

ASTHMA HEALTH OUTCOMES ACHIEVED THROUGH
A CLINIC-BASED QUALITY IMPROVEMENT PROGRAM

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Abstract

Asthma is a common and chronic condition that is prevalent in both children and adults. The goal of asthma management is to achieve asthma control. Through appropriate control, patients with the illness can maintain normal activity levels and avoid asthma exacerbations that lead to potentially preventable health events, such as emergency room visits and hospital admissions.

An effective quality improvement program is necessary to alleviate suboptimal asthma care in practice; suboptimal care impedes the achievement of asthma treatment goals. Previous research has well documented the difficulties among asthma care providers in applying asthma guidelines in their practice. Patients are not properly provided essential asthma management components, such as asthma education, a written asthma action plan, and a pulmonary function laboratory assessment. The apparent lack of asthma guideline-based recommendations has precipitated avoidable health events and high health care costs in patients with asthma. To suppress the health care burden, an asthma management program that encourages asthma guideline-based practice among providers is needed to improve the quality of asthma care and patient outcomes.

One such program is Enhancing Care for Patients with Asthma (ECPA). ECPA is a multi-state, multi-center quality improvement program that targeted the improvement of provider adherence to Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007. ECPA is an active 12-month program that used the Wagner chronic care model to initiate high-quality asthma management in health centers. To sustain asthma quality improvement processes, the Plan-Do-Study-Act (PDSA) cycle was presented in each participating center to initiate and maintain practice

improvement among health care providers. ECPA was launched through three cohorts with participation of a total of 65 health centers across four states: Illinois, Oklahoma, New Mexico, and Texas. Cohort introduction was staggered over a 3-year period, and each cohort contained at least one health center from one of the four states. The effect of ECPA on asthma outcomes, however, has not been revealed due to its complex and staggered implementation.

Therefore, the objective of this dissertation was to address the research and practice gaps by evaluating the effectiveness of ECPA in improving asthma guideline-based performance measures, avoiding potentially preventable health events, and lowering health care costs due to asthma. This dissertation utilized a research framework called “a multiple baseline design” to direct the analyses in conjunction with multilevel generalized linear models to estimate the effect of ECPA on the outcomes among patients with asthma.

The results of this dissertation are presented as three publishable manuscripts. By employing data collected from a chart review process in each participating health center, the first manuscript addresses the effect of ECPA on six clinic-based performance measures that adhered to the EPR-3 asthma guidelines. The second manuscript examines the effect of ECPA on asthma-related emergency room visits and hospitalizations, using patient-level administrative claims data. By applying the same data type, the third manuscript explores whether the ECPA implementation was associated with the reduction in total asthma-related health care costs.

The results of the three manuscripts consistently showed a positive association between the ECPA implementation and the center- and patient-level outcomes. Compared

with control data obtained prior to the implementation of ECPA, the rates of documenting the six asthma guideline-based performance measures increased significantly after ECPA had been completely implemented. Increased rates of documenting the measures ranged from 31.4% for asthma severity to 262.5% for the asthma control test. When using the 12-month pre-implementation period as a reference, the rates of either emergency room or hospitalization events that occurred during the 12-month implementation and 5-month post-program completion periods decreased by 42.1% and 50.0%, respectively. Multilevel, generalized linear models found that the ECPA implementation was associated with a 56.4% reduction in total asthma-related health care costs (95% CI -60.7%, -51.8%); and, post-program completion was associated with a 57.3% reduction (95% CI -61.7%, -52.3%).

This dissertation contributes significantly to both clinical and policy perspectives. First, this work provides important evidence for the enhancement of both provider- and patient-focused asthma-related outcomes after adoption of ECPA. Because ECPA has been executed in diverse geographic areas, the results of this dissertation could support decision making in adopting ECPA in other settings to further augment evidence-based care among patients with asthma. In considering policy research implications, this dissertation supplies and demonstrates an analytical framework for the evaluation of real-world health care interventions that underwent staggered implementation. Policy researchers could apply the framework in the evaluation of health outcomes not only for patients with asthma but also for patients with other chronic conditions.

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List of Abbreviations

ACT	Asthma Control Test
AHRQ	Agency for Healthcare Research and Quality
ALAUM	American Lung Association of the Upper Midwest
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
CPI	Consumer Price Index
CPT	Current Procedural Terminology
DME	Durable medical equipment
ECPA	Enhancing Care for Patients with Asthma
EPR-3	Expert Panel Report-3
ER	Emergency room
FCS	Fully conditional specification
FEV1	Forced expiratory volume in the first second
GLMM	Generalized linear mixed model
HCPCS	Healthcare Common Procedure Coding System
HCSC	Health Care Service Corporation
HEDIS	Healthcare Effectiveness Data and Information Set
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IRB	Institutional Review Board
ITS	Interrupted time series
NACP	National Asthma Control Program

NHLBI	National Heart, Lung and Blood Institute
NIH	National Institutes of Health
PDSA	Plan-Do-Study-Act
POS	Place of Service
PPPM	Per patient per month
RCT	Randomized controlled trial
RRs	Rate ratios
SABA	Short-acting beta-agonist
SD	Standard deviation
U.S.	United States

Chapter 1: Introduction

1.1. Overview

Emergency room (ER) visits and hospitalizations among patients with asthma are a significant burden, not only on the patients who experience these events, but also on the U.S. health care system. Asthma caused approximately two million ER visits in 2014 (Centers for Disease Control and Prevention [CDC], 2014a) and roughly 500,000 hospitalization episodes in 2010 (National Hospital Discharge Survey, 2010). These events were potentially preventable public health problems that cost the U.S. more than \$300 million per year (Torio, Elixhauser, & Andrews, 2013).

Although national efforts have been put forth to minimize the incidence of unpleasant and potentially unnecessary events related to acute exacerbations of asthma, the occurrences among patients with asthma have remained high. For instance, the CDC established the National Asthma Control Program (NACP) in 1999 to tackle the challenges. This national program aims to reduce the number of deaths, ER use, and inpatient episodes due to asthma. Since the program's inception, the NACP has financed \$238 million for asthma quality improvement activities (CDC, 2013). Because of such tremendous efforts (Research and Health Education Division, 2012), asthma mortality rates have decreased from 15.0 in 2001 to 10.5 per million people in 2009 (Moorman, Akinbami, & Bailey, 2012). However, the rates of asthma-related ER visits and hospitalizations among U.S. patients have not been minimized (Nath & Hsia, 2015).

Apart from national programs, several initiatives have been executed at an organizational level with limited outcome assessment (Clark et al., 2010). A systematic review conducted by Peytremann-Bridevaux, Arditi, Gex, Bridevaux, and Burnand (2015)

investigated the effectiveness of chronic disease management programs for adults with asthma. The management programs reviewed, referred to as interventions, involve the reorganization of the health care system to improve asthma care. Out of the 20 included studies, only nine studies evaluated ER visits or hospitalizations as an outcome. While some of these interventions showed their effect on adverse health events, a high proportion of the studies offered no obvious impact or analysis of the outcomes. The findings suggested two potential problems: the strategies do not tackle the fundamental cause of the high number of ER visits and hospitalizations among patients with asthma; and, the studies do not have sufficient data sources or appropriate analytical frameworks to demonstrate their effect on the outcomes.

Although ER visits and hospital admissions for asthma in the U.S. remain prominent, these events are usually preventable with proper asthma management. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma is a well-accepted asthma guideline that has been convened since 2007 by the National Heart, Lung, and Blood Institute. The guideline outlines the definition, causes, diagnosis, and exacerbation management of asthma. In addition to the clinical aspects of asthma, the guideline details four essential components of asthma management: assessing and monitoring asthma severity and control; developing a partnership for asthma care; controlling factors affecting asthma symptoms; and using pharmacologic therapy for asthma. These four components are critical for the achievement of the goal of asthma treatment, which is well-controlled asthma.

Despite the availability of comprehensive asthma management guidelines, the quality of asthma care in community settings remains suboptimal (Mangione-Smith et al., 2007). Asthma care in community-based clinics plays a critical role in diagnosis and

treatment to obtain well asthma control and long-term follow-up care to maintain control (National Institutes of Health [NIH], 2007). Nevertheless, primary care providers still have difficulties utilizing the guidelines. Previous research has reported several clinic-level barriers to adherence with asthma management guidelines, such as low self-efficacy among providers to implement the guidelines and non-familiarity with specific guideline elements (Okelo et al., 2013; Wisnivesky et al., 2008). Since health care providers do not fully adhere to asthma guidelines, studies have reported improper evaluations of asthma symptoms (Cabana, Slish, Nan, Lin, & Clark, 2005; Halterman et al., 2002). For instance, in a study conducted by Halterman et al. (2002), less than half of health care providers accurately evaluated the severity of their patients' symptoms, and only half of the patients received a preventive controller medication, a required daily medication for patients with persistent asthma, recommended by the EPR-3 guidelines. Less-than-optimal asthma care in community settings contributes to undesirable asthma outcomes (Akinbami, Moorman, Garbe, & Sondik, 2009, pp. 1980–200).

Because optimal asthma care in community settings is essential for achieving the goal of asthma therapy, Enhancing Care for Patients with Asthma (ECPA), a health center-based quality improvement program developed by the American Lung Association of the Upper Midwest (ALAUM), was implemented in 2013. The program's goal was to improve short- and long-term asthma outcomes by enhancing asthma care quality in community health centers. The program integrated EPR-3 recommendations and utilized a collaborative approach to implement changes in asthma management processes by facilitating guideline-based practices among providers and offering necessary tools to evaluate asthma progression. However, the effectiveness of the program has not yet been evaluated. It is unknown if the program, which originated at the patient care delivery level,

would result in subsequent improvements in potentially preventable ER visits and hospital admissions.

The great challenge in demonstrating if ECPA led to reducing costly yet preventable asthma-related ER visits and hospital admissions is the lack of an existing analytical framework to facilitate the assessment of this type of real-world programs. The implementation of ECPA involved a serial introduction in participating health centers on a staggered schedule (i.e., participating centers started receiving the program effect at different time points). Within the first three years of the program, three cohorts of health centers had been enrolled. In total, there were 65 community centers across four states: Illinois, New Mexico, Oklahoma, and Texas. To reveal the effect of this potential quality improvement program on health events, an analytical framework needed to be proposed to guide the process of evaluating this kind of real-life implementation. Since the effectiveness of ECPA on potentially preventable health events has not been studied and because no 'best-practice' standardized approaches for evaluating such programs have been identified, the focus of this dissertation is to evaluate ECPA's effectiveness on the outcomes by employing "a multiple baseline design" as an evaluation framework.

1.2. Objectives and specific aims

The overall objective of this dissertation was to examine the effectiveness of the staggered, multi-state, multi-center intervention for patients with asthma in three aspects: clinic-based performance measures; asthma-related ER visits and hospitalizations; and total health care costs for asthma-related care. This dissertation is predicated upon the central hypothesis that patients with asthma who received care from health centers that

participated in ECPA will have lower rates of asthma-related ER visits and hospital admissions and health care costs via an asthma guideline-recommended, six-pronged approach: provision of appropriate asthma severity rating, asthma control assessment, pulmonary function testing, asthma education, personalized asthma action plan, and controller medication. This dissertation entails three specific aims:

AIM 1: Determine whether ECPA leads to an improvement in clinic-based performance measures.

Hypothesis 1a: Clinic-based performance measures are significantly improved at the end of the ECPA implementation, compared to before the ECPA implementation.

Hypothesis 1b: Clinic-based performance measures are significantly improved at six months after the program completion, compared to before the ECPA implementation.

Hypothesis 1c: Clinic-based performance measures are significantly improved at six months after the program completion, compared to at the end of the ECPA implementation.

Unit of measurement: Number of patient charts documenting asthma severity, asthma control, pulmonary function testing, asthma education, an asthma action plan, and controller medication prescription.

AIM 2: Determine whether ECPA leads to a decrease in asthma-related ER visits and hospitalizations.

Hypothesis 2a: The implementation of ECPA was associated with a decrease in the rate of asthma-related ER visits among health center patients, compared to before the program was implemented.

Hypothesis 2b: The implementation of ECPA was associated with a decrease in the rate of asthma-related hospital admissions among health center patients, compared to before the program was implemented.

Hypothesis 2c: The implementation of ECPA was associated with a decrease in the rate of asthma-related ER visits and hospital admissions combined among health center patients, compared to before the program was implemented.

Unit of measurement: Asthma-related ER visits and hospitalizations per patient-month.

AIM 3: Determine whether ECPA leads to a decrease in annual asthma-related health care costs for patients with asthma.

Hypothesis 3a: The implementation of ECPA was associated with a decrease in total asthma-related costs per patient-year, compared to before the program was implemented.

Hypothesis 3b: The ECPA post-program completion was associated with a decrease in total asthma-related costs per patient-year, compared to before the program was implemented.

Hypothesis 3c: The ECPA post-program completion was associated with a decrease in total asthma-related costs per patient-year, compared to during the active implementation of ECPA.

Unit of measurement: Total asthma-related health care costs per patient-year of a study period.

1.3. Study design

This dissertation employs a retrospective, single-arm quasi-experimental design. This quasi-experimental study utilizes a non-randomized control design that involves pre-intervention, intervention, and post-intervention periods of the outcomes over time (Portela, Pronovost, Woodcock, Carter, & Dixon-Woods, 2015). The single-arm quasi-experimental design of this dissertation is suitable for evaluating the effect of ECPA on asthma outcomes for three reasons.

First, ECPA is a real-world quality improvement effort that is not feasible for randomized controlled trials (RCTs) (Neuhauser & Diaz, 2007). Although RCTs are referred to as the gold standard for clinical research, RCTs are not an option in community-based studies (Handley, Schillinger, & Shiboski, 2011). ECPA used EPR-3 as a model for the development of the program elements to improve asthma care quality in community settings. Since EPR-3 is an evidence-based guideline established from a reliable, rich body of data (NIH, 2007), there is reason to believe in the substantial positive impact of the program on the patients. Thus, it would be challenging to persuade health centers to engage in a randomization process given the potential benefit of the program.

Second, a single-arm quasi-experimental design is more appropriate to study ECPA, compared with a two-arm quasi-experimental structure. A two-arm study requires the homogeneity of intervention and comparison groups or, at a minimum, a random difference in all observed covariates (Stuart & Rubin, 2008). Whereas best practices in matching methods to find a comparison group for quasi-experimental studies have been augmented (Stuart & Rubin, 2008), the approaches are not applicable to study ECPA, where participating centers were derived from multi-geographical states. Even if a comparable center was ascertained, regarding all observed covariates, it would still be uncertain whether unobserved covariates are balanced.

Third, the structure of the quasi-experimental design that follows outcomes over time enables identification of the ECPA sustainable effect. ECPA observed the outcomes at three time periods. A quasi-experimental design that employs a time series analysis allows investigation of the ECPA effect by comparing the outcomes at pre-implementation with implementation periods, at pre-implementation with post-program completion periods, and at implementation with post-program completion periods. The investigation of the three program effects provides a comprehensive view of program sustainability when no structural support from ECPA was given to participating health centers by highlighting effect of the program occurring from baseline to implementation and from implementation to post-implementation.

1.4. Outcome measurements

This dissertation focuses on investigating the ECPA effect on both health center performance and patient outcomes. Addressing these complementary outcomes could

determine whether the ECPA implementation at the health center level, where asthma care pathways can be introduced, monitored, and revised more readily, translates into enhancing patient-level outcomes. Thus, the primary outcomes of this dissertation are: 1) clinic-based performance measures; 2) the number of ER visits and hospital admissions; and 3) annual asthma-related health care costs.

1.4.1. Clinic-based performance measures

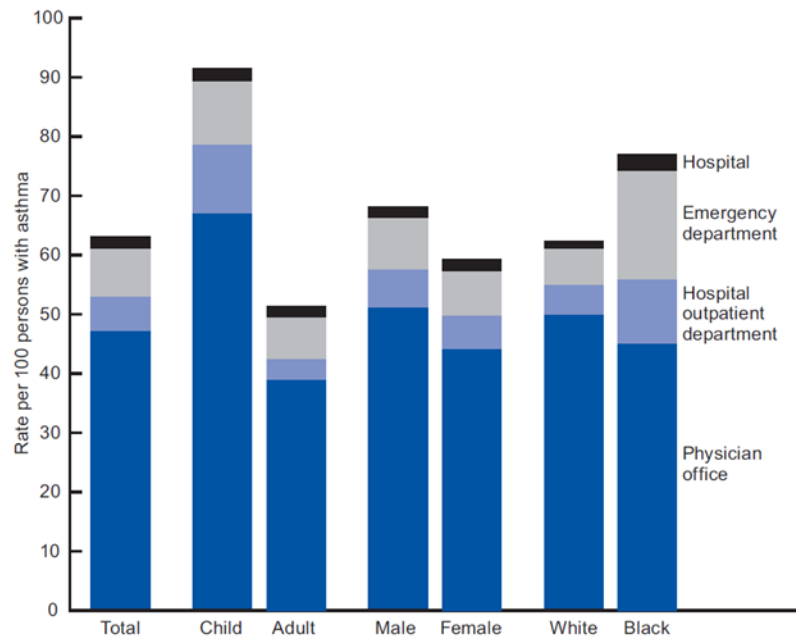
Clinic-based performance measures refer to the percentages of patients in each participating health center who have documented evidence for the six EPR-3 guideline-based management components. These components include: documentation of asthma severity, asthma control, and pulmonary function testing as measures of asthma assessment and monitoring; documentation of asthma education and an asthma action plan as measures of education and provider/patient partnerships in asthma care; and controller medication prescription as a measure of medication use.

1.4.2. The number of ER visits and hospital admissions

ER visits and hospital admissions among patients with asthma are of interest because the events are frequent but potentially preventable. In the U.S., the average annual rates of asthma-related ER visits and hospitalizations among children aged 0–17 years were 10.7 and 2.1 per 100 patients, respectively, and among patients aged at least 18 years old were 7.0 and 1.9 per 100 patients, respectively (see Figure 1.1). Since these events could be prevented with proper self-management and asthma medications (Lawson et al., 2014), this dissertation hypothesized that the providers of the ECPA-participating health centers would offer the patients appropriate self-management tools,

such as asthma action plans and education, contributing to reduced risks of visiting an ER or being admitted to a hospital.

Figure 1. 1 Rates of asthma physician office visits, hospital outpatient visits, ER visits and hospitalizations by age, gender, and race: The United States, average annual 2007-2009



(Source: <https://www.ncbi.nlm.nih.gov/pubmed/24252609>)

An asthma-related ER visit was defined using ER visit codes (Current Procedural Terminology (CPT) code: 99281 to 99285) and asthma ICD-9-CM codes 493.00 to 493.99 as a primary diagnosis or related reasons on the ER claim. In like manner, an asthma-related hospitalization was defined as a hospital discharge with Place of Service (POS) code 21 and revenue codes indicating hospital services (11x-48x) with asthma as the primary or related reasons for admission. The number of asthma-related ER visits alone,

hospitalizations alone, and ER and hospital admission episodes combined for each patient from a participating health center were calculated.

