated constraints, succeeded in reducing the health care costs for the patient and clinics treating the patients.

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[71] Johnson, William et. al. Evaluation of El Rio Community Health Center ' s Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

The area that Galeano noticed was still lacking for the pharmacists in the program was longitudinal care and re-entry into the program. While most patients were successful at lowering biometric markers while enrolled in PBDMP services, some patients cycled back into the program if their diabetes was not under control. Galeano wondered if nurse case managers could address this burden of patient re-admission.

Official Collaborative Drug Therapy Management (CDTM) Recognition

In the U.S., pharmacists are able to consult and advise patients within a limited scope of practice depending on state law.[72] Pharmacists are not recognized as healthcare providers under the Social Security Administration.[73] Some states do offer pharmacists limited scopes of prescribing power, a provider status title, and provider reimbursement mechanisms.[74] In Arizona, pharmacists are providers in title only. While the PBDMP functioned on a small scale at La Esperanza, a comprehensive pharmacist-inclusive team-based approach to patient care was not yet legal in Arizona.

Many types of employment and practice agreements currently exist between Nurse Practitioners, physicians, and Physician Assistants, however, a Collaborative Drug Therapy Management (CDTM) Collaborative Practice Agreement is specific to pharmacists. The CDTM designation is important because it is descriptive of the usual scope of practice between the physician and the pharmacist; e.g. drug therapy

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[72] More information on up-to-date- pharmacist provider status regulations is available from the Centers for Disease Control and Prevention.

[73] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

[74] Services UD of H and H. Collaborative Practice Agreements and Pharmacists' Patient Care Services: A Resource for Pharmacists. US Dept Heal Hum Serv Centers Dis Control Prev 2013. 2013.

management.[75] The Academy for Managed Care Pharmacy (AMCP) describes CDTM models as a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist(s) to manage a patient's drug therapy autonomously.[76]

Collaborative Practice Agreements (CPAs) can be arranged between any type of licensed health care provider in both inpatient and outpatient settings. CPAs define certain patient care functions that each care provider on a team, including pharmacists, can provide autonomously under specific situations and conditions.[77] Throughout La Esperanza, CPAs were in place to create formalized teams of physicians, nurses, and pharmacists for more effective patient care.

Without CDTM in Arizona, pharmacists could not change medications or prescribe new medications within the PBDMP. In January of 2011, the bill SB 1298 Pharmacists; Drug Therapy Protocols was introduced at the Arizona State Senate.[78] The state bill described the State Board of Pharmacy's clinical practice purview for Doctors of Pharmacy. The bill defined the circumstances when a pharmacist could be "implementing, monitoring, and modifying drug therapy and use; conditions; definitions" in the state of Arizona.[79]

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[75] AMCP. Practice Advisory on Collaborative Drug Therapy Management: Academy of Managed Care Pharmacy. 2012. p. 1–7.
[76] Ibid.
[77] Lisa Zubkoff. Using a Virtual Breakthrough Series Collaborative to Reduce Postoperative Respiratory Failure in 16 Veterans Health Administration Hospitals. Jt Comm J Qual Patient Saf. 2014;40(1).
[78] Barto S, Carter R, Antenori S, Meyer R. SB 1298 Introduced by the provider and the laboratory tests that may be ordered. 2011
[79] Ibid.

From January to April, the bill was modified and the pharmacist community of Arizona worked to better define pharmacist's role in Arizona state law. On April 13, 2011, the bill was made into law defining pharmacists expanded roles in clinical patient care. Further legislation followed, including Arizona Revised Statute 32-1970 which allowed qualified pharmacists in specified health care settings (such as a community health center) to implement, monitor, and modify drug therapy as described by written protocols in collaboration with physicians.[80]

Through these legislative processes and community advocacy, the practice model of CDTM was approved for use in Arizona. The CDTM model, aspects of which were already in place at the La Esperanza Health Center, was quickly embraced. Anzaldua knew the passage of CDTM in Arizona was important for the future development and flexibility of the PBDMP. With CDTM, pharmacists and Nurse Practitioners could essentially perform the same function, within a specific scope, in a clinical capacity. While pharmacists were stronger care providers for medication management due to their pharmacology educational background, Nurse Practitioners thrived in offering quality and individualized patient care. The clinic management also noted that Nurse Practitioners had a higher degree of flexibility in their training than pharmacists and could be assigned to different areas of the clinic as needed. By 2011, Anzaldua expanded the scope of practice for pharmacists and increased the number of CPA agreements for both pharmacists and nurses.

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[80] Philanthropies HF, Information H. Evaluation of El Rio Community Health Center's Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

Current La Esperanza Pharmacy-Based Diabetes Management Program

The program currently has eight clinical pharmacists (5.6 full-time equivalent clinical pharmacists) on staff. The PBDMP sees about 4,000 to 5,000 unique patient visits annually.[81] Each pharmacist sees approximately 275 to 350 individual patients per year. From 2001 to 2014, the PBDMP has served over 4,000 patients.[82]

There is data to document a decrease in hospital 30-day readmission rates of patients participating in the La Esperanza PBDMP.[83] To date, there are clinical pharmacists based in 16 of the 17 clinical sites of La Esperanza. While there is not clinical pharmacist coverage every day of the work week at each clinical site, usually four out of five days a week, there is a clinical pharmacist on-hand at each clinic.

Recently, more data was collected on comorbid hypercholesterolemia in diabetic patients treated in the PBDMP. A quick chart review on the NEXGEN system showed that hypercholesterolemia and cardiovascular disease were common among patients seeking services from the PBDMP. Anzaldua wondered to herself…just *how* common? Table 17 represents the patient population seeking services at La Esperanza as of 2010.

Different Levels of Readiness and Buy-in from Stakeholders

By 2014, La Esperanza was considered one of the largest non-profit community health centers in the United States. Due to the work of Galeano, Anzaldua, and their

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[81] Goldberg J. Program Director, El Rio, Key Informant Interview. Tucson, Arizona; p. 18.
[82] Ibid.
[83] Philanthropies HF, Information H. Evaluation of El Rio Community Health Center's Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.

teams, La Esperanza had become a national model for pharmacy-based outpatient health care delivery.[84] However, Anzaldua wanted more—she wanted to make her mark on the world of clinical pharmacy and expand services to include other allied health professionals to treat diabetes in El Rio's patient population.

While the efforts of Galeano and Anzaldua all directly addressed the high burden of diabetes among the patient population at La Esperanza, diabetes is still one of the largest burdens of chronic disease in the U.S. In 2011, 8.1 percent of adults in Arizona were diagnosed with diabetes, consistent with the 8.3 percent of percent of adults in the greater Phoenix area.[85] According to the Arizona Department of State Health Services, there has been an 80 percent increase in people diagnosed with diabetes from 1995 to 2012.[86] Research has shown that since one third of the U.S. population with diabetes is undiagnosed, it is estimated that there are nearly 600,000 adults with diabetes in Arizona.[87]

In 2014, the number of patients with uncontrolled diabetes enrolled in the program was the highest recorded in the history of La Esperanza. Anzaldua was not sure if patients were coming to the PBDMP explicitly for the diabetes management programming, or if the incidence of diabetes was increasing within the La Esperanza patient population. Anzaldua knew she needed to do more for the current patient

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[84] Johnson, William et. al. Evaluation of El Rio Community Health Center ' s Pharmacy-Based Diabetes Disease Management Program Sponsored by and Prepared for Heinz Family Philanthropies.
[85] Centers for Disease Control and Prevention; Diabetes Statistics, Arizona, 2012 [Internet]. [cited 2015 Mar 23]. Available from: http://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html
[86] Project IMPACT: Diabetes | APhA Foundation [Internet]. [cited 2015 Mar 23]. Available from: http://www.aphafoundation.org/project-impact-diabetes/communities/el-rio-health-center
[87] Ibid.

population with medication management. She also knew that there were multiple other clinical care options within medication management (utilizing pharmacists and nurses) that she could choose from to address chronic disease care management. How could she address this growing population of diabetes patients?

Anzaldua was not sure how to approach this potential program expansion. Anzaldua looked to her fellow Directors at La Esperanza for guidance. Would expanding the scope of the PBDMP would increase the breadth of care for potential comorbidities of La Esperanza's diabetic patients or dilute the program and undermine its current success? Additionally, the Registered Nurse Care Coordinators (RNCC)s at La Esperanza had recently presented Anzaldua with a proposal to build on the success of their current nurse case manager program. Anzaldua found herself at a decision point—should she expand the PBDMP to include cardiovascular disease, hypercholesterolemia, hypertension or another chronic condition comorbid with diabetes, or look to incorporate nurse care coordinators to work with the diabetic population at La Esperanza?

Anzaldua spoke with Hector Bonilla, the Chief Clinical Officer of La Esperanza, and Clarice Smith, the Chief Operations Officer. She sought assistance to help identify the potential benefits between a nurse case manager program and an expansion of the scope of the PBDMP.

Nurse Case Managers and Diabetes Care

Anzaldua knew that nurse case management was widely used at La Esperanza to provide high quality care with efficient utilization of medical resources. Nurse case managers served as patient connectors for specialty services at La Esperanza. They assisted in patient transitions of care and helped with 'warm' hand-offs between clinicians. Anzaldua knew that there was a role for nurses in outpatient clinical pharmacy—she just had to define their purview.