1.4.3. Annual asthma-related health care costs

Hospital admission episodes due to asthma have a substantial contribution to the total health care costs among patients with asthma (Bahadori et al., 2009). In 2010, average costs of an inpatient stay due to asthma among children and adults in the U.S. were \$3,600 and \$6,600, respectively (Barrett, Wier, & Washington, 2014). Moreover, among patients with asthma who have private coverage, average cost for an ER episode ranged from \$1,263 to \$3,423 (costs in 2008 U.S. dollars) (Wang, Srebotnjak, Brownell, & Hsia, 2014). Because these events are potentially avoidable, this dissertation hypothesized that the implementation of ECPA would contribute to the reduction in the number of ER visit and hospital admission events, their associated costs, and total health care costs due to asthma.

The total asthma-related health care costs are defined as the sum of the amounts paid by the insurer and amounts of patient cost-sharing across six types of asthma-related resource use (an episode with the ICD-9-CM code of 493.xx as primary or related reasons): ER visits, hospital admissions, physician office and outpatient visits, asthma medications, durable medical equipment (DME), and other services. The costs of each resource use are computed as the amounts per year for each study period. The costs of the six categories are then summed to provide the total annual health care costs due to asthma.

ER visit costs are computed as the sum of costs for all events with CPT code: 99281 to 99285. Hospital admissions costs are calculated from claims with POS code 21:

Inpatient Hospital. The costs for physician office and outpatient visits are calculated from claims with POS code 11: Office, POS code 22: Outpatient Hospital, and POS code 24: Ambulatory Surgical Center. For asthma-related medication costs, asthma medications are identified using the national drug code (NDC) lists from the Healthcare Effectiveness Data and Information Set (HEDIS) (National Committee for Quality Assurance, 2017). The costs regarding DME supplies were computed using POS code 12: Home and Healthcare Common Procedure Coding System (HCPCS) code Axxxx-Zxxxx. Other service costs include all types of resource use not previously mentioned: POS codes other than previously mentioned (e.g., 31: Skilled Nursing Facility and 41: Ambulance), CPT codes: 70010-79999 (Radiology Procedures), and CPT codes: 80047-89398 (Pathology and Laboratory Procedures). All cost components are inflated to 2014 U.S. dollars using Medical Care Services of the Consumer Price Index (CPI) retrieved from U.S. Bureau of Labor Statistics (U.S. Bureau of Labor Statistics, 2017).

1.5. Limitations

There are three main limitations to be acknowledged.

First, the data source of this dissertation was administrative claims data whose accuracy relies on medical coding professionals. Coders from different clinical settings may have different coding patterns, which may introduce misclassification bias (Tyree, Lind, & Lafferty, 2006). In addition, it is possible that some providers intentionally select the codes that maximize their payment, resulting in unrepresentative health care costs (Riley, 2009).

Second, the claims dataset is derived from a private insurance company. Since Medicaid is a dominant payer for inpatient stays among children with asthma (Barrett et al., 2014), the results of this dissertation might not be applicable to a majority of the U.S. child population. Moreover, the results can only be applied to the population with similar characteristics as those enrollees who received asthma care from the participating health centers.

Third, this dissertation utilized a retrospective, single-arm quasi-experimental approach. While this design uses participating health centers and their patients during the pre-implementation period as a comparison group, the design does not permit adjustment for time-varying covariates. Potential confounders that change over time, such as increasing age of patients over the study period, could bias the study results. Notably, older patients are less likely to be admitted to a hospital (Barrett et al., 2014).

1.6. Significance

The results from this dissertation are significant because it addresses the effect of a potential quality improvement process that aims to enhance asthma guideline-based practice and reduce potentially preventable health services use, which has been a national focus (CDC, 2013). Since 1999 the Centers for CDC's NACP and the Healthy People goals for asthma—a 10-year agenda for improving the Nation's health—have attempted to decrease the number of emergency room and hospital admission events among patients with asthma (Hasegawa et al., 2015; National Center for Health Statistics, 2012). Despite this effort, the rates of these outcomes have been relatively stable and have not

significantly diminished in recent years (Moorman et al., 2012). There is a large need for innovative asthma interventions to help minimize potentially preventable health events.

This dissertation tackles research barriers faced by real-life program evaluators tasked with determining if quality improvement activities at the practice level could translate into better asthma outcomes at the patient level. Despite rigorously developed asthma guidelines, asthma management in practice settings remains unsatisfactory (Usmani, 2014). Previous research has reported non-adherence with the guidelines among practitioners (Horne et al., 2007). Suboptimal care among asthma care providers includes inadequately prescribing controller medications (Barnes, 2004), misestimating the level of asthma control (Wechsler, 2009) and not comprehending the extent of the guidelines (Lugtenberg, Zegers-van Schaick, Westert, & Burgers, 2009). Instead, ECPA is a promising quality improvement approach that concentrates on modifying asthma management among practitioners through guideline-based processes. Because ECPA addressed the core of asthma management, this dissertation reveals whether changes in asthma management processes among providers at health-center settings would benefit providers, health centers, and patients with asthma.

Moreover, this dissertation supplies succinct evidence of whether the implementation of ECPA involves potential cost-savings and whether ECPA should be adopted nationwide. Over the past two decades, government agencies and stakeholders have made tremendous efforts to develop health care programs for patients with chronic conditions, including asthma (CDC, 2013). Although millions of tax dollars have been poured into implementing these programs (CDC, 2013), they are rarely sustained or adopted at other settings (Glasgow & Emmons, 2007). One of the key challenges to further expand these programs is the absence of assessment tools to understand their

effectiveness in non-controlled environments outside protocol-driven clinical trials (Nadeem, Olin, Hill, Hoagwood, & Horwitz, 2013). Policy makers are often reluctant to adopt health care interventions without clear evidence of clinically meaningful health outcomes (Dilley, Bekemeier, & Harris, 2012; Lavis, Oxman, Moynihan, & Paulsen, 2008) and potential cost-savings. Therefore, this dissertation indicates the real-world effect of ECPA on avoidable health resource use and financial outcomes among patients with asthma. Better understanding of the ECPA effectiveness could serve as evidence to determine if it should be further expanded in other settings.

Chapter 2: Literature review

This chapter synthesizes available evidence on the following aspects: 1) the epidemiology of asthma and its burden in the U.S.; 2) the Expert Panel Report 3 (EPR-3) Full Report 2007; and 3) quality improvement efforts and concerns with current asthma-related efforts.

An electronic search of relevant articles was conducted in MEDLINE via PubMed, EMBASE via Ovid, the Cochrane Library, and Google Scholar. Search terms included asthma, quality improvement, disease management, quasi-experimental design, non-randomized controlled trial, emergency room visit, emergency department visit, hospitalization, health care cost, health care expenditure, barrier, and guideline adherence. The search was limited to research published from January 2000 through December 2017. Only articles published in English were included.

The chapter also summarizes information about ECPA, the quality improvement program of interest. The information was retrieved from an ECPA manager who supervised ECPA program implementation in all states and cohorts.

2.1. Asthma

2.1.1. Definition of asthma

Asthma is a chronic illness that aggravates the airways (Murdoch & Lloyd, 2010). The persistence of airway inflammation brings on hyperresponsiveness, airflow limitation, and asthma symptoms (Busse & Holgate, 2008; Calhoun, 2014; Chung, Widdicombe, & Boushey, 2008). Most people with asthma experience common symptoms, such as

wheezing, chest tightness, coughing, and shortness of breath (National Heart, Lung, and Blood Institute, 2014). There is the potential for more severe symptoms of uncontrolled asthma due to moderate or severe asthma exacerbation, including breathlessness while resting, loud wheezing during inspiration and expiration, and drowsiness or confusion if patients are experiencing a life-threatening asthma exacerbation (Camargo, Rachelefsky, & Schatz, 2009; Pollart, Compton, & Elward, 2011). If an asthma attack is not brought under control, it can lead to death.

A diagnosis of asthma entails not only the presence of multiple key indicators from both a medical history and physical examination (NIH, 2007) but also pulmonary function test results from spirometry (Brigham & West, 2015; Ducharme et al., 2015; NIH, 2007). Assessments of pulmonary function using spirometry are critical because the results from spirometry confirm an asthma diagnosis and determine asthma severity (Chhabra, 2015). Asthma severity defines the intrinsic intensity of the asthma condition and can be categorized as intermittent or persistent (either mild, moderate or severe) (NIH, 2007). Ideally, severity should be evaluated immediately after diagnosis or before patients start a long-term control medication because the level of severity guides the selection of type, amount and scheduling of asthma therapy (NIH, 2007).

2.1.2. Epidemiology of asthma

Asthma is the most prevalent chronic condition facing children in the U.S. (World Health Organization, 2013) with a prevalence of 9.5% among children 17 years old and younger (Akinbami, Moorman, et al., 2012). This number reflects the current highest prevalence that has been reported in the U.S. With this prevalence, approximately 6.2 million children in the country experience the condition (National Center for Health Statistics, 2017).

The prevalence of asthma among U.S. adults is higher than other countries. According to asthma surveillance data provided by the National Center for Health Statistics and the Vital Statistics System, approximately 7.6% of U.S. adults suffer from the condition (CDC, 2016). Self-reported current asthma prevalence among U.S. adults is even higher—8.9% in 2014 (National Center for Environmental Health, 2016). In contrast, the global prevalence of adults diagnosed with asthma is only 4.3% (To et al., 2012). The widespread presence of asthma in the U.S. means that the country is prone to the negative societal impact of the illness because the patients are more likely to miss work, resulting in lower productivity and limited professional advancement (Nunes, Pereira, & Morais-Almeida, 2017).

2.1.3. The burden of asthma in U.S. patients

Asthma imposes an incredible financial and societal burden on the U.S. pediatric population and their caregivers. During 2008–2013 the total annual health care cost for children with asthma was \$1,737 in 2015 U.S. dollars (Nurmagambetov, Kuwahara, & Garbe, 2018). For children, asthma is the third leading cause of hospitalizations in the U.S. (American Lung Association, 2014), and more than \$300 million has been spent annually for asthma-related hospital care alone (Torio et al., 2013). ER visits and hospital admissions due to asthma are not only an economic burden, but asthma also affects the education of children as they tend to miss more school (Erbstein, 2014; Moonie, Sterling, Figgs, & Castro, 2008) and have poorer social and intellectual growth (Levy, Winickoff, & Rigotti, 2011). Additionally, caregivers of school-aged children with asthma are 16% more likely to miss work due to their sick child (Sullivan et al., 2017), bringing indirect productivity loss consequences (Zhang, Sun, Woodcock, & Anis, 2017).

Asthma also causes major financial difficulty in the U.S. adult population. Sullivan et al. (2011) reported comprehensive obstacles that the patients have experienced. The study found that the total health care expenditures among these patients are approximately 18 billion dollars each year. The patients also incurred \$1,907 additional annual health care costs in 2008 U.S. dollars, compared to the general U.S. population without asthma. In terms of employment perspectives, the same study revealed that patients with asthma are associated with 22% more likely to be unemployed. Annually, asthma also causes approximately 14.2 million workdays missed (CDC, 2013). To alleviate this burden, a rigorous asthma management program should be promoted among adults with asthma.

2.2. Expert Panel Report 3 (EPR-3)

Although asthma is not a curable disease (Levy, Vachier, & Serhan, 2012; Thomas, 2015), it is unquestionably manageable with collaboration between health care providers and patients (NIH, 2007). The EPR-3 (Guidelines for the Diagnosis and Management of Asthma), a well-recognized asthma guideline assembled since 2007 by the National Heart, Lung, and Blood Institute, has declared that the goal of asthma therapy is to optimize asthma control resulting in the full ability of a person with asthma to participate in normal activities and minimization of unnecessary health services utilization (Fromer, 2010; NIH, 2007). Good asthma control will reduce asthma impairment by preventing chronic symptoms, decreasing the need for short-acting beta 2-agonist (SABA) medications, maintaining normal pulmonary function, and sustaining normal activity levels.

It will also reduce the chance of having asthma exacerbations and lower the need for ER visits or hospitalizations (Rance, 2011; Rogers & Reibman, 2012).

The EPR-3 guideline outlines four components for long-term asthma management (NIH, 2007). The first component focuses on assessing and monitoring asthma severity and control. Asthma severity should be evaluated while persons with asthma is not using medications to select an appropriate therapy. After therapy has been initiated, asthma control should be monitored to determine if the treatment should be maintained or adjusted, using the “Stepwise Approach for Managing Asthma” found in the EPR-3 guidelines. The guidelines clarify how often patients should be seen by a provider, depending on how well their asthma is controlled. An office visit should be scheduled as often as every two weeks when the patients have not gained asthma control. Once asthma control is achieved, office visits could be less often—two times per year.

The second component for long-term asthma management emphasizes the importance of asthma self-management. All patients should receive a written asthma action plan and asthma education so that they are empowered in assessing asthma control, correctly taking medications, and obtaining medical care when needed.

The third long-term asthma management component stresses the importance of controlling environmental factors that could trigger asthma exacerbations and managing other health conditions that could interfere with asthma. The guidelines suggest that providers advise their patients to avoid allergen exposures, such as indoor mold, smoking, and cold air that may trigger an asthma exacerbation. Comorbidities, such as sinusitis, should be investigated due to its interrelationship with asthma control.

The fourth asthma management component highlights the two types of asthma medication necessary for achieving asthma control for persistent asthma: long-term controller and short-acting reliever medications. These two treatment categories have different functionalities in asthma management. Long-term controllers, such as inhaled corticosteroids, should be used daily in patients with persistent asthma to maintain asthma control. These treatments lessen the inflammation of the bronchial tree that results in a temporary narrowing of the airways that carry oxygen to the lungs. In contrast, short-acting medications, such as SABAs, are referred to as 'rescue' treatments and should be used for quick relief during asthma attacks. The medications relax the tightening, smooth muscles of the airways. Figure 2.1 summarizes the steps for quality asthma care provision (National Heart Lung and Blood Institute, 2011).

Figure 2. 1 Steps for quality asthma care provision defined by the Expert Panel Report 3



(Source: https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf)

While actualizing the EPR-3 guidelines in real-life settings would optimize the quality of asthma care, implementing the guidelines into practice is somewhat challenging (Gagliardi & Alhabib, 2015). The barriers to guideline adoption are, for instance, low familiarity with the guidelines or time constraints (Fischer, Lange, Klose, Greiner, & Kraemer, 2016). Therefore, interventions that simplify the guidelines and facilitate their implementation may furnish better health outcomes for patients with asthma.

2.3. Quality improvement efforts

Quality improvement approaches have been employed widely in the health care setting (Reed & Card, 2016) to close the gap between research and current practice (Fernandopulle et al., 2003). The goal of quality improvement efforts is to enhance the efficiency or effectiveness of health care interventions and eradicate suboptimal practice (Landrum & Baker, 2004). A methods research report prepared for the Agency for Healthcare Research and Quality (AHRQ) (McDonald, Chang, & Schultz, 2013) has defined nine main quality improvement strategies that have been exercised:

- ❖ Provider reminder systems: a system that offers providers with specific messages regarding a patient encounter. The information could offer providers evidence-based care recommendations.
- ❖ Facilitated relay of clinical data to providers: a method that passes on clinical information that is not collected during an office visit to the providers. The information could be gathered from the patients themselves or from other health care settings.

- ❖ Audit and feedback: clinical performance measures of providers or health care facilities that have been collected to assess their care qualities.
- ❖ Provider education: educational-focused approaches that are designed to target improvement in the providers' practice.
- ❖ Patient education: efforts that concentrate on enhancing patient education at either the in-person patient level or the community-outreach level.
- ❖ Promotion of self-management: strategies that center on providing patients with needed resources that empower them to manage their health conditions.
- ❖ Patient reminders: approaches that assist providers in reaching out to patients to ensure adherence to care plans.
- ❖ Organizational change: strategies that involve disease management (an integrated care approach to improve care processes), personnel changes, discussion of patient treatment plans with distant providers, and quality improvement activities that identify problems and implement interventions to address challenges in the setting.
- ❖ Financial, regulatory, or legislative incentives: interventions that incorporate financial incentives to the provider or patient payment, alter the reimbursement structures, and modify the provider licensure or institutional accreditation requirements.

Previous research regarding quality improvement strategies indicated that quality improvement efforts for patients with chronic conditions apparently lack a long-term evaluation of the program effect. Wells et al. (2017) conducted a systematic review to determine the effectiveness of quality improvement interventions. Out of the 64 included quality improvement interventions, only eight studies assessed the sustainable effect of

the programs, defined as the data analyses of outcomes at least six months after the end of program implementation. The low number of such quality improvement studies may hinder the expansion of improvement program in other settings. Glasgow and Emmons (2007) revealed that the self-sustaining difficulty of the program design and the inability to evaluate sustainability are barriers to adoption of translation research findings into practice.

2.3.1. Concerns with current quality improvement programs for asthma

This section delineates three problems with current quality improvement programs for asthma highlighted in the literature: a lack of evaluation of quality improvement programs on avoidable health resource use, relatively short follow-up periods for assessing endpoints, and potential data issues. The concerns were abridged from two systematic reviews that summarized the quality improvement evidence of children and adults with asthma.

Several quality improvement programs have been executed to enhance asthma care at an organizational level, but very few have evaluated the program's effect on preventable health events and financial outcomes. Bravata et al. (2009) carried out a systematic review of quality improvement strategies for children with asthma. Among the 79 included studies, 13 attempted to improve the asthma care quality at an organizational level. Less than 50% of the organizational-change programs investigated their effect on ER visits; none of the studies found statistically significant results. Furthermore, of the 79 included studies, only seven assessed asthma-related health care costs (Bravata et al., 2009). The systematic review also indicated that most studies examined outcomes for less than a year after implementation. The unaddressed outcomes, in combination with a short

follow-up period, could contribute to the unwillingness of other health centers to adopt the quality improvement programs in other settings. Decision makers might be uncertain of program benefits to their patients and health care system long term.

Concurrent with Bravata's review, the results of another systematic review that summarized the effect of asthma disease management among adult patients manifested similar concerns (Peytremann-Bridevaux et al., 2015). According to this review, nine out of the 20 studies identified ER or unscheduled visits among adults with asthma as their endpoints. Only one included study, evaluating the effect of a telemedicine system, reported a decrease in daytime ER visits in the 6-month follow-up period, but the study did not find a statistical reduction in nighttime ER visits. None of the other eight studies found a meaningful reduction in ER or unscheduled visits. Furthermore, these studies all had short follow-up periods (between one to twelve months).

The same systematic review of adults with asthma also identified research completion problems among asthma management programs (Peytremann-Bridevaux et al., 2015). First, only seven out of the 14 studies executed in primary care, outpatient, or health management organization settings provided adequate information to assess missing data. The findings imply that the completeness of the outcomes is often overlooked among studies focusing on improving asthma care quality in practice settings. In addition to the quality of the data, the authors stressed that the program descriptions of most reviewed studies were unclear, further complicating the adoption of these interventions in other settings.

In conclusion, there have been numerous asthma-related quality improvement interventions, but their effects on potentially preventable health care utilizations—ER visits

and hospital admissions due to asthma—have been insufficiently studied. Hence, further research is necessary to bridge the gap between scientific evidence and the translation of quality improvement evidence to real-world practice.

2.4. Enhancing Care for Patients with Asthma

This section provides information about the establishment of the ECPA quality improvement program. The program description illustrates how ECPA was implemented in each health center. Then, a summary of what about the centers is asserted.

2.4.1. ECPA program initiation

ECPA is a quality improvement program initiated by the ALAUM. The association is a voluntary health organization that strives to improve care for persons with lung diseases through education, advocacy, and research (American Lung Association, 2016). The goal of ECPA is to make a direct impact on the quality of primary care, resulting in improved long-term care outcomes for persons with asthma (Health Care Service Corporation, 2016).

In 2011, the ALAUM inaugurated a joint initiative to expand ECPA, a multi-state, multi-center quality improvement program to augment the quality of asthma care in health centers that served patients with asthma in four states: New Mexico, Oklahoma, Texas, and Illinois. The ALAUM worked closely with participating centers to fulfill their needs and achieve guideline-based asthma care. The ECPA program aimed at improving short- and long-term asthma outcomes by integrating evidence-based recommendations into real-life clinical practices.

2.4.2. ECPA program description

ECPA was a 12-month collaborative, continuous-quality-improvement approach in the community health centers that served patients with asthma in the four identified states. The overall goal of ECPA was to improve asthma-related health outcomes by supporting the implementation of the EPR-3 asthma guidelines at participating health centers. ECPA embraced the Wagner Chronic Care Model, a broadly adopted strategy for quality improvement initiatives (Coleman, Austin, Brach, & Wagner, 2009). The model characterizes a method for restructuring health care (Stellefson, Dipnarine, & Stopka, 2013). To create effective, standardized asthma care that complied with the EPR-3 guidelines, the Plan-Do-Study-Act (PDSA) cycle guided action-oriented learning in each center.

Before the program was executed, the ALAUM engaged four public health professionals to serve as each state's project manager. The managers then invited potential health centers to participate in ECPA through phone calls and face-to-face meetings. This personalized contact approach facilitated a successful partnership between the centers and ECPA personnel. When the centers agreed to join the quality improvement program, they were evaluated according to their readiness to carry out improvement activities. All centers were required to have 1) a provider and staff champion who were willing to commit to the 12-month program, 2) support from the various levels of administration, and 3) no other organizational initiatives that would compete with ECPA, such as a recent administrative turnover, new medical directors, an in-progress implementation of electronic medical record systems.

To effectively manage the improvement effort, ECPA divided center recruitment and participation into three chronological cohorts; each cohort contained at least one center from each state. Figure 2.2 shows the implementation timeline of each cohort.

Regarding quality improvement efforts, ECPA included two chief components:

- ❖ Improvement activities through organizational change within each participating center using the PDSA cycle and
- ❖ Learning collaboratives with other centers within the same cohort.

The activities within each center occurred by first forming a multidisciplinary quality improvement team to champion the initiative. Then, each center determined achievable asthma guideline-based objectives. ALAUM provided step-by-step, training, research, and technical assistance that centers used to improve the asthma care process. Every other month, the ALAUM state manager conferred with clinic staff about steps in the improvement process. In addition to meetings, monthly technical assistance calls from ALAUM were made to address individual, unique implementation problems at each center.

In addition to within-center ongoing improvement processes, representatives from participating health centers engaged in a learning consortium with peers from other centers. Through bi-monthly meetings, representatives from the health centers shared ideas, challenges, and successes in their improvement efforts with other centers in their cohort. The learning collaboratives created an environment that facilitated exchanging successes, troubleshooting challenges, providing continuing asthma education, and developing concrete quality improvement plans for each center once the representatives returned to their settings.

Overall, the specific EPR-3 elements (NIH, 2007) on which participating health centers focus, include:

- ❖ Asthma severity: asthma severity should be evaluated to support clinical decisions on appropriate medications.
- ❖ Asthma control: asthma control should be evaluated to determine treatment maintenance and adjustments.
- ❖ Pulmonary function testing: pulmonary function obtained by spirometry should be measured for diagnosis and to monitor asthma control.
- ❖ Patient education: asthma self-management education should be incorporated into routine care for patients who have asthma.
- ❖ Asthma action plan: a written provider's instruction for self-management should be given to all patients. The plan specifies outlines for daily management, recognizing and handling worsening asthma and adjusting medication dosage.
- ❖ Controller medication: long-term control medications should be prescribed to patients with persistent asthma. To achieve and maintain control, controller medications should be utilized daily on a long-term basis.

2.4.3. Characteristics of participating health centers

One reason that the four states were of interest to ECPA was the relatively high prevalence of asthma and uncontrolled asthma in these state populations, compared to the national prevalence (Child and Adolescent Health Measurement Initiative, 2013; National Center for Environmental Health, 2016). Particularly, the prevalence of asthma in Oklahoma children and adults was 11.4% and 9.7%, respectively. In line with the disease prevalence, the rates of uncontrolled asthma among adult patients in Oklahoma

(57.3%) and New Mexico (51.9%) were greater than the U.S. average rate (50.0%) (See Figure 2.3) (CDC, 2014b). These high numbers reflect a growing need for asthma management that would help patients stabilize their symptoms and live with their full capacities.

From January 2013 to July 2015, 65 health centers were recruited to participate in ECPA. The program consisted of three chronological cohorts, and each cohort contained at least one health center from the four states. In total, there were 23, 23, and 19 health centers in the first, second, and third cohorts, respectively. Illinois had the highest number of participating centers (22 centers), contrasting with 18 centers from New Mexico, with the lowest number. The types of participating health centers included primary care clinics, pediatric clinics, multi-specialty health centers, and school-based and mobile clinics. Seventy-five percent of participating centers were located in urban areas, using the definition of the Centers for Medicare & Medicaid Services (Centers for Medicare & Medicaid Services, 2016).

2.4.4. Remaining gaps in the ECPA outcomes

While the ALAUM was successful in recruiting participating centers and sustaining the program implementation in the three cohorts, complete analysis of the outcome evaluation of ECPA had not yet been carried out. Advanced analyses to determine whether the program translated into improved guideline-based performance measures, attenuating preventable asthma-related ER visits and hospital admissions, and reducing health care costs among patients who received asthma care from the participating centers were needed. Since ECPA's effectiveness had not been determined, there was a current

gap between the reality and the vision to expand ECPA in other settings to further enhance asthma care processes.

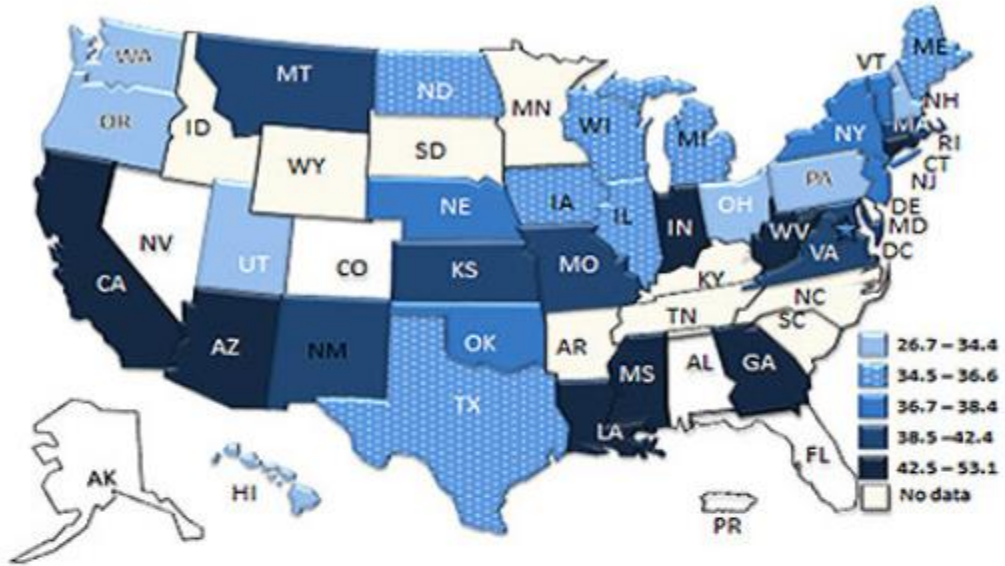
This dissertation, therefore, will investigate the association between ECPA and subsequent improvements in center-level asthma performance measures and in patient-level health services utilization outcomes. This research took advantage of a natural experiment and three years of administrative claims data (January 2012-May 2015) to provide the needed evidence. An administrative dataset from a private insurance plan that provided health coverage to the center patients, coupled with performance data collected at the participating clinics, were analyzed. This dissertation used a quasi-experimental design to examine the effect of the program. “A multiple baseline design” was employed to guide the program evaluation where each cohort received the ECPA effect at different time points.

Figure 2. 2 The implementation timeline of each participating cohort

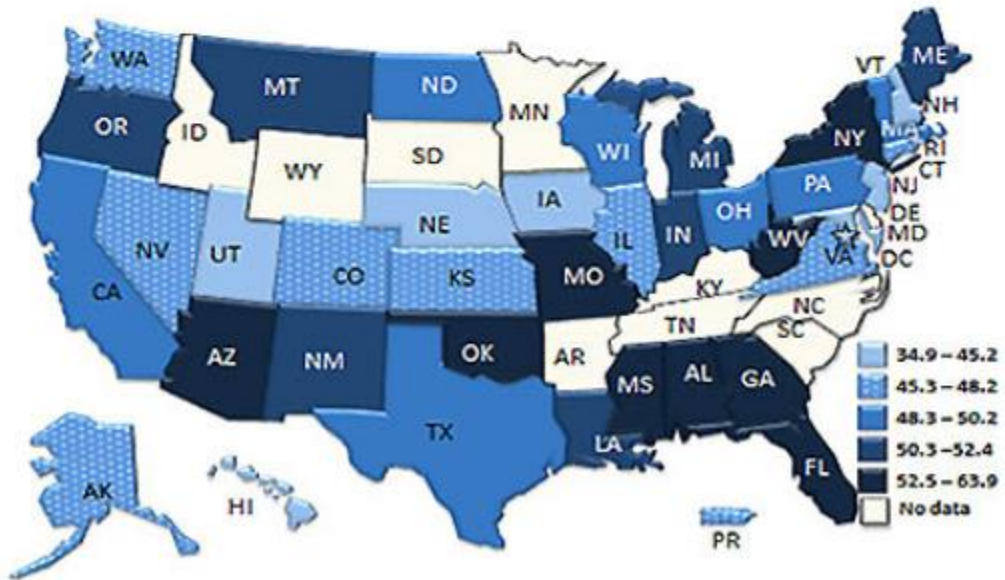
2013												2014												2015						
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
Cohort 1: New Mexico – 7 centers																														
Cohort 1: Oklahoma – 3 centers																														
Cohort 1: Texas – 5 centers																														
Cohort 1: Illinois – 8 centers																														
									Cohort 2: New Mexico – 4 centers																					
									Cohort 2: Oklahoma – 4 centers																					
									Cohort 2: Texas – 7 centers																					
												Cohort 2: Illinois – 8 centers																		
																		Cohort 3: New Mexico – 7 centers												
																		Cohort 3: Oklahoma – 1 center												
																		Cohort 3: Texas – 5 centers												
																		Cohort 3: Illinois – 6 centers												

Figure 2. 3 The percentages of children and adults with current asthma who had uncontrolled asthma by states

Percentage with uncontrolled asthma: Children



Percentage with uncontrolled asthma: Adults



(Source: https://www.cdc.gov/asthma/asthma_stats/uncontrolled_asthma.htm)

Chapter 3: Conceptual Framework

The conceptual framework of this dissertation is based on the Wagner chronic care model, Plan-Do-Study-Act (PDSA) Cycle, and a multiple baseline design. The chronic care model was used to provide the theoretical basis for restructuring asthma care at participating clinics by the ALAUM. The PDSA cycle was used to explain the emphasis on collecting data to arrange and track the progress in the quality improvement activities at ECPA-participating health centers. A multiple baseline design was used to guide analysis of time-series data and to estimate the effect of ALAUM's quality improvement program on the outcomes of interest.

3.1. The Wagner chronic care model

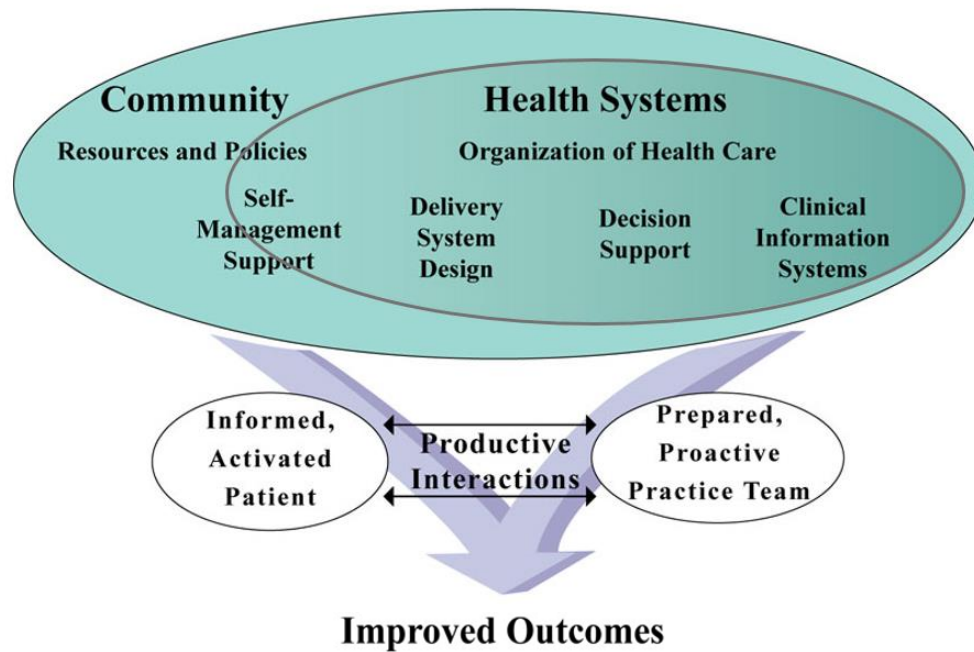
The Wagner chronic care model is a broadly adopted strategy for a primary care improvement study (Coleman et al., 2009). The model characterizes a method for restructuring health care through interactions between health systems and communities (Stellefson et al., 2013). This model identifies six modifiable elements of care delivery environments (see Figure 3.1) that are described below.

- ❖ Organization of health care: staff from all organizational levels should value the importance of health quality care. The health care system should create an environment where both effective improvement and error handling mechanisms are encouraged (Improving Chronic Illness Care, 2006d).
- ❖ Delivery system design: the health care system should actively involve both health care providers and patients in chronic disease management. The roles of health care providers should be clearly defined to assure that patients

receive culturally-sensitive, self-management education (Improving Chronic Illness Care, 2006c).

- ❖ Decision support: the health care system should assist the adoption of evidence-based care into practice. Primary care providers and specialists should receive regular training to be apprised of current evidence. The providers should openly discuss guideline-based approaches with their patients, so the patients appreciate the standard care (Improving Chronic Illness Care, 2006b)
- ❖ Clinical information systems: the health care system should advance patient data sharing between patients and their collaborative team of providers. The patient-data-sharing process would ease individualized patient care planning (Improving Chronic Illness Care, 2006a).
- ❖ Self-management support: patients are the core of disease management and should be encompassed in health care decision-making. Patients and their providers should work together to understand their health problems, define their treatment goals, and incorporate various ways to accomplish the goals (Improving Chronic Illness Care, 2006e).
- ❖ Community resources: in order for patients with chronic illnesses to effectively manage their conditions, the health care system can facilitate the partnership between patients, community organizations, and profit and nonprofit stakeholders (Improving Chronic Illness Care, 2006f).

Figure 3. 1 Wagner chronic care model



(Graphic prepared by the MacColl Institute® ACP-AASIM Journals and Books; Source: http://www.improvingchroniccare.org/index.php?p=the_chronic_caremodel&s=2)

ECPA used this model to outline the six elements to form a system with high-quality asthma management: health system, delivery system design, decision support, clinical information systems, self-management support and community resources as follows (Improving Chronic Illness Care, 2016):

- ❖ Organization of health care: to build a culture and mechanisms that ensure safe, high-quality care in the organization. ECPA required all levels of clinic staff to support the system change process.

- ❖ Delivery system design: to ensure the delivery of adequate, efficient clinical care and self-management support. ECPA helped all participating health centers improve the process of scheduling asthma follow-up visits.
- ❖ Decision support: to promote clinical care by embedding evidence-based guidelines into daily clinical practice. ECPA created activities that adhere to the EPR-3 guidelines. ECPA activities include documenting asthma severity, promoting patient self-assessment usage, increasing asthma controller prescription for patients with persistent asthma, developing written asthma action plans and providing self-management education.
- ❖ Clinical information systems: to organize patient data to facilitate efficient and effective care. ECPA emphasized the use of electronic health information to better manage patient health.
- ❖ Self-management support: to allow patients to manage their own health. The ECPA activities that promoted patient self-management and were consistent with the EPR-3 recommendations include provision of personalized asthma action plans, education to patients and their caregivers, and self-assessment of asthma exacerbation severity and the need in health services use.
- ❖ Community resources: to develop collaboration with community organizations to support and create interventions that fill gaps in needed services. This element is the core philosophy of the ECPA implementation.