What is a Nurse Case Manager?
A nurse case manager is responsible for organizing and coordinating resources and services in response to individual healthcare needs. Case management is directed toward a targeted or selected client or family population such as transplant, head-injured, or diabetic patients. The goals of nurse case management are to foster patient self-managed care, and maximize the efficient and cost-effective use if health resources for the health care setting and patent. *Citation: Case Management Society of America. Chapter [Internet]. [cited 2015 Mar 24]. Available from: http://www.cmsa.org/chapter/tabid/63/default.aspx*

After consulting with the Chief Operating Officer, Clarice Smith, who herself is a registered nurse, Anzaldua decided to learn more about the essence of nurse patient-centered, multidisciplinary approach of case management. She identified the elements of patient navigation of the nurse's roles that were highly effective in patient coordination. Through a literature review and key informant interviews of successful nurse case management programs, Anzaldua learned that to perform holistic care, nurse case managers place great importance on individualized care. They develop partnership and trust with patients, facilitate communication between patients and care providers, and empower patients with knowledge of disease care.

Anzaldua knew that nurses had less of a background in pharmacotherapies than pharmacists and similar to pharmacists, had prescription power limited to a pre-

established formulary. However, she was sure they had a high potential for effectiveness with the diabetes management patients due to their heightened sensitivities of patient awareness. Not all pharmacists complete a clinical residency; however, all nurses must be certified on their clinical skills to be able to practice clinically.

Anzaldua found that in comparable clinical settings, nurse case managers had shown a measurable difference in increasing positive patient outcomes as compared to a control group.[88] Studies have shown the benefit of nurse case management through patient empowerment that promotes adjustment to new chronic illness diagnoses.[89] The data from nurse case managers in a diabetes self-management program showed that after the intervention, there were a lower number of hospitalizations, better recovery, and better quality of life for the patient population in the intervention group as compared to the control.[90] Table 18 describes many of these benefits.

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[88] Goldberg J. Program Director, El Rio, Key Informant Interview. Tucson, Arizona; p. 18.
[89] Chen Y-C, Chang Y-J, Tsou Y-C, Chen M-C, Pai Y-C. Effectiveness of nurse case management compared with usual care in cancer patients at a single medical center in Taiwan: a quasi-experimental study. BMC Health Serv Res [Internet]. BMC Health Services Research; 2013;13(1):202. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3673875&tool=pmcentrez&rendertype=abstract
[90] Ibid.

Table 18. Benefits of Nurse Case Management[91]

• Planning with all stakeholders to maximize healthcare responses, quality, and cost-effective outcomes
• Facilitating communication and coordination among stakeholders, involving the patient in the decision-making process in order to minimize service fragmentation
• Empowering the patient to problem solve by exploring care options and alternative plans, when necessary, to achieve desired outcome
• Encouraging the appropriate use of healthcare services and striving to improve the quality of care and maintain cost-effectiveness on a case-by-case basis
• Assisting the client in safe transitions of care to the next most appropriate level

Other studies showed that patients with poor social support received greater benefit from nurse case management as compared to any other provider. Case management programs have demonstrated positive outcomes through various methodologies and settings including: diversity in target groups, intervention settings, outcome measures, and disease profiles.[92] Rigorous methods and unequivocal outcome measures are required to validate the effects of nurse case management and collaborative pharmacist models.

One of the studies supported positive effects of nurse case management in timeliness and frequency of treatment regimen.[93] Utilizing nurse case managers reduced unplanned readmission due to complications, improved patients' self-reliance, and further enhanced treatment continuity of patients. Importantly, nurse case managers were shown

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[91] Leonard, Margaret, et al., Nursing Case Management Review and Resource Manual, 4th Edition, 2012 Dec [cited 2015 June 11]. Available from: http://www.nursecredentialing.org/documents/certification/reviewmanuals/nursecasemgmtsamplechap.aspx.

[92] Chen Y-C, Chang Y-J, Tsou Y-C, Chen M-C, Pai Y-C. Effectiveness of nurse case management compared with usual care in cancer patients at a single medical center in Taiwan: a quasi-experimental study. BMC Health Serv Res [Internet]. BMC Health Services Research; 2013;13(1):202. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3673875&tool=pmcentrez&rendertype=abstract

[93] Ibid.

to be effective in treating multiple chronic disease profiles during one patient visit, including diabetes, hypercholesterolemia, and hypertension.

Moreover, Anzaldua was fascinated by the cost benefit analyses of the nurse case management studies. The initial results of a diabetes management program showed greater reduced costs per patient per year using a nurse case manager model than a pharmacist-inclusive model. Of the studies researched, they showed that mean costs for insurance claims decreased by $10,312 per patient per year in 2010 and by $19,691 per patient per year in 2011. During the same period in a comparable setting, payers realized decreases in total direct medical costs that ranged from $3,752 to $6,853 per patient per year. These findings support the significant cost effectiveness and increased flexibility of nurse case manager care as compared to a pharmacist-inclusive practice.

Task-Shifting and Management

As Anzaldua contemplated the benefits of nurse case management at La Esperanza, she realized that flexibility was integral for the management of her staff. Due to their educational background, Anzaldua and the senior leadership felt that nurses and Nurse Practitioners were able to task-shift around the clinic at more seamlessly than pharmacists. Nurses were able to work in the PBDMP, float to cardiovascular clinics or other internal medicine departments with minimal transition and workflow disruption. However, clinical pharmacists were only able to task shift into two key areas—a drug-dispensing pharmacy and an outpatient clinic.

Another factor Anzaldua needed to weigh was salary differences between pharmacists and nurses or Nurse Practitioners. In Phoenix, an experienced pharmacist practicing in a drug-dispensing pharmacy earned $126,460 annually.[94] In contrast, a registered nurse in Arizona earned $55,000 annually, which was 18 percent lower than national averages.[95] Nurse Practitioners in Arizona earned an average of $72,000 annually.[96] Anzaldua realized that each care provider brought a specific set of strengths to a team, regardless of salary. She needed to define her clinical needs, stay within a set budget, and ensure that the programmatic decision she made were in line with other senior leadership.

External Pressures and Organizational Challenges

Like many Federally Qualified Health Centers, a key challenge for La Esperanza was self-sufficiency for long-term sustainability. In 2011, the federal government cut the appropriation for health centers by 27 percent (from $2.2 billion to $1.6 billion).[97] Due to the appropriation cut, a substantial amount of the FY 2011 Patient Protection and Affordable Care Act (ACA) was diverted to maintain existing health center operations.[98] The diversion of ACA funds meant that HRSA was no longer allowed to fund "new access points" or "expanded services" grant applications.[99] This cut represented the first federal health center budget reduction since 1982. Anzaldua and La Esperanza

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[94] Salary.com (http://www1.salary.com/AZ/Pharmacist-salary.html)
[95] Salary.com (http://www1.salary.com/AZ/Phoenix/Staff-Nurse-RN-salary.html)
[96] Salary.com (http://www1.salary.com/AZ/Nurse-Practitioner-salary.html)
[97] Goldman, L. E., Chu, P. W., Tran, H., & Stafford, R. S. (2012). Federally Qualified Health Centers and, 1–8.
[98] Ibid.
[99] Ibid.

management worried that a HRSA grant would not fund the creation of a new access point for care utilizing nurse case managers and pharmacists. Adding to current services was still an option, but Anzaldua wondered how she could work around this potential challenge.

This reduction in potential HRSA funding for expanded services worried Anzaldua and La Esperanza senior leadership. In addition to these fiscal challenges, La Esperanza continued to serve as an important public safety net for undocumented and uninsured families. The ACA's Medicaid expansion also excludes undocumented immigrants regardless of income level. Since La Esperanza did not ask patients for citizenship status upon receipt or enrollment of care services, the leadership worried that they could lose funding if it were perceived that federal dollars were being spent on undocumented immigrants.

La Esperanza was also facing growing challenges of increased need in rural and hard-to-reach communities. Patients were traveling farther distances to reach a clinic site and patient no-shows were rising in low income patient clientele. Many patients requested clinical services closer to their home communities near Native American reservations and farming communities outside of the greater Phoenix area. Many of these communities did not have a health center, pharmacy, or physician within a 50-mile radius, and patients were putting off medical visits with potentially dangerous complications. While the telemedicine program at La Esperanza was strong, clinical pharmacists had never been included as part of a potential long distance care team.

The leadership at La Esperanza was committed to address the issues of federal reimbursement of services and the distances patients traveled to visit a clinician.

Recommendations for Action: Criteria for Decision

Anzaldua knew that she had to create criteria for the Administrators to evaluate the two potential programs—include nurse case management in the patient population utilizing the PBDMP or expand the scope of comorbid chronic disease care management with pharmacists in the PBDMP. Anzaldua had to present clear data about both program options to Clarice Smith and Hector Bonilla so they could make a clinic-wide decision. She knew that criteria profoundly influence decision making and they needed to be relevant, kept to the minimum necessary for a sound decision, and be able to relate a significant amount of the available evidence to the options.[100]

As Anzaldua began to draw up the strategic plan for 2015-2016, she immediately thought of financial stability. Which program model is the most financially sustainable and provides continued positive clinical outcomes in the future? She wanted to make sure that the practitioners at La Esperanza were being used to the top of their education level as well. She wondered which model utilizes the skills of the health care team to the fullest potential. Positive patient outcomes were clear from employing both nurse case managers as well as pharmacists, but what would be the patient outcomes that would matter most to La Esperanza in the coming years? Which program would be able to deliver those outcomes? Lastly, Anzaldua thought about program impact in the El

[100] Ellet W. The Case Study Handbook: How to Read, Discuss, and Write Persuasively About Cases. Boston, MA: Harvard Business School Press; 2007.

Esperanza community. Which program provided the greatest good for the greatest number? She wondered which program affected the largest number of people in a positive and impactful way. The choice would come down to these key concepts, organized by specific criterion.

Anzaldua knew that she could widen the scope of the questions or make the criteria more specific to one of the programs or another, but she felt that the four basic criteria were the best solution for how to evaluate the potential programs.