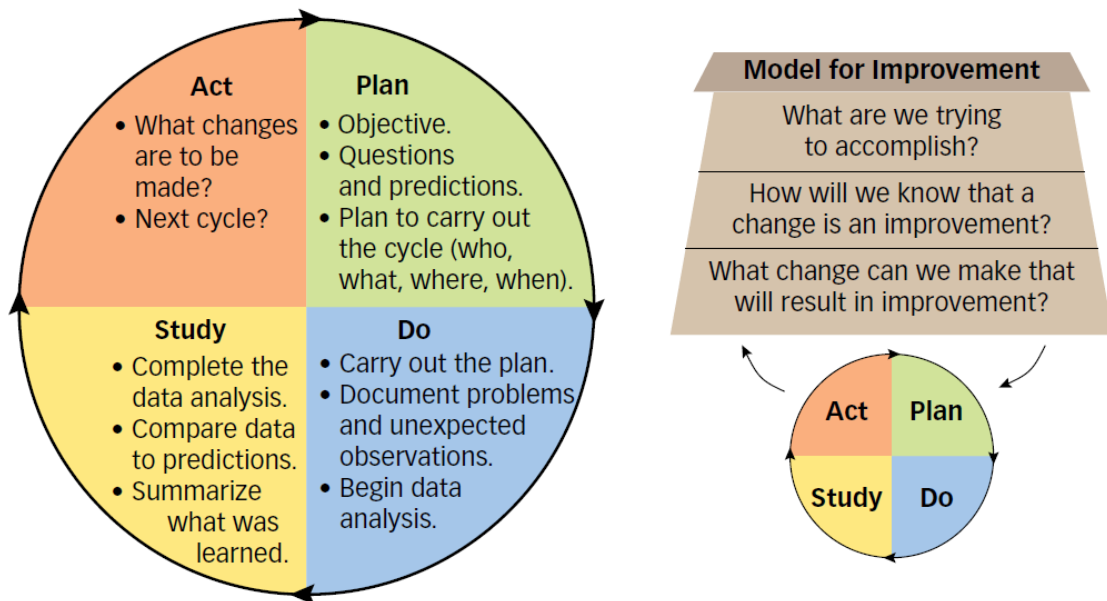
3.2. Plan-Do-Study-Act Cycle

The PDSA cycle is a systematic framework for organizing the iterative development of change (The W. Edwards Deming Institute, 2018). The PDSA cycle has been used to introduce changes into a complex health care environment (Taylor et al., 2013). Dr. W. Edwards Deming originated the cycle in 1993, which has been further revised to emphasize a change that would result in improvement of regular health care practice (Moen & Norman, 2006). Figure 3.2 shows Model of Improvement, a combination of three essential questions and the PDSA cycle that provides a core component for testing changes in quality improvement initiatives (Moen & Norman, 2006). The three questions mean to explicitly state the aims, measures, and actions for improvement in a setting (Moen & Norman, 2006). When staff members who will carry improvement activities have been established, the four steps of the PDSA cycle are processed as follows:

- ❖ Step 1 – Plan: to determine the objectives of improvement processes and plan to execute the cycle.
- ❖ Step 2 – Do: to implement the plan, collect problems and unexpected effects occurring during the process, and start analyzing collected data.
- ❖ Step 3 – Study: to complete the analysis, compare the results with predicted outcomes, and determine what the team has learned from carrying out the plan.
- ❖ Step 4 – Act: to standardize the successful plan into regular practice and return to Step 1 – Plan; to reevaluate the process for further improvement that would result in success.

In ECPA implementation in each participating center, the PDSA cycle was used as a strategy for improvement activities and strategic planning processes. The PDSA cycle was chosen because it is an easily understood rubric for testing a quality improvement initiative that utilizes a 4-step approach—create a plan to assess the initiative (P), carry out the plan (D), measure outcomes identified in the plan (S), and determine modifications needed based on the findings (A) (Agency for Healthcare Research and Quality, 2013; Taylor et al., 2013).

Figure 3. 2 PDSA cycle and Model for Improvement

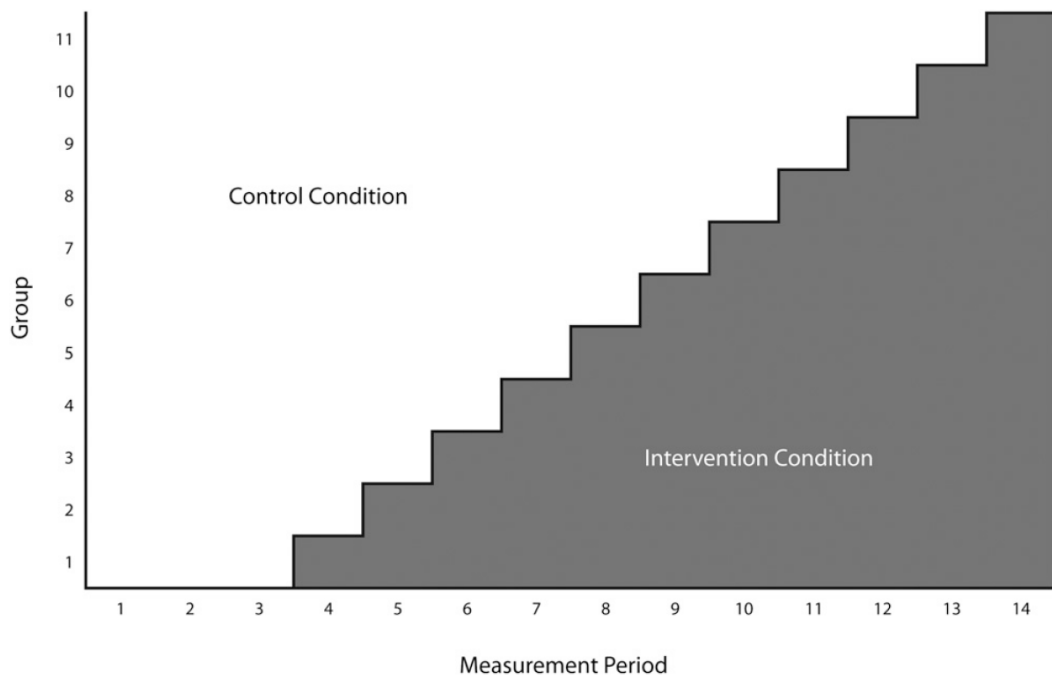


(Source: <http://www.apiweb.org/circling-back.pdf>)

3.3. Multiple baseline design

A non-concurrent multiple baseline design across individuals was applied to examine the effect of ECPA multi-state, multi-center quality improvement program. A multiple baseline design is a class of interrupted time series analysis that involves 1) repeated measurement of outcomes over a period and 2) the serial introduction of an intervention to each study unit on a staggered schedule (See Figure 3.3) (Hedges, Pustejovsky, & Shadish, 2013; Rhoda, Murray, Andridge, Pennell, & Hade, 2011). In this dissertation, a study unit refers to each participating health center. ECPA was introduced to health centers in each cohort at different points in time after a series of baseline measurements (Biglan, Ary, & Wagenaar, 2000).

Figure 3. 3 Conceptual diagram of a multiple baseline design



(Source: <https://doi.org/10.2105/AJPH.2011.300264>)

A multiple baseline design is suitable for guiding the ECPA program evaluation because the practical implementation of ECPA is consistent with a multiple baseline design. The actual ECPA implementation was not initiated across all participating centers at the same time. Instead, the first cohort of clinics was formed in January 2013, and other health centers from the four states were continuously recruited at different points in time. Thus, the intervention was staggered across time and participating centers.

A single interrupted time-series design is a time series of a repeated outcome that is interrupted by a health care implementation at a known point in time (Soumerai, Starr, & Majumdar, 2015). The limitation of conventional single time-series design is that a change in outcomes could be due to other external events that co-occurred with the change in the program implementation (Biglan et al., 2000). However, the influence of external factors is less problematic for a multiple baseline design. A visualization of the program implementation in different settings at different time points can demonstrate a repeated pattern of change in measured outcomes following the implementation in each cohort center, along with the absence of considerable fluctuations in the data at other time points (Pustejovsky, Hedges, & Shadish, 2014). Consistent changes in outcomes across cohort groups initiating at different times may suggest that reduction of the outcomes is attributed to the intervention, not to external events (Sanson-Fisher, D'Este, Carey, Noble, & Paul, 2014).

Chapter 4: Manuscript 1

Enhancing guideline-based asthma care processes through a multi-state, multi-center quality improvement program

4.1. Manuscript overview

This manuscript addresses the effect of ECPA on six guideline-based performance measures. The results of this manuscript accomplished the first aim of this dissertation.

4.2. Author list

The authors of this manuscript include Sirikan Rojanasart, Jill Heins Nesvold, Angeline M Carlson, Wendy L St. Peter, Pinar Karaca-Mandic, Julian Wolfson, and Jon C Schommer.

4.3. Target journal

The manuscript has been submitted for publication in *Journal of Asthma*. This manuscript is suitable for the journal because the journal aim is to disseminate asthma research that includes asthma management (Journal of Asthma, 2017). Since ECPA assembled quality improvement approaches with potential replicability in diverse geographical settings, the results regarding the improvement in clinic-based performance measures would be beneficial to the target audience, such as asthma care providers and primary care practitioners to consider the further adoption of ECPA in their practice.

4.4. Pre-publication history

This manuscript has been submitted to *Journal of Asthma* on December 24th, 2017. Minor revision request has been received on February 12th, 2018. A revised version of the manuscript has been resubmitted on February 23rd, 2018.

4.5. Abstract

Objective: This study investigated the effectiveness of Enhancing Care for Patients with Asthma (ECPA)—a collaborative quality improvement program implemented in 65 community health centers that serve asthma patients in four states—on clinic-based asthma performance measures consistent with national guidelines.

Methods: This study utilized a pretest-posttest quasi-experimental design. Six clinic-based performance measures of each center were collected from a retrospective chart review at time points: before the ECPA implementation; at the end of the 12-month long ECPA program; and six months after program completion. The effectiveness of ECPA was assessed using generalized linear mixed models with a Poisson distribution and log link by evaluating the change in each measure from baseline to program completion, from baseline to 6-month post-program completion and from program completion to 6-month post-program completion.

Results: The ECPA implementation was positively associated with improvement in all measures from baseline to program completion: documentation of asthma severity (RR 1.314; 95% CI 1.206, 1.432); Asthma Control Test (RR 3.625; 95%CI 3.185, 4.124);

pulmonary function testing (RR 1.771; 95% CI 1.527, 2.054), asthma education (RR 2.246; 95%CI 2.018, 2.501), asthma action plan (RR 2.335; 95% 2.070, 2.634) and controller medication (RR 1.961; 95%CI 1.504, 2.556). Improvement was sustained for all six measures at the 6-month post-program completion time point.

Conclusion: This study demonstrated the favorable effect of the ECPA program on evidence-based asthma quality measures. This program could be considered a model worth replication on a broader scale.

4.6. Introduction

Evidence-based asthma guidelines have been developed and put into practice, but achieving asthma management goals in practice remains challenging. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma, a well-accepted asthma guideline published in 2007 (CDC, 2013a), stresses the importance of maintaining asthma control by reducing impairment and future risk, such as asthma exacerbation and the need for ER visits and hospitalizations. The guidelines underline four components in long-term asthma management (NIH, 2007). Component 1 focuses on assessing and monitoring asthma through appropriate severity and control evaluation. Component 2 emphasizes the importance of asthma self-management that includes provision of a written asthma action plan and development of a provider-patient partnership. Component 3 stresses the need for evaluating patients' triggers and minimizing exposure to them. Component 4 highlights two categories of asthma medications: long-term controllers and short-term relievers. Despite the four comprehensive asthma components, the difficulties in achieving control of asthma, with

issues such as misdiagnosis, poor inhaler technique, and poor adherence to treatment, have been well documented (Haughney et al., 2008). Regardless of the barriers, previous research suggests that asthma control could be optimized through the implementation of EPR-3 guidelines in primary care practices (Carlton et al., 2005).

Although the implementation of asthma guidelines may result in improved asthma control, the guidelines remain underutilized in practice (Baddar, Worthing, Al-Rawas, Osman, & Al-Riyami, 2006; Gipson, Millard, Kennerly, & Bokovoy, 2000; Halterman et al., 2002; Wisnivesky et al., 2008). Wisnivesky et al. (2008) have reported that less than half of primary care providers have used these guidelines to manage their patients, and only 9% adhere to asthma action plan provision, a specific EPR-3 guidelines component. Prior research has also reported that physicians indicated that they appropriately utilized asthma guidelines in their practice when they actually did not (Cloutier, Wakefield, Carlisle, Bailit, & Hall, 2002). Due to the gaps in asthma care quality, several interventions have been put forth to enhance asthma guideline usage (Okelo et al., 2013). For instance, Cloutier et al. implemented a previous version of the EPR-3 guidelines in 20 private practices in Connecticut to improve care for children with asthma since 2001 (Cloutier, Wakefield, Sangeloty-Higgins, Delaronde, & Hall, 2006). Despite these numerous and long-standing efforts, the replicability and sustainability of interventions remain somewhat questionable. There is a need for effective efforts that could be replicated in a broader sense to improve evidence-based practice among providers of patients with asthma.

Quality improvement approaches have been employed in health care to generate effective care in real-world settings (Reed & Card, 2016). The approaches aim at bridging the gap between the current practice and what is considered best practice (Fernandopulle et al., 2003). While asthma quality improvement efforts have commenced, the goal of

optimal asthma care across the country demands an effective, sustainable, and replicable quality improvement program. To enhance guideline-based asthma care processes in health centers serving patients with asthma, in 2012 the American Lung Association of the Upper Midwest (ALAUM) launched Enhancing Care for Patients with Asthma (ECPA).

ECPA is a partnership between ALAUM and a private health insurer with the purpose of leveraging a 12-month collaborative, continuous quality improvement approach in community health centers that serve asthma patients in Illinois, New Mexico, Oklahoma, and Texas. The overall goal of ECPA was to improve asthma-related health outcomes by supporting the implementation of EPR-3 asthma-care guidelines in participating health centers: primary care clinics, pediatric clinics, multi-specialty health centers, school-based and mobile clinics. ECPA embraced the Wagner Chronic Care Model, a broadly adopted strategy for quality improvement initiatives (Coleman et al., 2009), that characterizes a method for restructuring health care (Stellefson et al., 2013). Specifically, ECPA adapted the six elements identified in the model as necessary to form a system with high-quality chronic disease management for asthma: an integrated health system, delivery system design promoting efficient workflow, clinical care decision support, clinical information systems supporting the use of electronic medical records, patient self-management support tools, and community resources. To create effective, standardized asthma care that complied with the EPR-3 guidelines, the Plan-Do-Study-Act (PDSA) cycle guided action-oriented learning in each center.

ECPA has demonstrated its replicability since the program was successfully re-implemented in multiple health centers in four states within a 3-year period. Nevertheless, effectiveness and sustainability of ECPA on clinic-based performance measures have not been evaluated. The objective of this study was to assess the effectiveness of ECPA on

asthma performance measures in multiple health centers in four states during a recent 3-year period.

4.7. Methods

Centers were invited to participate in ECPA through personal phone calls and face-to-face meetings with ALAUM state managers to facilitate a successful partnership. The centers that agreed to participate in ECPA were formally assessed to ensure they had a provider and staff champion who were willing to commit to the 12-month program, had support from the various levels of administration, and did not have other organizational initiatives that would compete with ECPA, such as recent administrative turnover, new medical directors, implementation in progress of electronic medical record systems. To effectively organize the improvement effort, ECPA divided center recruitment and participation into three chronological cohorts: each cohort contained at least one center from each state. Figure 4.1 summarizes the implementation timeline of each cohort.

4.7.1. ECPA Quality Improvement Efforts

Quality improvement efforts through ECPA contain two main components: 1) improvement activities within each participating center using the PDSA cycle, and 2) learning collaboratives with other centers within the same cohort. The PDSA cycle was chosen because it is an easily understood rubric for testing a quality improvement initiative that utilizes a four-step approach—create a plan to assess the initiative (P), carry out the plan (D), measure outcomes identified in the plan (S), and determine modifications needed based on the findings (A) (Agency for Healthcare Research and Quality, 2013; Taylor et al., 2013).

Each center formed a multidisciplinary quality improvement team to champion the initiative and established asthma guideline-based objectives to accomplish goals. Within each center, the PDSA cycle was used as a strategy for improvement activities. ALAUM provided step-by-step, training, research, and technical assistance that centers used to improve the asthma care process. Every other month, the ALAUM state manager conferred with clinic staff about steps in the improvement process. In addition to meetings, monthly technical assistance calls from ALAUM were made to address individual, unique implementation problems at each center.

Representatives (minimally a clinician champion and a staff champion) from participating health centers attended learning collaboratives, facilitated by the ALAUM. In-person meetings were organized every other month to allow attendees to 1) share ideas, challenges, and successes in their ongoing improvement efforts, 2) to participate in a continuing education topic related to asthma care and guidelines, and 3) to strategize the next step of participating health centers' PDSA cycle. Representatives who could not attend the meetings in person, they participated by remote options. The learning collaboratives were meant to create a learning environment to exchange successes, troubleshoot challenges, provide continuing asthma education, and develop concrete quality improvement plans for each center once the representatives returned to their settings.

4.7.2. Data collection process

Since ECPA's goal was to support the implementation of the EPR-3 guidelines in practice, ECPA employed a retrospective chart review to obtain six clinic-based performance measures at three different time points. A team member from each center, usually a nurse or a health center manager, conducted a review of approximately 30

randomly selected charts of patients with asthma seen within the previous two months at each of the three time points: baseline before the ECPA implementation (time=0); at the end of the 12-month long program of ECPA activities (time=12); and six months after program completion with no structural support from ECPA (time=18). All charts were reviewed in centers that had fewer than 30 patients at any of the three time points. Centers could also elect to report the measures from all patients with asthma they served in the previous two months. To ensure the consistency of chart extraction, a standardized chart audit tool with key data collection for the six measures was provided to all centers, and ALAUM state program managers worked closely with each participating center during the data collection process to ensure its completeness.

4.7.3. ECPA outcomes

Six clinic-based performance measures consistent with the EPR-3 guideline recommendations were the outcomes of interest. The clinic-based measures included documentation of asthma severity, asthma control, and pulmonary function testing as measures of asthma assessment and monitoring; documentation of asthma education and an asthma action plan as measures of education and provider/patient partnership in asthma care; and controller medication prescription as a measure of medication use. Performance measures were reported as the number of patient charts that documented the asthma care element and the total number of charts reviewed at that time point.

In the chart review process, asthma severity was assessed as documentation of the asthma severity rating (intermittent, mild persistent, moderate persistent and severe persistent) in patient medical record as defined in the EPR-3 guidelines. Asthma control was evaluated as documentation of the Asthma Control Test (ACT) completed by the

patient or caregiver. Pulmonary function testing was a spirometry test, using a laptop-based spirometer, within the past 12 months. Asthma education was assessed as documentation of assessment and teaching on the use of the patient's medication delivery device. Asthma action plan (Figure 4.1) was defined as a personalized written plan, including the patients' asthma severity classification, their asthma triggers, and the green, yellow, and red zones for medication therapy based on either personal best for peak flow measurement or symptoms. Lastly, controller medication was reported as documentation of a prescription issued for a controller medication, such as inhaled corticosteroids, to patients with persistent asthma.

4.7.4. Statistical Analyses

For data analysis, this quasi-experimental study employed a one-group pretest-posttest design (Harris et al., 2006), in which each cohort center served as its own control before the ECPA implementation. Characteristics of participating centers from each state were reported using descriptive statistics. Characteristics included participating cohort number, specialty, number of providers, and geographic area. Participating cohorts were assigned a number from one to three based on the date of ECPA initiation. Specialty refers to how the participating centers described their specialties (stand-alone primary care, including designation of family medicine and internal medicine, stand-alone pediatric clinic, multi-specialty health center, and school-based clinic and/ or mobile clinic). Number of providers was defined as the number of providers with qualifications to prescribe medication. Providers were medical or osteopathic physicians, physician assistants, and nurse practitioners. Geographic area defined by the Centers for Medicare & Medicaid Services was used to classify the zip code of each participating center into urban and rural/super-rural areas. These definitions of geographic areas were selected because they

were used for billing and payment purposes (Centers for Medicare & Medicaid Services, 2016).

This study calculated the proportions of each clinic-based performance measure at baseline, program completion, and six months after program completion. Descriptive statistics were reported using the mean and standard deviation; median, interquartile range, minimum, and maximum values. A Wilcoxon Signed Rank Test (Siegel, 1956) was computed to compare the performance measure: 1) at baseline with program completion, and 2) at program completion with 6-month post-program completion. The null hypothesis of the test was that the median difference between pairs of time=12 and baseline (or time=18 and time=12) equals zero.

The effectiveness of the ECPA was assessed in three ways: 1) the change in each clinic-based performance measure from baseline to program completion, 2) the change in each clinic-based performance measure from baseline to 6-month post-program completion, and 3) the change in each clinic-based performance measure from program completion to 6-month post-program completion. To determine implementation effects, this study adopted a generalized linear mixed model (GLMM) to account for repeated within-center measures. Since the clinic-based performance measures were collected as the number of patient charts documenting the asthma care element and the total number of charts reviewed, which could be different by centers and time points, a Poisson distribution with an offset (SAS Institute, 2011a) and its canonical log link were selected to model the outcomes. Cohort, state, specialty, number of providers, and geographic area were used as adjusting covariates in the model. The adjusted rate ratios (RRs), 95% confidence intervals (CIs), and corresponding p-values were computed.

Due to the real-world nature of ECPA, missing data on the six clinic-based performance measures was expected. Patient care demands relative to staff workload could hinder completion of all chart extractions, resulting in missing data. For transparency, this study reported the percentage of missing data for each measure. Review of the missing data patterns showed no monotonic patterns, meaning that ECPA's missing data could be defined as an arbitrary missing pattern (Smith & Kosten, 2017). Thus, this study conducted multiple imputation with a fully conditional specification (FCS) method (Liu & De, 2015; SAS Institute, 2011b; Smith & Kosten, 2017). Cohort, state, specialty, number of providers, and indicators for geographic area were included as predictors in the imputation procedure. PROC MI, a SAS analysis procedure, was used to impute the missing values of the six clinic-based performance measures, with five sets of imputations for each measure. After obtaining the imputed datasets, an analysis of each dataset using GLMM was performed. PROC MIANALYZE was used to combine the analytical results and form a single inference.

All analyses were conducted using SAS software, version 9.3 of SAS System for Windows (SAS Institute, Inc., Cary, NC, USA). A 2-sided alpha level set at 0.05 was used for hypothesis testing. The use of the data for the analyses was determined to be exempt from the University of Minnesota's Institutional Review Board (IRB) review.

4.8. Results

Eighty centers were invited to participate in ECPA. Of those, 65 agreed to join the improvement program (participation rate=81.25%). At the end of program implementation (time=12), none of the 65 centers had dropped out of program participation (100%

retention rate). Table 4.1 summarizes the characteristics of the participating centers overall and by the four states. Illinois had the highest number of participating centers (22 centers representing 23 distinct physical locations); Oklahoma had the lowest number of participating centers (8 centers representing 16 distinct physical locations). The majority of participating centers were stand-alone primary care clinics and were located in urban areas. The median number of providers in participating centers was ≤ 13 in each state.

Table 4.2 shows descriptive statistics for the six clinic-based performance measures at three different time points. In total, 1,616 charts before the ECPA implementation, 1,409 charts at the end of the 12-month long ECPA program, and 1,368 charts at six months after program completion were reviewed. Before the ECPA implementation, at least three-fourths of the participating centers reported less than half of patients having documentation for the following guideline-based components: ACT, pulmonary function testing, asthma education, and asthma action plan. At baseline, median asthma severity reporting and pulmonary function testing was zero, meaning that, before the ECPA implementation, patients attributed to at least 50% of participating centers did not have ACT or pulmonary function testing documented.

After program implementation, the median of all measures increased from baseline to program completion and from baseline to 6-month post-program completion. ACT documentation had the highest absolute median improvement from 0% at baseline to 79% at time=12 and 88% at time=18. Moreover, at least 50% of participating centers had 100% of patients with documentation of a prescribed controller medication at program completion and at six months after program completion. Asthma severity and ACT performance measures revealed a slight uptrend from month 12 to month 18, and no performance measures returned to baseline levels. There was a statistically significant

improvement in all measures from baseline to 12-month post-implementation and from baseline to 6-month post-program completion.

The percentage of missing data for each measure at each time point is reported in Table 4.2. ACT and controller medication documentation at 6-month post-program completion had the highest percentage of missing data with 28% and 20%, respectively.

Tables 4.3 and 4.4 report the results of adjusted mixed-effect models from complete case and multiple imputation analyses, respectively. The findings from the two analyses are nearly identical for the changes in the six clinic-based performance measures. The adjusted rate ratios of change from baseline (time=0) to program completion (time=12) and to 6-month post-program completion (time=18) of all measures were significantly greater than one, indicating that completing the ECPA implementation and six months after the ECPA implementation were associated with positive improvement rates in the performance measures. Specifically, centers instituting the quality improvement initiative were associated with approximately four times higher documentation of ACT at program completion, compared to before the program was implemented (adjusted RR from a complete case analysis = 3.625; 95% CI 3.185, 4.124; adjusted RR from multiple imputation = 3.852; 95% CI 3.406, 4.355).

Additionally, in terms of the change from program completion to 6-month post-program completion, quality improvement program implementation was associated with statistically significant increased improvement in documentation of a prescription issued for a controller medication (adjusted RR from a complete case analysis = 1.387; 95% CI 1.254, 1.534; adjusted RR from multiple imputation = 1.287; 95% CI 1.175, 1.411). However, at 6-month post-program completion documentation of pulmonary function

testing was 25% lower as compared to at time=12 (adjusted RR from a complete case analysis = 0.750; 95% CI 0.655, 0.860; adjusted RR from multiple imputation = 0.768; 95% CI 0.656, 0.900). The changes of other measures did not show statistically significant results. Similar results were seen when multiple imputation method was used.

4.9. Discussion

This study showed the effectiveness of a staggered, multi-state, and multi-center quality improvement program (Enhancing Care for Patients with Asthma Program or ECPA) on asthma guideline-based performance measures. The program was successfully implemented with 100% retention rate in 65 health centers from four states. By employing both complete case and multiple imputation analyses, this study demonstrated a significant improvement in all clinic-based performance measures before the implementation and completion of ECPA. The study revealed an increase in controller prescription among patients attributed to the participating health centers 6-month post-program completion. The overall findings of this study pinpoint that ECPA is an effective and replicable quality improvement program with positive impact on measures adhering to the EPR-3 guidelines and with potential sustainability.

Before the ECPA implementation, there were huge needs for an effective quality improvement program that supports asthma care processes in health centers serving patients with asthma. Before the program implementation, at least three-quarters of the health centers joining ECPA had less than 50% of their patients having documentation of ACT, pulmonary function testing, asthma education, and an asthma action plan. The apparent lack of guideline-based asthma care components is consistent with results from

another quality improvement initiative implemented in 1999 in 16 health centers located in the Chicago metropolitan area (Patel, Welsh, & Foggs, 2004). This initiative utilized a coordinated care approach and reported that, before its implementation, only 20% of adults and 62% of children with asthma received a treatment plan for asthma exacerbation. The coherent results illustrate a compelling and continuing need for an effective approach to improving evidence-based practice among providers of patients with asthma.

ECPA demonstrated its effectiveness in improving clinic-based performance measures that are consistent with the EPR-3 guidelines. Notably, the probability of participating centers having documented evidence for all performance measures at program completion was significantly higher than the probability at baseline. The findings are compatible with a systematic review evaluating interventions that aim at improving health care provider adherence to asthma guidelines (Okelo et al., 2013). The review reported that two out of three quality improvement programs, using a learning collaborative or a team-based improvement process, increased the percentage of patients with an asthma action plan. The overall improvement in the guideline-based measure after the ECPA completion suggest an effective practical application of the ECPA quality improvement approach, consisting of improvement activities within each center via the PDSA cycle and use of learning collaboratives with other participating centers. The findings also confirm the success of the quality improvement program in health centers with diverse characteristics and within different states.

Participating centers at six months after program completion had higher rates of documenting controller medication prescription compared to at program completion, revealing the sustainability of ECPA on the measure. After health centers participated in

ECPA, it is plausible that ALAUM facilitated the provision of controller medications among health-center patients. For instance, ALAUM provided the centers with a spirometer for better assessment of asthma control and manifestations to adjust therapy. The appropriate support may enable providers at the participating centers to select proper controllers and dosing, resulting in higher documentation of controller medication prescription among patients with asthma.

Compared to program completion, pulmonary function testing measure showed a small decrease at 6-month post-program completion. This result indicates the possibility that pulmonary function testing could continue to decline without periodic reminders. Once ECPA ended, clinic staff may have been required to engage in other new, competing priorities requiring efforts in other-disease improvement programs (Dixon-Woods, McNicol, & Martin, 2012). It is also possible that, once health centers realize their declining asthma performance, they could take Step 4 (Act) of the PDSA cycle to refine what action they should take to improve the performance back to a higher stage. Anecdotally, participating health centers have applied the PDA to other priority needs, such as depression, chronic obstructive pulmonary disease, attention deficit hyperactivity disorder, and child immunization, based on the framework that has been presented by ALAUM. Since the PDSA cycle is an essential component of ECPA and potentially contributes to the sustainability of asthma care quality improvement, clinic staff should be proficient in the PDSA mechanism. For health centers to maintain high performance on measures for varied conditions, they should construct a performance assessment (PDSA) calendar to review each set of measures on a regular basis.

One strength of the ECPA program was 100% retention of the 65 participating health centers during a 12-month program implementation. It is likely that the relationships

that developed through technical calls and participation in a learning collaborative contributed to this retention rate, although this was not evaluated in this study. The continued participation of all centers offers encouraging evidence about collaboration between ECPA and participating centers.

Another strength of this study is the fairly small amount of missing data from the six clinic-based performance outcomes. ACT documentation at 6-month post-program completion was the only data variable with more than 20% missing data, reducing the potential for bias (Needham et al., 2009). Moreover, this study utilized both complete case and multiple imputation analyses to derive estimates of ECPA implementation effects on the clinic-based measures. The two analyses reveal complementary results that strengthen the reliability of the study. According to a systematic review investigating the effectiveness of chronic disease management programs for adults with asthma, seven out of 14 controlled trials executed in primary care, outpatient, or health management organization settings provided inadequate information to assess missing data (Peytremann-Bridevaux et al., 2015). This implies that the completeness of outcome data is often overlooked among studies focusing on improving asthma care quality.

There are two main limitations to this study. First, this study did not randomize centers into intervention and control groups. Although randomized controlled trials are known as the standard for the evaluation of health care interventions (Cochrane, 1999), their limited generalizability hinders their use in evaluating the effect of quality improvement efforts in real-world settings (Neuhauser & Diaz, 2007). This study employed a one-arm quasi-experimental design, which is suitable for use in real-life practice because each participating center served as its own control. This pre-post study design is widely used in program evaluation (McDavid, Huse, Hawthorn, & Ingleson, 2012), when a

clear control group cannot be established. Second, the outcomes of this study were derived from a retrospective chart review, so the quality of the outcomes depends on the accuracy and consistency of the chart review process (Matt & Matthew, 2013). Nevertheless, formal training and a standardized chart audit tool with data collection keys were provided to all centers to ensure the consistency across all participating centers. Third, all clinic-based performance measures were intermediate, provider-focused outcomes that indicate the adoption of the asthma guidelines in practice.

Because of the clinic focus, patient outcomes were not evaluated in this study. However, previous research has revealed a positive association between the clinic-level performance measures and asthma patient outcomes, such as hospital admissions and emergency room visits (Mishra et al., 2017). In addition, further understanding of the impact of the ECPA on asthma outcomes should include other patient-centered measures of satisfaction with care and improvement of quality of life. The Chronic Care Model, on which the ECPA program is based, suggests that optimal care for chronic diseases such as asthma are best achieved when there is an prepared, proactive practice team and an informed, activated patient that is highly satisfied with the care they receive (Wagner et al., 2001). This study has addressed the former component, but additional work will elucidate the patient aspect that has not been discussed in this study.

4.10. Conclusion

This study provides solid evidence of the effectiveness of the ECPA program on important asthma quality measures as defined in a national asthma guideline. The ECPA implementation may serve as a model for other statewide quality improvement initiatives

in enhancing guideline-based asthma care processes in health-center settings. There is a need to further explore the effect of the ECPA program on health care utilization and costs.

4.11. Supplementary figures and tables

Figure 4. 2 The implementation timeline of each participating cohort in Enhancing Care for Patients with Asthma Program

Year	2013												2014												2015												2016	
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2
Cohort 1	i												ii												iii													
Cohort 2										i			*						ii			iii																
Cohort 3																			i						ii						iii							

ⁱChart review process performed at baseline before the implementation

ⁱⁱChart review process performed after the 12-month long program was completely implemented

ⁱⁱⁱChart review process performed six months after the program's completion

*Participating health centers in Cohort 2 from New Mexico, Oklahoma, and Texas joined the program in October 2013. The eight Illinois centers joined the program in January 2014.

Table 4. 1 Characteristics of participating centers in Enhancing Care for Patients with Asthma Program

Characteristics	4 states 65 centers; 75 locations	Illinois 22 centers; 23 locations	New Mexico 18 centers; 19 locations	Oklahoma 8 centers; 16 locations	Texas 17 centers; 17 locations
Participating cohort (number of centers)					
Cohort 1 (January 2013)	23 (35.4%)	8 (36.4%)	7 (38.9%)	3 (37.5%)	5 (29.4%)
Cohort 2 (October 2013)	23 (35.4%)	8 (36.4%)	4 (22.2%)	4 (50.0%)	7 (41.2%)
Cohort 3 (August 2014)	19 (29.2%)	6 (27.3%)	7 (38.9%)	1 (12.5%)	5 (29.4%)
Specialty					
Stand-alone primary care clinic	24 (36.9%)	5 (22.7%)	8 (44.4%)	2 (25.0%)	9 (52.9%)
Stand-alone pediatric clinic	12 (18.5%)	3 (13.6%)	4 (22.2%)	3 (37.5%)	2 (11.8%)
Multi-specialty health center	15 (23.1%)	2 (9.1%)	5 (27.8%)	3 (37.5%)	5 (29.4%)
School-based or mobile clinic	14 (21.5%)	12 (54.5%)	1 (5.6%)	0 (0.0%)	1 (5.9%)
Number of providers					
Mean (standard deviation)	23.63 (40.2)	18.18 (46.7)	20.89 (26.0)	25.71 (40.6)	40.38 (49.1)
Median	6	2	11	9	13
Interquartile range	2-21	2-11	4-19	3.5-80	4-17
Minimum-Maximum	1-219	1-219	1-73	2-156	3-127
Geographic Area					
Urban	49 (75.0%)	22 (100.0%)	3 (16.7%)	7 (87.5%)	17 (100.0%)
Rural and super rural	16 (25.0%)	0	15 (83.3%)	1 (12.5%)	0

Table 4. 2 Overall performance on clinic-based performance measures

Measures	Time points ^a	Median	Interquartile range	Minimum-Maximum	Wilcoxon Signed Ranks Test (p-value) ^b	% Missing
Asthma severity	Baseline	67%	20-95%	0-100%	NA	0%
	Program completion	94%	71-100%	20-100%	402.5 (<.0001)*	14%
	6-month post-completion	96%	68-100%	0-100%	43 (0.5400)	11%
Asthma Control Test	Baseline	0%	0-24%	0-100%	NA	0%
	Program completion	79%	60-97%	70-100%	599 (<.0001)*	17%
	6-month post-completion	88%	53-100%	0-100%	29.5 (0.6357)	28%
Pulmonary function testing	Baseline	0%	0-30%	0-100%	NA	0%
	Program completion	29%	40-54.5%	0-100%	363 (0.0001)*	8%
	6-month post-completion	17%	0-30%	0-100%	-184 (0.0362)*	6%
Asthma education	Baseline	23%	0-46%	0-100%	NA	0%
	Program completion	72%	42-95%	0-100%	690.5 (<.0001)*	6%
	6-month post-completion	57%	30-90%	0-100%	-219.5 (0.0326)*	6%
Asthma action plan	Baseline	12%	0-40%	0-95%	NA	0%
	Program completion	57%	27-85%	0-100%	717 (<.0001)*	6%
	6-month post-completion	50%	16-87%	0-100%	-72 (0.4520)	6%
Controller medication	Baseline	80%	0-100%	0-100%	NA	0%
	Program completion	100%	89-100%	0-100%	342 (<.0001)*	17%
	6-month post-completion	100%	86-100%	39-100%	-19 (0.6732)	20%

NA=Not applicable

^aChart review was completed to collect the six clinic-based performance measures at three time points: baseline (time=0), program completion (time=12), and 6-month post-completion (time=18).

^bA Wilcoxon Signed Ranks Test compared the clinic-based performance measures at baseline to program completion and at program completion to 6-month post-completion.

*Asterisks indicate statistical significance of a Wilcoxon Signed Ranks Test at a significance level of 0.05.

Table 4. 3 Estimates from a complete case analysis of implementation effects on clinic-based performance measures

Measures	Change from reference	Rate ratio	95% Confidence interval		p-value
Asthma severity	Baseline	Ref	N/A	N/A	N/A
	Program completion	1.314	1.206	1.432	<.0001*
	6-month post-program completion	1.368	1.256	1.490	<.0001*
Asthma Control Test	Baseline	Ref	N/A	N/A	N/A
	Program completion	3.625	3.185	4.124	<.0001*
	6-month post-program completion	3.048	2.678	3.469	<.0001*
Pulmonary function testing†	Baseline	Ref	N/A	N/A	N/A
	Program completion	1.771	1.527	2.054	<.0001*
	6-month post-program completion	1.575	1.343	1.847	<.0001*
Asthma education	Baseline	Ref	N/A	N/A	N/A
	Program completion	2.246	2.018	2.501	<.0001*
	6-month post-program completion	2.006	1.794	2.243	<.0001*
Asthma action plan	Baseline	Ref	N/A	N/A	N/A
	Program completion	2.335	2.070	2.634	<.0001*
	6-month post-program completion	2.219	1.967	2.503	<.0001*
Controller medication‡	Baseline	Ref	N/A	N/A	N/A
	Program completion	1.961	1.504	2.556	<.0001*
	6-month post-program completion	2.186	1.691	2.826	<.0001*

Ref=Reference; N/A=Not applicable

*Asterisks indicate statistical significance at a significance level of 0.05.