Conclusion

Anzaldua knew that the PBDMP needed modifications to address the growing number of diabetic patients. As 2014 drew to a close, Anzaldua and her top managers were preparing for their second meeting with La Esperanza administration. The meeting was instituted the year before as a forum for discussing major problem areas and developing a commitment to division objectives for the coming year. Now it was time to look ahead to 2015, and Anzaldua had to make the case for both programs. Would Smith, Bonilla and the rest of La Esperanza's administration endorse a nurse case management model, focus on an outpatient clinical pharmacy model, or suggest that the pharmacists expand their scope of chronic disease care management? She knew the Administrators could choose either program, and she was aware of the benefits and potential downfalls of both. As the door closed behind her, Anzaldua's thoughts drifted to memories of Tony Galeano and his passion and commitment to serving the needs of the community.

APPENDIX A

Key Informant Interview Template

-Explain dissertation topic
    -goals
    -outputs: 1) interventional guidelines, 2) data tool and 3) management case study
-Interview Itself
    -what you will do with the interviews
    -keeping them short and to the point
-Consent
    -recording

Interviewee Name:

1. When you arrived at *XX* how was chronic disease management addressed?
   -what are these goals based on?
   -what are the benchmarks?

2. What programs does *XX* believe address chronic disease care management well?

3. What programs are currently in place at *XX* that address chronic disease management?

4. How and why was a (CDTM model) specifically chosen to address chronic disease care management?

5. When did the (CDTM model) begin at *XX*?

6. What was the ecology of Tucson/ *XX* when the program began? Why do you think it started? Was it about charismatic leadership? What was it?

7. Did the Tucson ACO support these goals? How? Why or why not?

8. What are the steps to implementation of the CDTM model?

9. How do patients get referred to the program?

10. Do you have pharmacists on staff? Why? Why not?

11. Do you have care coordinators on staff? Why? Why not?

12. What happens to patients once they are in the program? How does the program work?

13. What is the patient volume that uses the CDTM model now?

14. Based on clinical 30 day re-admission data, patient feedback, and satisfaction surveys, what were the successes and failures of the program within the first few years of implementation?

15. What are the future plans for the program? Any changes?

16. What changes in population data have you seen that could be/are attributable to the CDTM model?
    -Care coordinators?
    -How can we show their effectiveness?
    -How do we know it is the care coordinators?

17. Have you seen evidence that pharmacist provider status affects chronic disease care management?

18. According to Arizona statewide data (data that is not from *XX*), did the CDTM model affect health on a community level?

19. What are the barriers or road blocks to a successful CDTM model?

20. Are there others you think I should speak with? Why?

APPENDIX B

Code Book Definitions

Payment

1) Clinic support
    a) Internal monetary support from the clinic. Budgeted funds for the program or funds transferred from a different department all fall under this category. Clinical support is also understood as time and staff donated/dedicated to the program's success.
2) Outside support
    a) External monetary support from a third party payer excluding insurance companies. This definition includes hospitals, reimbursements, government funds, and grants. Any support for the program that comes from outside the clinic is considered outside support. Outside support is also understood as time and staff.
3) Insurance
    a) Insurance is the monetary transaction and payments related to patient or clinical services. This definition includes the insurance payments given or received by clinics and hospitals. Insurance billing and related definitions around lack of insurance, or an existence of insurance are also defined in this node.
4) Total Costs
    a) Total costs relates to the actual reference of total costs in the interview transcript. When a total is mentioned or sum amount of anything—payment, reimbursement, expenditures, etc., it is identified in this category.
5) Payment Successes
    a) Payment success is a term used to code for any type of model or modality that is perceives as a billing, cost, or payment 'win' at the clinic. When a payment is made more effective, or a provider is able to be reimbursement—it is a payment success.
6) Payment Failures
    a) Payment failure is a disconnection, barrier, failure or inefficient way for a payment to be made or received. It is defined by a comment or discussion or failures within a payment mechanism.

Teamwork

1) CDTM
    a) Collaborative Drug Therapy Management (CDTM) is literally defined by the mention of a CDTM model. CDTM can also be defined when medication management models in pharmacist-inclusive practices are present.
2) CPA
    a) A Collaborative Practice Agreement (CPA) can be coded when the definition is literally defined and when a model of collaborative practice is discussed. A team-

based care model that emphasizes collaborative practice is also included in this definition.

3) Team-based care
   a) Team-based care is defined as care given in a team-based approach that does not fall under the guidelines of a specific CPA or CDTM. This definition is also inclusive of generalized teamwork within a clinical setting.
4) Teamwork Successes
   a) Teamwork successes are examples of teamwork executed well. A program, patient, or situation that is enhanced by teamwork falls under this category.
5) Teamwork Failures
   a) Teamwork failures are examples of teamwork not executed well. A program, patient, or situation that is not enhanced or is diminished by teamwork failures or general teamwork barriers falls under this category.

Pharmacists

1) Education
   a) Education of pharmacists is defined by the literal mention of what pharmacists are taught to do/complete during their training. Education is the knowledge base of pharmacists. Education can also be understood as continuing education for current pharmacists.
2) Scope of Work
   a) The scope of work for pharmacists is the work purview for pharmacists in clinical practice and in drug dispensing pharmacy. Scope of work relates to the tasks pharmacists are assigned to complete and what their day-to-day work practices entail with a CDTM, CPA, or just teamwork—it is all inclusive.
3) Provider Status
   a) Provider status relates to both the existence and absence of provider status for pharmacists. Provider status refers to the Social Security Administration (SSA)'s definition of a clinician. Pharmacists do not have a clinical status according to the SSA and therefore do not have provider status. Barriers to or successes related to provider status are both categorized in this same node.
4) Pharmacists Successes
   a) Pharmacist's successes are defined by major 'wins' or efficiencies either created by or for pharmacists to work for effectively in the clinical setting.
5) Pharmacist Failures
   a) Pharmacist's failures are defined by major 'losses' or inefficiencies either created by or for pharmacists that do not allow pharmacists to work effectively and efficiently in the clinical setting.

El Rio

1) History
   a) El Rio history relates to the history of the clinic's development, creation, or past clinical or patient practices. It encompasses the past—writ large—at El Rio. Past

leaders, supporters, barriers, programs, etc. are all categorized under this definition.

2) Present
   a) Present refers to the current practices at El Rio. The definition also includes current employees, programs, and practices in place. This definition includes all programmatic support and information about the present at El Rio except for the Pharmacy-Based Diabetes Management Program.
3) Future
   a) Future defined El Rio's plans for the future in programming, staffing, and goal setting. Items or aspects of current programs or situations that an interviewee wants to change for the future are also defined under this node.
4) El Rio Strengths
   a) El Rio strengths define the literal strengths of El Rio. This definition includes only aspects of El Rio from items that are currently in place. Strengths can be understood as people, programs, attitudes, behaviors, etc. Past strengths and future goals are not identified under this definition.
5) El Rio Failures
   a) El Rio failures define the literal failures or barriers of El Rio. This definition includes only aspects of El Rio from items that are currently in place. Failures or barriers can be understood as people, programs, attitudes, behaviors, etc. Past strengths and future goals are not identified under this definition.

<u>Process</u>

1) Efficiencies
   a) Efficiencies are programs, decisions, changes in work flow, etc. that improve efficiency. This definition refers to any efficiency in place now or set in place in the past to increase efficiency.
2) Quality Improvement
   a) Quality improvement refers to goals or programs in place to improve quality. The definition can be for programs defined as 'QI' projects or improvements that were directly aimed at quality improvement. This definition refers to any efficiency in place now or set in place in the past to increase efficiency.
3) Current State
   a) Current state is the current status of the Pharmacy-Based Diabetes Management program. The definition includes how the program functions on a day-to-day basis.
4) Process strengths
   a) Process strengths refer to the strengths, successes and supports of the Pharmacy-Based Diabetes Management Program.
5) Process weaknesses
   a) Process weaknesses refer to the barriers, weaknesses and lack of supports for the Pharmacy-Based Diabetes Management Program.

Successes *(Same definitions as above, just re-collated for data analysis)*

1) Payment
   a) Payment Success is a term used to code for any type of model or modality that is perceives as a billing, cost, or payment 'win' at the clinic. When a payment is made more effective, or a provider is able to be reimbursement—it is a payment success.
2) Teamwork
   a) Teamwork successes are examples of teamwork executed well. A program, patient, or situation that is enhanced by teamwork falls under this category.
3) Pharmacists
   a) Pharmacist's successes are defined by major 'wins' or efficiencies either created by or for pharmacists to work for effectively in the clinical setting.
4) El Rio
   a) El Rio strengths define the literal strengths and successes of El Rio. This definition includes only aspects of El Rio from items that are currently in place. Strengths can be understood as people, programs, attitudes, behaviors, etc. Past strengths and future goals are not identified under this definition.
5) Process
   a) Process successes refer to the strengths, successes and supports of the Pharmacy-Based Diabetes Management Program.

Failures

1) Payment
   a) Payment failure is a disconnection, barrier, failure or inefficient way for a payment to be made or received. It is defined by a comment or discussion or failures within a payment mechanism.
2) Teamwork
   a) Teamwork failures are examples of teamwork not executed well. A program, patient, or situation that is not enhanced or is diminished by teamwork failures or general teamwork barriers falls under this category.
3) Pharmacists
   a) Pharmacist's failures are defined by major 'losses' or inefficiencies either created by or for pharmacists that do not allow pharmacists to work effectively and efficiently in the clinical setting.
4) El Rio
   a) El Rio failures define the literal failures or barriers of El Rio. This definition includes only aspects of El Rio from items that are currently in place. Failures or barriers can be understood as people, programs, attitudes, behaviors, etc. Past strengths and future goals are not identified under this definition.
5) Process
   a) Process weaknesses refer to the barriers, weaknesses and lack of supports for the Pharmacy-Based Diabetes Management Program.