Complete case analyses of generalized linear mixed regression assuming Poisson distribution with an offset and its canonical log link were used to estimate the implementation effects of ECPA on clinic-based performance measures, accounting for cohort, state, specialty, number of providers, and geographic area.

Example of interpretation:

- At program completion, participating centers were associated with 1.314 times higher improvement rate in documenting asthma severity, compared to the centers at baseline (95% CI 1.206, 1.432).
- At 6-month post-program completion, participating centers were associated with 1.368 times higher improvement rate in documenting asthma severity, compared to the centers at baseline (95% CI 1.256, 1.490).

†At 6-month post-program completion, participating centers were associated with a 25% reduction in the rate of documenting pulmonary function testing compared to the centers at program completion (RR=0.750; 95% CI 0.655, 0.860; p-value <.0001).

‡At 6-month post-program completion, participating centers were associated with 1.387 times higher improvement rate in documenting controller medication, compared to the centers at program completion (95% CI 1.254, 1.534; p-value <.0001).

Table 4. 4 Multiple-imputation estimates of implementation effects on clinic-based performance measures

Measures	Change from reference	Rate ratio	95% Confidence interval		Minimum	Maximum	p-value
Asthma severity	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	1.440	1.330	1.559	1.439	1.441	<.0001*
	6-month post-program completion	1.295	1.142	1.469	1.253	1.369	0.0005*
Asthma Control Test	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	3.852	3.406	4.355	3.812	3.954	<.0001*
	6-month post-program completion	3.781	3.193	4.479	3.653	3.966	<.0001*
Pulmonary function testing†	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	1.948	1.623	2.339	1.825	2.079	<.0001*
	6-month post-program completion	1.488	1.279	1.731	1.467	1.518	<.0001*
Asthma education	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	2.210	1.993	2.450	2.195	2.228	<.0001*
	6-month post-program completion	1.919	1.717	2.145	1.873	1.951	<.0001*
Asthma action plan	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	2.315	2.026	2.645	2.266	2.434	<.0001*
	6-month post-program completion	2.254	1.986	2.557	2.197	2.309	<.0001*
Controller medication‡	Baseline	Ref	N/A	N/A	N/A	N/A	N/A
	Program completion	1.972	1.516	2.565	1.961	1.992	<.0001*
	6-month post-program completion	2.185	1.700	2.809	2.184	2.187	<.0001*

Ref=Reference; N/A=Not applicable

*Asterisks indicate statistical significance at a significance level of 0.05.

Multiple imputation with five sets of imputations for generalized linear mixed regression assuming Poisson distribution with an offset and its canonical log link were used to estimate the implementation effects of ECPA on clinic-based performance measures, accounting for cohort, state, specialty, number of providers, and geographic area.

Example of interpretation:


- At program completion, participating centers were associated with 1.440 times higher improvement rate in documenting asthma severity, compared to the centers at baseline (95% CI 1.330, 1.559).
- At 6-month post-program completion, participating centers were associated with 1.295 times higher improvement rate in documenting asthma severity, compared to the centers at baseline (95% CI 1.142, 1.469).

†At 6-month post-program completion, participating centers were associated with a 23.2% reduction in the rate of documenting pulmonary function testing compared to the centers at program completion (RR=0.768; 95% CI 0.656, 0.900; p-value 0.0017).

‡At 6-month post-program completion, participating centers were associated with 1.287 times higher improvement rate in documenting controller medication, compared to the centers at program completion (95% CI 1.175, 1.411; p-value <.0001).

Figure 4. 3 The American Lung Association of the Upper Midwest Asthma Action Plan

Asthma Action Plan



Name _____ DOB ____/____/____

Severity Classification Intermittent Mild Persistent Moderate Persistent Severe Persistent

Asthma Triggers (list) _____

Peak Flow Meter Personal Best _____

Green Zone: Doing Well

Symptoms: Breathing is good – No cough or wheeze – Can work and play – Sleeps well at night
 Peak Flow Meter _____ (more than 80% of personal best)

Control Medicine(s)	Medicine	How much to take	When and how often to take it
	_____	_____	_____
	_____	_____	_____

Physical Activity Use albuterol/levalbuterol ____ puffs, 15 minutes before activity
 with all activity when you feel you need it

Yellow Zone: Caution

Symptoms: Some problems breathing – Cough, wheeze, or chest tight – Problems working or playing – Wake at night
 Peak Flow Meter _____ to _____ (between 50% and 79% of personal best)

Quick-relief Medicine(s) Albuterol/levalbuterol ____ puffs, every 4 hours as needed

Control Medicine(s) Continue Green Zone medicines
 Add _____ Change to _____

You should feel better within 20–60 minutes of the quick-relief treatment. If you are getting worse or are in the Yellow Zone for more than 24 hours, THEN follow the instructions in the RED ZONE and call the doctor right away!

Red Zone: Get Help Now!

Symptoms: Lots of problems breathing – Cannot work or play – Getting worse instead of better – Medicine is not helping
 Peak Flow Meter _____ (less than 50% of personal best)

Take Quick-relief Medicine NOW! Albuterol/levalbuterol ____ puffs, _____ (how frequently)

Call 911 immediately if the following danger signs are present

- Trouble walking/talking due to shortness of breath
- Lips or fingernails are blue
- Still in the red zone after 15 minutes

Emergency Contact Name _____ Phone (____) _____-_____

Healthcare Provider Name _____ Phone (____) _____-_____

1-800-LUNGUSA | LUNG.org

Date ____/____/____

Chapter 5: Manuscript 2

Reducing potentially preventable health events among patients with asthma through a multi-state, multi-center quality improvement program

5.1. Manuscript overview

This manuscript addresses the effect of ECPA on the rates of ER visits and hospital admissions. The results of this manuscript accomplished the second aim of this dissertation.

5.2. Author list

The authors of this manuscript include Sirikan Rojanasart, Angeline M Carlson, Wendy L St. Peter, Jon C Schommer, Pinar Karaca-Mandic, and Julian Wolfson.

5.3. Target journal

The manuscript will be submitted for publication in *BMJ Quality & Safety*. This manuscript is suitable for the journal due to its potential audience: clinicians, health care managers and policy makers (BMJ Quality & Safety, 2018). The journal's goal is to disseminate innovative research that focuses on improving patient care through quality improvement approaches. This manuscript directly emphasizes the two aspects of the journal because this manuscript demonstrates a positive effect of ECPA on patient-level outcomes: asthma-related ER visits and hospital admissions.

5.4. Abstract

Background: Enhancing Care for Patients with Asthma (ECPA) is a quality improvement program establishing asthma guideline-based processes in health centers across four states. The program has demonstrated its effectiveness in increasing the quality of asthma care in these centers. However, the translational effect of the program on patient-level, potentially preventable health events among patients with asthma has not been analyzed. The objective of this study was to estimate the effect of ECPA on improving rates of asthma-related emergency room (ER) visits and hospital admissions for participating clinic patients.

Methods: This study used a retrospective, interrupted time series (ITS) design to determine ECPA's effectiveness. The administrative claims data was obtained from a private insurer that provided health coverage to patients receiving care from participating health centers. Three-level generalized linear mixed models with Poisson distribution and log link were used to examine the association between ECPA implementation and outcomes.

Results: Among two cohorts of ECPA, 1,828 patients with asthma were attributed to one of the 15 health centers. By using the pre-implementation period as a reference, patients in the implementation period had 42.1%, 37.7%, and 47.1% lower rates of an ER visit or hospital admission (combined), ER visit alone, or hospital admission alone, respectively. Subgroup analysis results support the sustainability of the program effect on reducing ER visits and hospital admissions.

Conclusion: This study showed a sustainable effect of a multi-state, multi-center asthma care quality improvement program on patient-level, potentially avoidable asthma-related health events.

5.5. Introduction

Emergency room (ER) visits and hospital admissions are frequent for patients with asthma (Andrews, Simpson, Basco, & Teufel, 2013). These events are potentially preventable public health problems and a major contributor to the high costs of health care. Each year, asthma-related ER visits and hospital admissions cost the U.S. health care system at least \$300 million (update citation). Since these events are usually avoidable with proper asthma management (Barrett et al., 2014), high-quality asthma care is needed to assist patients in living better with this chronic condition.

Although asthma care provided in community settings plays a critical role in achieving optimal patient outcomes, asthma care quality remains suboptimal (Mangione-Smith et al., 2007) due to the underutilization of evidence-based asthma guidelines. The Expert Panel Report 3 (EPR-3) guidelines have outlined essential asthma care components for the achievement of asthma control. However, research has reported several community-setting barriers to adherence to management guidelines. Barriers include low self-efficacy among providers for implementing the guidelines and non-familiarity with specific guideline elements (Wisnivesky et al., 2008; Okelo et al., 2013). Low provider adherence to guidelines contributes to avoidable ER visits and hospital admissions (Akinbami et al., 2009, pp. 1980–200). Therefore, an effective quality

improvement action that facilitates the implementation of guideline recommendations would translate into reducing potentially preventable ER visits and hospital admissions.

Enhancing Care for Patients with Asthma (ECPA) is a multi-state, multi-center quality improvement program that was developed to augment guideline-based asthma care processes (Appropriate assessment of asthma severity rating, administration of Asthma Control Test, lung function testing, asthma education, development of personalized asthma action plan, and prescription of asthma controller medication) in health centers in four states: Illinois, New Mexico, Oklahoma, and Texas. During a 12-month implementation period, ECPA assisted participating health centers with improvement activities through the Plan-Do-Study-Act (PDSA) cycle to carry out changes that led to asthma guidelines adoption in each center. ECPA divided the recruitment and participation of centers into different chronological cohorts. Each cohort had at least one center from each state to ensure the high quality of the improvement effort. The full description of the program is published elsewhere (Rojanasarot, Heins Nesvold, et al., 2018).

Previous research has demonstrated the effectiveness of the program in improving clinic-based performance measures consistent with the EPR-3 guidelines (Rojanasarot, Heins Nesvold, et al., 2018). The question of whether center-based quality improvement effort is associated with a decrease in ER visits and hospital admissions among patients who have received asthma care in the participating health centers has not been answered. Thus, the objective of this study was to examine the association between the implementation of ECPA and subsequent changes in asthma-related health events for patients with asthma. The hypothesis was that patients with asthma who received care

from health centers that participated in ECPA would have lower rates of ER visits and hospital admissions after program implementation.

5.6. Methods

5.6.1. Study design

This study employed a retrospective quasi-experimental approach using an interrupted time series (ITS) design. The ITS design is the most powerful approach in quasi-experimental studies (Penfold & Zhang, 2013) and has been recommended for evaluation of health care interventions having a clear implementation segment (Lopez Bernal, Cummins, & Gasparrini, 2016). The ECPA implementation could be considered as a multiple interrupted time series where the sequential introduction of ECPA in different health center cohorts. Each ECPA cohort started and completed the quality improvement activities within a well-defined month. This study concentrated on Cohort 1 and Cohort 2 of ECPA. For Cohort 1, the 12-month implementation period started in January 2013 for all centers. For Cohort 2 started in October 2013 for centers in New Mexico, Oklahoma, and Texas, and in January 2014 for centers in Illinois. The ITS approach is also appropriate for the ECPA program evaluation because the sequential measures of the outcome are available both before, during, and after program implementation (Lopez Bernal et al., 2016).

5.6.2. Data source

The primary data source was administrative claims from a private insurance company that provides coverage to enrollees who received care in ECPA-participating health centers. Patient enrollment and hospital and office-based claims data from January 2012 to May

2015 were provided for analysis. The dataset was fully de-identified and HIPAA (Health Insurance Portability and Accountability Act of 1996) compliant.

The administrative claims dataset covered the 12-month period before ECPA implementation in Cohort 1 and ended five months after ECPA completion in Cohort 2. Therefore, this study divided observations into three segments: 12-month pre-ECPA implementation, 12-month ECPA implementation, and 5-month post-ECPA completion. The comparison of the outcomes in each segment allows this study to investigate the effect of ECPA while improvement activities were ongoing in each health center and after program completion with no structural support from the program. Figure 5.1 summarizes administrative claims availability of this study.

5.6.3. Patient population

Eligible patients were identified and attributed to a participating health center using the following inclusion criteria: continuously enrolled from January 1, 2012, to May 31, 2015; had at least one claim at a participating health center during the 12-month pre-implementation period with a primary or secondary diagnosis of asthma (International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code of 493.xx). Patients were excluded if they disenrolled from their insurance plans between January 2012 and May 2015. Patients who could be attributed to more than one health center were assigned to the health center they visited more frequently.

5.6.4. Outcomes of interest

The outcome of interest was ER visits and hospital admissions with a primary or secondary diagnosis of asthma (ICD-9-CM code 493.xx). ER visits were defined using CPT code 99281-5. Hospital admissions were defined using Place of Service (POS) code 21 and

revenue codes indicating hospital services (11x-48x). An ER visit that resulted in hospital admission was counted as a hospital admission episode. Asthma-related ER visits and hospital admissions were then constructed into: 1) combined number of both events per patient per month (PPPM); 2) number of ER visits PPPM; and 3) number of hospital admissions PPPM.

5.6.5. Analyses

Descriptive statistics

Patient baseline demographics were reported by state. Patients' age at baseline was referred to as the patient age one year before the ECPA implementation at their attributed center was executed. To clarify, the baseline age of all patients equaled their age in 2012, except the patients who received asthma care from Illinois health centers in the second cohort. The baseline age of these Illinois patients equaled their age in 2013. The age was calculated and described using mean, standard deviation, median, interquartile range, minimum, and maximum values. The percentage of patients aged less than 18 was reported. Patient percent by gender was calculated.

To combine the number of ER visits and hospital admissions from both ECPA cohorts, a dummy variable was created for the month when outcomes were observed that was centered for each cohort; zero corresponded to the last observation of the pre-ECPA implementation period (values range from -11 to 17). The average rates of ER visits and hospital admissions during 12-month pre-implementation and 12-month implementation periods were calculated. A bar graph of combined number of ER visits and admissions and scatter plots of number of ER visits alone and admissions alone were presented to identify the underlying trend (Lopez Bernal et al., 2016).

Statistical inferences

To determine ECPA effect on outcomes, the 3-level multilevel generalized linear mixed model (GLMM) was selected because of the three nested levels and repeated time series data of this study. Within the same patient, ER visit and hospital admission numbers from different months are correlated and considered the level-1 measurement. These numbers are nested within that patient, which is the level-2 cluster. Patients from the same health center are also nested in that center, which is the level-3 cluster. This study allows individual patients and individual participating health centers to have their own random intercepts to partition their variation.

The 3-level GLMM permits investigation of the within-patient effect and quantification of improvement in ER visits and hospital admissions for three comparisons. First, outcomes between pre-ECPA implementation and 12-month ECPA implementation periods were compared to determine the effect of ECPA while it actively supported health centers. Second, outcomes between pre-ECPA implementation and 5-month post-ECPA completion periods were compared to determine the short-term, sustainable effect of ECPA during no active support to health centers following program completion. Third, outcomes between 12-month ECPA implementation and 5-month post-ECPA completion periods were compared to determine if there were statistically significant differences in the outcomes between the two segments. The effectiveness of ECPA from these three comparisons were reported using rate ratio (RR), 95% confidence interval (CI), and p-value.

Seasonality is an environmental factor widely acknowledged in asthma research (Johnston & Sears, 2006). Therefore, a dummy variable for season was included: winter

(December-February), spring (March-May), summer (June-August), and fall (September-November) (Buckley & Richardson, 2012). The ITS design is not impacted by the common, non-time-dependent covariates such as age, gender, race or ethnicity, or educational level (Lopez Bernal et al., 2016). Thus, these standard covariates were not included in final statistical models.

All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). The number of ER visits and hospital admissions PPM are count data. The GLMM estimates assumed Poisson distribution and its canonical log link to determine the ECPA effect. Poisson distribution was appropriate since the data used for this study did not present overdispersion after the scaled Pearson statistic for the conditional distribution of each GLMM was tested (SAS Institute Inc, n.d.). All models included seasonality as a confounding factor. An estimation of the parameters was achieved using a PROC GLIMMIX (Austin, 2010). A significance level of less than 0.05 (2-tailed) was adopted for all analyses. This study was considered exempt by the institutional review board of the University of Minnesota due since we used de-identified existing administrative claims data.

5.6.6. Subgroup analysis

The claims segment submitted until December 2014 was used for subgroup analysis in Cohort 1 to investigate whether there was a longer-term, sustainable effect of ECPA on ER visits and hospital admissions 12 months post-ECPA completion.

5.7. Results

Table 5.1 summarizes the baseline characteristics of 1,828 patients who received asthma care from the 15 health centers participating in the two cohorts of ECPA included in the analysis. Illinois and New Mexico have the highest number of participating health centers. More than 90% of patients who received asthma care during the study period received their care from health centers from the first cohort. Patients from New Mexico had the highest average age of 42.3 years, compared to the other states. The number of male and female patients from each state was comparable.

The average rates of ER visits and hospital admissions due to asthma as a primary or secondary diagnosis decreased from 2.22 to 1.38 and 1.97 to 1.04 per 100 patients per month, respectively, in the 12-month pre-implementation period as compared to 12-month ECPA implementation period. The average rates of ER visits and hospital admissions during the 5-month post-program completion phase were 1.02 and 1.09 per 100 patients per month, respectively. Figure 5.2 shows the number of ER visits and hospital admissions for three time periods (12-month pre-implementation, 12-month implementation, and 5-month post-program completion). After ECPA was implemented in participating health centers, ER visits and hospital admissions showed clear downward trends.

The ECPA effect on the rates of combined asthma-related ER visits and hospital admissions, asthma-related ER visits alone, and asthma-related hospital admissions alone, after accounting for seasonality, is depicted in Table 5.2. RRs represent the change in outcome occurrence comparing a particular period to a reference period. During the 12-month ECPA implementation period, patients had 42.1%, 37.7%, and 47.1% lower rates of combined asthma-related ER visits or hospital admissions, ER visits only, and hospital

admissions, respectively, compared to the patients during the 12-month pre-implementation period (p-value<0.001 in all three comparisons).

The magnitude of the ECPA effect on asthma-related outcomes when comparing pre-implementation to post-program completion periods was somewhat larger as compared to the ECPA effect when comparing pre-implementation to implementation periods. Specifically, the rate of asthma-related ER visits alone in the post-program completion period was 55.7% lower as compared to the pre-implementation phase (Table 5.2).

When comparing the implementation and post-program completion segments, the rate of ER visits alone was significantly lower (RR=0.728; 95% CI 0.562, 0.942 p-value 0.0158). However, this was not the case for combined hospital admissions and ER visits (RR= 0.848; 95% CI 0.705, 1.022; p-value 0.0828) or hospital admissions alone (RR= 1.005; 0.768, 1.315; p-value 0.9701).

In addition to the main analyses, the subgroup analyses focusing only on patients who received asthma care from health centers in the first study cohort found that the average rates of ER visits and hospital admissions due to asthma as a primary or secondary diagnosis decreased from 2.17 to 1.28 and 1.94 to 1.01 per 100 patients per month, respectively, in the 12-month pre-implementation period as compared to 12-month ECPA implementation period. The average rates of ER visits and hospital admissions during the 12-month post-program completion phase were 0.97 and 1.05 per 100 patients per month, respectively. The results from the GLMM analyses are reported in Table 5.3. The rate ratio of the three outcomes ranged from 0.448 (ER visits) to 0.542 (hospital admissions) when comparing the event rates of pre-implementation to post-program

completion periods. Using the implementation period as a reference, the rates of ER visits alone and ER visit or hospital admission combined significantly decreased during the 12-month post-program completion period (RR=0.758; 95% CI 0.634, 0.906; p-value 0.0023 and RR=0.879; 95% CI 0.774, 0.999; p-value 0.0486, respectively).

5.8. Discussion

This analysis of the effectiveness of a multi-state, multi-center, quality improvement program for patients with asthma showed that implementation of Enhancing Care for Patients with Asthma (ECPA), a quality improvement program designed to improve asthma care processes at the clinic level, was associated with significant reduction of asthma-related ER visits and hospital admissions. Rates of ER visits and hospital admissions in the implementation and post-program completion periods were decreased roughly by half, compared to rates 12 months before ECPA implementation. The magnitude of the program effect was greater on the rate of ER visits when focusing on the improvement from pre-implementation to post-program completion periods (more than 50% reduction in the ER visit rate). Subgroup analysis also demonstrated a potential long-term, sustainable effect of ECPA on asthma-related adverse events; patients, attributed to health centers in Cohort 1 were less likely to experience asthma-related outcomes in the 12-month post-program completion period. Therefore, the results of this study provided substantial evidence for the effective, translational effect of ECPA on patient outcomes.

The findings regarding the translational effect of ECPA is critically important in quality improvement approaches that target the quality of asthma care at the health center

level, given the high impact of the program effect on the patient outcomes. Woods et al. investigated the effectiveness of a quality improvement program through nurse case management and home visits (Woods et al., 2012). While their program demonstrated a decrease in the number of ER visits and hospital admissions after patients engaged in the program, home visits are time-consuming and expensive. ECPA, instead, concentrated on improving enhance guideline-based asthma care processes in health centers. With approximately 50% improvement in ER visits and hospital admissions, ECPA established its translational effect on patient-level outcomes and appropriateness for being replicated at a population level.

The highest magnitude of ECPA effect (comparing post-program completion to pre-implementation periods) was on preventing ER visits. Asthma-related ER visits are mostly preventable (Agency for Healthcare Research and Quality, 2015) with proper asthma management. Comprehensive asthma care could improve asthma symptoms (Rojanasarot & Carlson, 2017) and decrease asthma exacerbation (Couturaud et al., 2002), a major reason that patients with asthma visit an ER (L. H. Johnson, Chambers, & Dexheimer, 2016). In previous work, ECPA showed impact on improving asthma guideline-based performance measures, such as documentation of asthma action plan, asthma education, and controller medication (Rojanasarot, Heins Nesvold, et al., 2018). Improvement in these essential care components among patients receiving care from ECPA-participating health centers most likely contributed to minimizing asthma-related ER visits.

In addition, results showed ECPA effectiveness in decreasing the rates of ER visits and hospital admissions long term. The post-program completion phase for the first cohort in subgroup analyses contained additional seven months of data, meaning that the post-

program completion period of the analyses comprised of total 12 months of data. Therefore, the rate ratios could be referred to as a potential long-term, sustainable effect of ECPA on the asthma-related events once the participating health centers did not have active quality improvement support from ECPA. Compared to the rates of the outcomes 12 months before ECPA was executed, patients attributed to health centers in Cohort 1 had approximately 40% lower outcomes in the 12-month period after program completion. After program completion, participating health centers did not receive active support from ECPA. Instead, health centers could continue improving guideline-based asthma care through the internal use of the PDSA cycle (Rojanasarot, Heins Nesvold, et al., 2018) or communicating with other participating health centers to gain their perspectives on tackling quality improvement challenges. This long-term effect of ECPA on reducing potentially preventable asthma-related health events provides evidence that the ECPA process produces sustainable effects; sustainability has been a problem for other quality improvement efforts (Dixon-Woods et al., 2012).

One strength of this study is that the analyses evaluated the effect of ECPA through multiple aspects, showing program generalizability. ECPA decreased asthma-related outcomes while the program was ongoing in participating centers and after program had been completed (5-month short-term effect and 12-month long-term effect). These results support internal validity of ECPA in improving patient outcomes (Øvretveit, Leviton, & Parry, 2011). Moreover, ECPA was shown to be a generalizable program demonstrating external validity in multiple health centers with various characteristics in four different states (Rojanasarot, Heins Nesvold, et al., 2018). This study provides a further understanding of ECPA's generalizability and could enable decision-makers in supporting effective quality improvement programs for patients with asthma.

Another strength of this study is the evaluation of ER visits and hospital admissions using the ITS approach. A systematic review by Peytremann-Bridevaux et al. reported that less than half of published studies they examined evaluated the improvement in ER visits and hospital admissions among patients with asthma (Peytremann-Bridevaux et al., 2015) and these are important outcomes to consider when evaluating effects of asthma management programs. This study employed ITS, the most appropriate approach for evaluating real-world health care interventions (Kontopantelis, Doran, Springate, Buchan, & Reeves, 2015), to evaluate ECPA effect on potentially preventable asthma-related health events. Since these outcomes are less often observed in the evaluation of quality improvement programs, this study provides meaningful evidence to the scientific community.

Several limitations should also be noted. First, the data source was secondary, administrative claims data. While these data enabled examination of outcomes patient outcomes across multiple health centers, administrative data is subject to coding errors (E. K. Johnson & Nelson, 2013). Second, this study used the provider tax identification number of participating health centers to attribute patients to each center. Some clinic locations shared the same identification number. Thus, we could not attribute patients to a specific location and could not include the location data as a random intercept. Third, while the GLMM analyses of this study include seasonality as an adjusting covariate, other unobserved time-varying factors, such as outdoor air pollution (Guarnieri & Balmes, 2014), could contribute to asthma exacerbation and result in the use of ERs or admission to a hospital. However, this problem is relatively small because of ITS approach, which is not affected by a time-varying confounder that is relatively constant over a short-time period (Lopez Bernal et al., 2016). Despite these limitations, this study provides insights into a

multi-state, multi-center quality improvement strategy that mitigates potentially preventable health events among patients suffering from asthma.

5.9. Conclusion

ECPA is an effective quality improvement program which was associated with reductions in asthma-related ER visits and hospital admissions. ECPA effects on asthma-related health events were sustainable in the 12-month period post-program completion. These findings augment previous research that showed the effectiveness of ECPA on asthma guideline-based performance measures and supplied succinct evidence for widespread the ECPA implementation. Further research could build on the body of literature by investigating whether ECPA could also reduce overall health care expenditure among patients with asthma.

Table 5. 1 Baseline demographic characteristics of patients receiving asthma care from participating health centers

Characteristics	Total	Illinois	New Mexico	Oklahoma	Texas
Health centers (n=15)	15 (100.0%)	6 (40.0%)	6 (40.0%)	2 (13.3%)	1 (6.7%)
Cohort 1	9 (60.0%)	4 (44.4%)	3 (33.3%)	2 (22.2%)	0 (0.0%)
Cohort 2	6 (40.0%)	2 (33.3%)	3 (50.0%)	0 (0.0%)	1 (16.7%)
Patients (n=1,828)	1,828 (100.0%)	1,135 (62.1%)	580 (31.7%)	64 (3.5%)	49 (2.7%)
Cohort 1	1,683 (92.1%)	1,121 (98.8%)	498 (85.9%)	64 (100.0%)	0 (0.0%)
Cohort 2	145 (7.9%)	14 (1.2%)	82 (14.1%)	0 (0.0%)	49 (100.0%)
Baseline age, years					
Mean (SD)	30.5 (23.9)	25.6 (23.0)	42.3 (22.1)	29.2 (21.7)	8.4 (4.5)
Median	19	15	48	25	8
Interquartile range	9-52	8-45	19-61	11-47	5-12
Minimum-Maximum	1-93	1-93	1-90	1-81	1-17
Age less than 18 (%)	861 (47.1%)	656 (57.8%)	131 (22.6%)	25 (39.1%)	49 (100.0%)
Gender					
Female	999 (54.7%)	583 (51.4%)	366 (63.1%)	33 (51.6%)	17 (34.7%)
Male	829 (45.3%)	552 (48.6%)	214 (36.9%)	31 (48.4%)	32 (65.3%)

SD=Standard deviation

Due to rounding, percentages may not always add up to 100%.

Figure 5. 2 The total number of asthma-related emergency room visits and hospital admissions per month in three study periods from 1,828 included patients (pre-implementation, implementation, post-program)

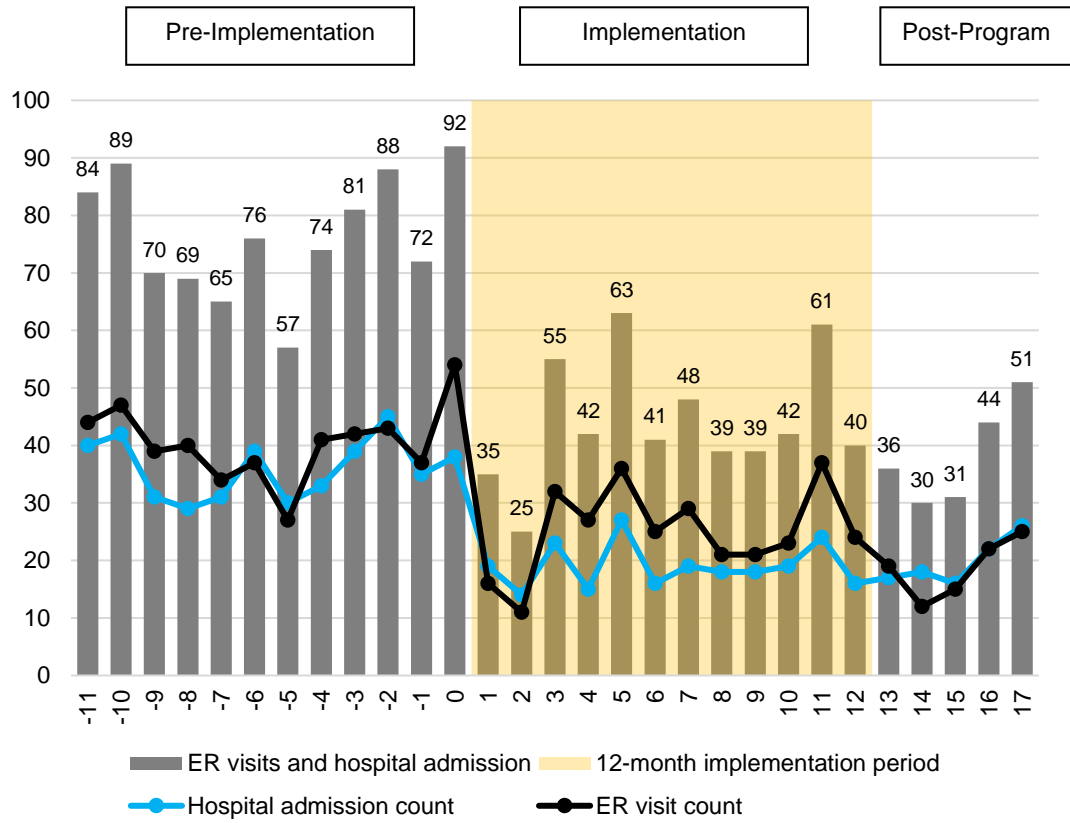


Table 5. 2 ECPA effect on emergency room visits and hospital admissions among 1,828 included patients after adjusting for seasonality

Outcomes	ECPA effect	Rate ratio	95% CI		p-value
Either emergency room visit or hospital admission	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.579	0.520	0.644	<.0001*
	5-month post-completion	0.500	0.422	0.591	<.0001*
Emergency room visit alone	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.623	0.540	0.719	<.0001*
	5-month post-completion	0.443	0.350	0.562	<.0001*
Hospital admission alone	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.529	0.450	0.621	<.0001*
	5-month post-completion	0.567	0.446	0.720	<.0001*

ECPA=Enhancing Care for Patients with Asthma; Ref=Reference; CI=Confidence interval; N/A=Not applicable

Generalized linear mixed regression assuming Poisson distribution and its canonical log link was used to estimate the effect of ECPA on the three outcomes, accounting for seasonality.

Example of interpretation:

- On average, patients had a 42.1% lower rate of combined emergency room visits or hospital admissions during the 12-month ECPA implementation period, compared to the 12-month pre-implementation period.

Asterisks indicate a statistically significant result at a significance level of 0.05.

Table 5. 3 Subgroup analyses of the Cohort 1-ECPA effect among 1,683 patients on emergency room visits and hospital admissions after adjusting for seasonality

Outcomes	ECPA effect	Rate ratio	95% CI		p-value
Either emergency room visit or hospital admission	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.560	0.502	0.624	<.0001*
	12-month post-completion	0.492	0.439	0.552	<.0001*
Emergency room visit alone	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.591	0.510	0.685	<.0001*
	12-month post-completion	0.448	0.381	0.527	<.0001*
Hospital admission alone	12-month pre-implementation	Ref	N/A	N/A	N/A
	12-month implementation	0.525	0.446	0.617	<.0001*
	12-month post-completion	0.542	0.461	0.636	<.0001*

ECPA=Enhancing Care for Patients with Asthma; Ref=Reference; CI=Confidence interval; N/A=Not applicable

Generalized linear mixed regression assuming Poisson distribution and its canonical log link was used to estimate the effect of ECPA on the three outcomes, as subgroup analyses focusing only on patients receiving asthma care from Cohort-1 health center.

Example of interpretation:

- On average, patients had a 44.0% lower rate of combined emergency room visits or hospital admissions during the 12-month ECPA implementation period, compared to the 12-month pre-implementation period.

Asterisks indicate a statistically significant result at a significance level of 0.05.

Chapter 6: Manuscript 3

Translational and sustainable effect of a provider-focused, multi-state, multi-center asthma care quality improvement program on patient-level health care costs

6.1. Manuscript overview

This manuscript addresses the translational and sustainable effect of ECPA on total asthma-related health care costs. The results of this manuscript accomplished the third aim of this dissertation.

6.2. Author list

The authors of this manuscript include Sirikan Rojanasart, Angeline M Carlson, Wendy L St. Peter, Pinar Karaca-Mandic, Julian Wolfson, and Jon C Schommer.

6.3. Target journal

The manuscript will be submitted for publication in *Health Services Research* due to the alignment of the study findings and the journal's mission, which is to "promote translation of health services research into improved practice and policy (Health Research & Educational Trust, 2017)." The results of this study increase understanding of the translational effects of a real-world quality improvement program. This program attempted to enhance asthma care within participating clinics through collaborative approaches—as

discussed in the first manuscript—at the care delivery level in order to lower patient-level health care costs.

6.4. Pre-publication history

This manuscript abstract was submitted to the 23rd International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Annual International Meeting on January 17, 2018. The title of the abstract was “Effect of a provider-focused, asthma care quality improvement program on patient-level asthma-related health care costs.”

6.5. Abstract

Objective: To investigate the translational and sustainable effects of improved care through Enhancing Care for Patients with Asthma (ECPA), a multi-state, multi-center quality improvement program, on individual-level total health care costs due to asthma.

Data Sources: Administrative claims data were obtained from a private insurer that provided health coverage to patients with asthma who received asthma care at one of the nine participating health centers located in Illinois, New Mexico, and Oklahoma.

Study Design: We conducted a retrospective pretest-posttest quasi-experimental study in which attributed 1,683 patients in a 12-month pre-implementation period served as their own control. We constructed the total annual asthma-related health care costs per patient occurred during pre-implementation, ECPA implementation, and post-program completion. We used 3-level generalized linear mixed models (GLMMs) to estimate the ECPA effect on the annual health care costs and account for correlation between the

repeated outcome measures for each patient and nested health centers. All costs were adjusted for inflation to 2014 U.S. dollars.

Principal Findings: Total asthma-related health care costs among the 1,683 included patients decreased from an average of \$7,033 to \$3,237 per person-year (pre-implementation vs implementation). Using the cost data from the 12-month pre-implementation period as a reference, GLMMs found that the ECPA implementation was associated with a reduction in total annual asthma-related health care costs by 56.4% (95% CI -60.7%, -51.8%). During the 12-months after ECPA completion period, health care costs were also found to be significantly lower, experiencing a 57.3% reduction.

Conclusions: ECPA sequentially and sustainably reduced patient-level health care costs.

6.6. Introduction

Asthma, a chronic inflammatory disease of the airways (Murdoch & Lloyd, 2010), is prevalent and economically burdensome for the U.S. health care system. According to the National Center for Health Statistics, asthma prevalence has risen from 7.3% in 2001 among all people (Akinbami, Moorman, et al., 2012, pp. 2001–2010) to 8.4% among children and 7.6% among adults in 2015 (CDC, 2016). This chronic condition is a significant contributor to the high costs of health care. In a single year, asthma costs the health care system a staggering \$56 billion, or at least \$3,000 per patient, in direct health care expenditures. This value includes office-based medical provider visits, prescription drugs, and outpatient, inpatient, and emergency room (ER) visits (Barnett &

Nurmagambetov, 2011). Nevertheless, the expenditures associated with these health services are preventable and could be minimized through proper asthma management.

Despite the availability of comprehensive asthma management guidelines, patients with asthma are at a higher risk of visiting the ER visits and experiencing hospitalization. Expert Panel Report 3 (EPR-3), Guidelines for the Diagnosis and Management of Asthma, has detailed essential components of asthma care for optimal asthma management that could reduce the need for ER and inpatient hospital use (NIH, 2007). Despite the creation of these guidelines for care, in 2014 alone, asthma still accounted for approximately two million ER visits (CDC, 2014a). The CDC statistics also indicated that patients with asthma are prone to avoidable inpatient utilization of hospitals as high as 500,000 episodes per year in U.S. (CDC, 2017). Since hospital admissions are the main cost contributor due to their high, overall costs (Weiss, Gergen, & Hodgson, 1992; Bahadori et al., 2009) and ER use is very prevalent in patients with asthma (Fingar, Barrett, Elixhauser, Stocks, & Steiner, 2006), an intervention that reduces the number of these events may facilitate a reduction in total direct costs due to asthma.