Assertions/Generalizations

- Assertions and generalizations refer to a 'crowning' comment, or a key phrase that is repeated. If a sweeping generalization is made about an area of study, type of practitioner or the program, it is categorized under this definition.

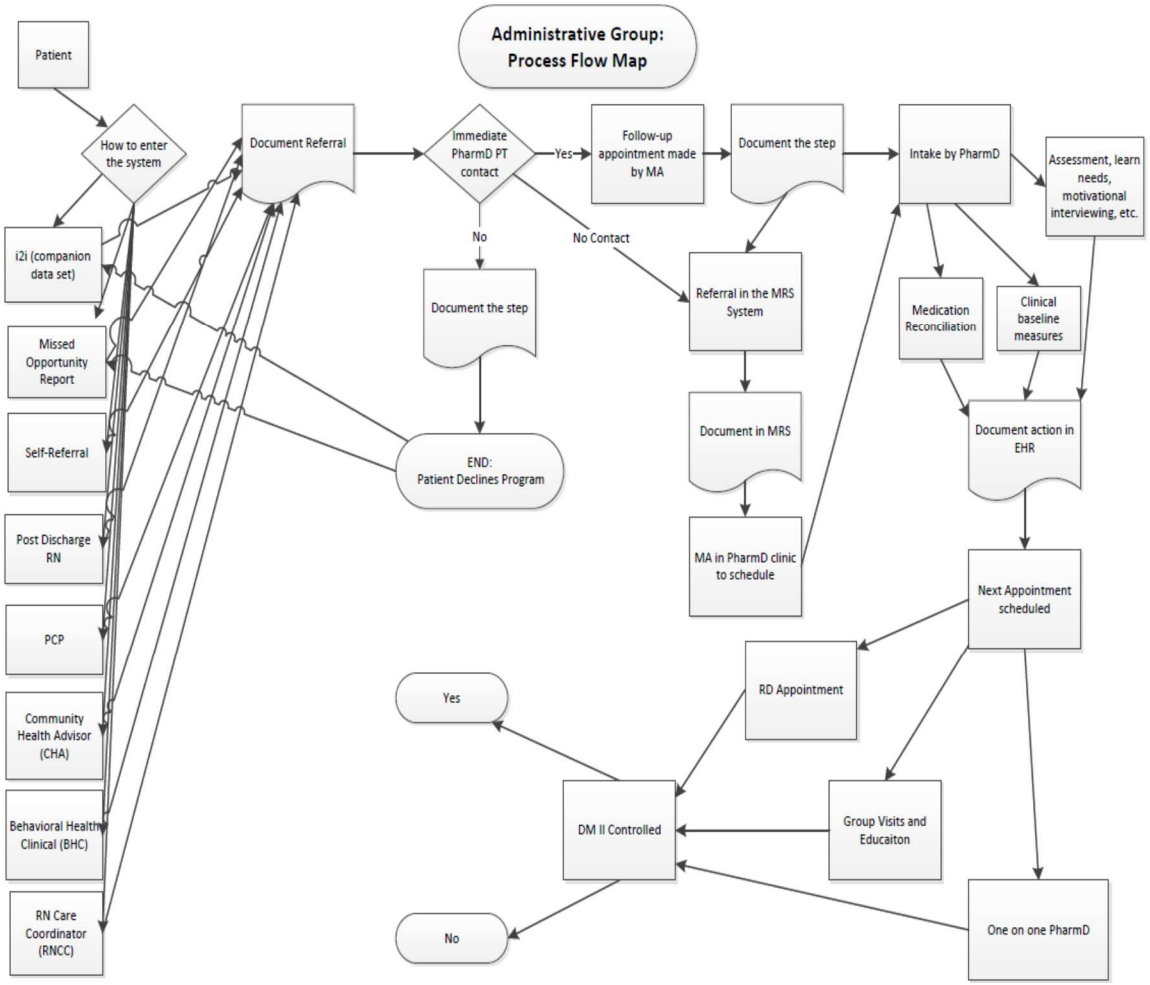
Sustainability of Model

- Sustainability of the model refers to any aspect of description that directly hints at plans, changes, or current practices supporting the sustainability of the current model or program.

APPENDIX C

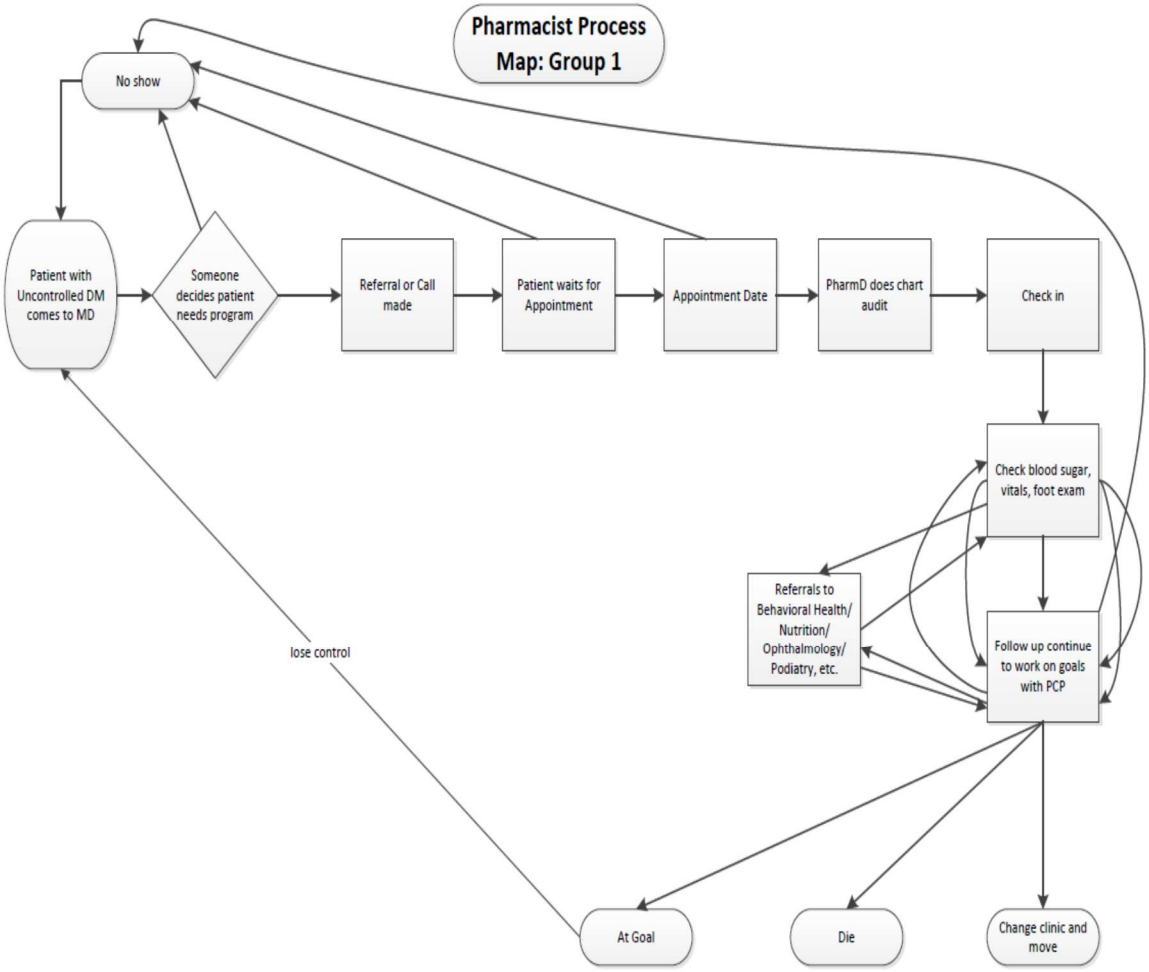
Process Maps

Administrative Group

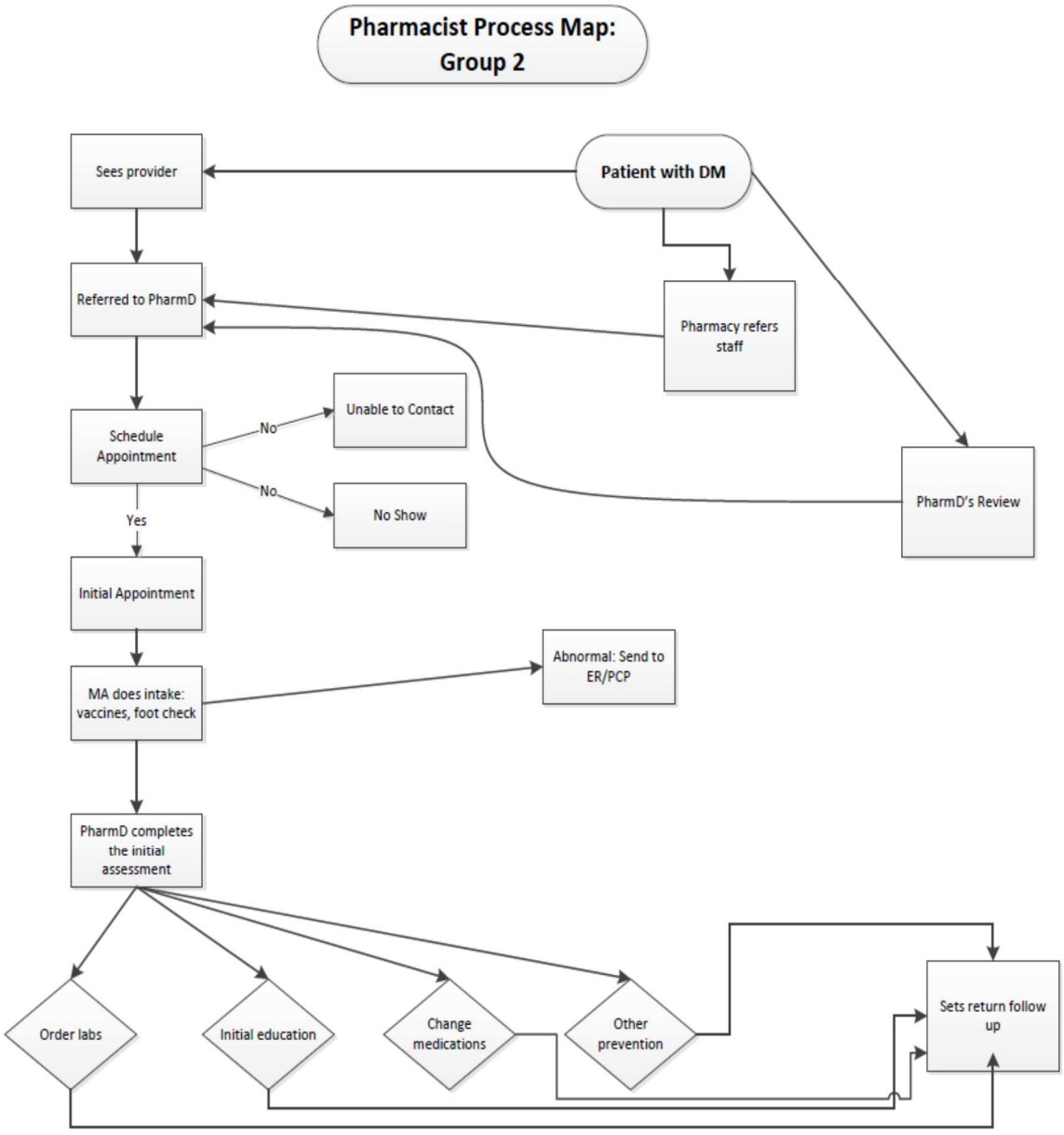


Pharmacist Groups 1-3

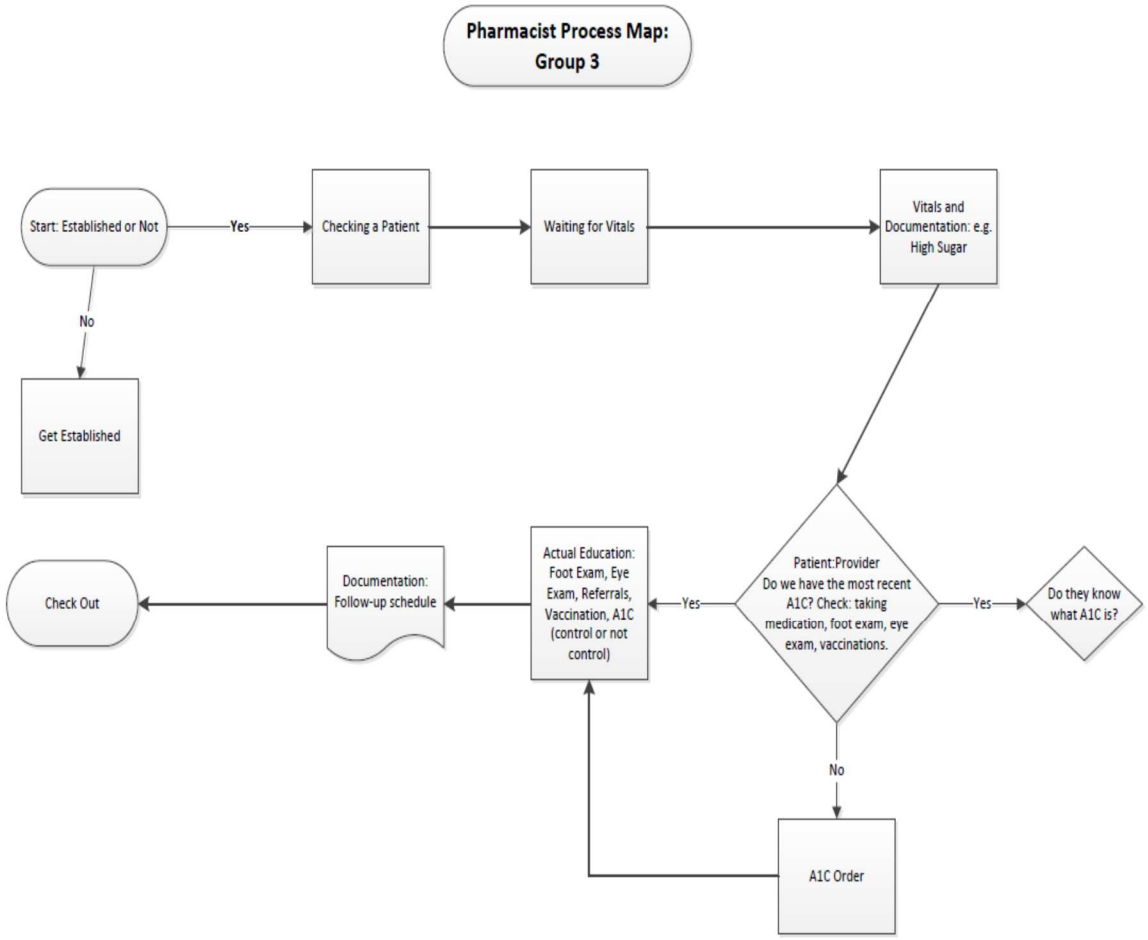
Group 1



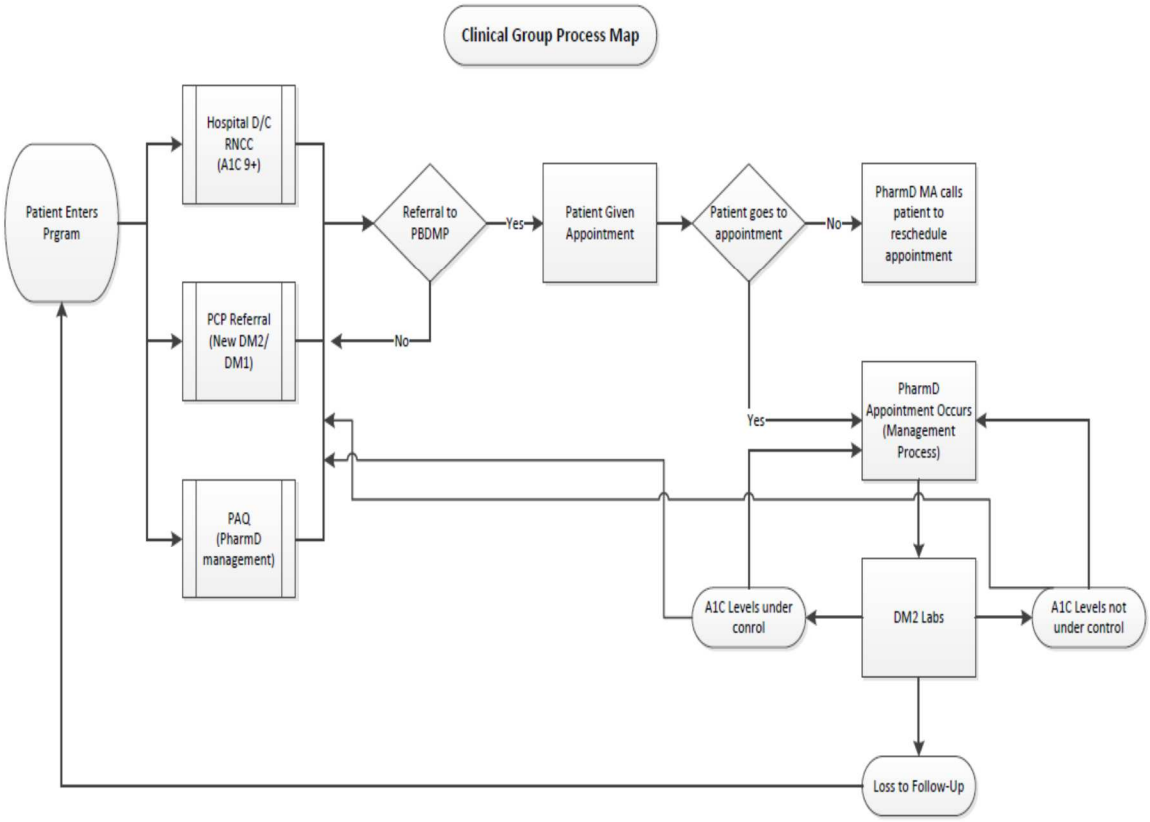
Group 2


Pharmacist Process Map: Group 2
Sees provider
Patient with DM
Referred to PharmD
Pharmacy refers staff
Schedule Appointment
No
Unable to Contact
No
No Show
Yes
PharmD's Review
Initial Appointment
MA does intake: vaccines, foot check
Abnormal: Send to ER/PCP
PharmD completes the initial assessment
Order labs
Initial education
Change medications
Other prevention
Sets return follow up

Group 3


Pharmacist Process Map: Group 3
Start: Established or Not
Yes
Checking a Patient
Waiting for Vitals
Vitals and Documentation: e.g. High Sugar
No
Get Established
Patient:Provider Do we have the most recent A1C? Check: taking medication, foot exam, eye exam, vaccinations.
Yes
Do they know what A1C is?
Yes
Actual Education: Foot Exam, Eye Exam, Referrals, Vaccination, A1C (control or not control)
Documentation: Follow-up schedule
Check Out
No
A1C Order

Clinical Group

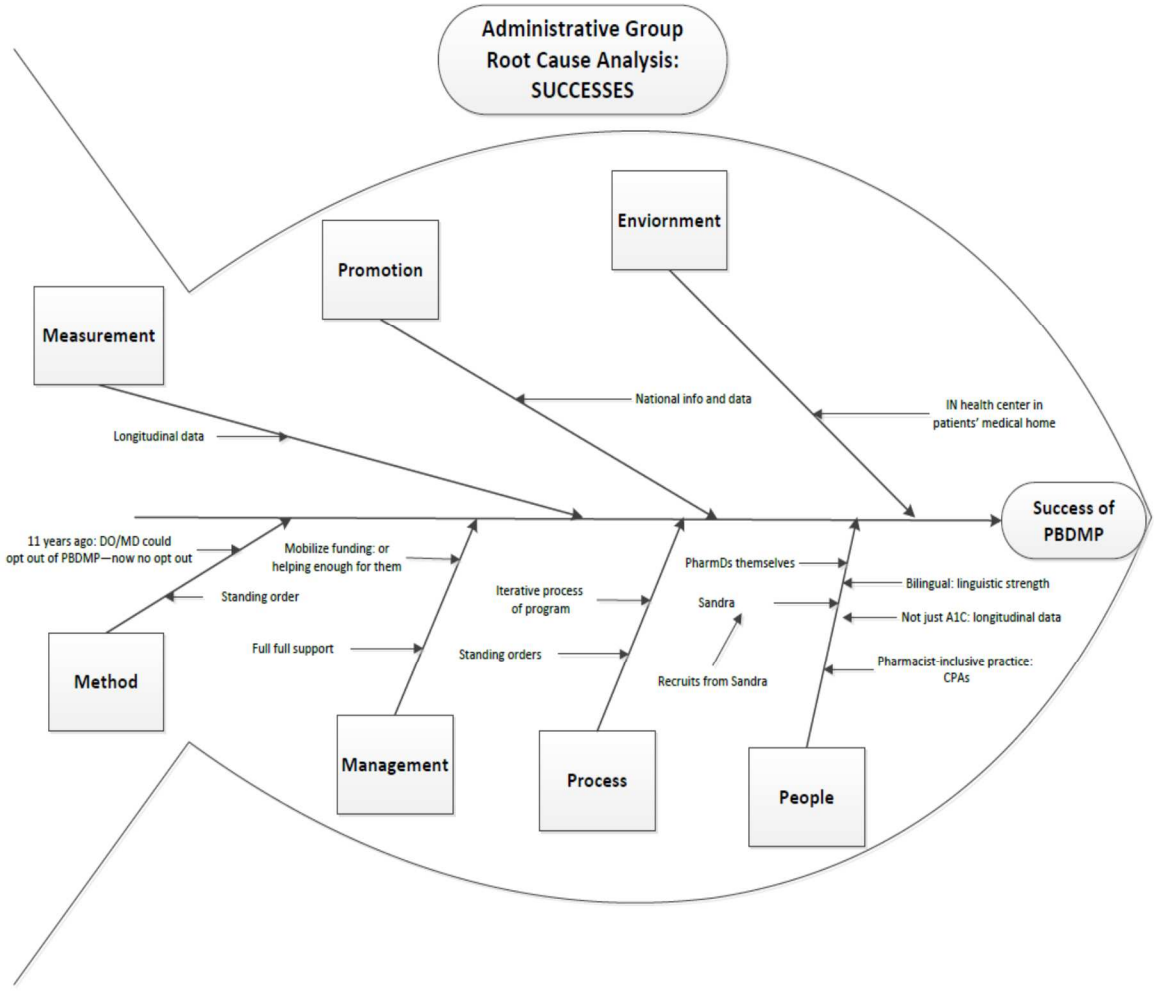


APPENDIX D

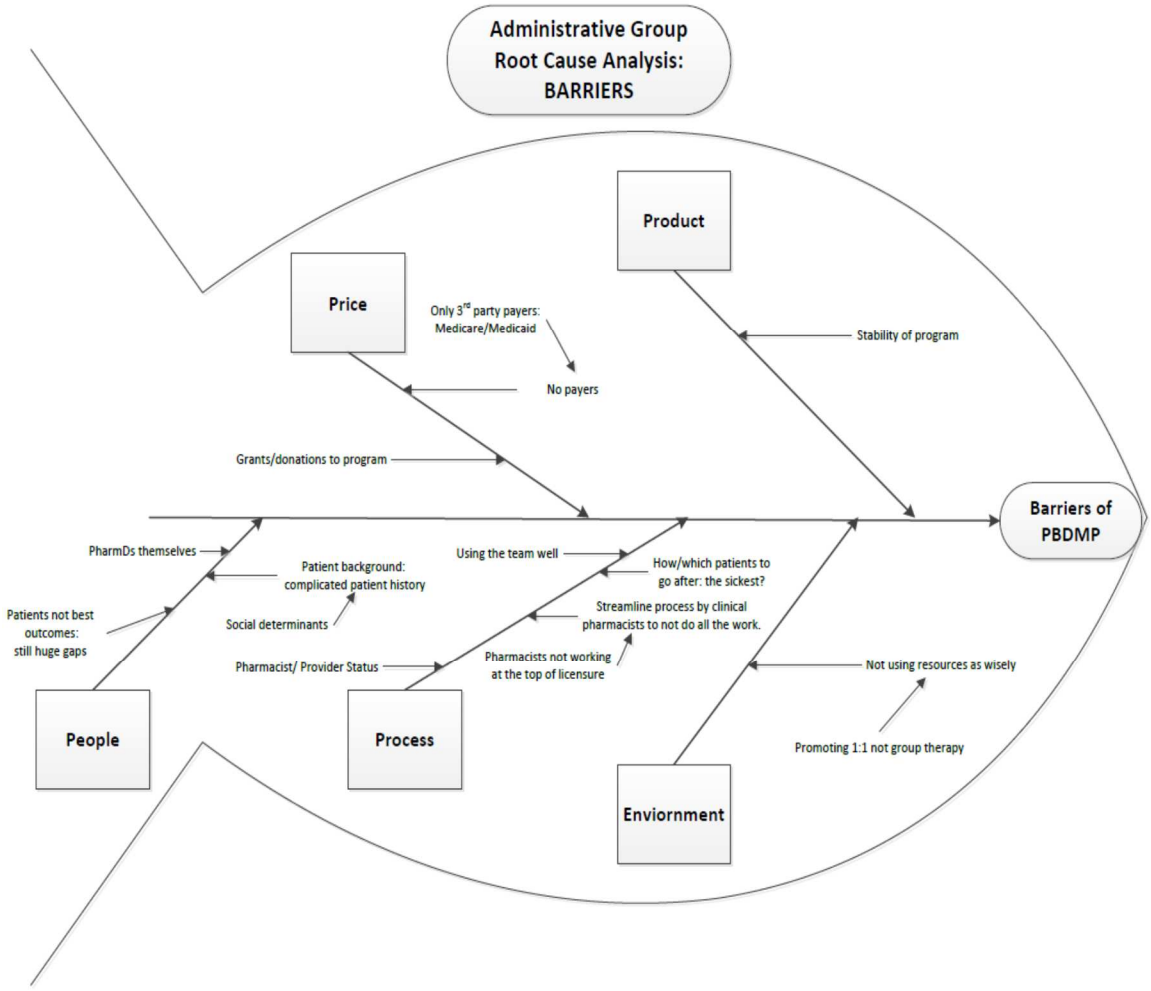
Root Cause Analysis Diagrams (Fishbone Diagrams)

Administrative Group

RCA: Successes

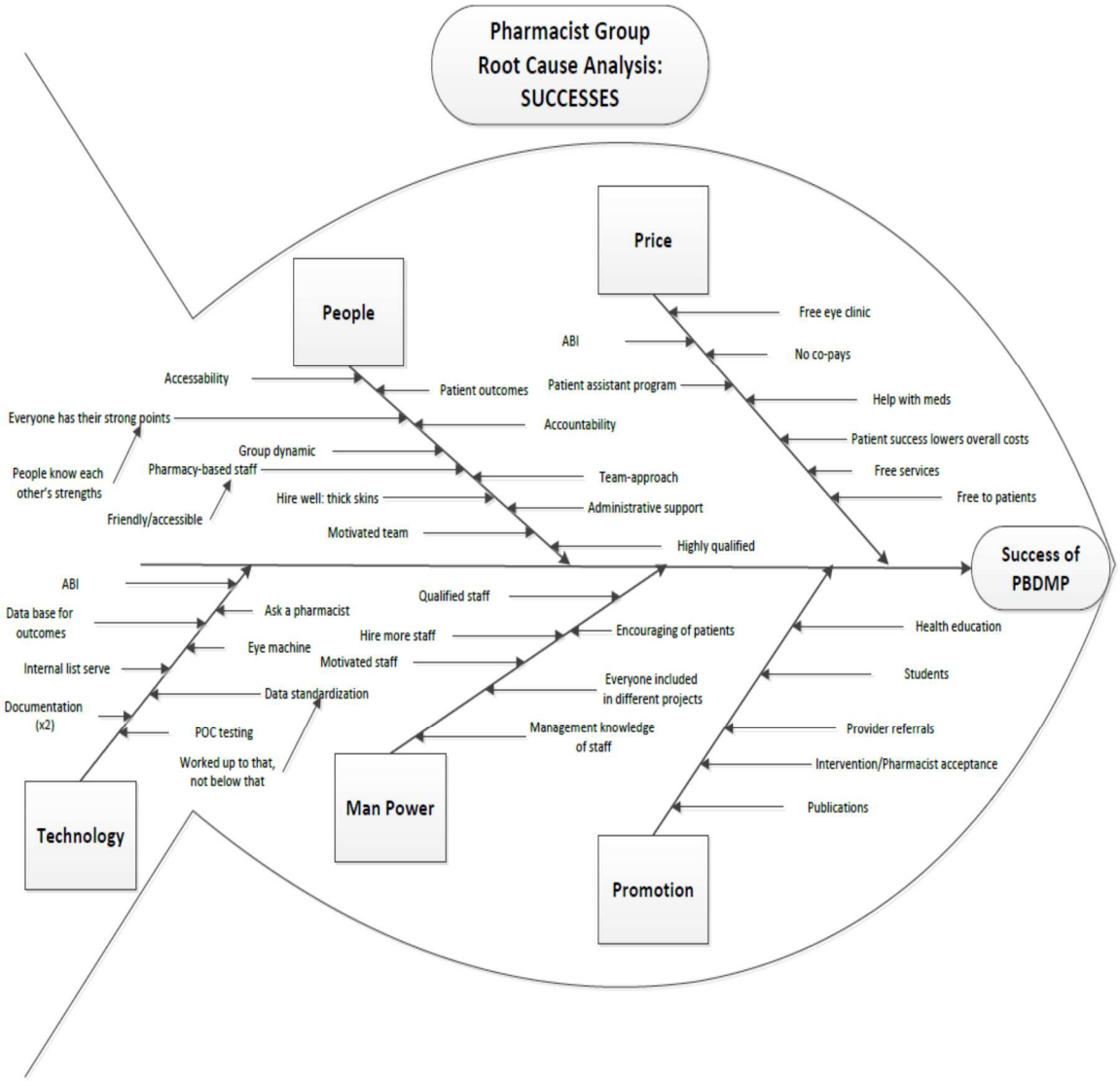


RCA: Barriers

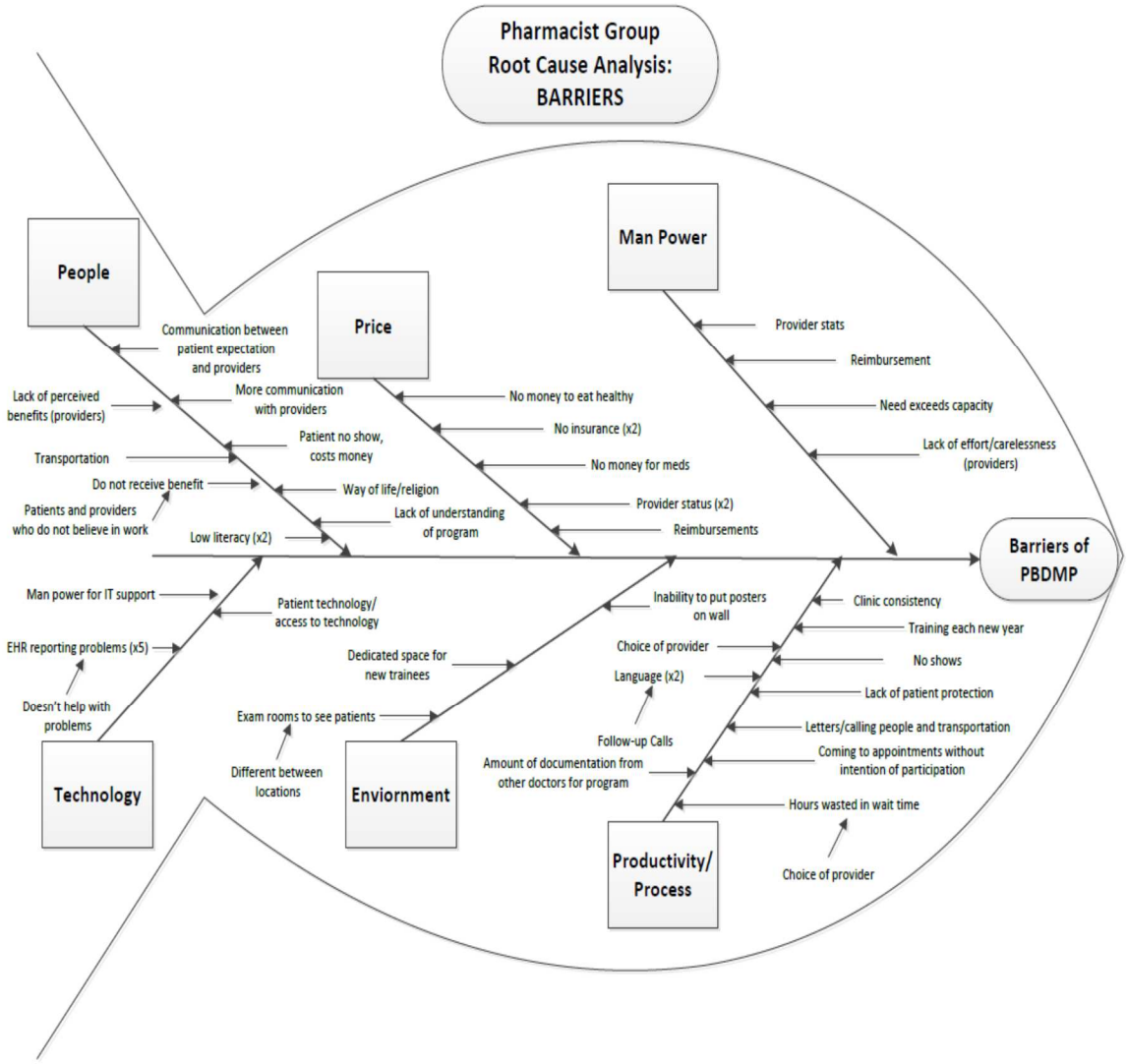


Pharmacist Group

RCA: Successes

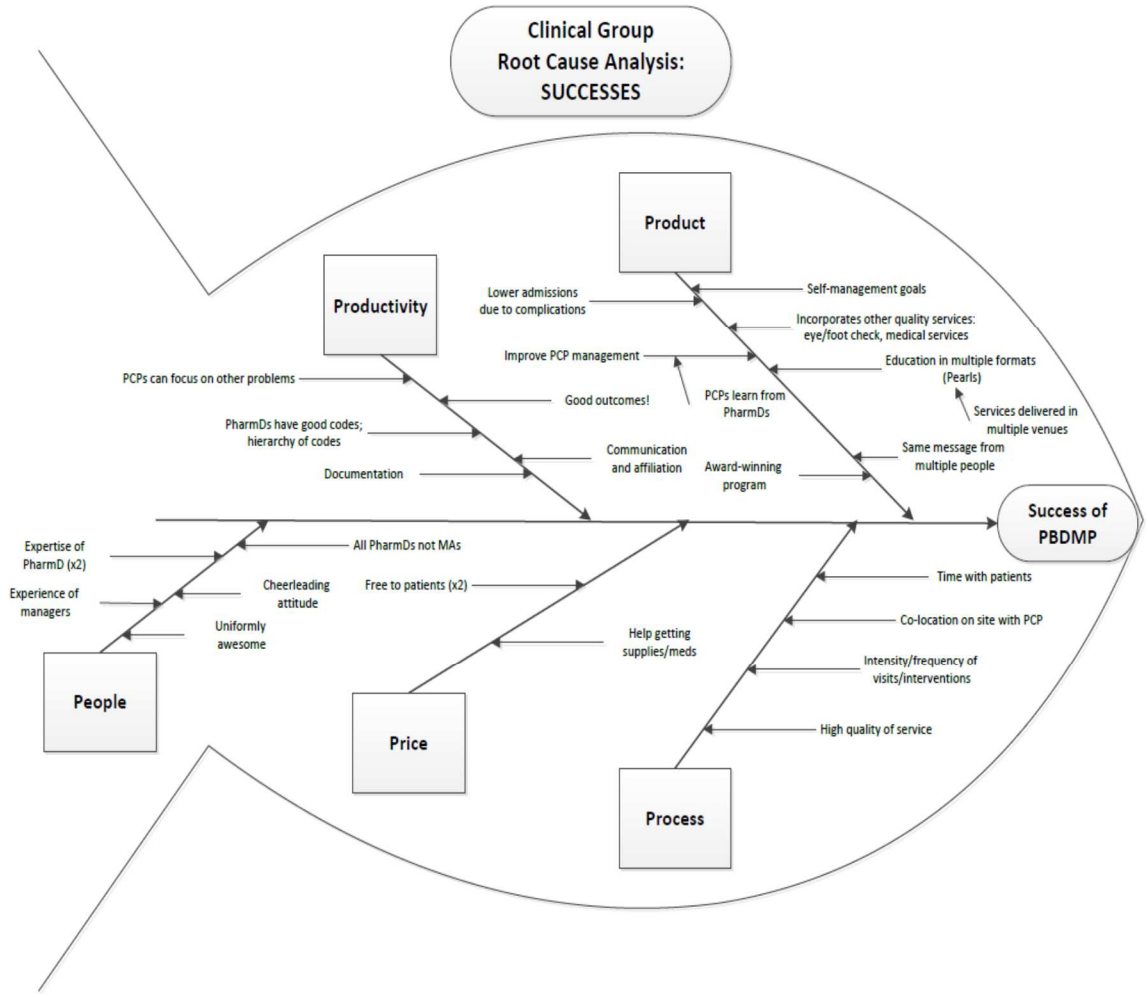


RCA: Barriers

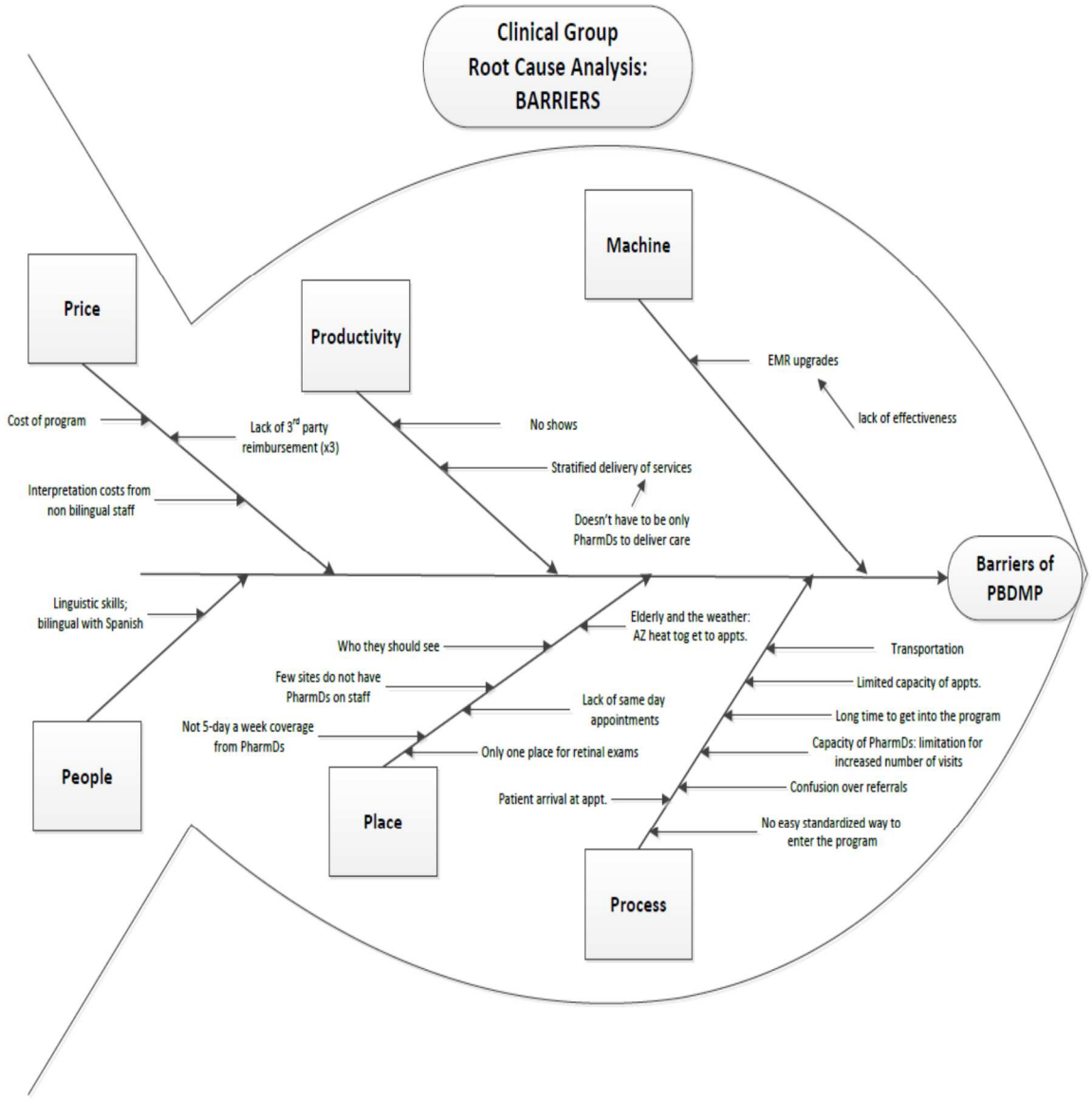


Clinical Group

RCA: Successes



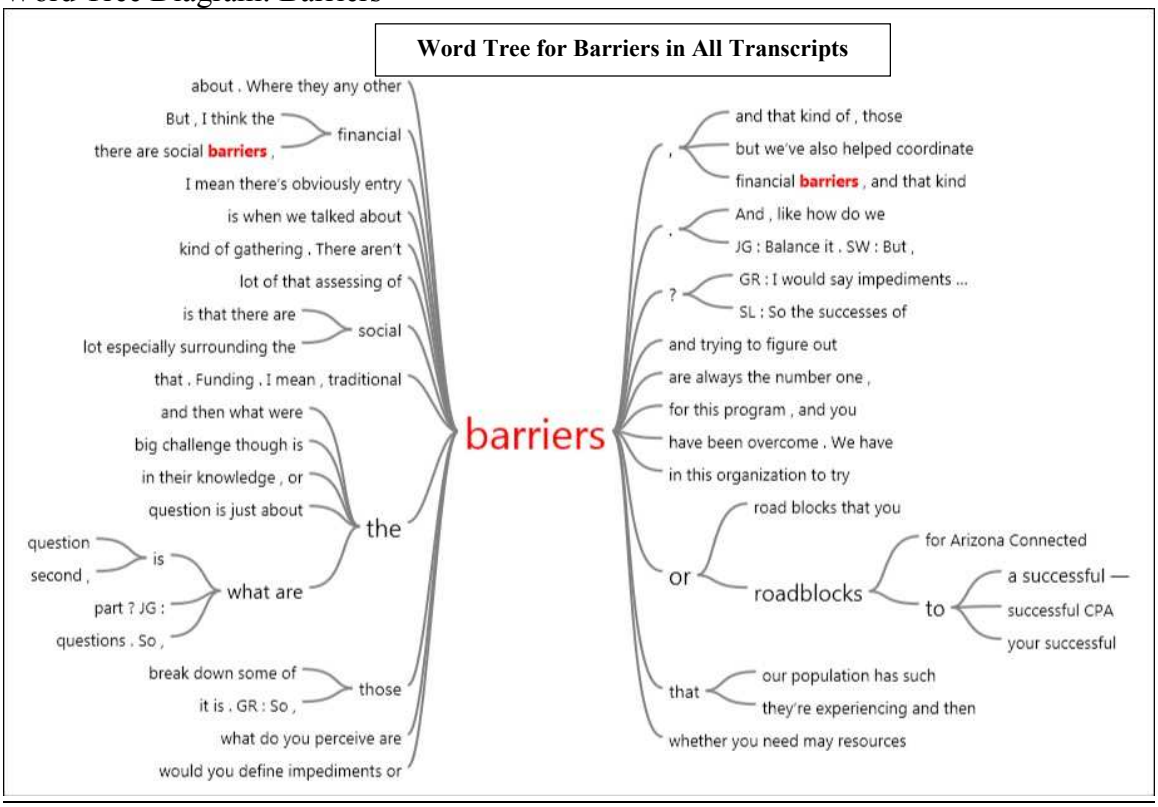
RCA: Barriers



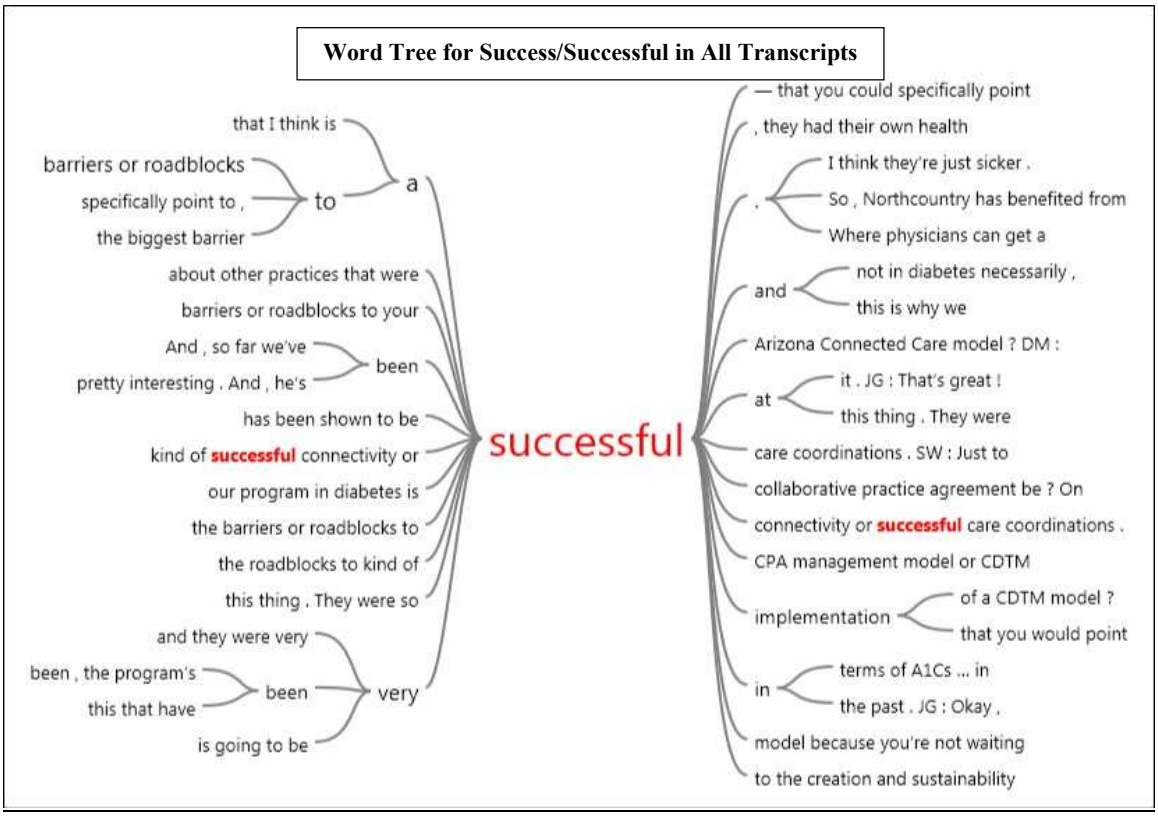
APPENDIX E

Key Informant Interview Word Tree Diagrams

Word Tree Diagram: Barriers



Word Tree Diagram: Success/Successful



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