Enhancing Care for Patients with Asthma (ECPA), a quality improvement program attempting to enhance asthma care processes at the health center level, has demonstrated its translational effect on decreasing asthma-related ER visits and hospital admissions measured at the individual level. During the 12-month active improvement period, this multi-state, multi-center program enriched guideline-based asthma care processes among health care providers in participating health centers. ECPA used the Plan-Do-Study-Act (PDSA) approach to accelerate quality improvement actions in the health-center settings. As a complementary mechanism to the within-center activities, staff from each center engaged in a bi-monthly learning consortium to exchange ideas on

improvement processes (Rojanasarot, Heins Nesvold, et al., 2018). Previous analyses have revealed that the implementation of ECPA was associated with reducing patient-level ER visits and hospitalizations by 37.7% and 47.1%, respectively (Rojanasarot, Carlson, et al., 2018). Moreover, this midstream intervention has a long-term, sustainable effect on preventable use of health services since the rates of ER visits and hospital admissions at 12-months post-program completion were 55.2% and 45.8% lower than the pre-ECPA implementation period, respectively.

Given the translational, sustainable effect of ECPA on the patient-level preventable health care utilization, this study hypothesized that the ECPA implementation was also associated with alleviating asthma-related total direct health care costs among patients receiving asthma care from participating health centers. Therefore, the study's objective was to determine the effect of ECPA on the total costs among health center patients with asthma.

6.7. Methods

This retrospective study utilized a quasi-experimental, pretest-posttest design to evaluate the effect of ECPA on asthma-related health care costs. The study design addressed internal validity issues by comparing the same patient group both before and after the implementation of ECPA; a randomization process in this real-world setting was not possible (Toulany, McQuillan, Thull-Freedman, & Margolis, 2013).

6.7.1. Data Source

The study was conducted using administrative claims data from a private insurer. That insurer provided health care benefits to patients who received care in ECPA-participating health centers. Data from January 1, 2012 to December 31, 2014 were utilized. Over this period, the study was segmented into three parts: 1) 12-month pre-ECPA implementation (January-December 2012); 2) 12-month ECPA implementation (January-December 2013); and 3) 12-month post-ECPA completion (January-December 2014). A 12-month measurement period is recommended by the National Institutes of Health (NIH) to avoid a seasonality effect among patients with asthma for cost and utilization analyses (Akinbami, Sullivan, et al., 2012). The claims dataset contained information on patient enrollment, inpatient and outpatient visits, pharmacy use, and durable medical equipment (DME)-based claims and related costs. The data were de-identified and HIPAA (Health Insurance Portability and Accountability Act) compliant.

6.7.2. Patient Selection

The ECPA implementation included three chronological cohorts of participating health centers. This study focused only on patients receiving asthma care from the health centers of the first ECPA cohort as it was the only cohort that had three full consecutive years of administrative claims data.

The provider identification number of each health center was used to attribute patients to each participating center. Patients were included in this study if they had both: continuous enrollment from January 1, 2012, to December 31, 2014 and presence of at least one claim at a participating center during the 12-month pre-implementation period with a primary or secondary diagnosis of asthma (ICD-9-CM code of 493.xx). Patients

were excluded if they disenrolled from their insurance plans between January 2012 and December 2014.

6.7.3. Outcome measurements

The primary outcomes of this study were lowered costs for total asthma-related health care over three study periods (12 months per period). Total asthma-related health care costs were defined as the sum of amounts paid by the insurer and patient cost-sharing across use of six types of asthma-related resources: ER visits, hospital admissions, physician office or outpatient visits, prescriptions, DMEs, and other services with the ICD-9-CM code of 493.xx as primary or related reasons. The costs of each resource use were computed in each 12-month study period and then summed to determine total annual asthma health care costs.

ER visit costs were computed as the sum of costs for all events with CPT code 99281-99285. The costs for hospital admissions were calculated from claims with Place of Service (POS) code 21: Inpatient Hospital. The costs for physician office and outpatient visits were calculated from claims with POS code 11: Office, POS code 22: Outpatient Hospital, and POS code 24: Ambulatory Surgical Center. For asthma-related medication costs, asthma medications were identified using the national drug code (NDC) lists from the Healthcare Effectiveness Data and Information Set (HEDIS) (National Committee for Quality Assurance, 2017). The costs for DME supplies were computed using POS code 12: Home and Healthcare Common Procedure Coding System (HCPCS) code Axxxx-Zxxxx. Other service costs included anything outside of the five categories of resource use: POS codes other than previously mentioned (e.g., 31: Skilled Nursing Facility and 41: Ambulance), CPT code 70010-79999 (Radiology Procedures), and CPT code 80047-

89398 (Pathology and Laboratory Procedures). All cost components in this study were inflated to 2014 U.S. dollars values using Medical Care Services of the Consumer Price Index (CPI) retrieved from U.S. Bureau of Labor Statistics (U.S. Bureau of Labor Statistics, 2017).

6.7.4. Analyses

Descriptive statistics

The age and gender of included patients were reported as demographic characteristics. The mean, standard deviation (SD), median, minimum, and maximum number of patients by state were presented along with the percent of patients under age 18 and the percent of patients assigned a particular gender (male or female). Asthma-related health care costs (mean, SD) per patient-year were computed according to study period and type of resource used. The differences between each cost element—1) pre-implementation and implementation; 2) pre-implementation and post-program completion; and 3) implementation and post-program completion—were computed as means and SDs and then assessed by the Wilcoxon Signed Rank Test (Siegel, 1956).

To display changes in total health care costs within a 12-month period, scatter plots of the costs per month were presented and stratified by study period. Bar graphs were also introduced, representing cost changes from the same month of the pre-implementation and implementation periods; the pre-implementation and post-program completion periods; and the implementation and post-program completion periods.

Statistical inferences

Three-level generalized linear mixed models (GLMMs) were used to estimate the effects of ECPA on asthma-related ER visits, hospital admissions, and total health care costs per study period. GLMMs were selected because within-patient effects were of interest (change in the annual cost data of each patient from pre-implementation to implementation phases, from pre-implementation to post-program completion phases, and from implementation to post-program completion phases). GLMMs also account for multi-level data of ECPA as costs per period of each patient are nested within that patient. Patients who were attributed to the same participating health center are also nested in that center.

Due to the right-skew of the health care cost data, the distribution of the costs was assessed to determine an appropriate distribution assumption. Following recommendations by Canes (2016), both non-transformed and log-transformed scales of the cost data were reviewed. We then assessed the histogram, quantile measurements (Canes, 2016) and the Anderson-Darling statistics of the two scale values with different distributions (i.e., exponential, gamma, normal, and lognormal) along with their p-values (Minitab, 2017). Lognormal distribution was chosen because its p-value for the Anderson-Darling test was the largest, suggesting the optimal match. In addition, the observed and estimated quantiles of the log-transformed data were most similar to the normal distribution.

The association between the ECPA effect and health care costs were analyzed using GLMMs with lognormal distribution and identity link (Canes, 2016). All models allowed random-effects for patients and participating health centers. All statistical

analyses were completed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). The PROC GLIMMIX procedure was utilized for statistical modeling. Regression coefficients from GLMMs were expressed as the percentage change in the cost outcome when the study period changed from a reference period (i.e., $100(e^{\beta_1} - 1)$). A significance level of less than 0.05 (2-tailed) was adopted for all analyses. This study was determined to be exempt from Institutional Review Board (IRB) review by the University of Minnesota IRB due to use of existing administrative claims data.

In additional analyses, we explored annual costs per study period of different types of health resource use due to respiratory-related conditions. Respiratory-related conditions, including asthma, were identified by the following ICD-9-CM codes as a primary or secondary diagnosis: 460.xx-466.xx (acute respiratory infections), 470.xx-478.xx (other diseases of upper respiratory tract), 480.xx-488.xx (pneumonia and influenza), 490.xx-496.xx (chronic obstructive pulmonary disease and allied conditions), 500.xx-508.xx (pneumoconioses and other lung diseases due to external agents), and 510.xx-519.xx (other diseases of respiratory system).

6.8. Results

Patients were attributed to one of the nine health centers from Illinois (four centers), New Mexico (three centers), and Oklahoma (two centers). Of 1,683 included patients, 1,121 (67%) received asthma care from centers in Illinois. Health centers in New Mexico included oldest group of patients (mean=45.6 years). Most patients were female. Table 6.1 summarizes the demographics of the included patients with asthma.

Table 6.2 summarizes annual asthma-related costs stratified by study period according to the six types of health resource used. The total annual asthma-related health care costs in the implementation and post-program completion were 54.0% and 58.6% lower than the pre-implementation period, respectively. Costs due to hospital admissions and physician office and outpatient visits were the two highest asthma-related direct expenditures across all three study periods. All cost types demonstrated a reduction when comparing pre-implementation to implementation costs and pre-implementation to post-program completion costs. ER visit and hospital admission costs showed a 46.0% reduction at minimum, using the pre-implementation phase as a reference. Costs of asthma medications were reduced least (reductions of 17.8% and 25.9% after implementation and program completion, respectively).

Average asthma-related costs per patient in each study period are reported in Table 6.3. The total health care costs decreased from \$7,033 per patient in the pre-implementation period to \$3,237 and \$2,913 in the active ECPA-implementation period and post-program completion period, respectively. Costs per year across the six types of health resources used were significantly reduced from pre-implementation to implementation phases and from pre-implementation to post-program completion phases (all p-values for the Wilcoxon Signed Ranks Test were less than 0.0001).

To further explore total health care costs due to asthma, the costs per month were stratified and plotted (Figure 6.1). Monthly health care costs of the pre-implementation period were greater than the cost in the implementation and post-program completion periods. During the pre-implementation period, the month of February had the highest total health care costs. The total health care costs of the three study periods formed a trough from April to August.

Regarding GLMM analyses, the 12-month ECPA implementation was associated with a 56.4% reduction in total annual asthma-related health care costs compared to 12 months before the ECPA implementation (95% CI -60.7%, -51.8%; p-value <.0001). In addition, the 12-month post-program completion period was also significantly associated with a 57.3% reduction in total annual asthma-related health care costs compared to the pre-implementation period (95% CI -61.7%, -52.3%; p-value <.0001). No statistically significant difference was found when comparing the total health care costs between the 12-month implementation and post-program completion periods (percent change -2.2% 95% CI -12.0%, 8.6%; p-value 0.6754).

Results from additional analyses concentrating on respiratory-related health care costs were consistent with the results from the analysis of asthma-related health care costs (Table 6.4). Respiratory-related health care costs of implementation and post-program completion periods were \$5,720,610 and \$5,290,220, respectively. This presented a 60.8% cost reduction compared to the 12-months before ECPA was implemented (\$14,583,154 in 2014 U.S. dollars).

6.9. Discussion

This study revealed the positive, translational effect of ECPA on health care costs among patients with asthma. After ECPA introduced asthma care improvement processes among providers at the health center level, asthma-related health care costs among 1,683 patients decreased by 54.0% (from \$11,836,254 in pre-implementation to \$5,448,481 in implementation phases). ECPA was significantly associated with decreased total asthma-related costs during the 12-month implementation and 12-month post-program completion

phases compared to pre-implementation phase. The effects of the ECPA program appeared to be sustainable because GLMMs revealed a 57.3% reduction in the total annual health care costs, incurred during the 12-month post-program completion period. These results indicate that ECPA is an effective real-world quality improvement program that reduces asthma-related health care costs among patients who received asthma care from participating health centers.

Costs across the six types of health resources used decreased from the pre-implementation period to active and post-implementation periods. Cost reduction of these elements contributed to the 54.0% and 58.6% reduction in the total annual asthma-related health care costs, using the 12-month pre-implementation period as a reference. Results of additional analyses examining the total respiratory-related costs also presented a similar magnitude of cost reduction. Improvement in asthma control may positively impact respiratory infection- and chronic obstructive pulmonary disease (COPD)-related costs. Executing ECPA, which incorporates guideline-based asthma care processes into real-world clinic settings, could contribute to sustained reductions in financial burdens to insurers and patients.

ER visits and office and outpatient visit costs were reduced approximately 60-70%. ER cost reduction resulted from a 37.7% reduction in the rate of ER visits from the pre-implementation to ECPA-implementation phases (Rojanasarot, Carlson, et al., 2018). The large reduction in physician office and outpatient visit costs may be attributable to improvements in asthma self-management among the center patients as learned and developed through appropriate asthma education and asthma action plan creation (Rojanasarot, Heins Nesvold, et al., 2018). These self-management components are necessary for optimizing asthma control (Agrawal, Singh, Mathew, & Malhi, 2005; Pinnock

et al., 2017). EPR-3 guidelines for scheduling follow-up care depend on how well patients control their symptoms (NIH, 2007). An office visit should be scheduled every two to six weeks when asthma symptoms are not well controlled. Follow-up care could then be reduced to only two times per year when asthma symptoms are well maintained.

Results from the 3-level GLMMs show that the quality improvement efforts among asthma care providers at the health center level substantially and sustainably improve patient-level cost outcomes. ECPA was significantly associated with a 56.4% decrease in total annual asthma-related health care costs when using the costs from the pre-ECPA implementation period as a reference. The program was also explicit in its sustainable effect on the asthma-related expenditures since the total health care costs occurred 12 months after the program completion was also significantly reduced. As per prior research stressed, most public health policy research has focused on a downstream intervention (e.g., interventions that are directly provided to patients to encourage behavioral change) (Brownson, Seiler, & Eyster, 2010). Moreover, those upper-level quality improvement initiatives have not emphasized patient-level health outcomes as their evaluation goals (Dilley et al., 2012). The patient-level cost reduction findings of this current study along with the demonstrated ECPA effect on minimizing rates of potentially preventable health events (Rojanasarot, Carlson, et al., 2018), however, have built empirical evidence for the development of patient-level measures derived from real-world, upper-level quality improvement interventions.

The cost patterns of total asthma-related health care due to asthma were in accordance with previous studies. For example, among Illinois patients, the observable peak was evident in February of the pre-implementation period, consistent with the published literature for that state. A majority of included patients were from ECPA-centers

located in Illinois; Whitaker (2007) found that asthma-related hospital admissions in Illinois peak in February. Therefore, the included Illinois patients might be the main contributors to the cost peak. Moreover, the total health care costs due to asthma reached a nadir between April and August. This finding may reflect lower hospital admission expenditure during that period since the number of asthma-related hospitalizations among U.S. patients were at their lowest from June to August (Weiss, 1990).

This study has several strengths. First, this study used three years of cost data on all patients. Data from the 12-month period after program was completion allowed us to evaluate the potentially sustainable effects of the program on the cost outcomes. Second, we calculated all respiratory-related health care costs to fully capture the claims of health resource used that may be associated with asthma. For instance, upper respiratory infections could lead patients with asthma to seek care at a physician office, resulting in health care costs that might not be claimed as an asthma office visit event. Third, this study allowed a unique random intercept of each patient and health center in the GLMM analyses to account for within-patient and within-center variation, resulting in precise estimates of the model parameters.

Several limitations should also be considered. First, this study included only the patients who received asthma care from the health centers of the first ECPA cohort. While there were five health centers from Texas in this cohort, none of their patients could be located in the administrative claims data because they were not covered by this particular insurer. Thus, these study findings could not be generalized to the center patients from Texas. Second, this study used administrative claims data which were subject to coding errors and potential bias derived from providers' payment maximization effort (Riley, 2009). Last, this study used the same group of patients before the program was

implemented as a comparison group. While all non-time dependent variables—gender, race, and ethnicity—remained stable during the three-year study period, this study could not account for time-dependent variables, such as patient age. This time-varying confounder might have biased our implementation and post-implementation modeled results towards the mean because asthma costs increase as patients age (Kamble & Bharmal, 2009). Nevertheless, the results from this study, in conjunction with the alleviation of the asthma-related ER visits and hospital admission rates (Rojanasarot, Carlson, et al., 2018), could support administrative decision-making in adopting the center-based quality improvement approach of ECPA in other settings.

6.10. Conclusion

This study provides evidence that quality improvement efforts at the health center level through ECPA are associated with substantially reduced patient-level, asthma-related health care costs. Implementation of ECPA contributed to a \$6,369,790 reduction in total asthma-related health care costs among 1,683 included patients. The results from generalized linear mixed models revealed that ECPA was significantly associated with the reduction in asthma-related total health care costs during the 12-month ECPA implementation and 12-month post-program completion periods. Given the favorable effect of ECPA on short-term and relatively long-term asthma expenditures, ECPA was an effective quality improvement program that enhanced asthma care processes at the practice-level and resulted in cost savings at the patient-level.

6.11. Supplementary figures and tables

Table 6. 1 Baseline demographic characteristics of patients receiving asthma care from participating health centers

Characteristics	Total	Illinois	New Mexico	Oklahoma
Health centers (%)	9 (100.0%)	4 (44.4%)	3 (33.3%)	2 (22.2%)
Patients (%)	1,683 (100.0%)	1,121 (66.6%)	498 (29.6%)	64 (3.8%)
Age in 2012, years				
Mean (SD)	31.2 (24.0)	25.5 (22.9)	45.6 (20.5)	29.2 (21.7)
Median	22	15	51	25
Minimum-Maximum	1-93	1-93	1-90	1-81
%patients aged less than 18 years	44.6%	58.0%	15.3%	39.1%
Gender				
Female	929 (55.2%)	574 (51.2%)	322 (64.6%)	33 (51.6%)
Male	754 (45.8%)	547 (48.8%)	176 (35.3%)	31 (48.4%)

SD=Standard deviation

Due to rounding, percentages may not always add up to 100%.

Table 6. 2 Asthma-related costs by types of health resource use in 1,683 patients with asthma

Health resource use	Costs of the attributed 1,683 patients (% of the total cost)			%Cost difference		
	Pre-Implementation Year 2012	Implementation Year 2013	Post-Completion Year 2014	Δ Pre to Imp	Δ Pre to Post	Δ Imp to Post
Emergency room visit	\$450,439 (3.8%)	\$166,077 (3.0%)	\$137,743 (2.8%)	-63.1%	-69.4%	-17.1%
Hospital admission	\$5,828,720 (49.2%)	\$3,146,847 (57.8%)	\$2,791,507 (56.9%)	-46.0%	-52.1%	-11.3%
Physician office and outpatient visits	\$4,380,885 (37.0%)	\$1,495,675 (27.5%)	\$1,417,547 (28.9%)	-65.9%	-67.6%	-5.2%
Asthma medications	\$661,344 (5.6%)	\$543,869 (10.0%)	\$489,785 (10.0%)	-17.8%	-25.9%	-9.9%
Durable medical equipment	\$176,357 (1.5%)	\$85,795 (1.6%)	\$49,420 (1.0%)	-51.4%	-72.0%	-42.4%
Other	\$338,509 (2.9%)	\$10,217 (0.2%)	\$16,215 (0.3%)	-97.0%	-95.2%	58.7%
Total	\$11,836,254 (100.0%)	\$5,448,481 (100.0%)	\$4,902,218 (100.0%)	-54.0%	-58.6%	-10.0%

Δ=Cost difference; Pre=12-month pre-implementation period; Imp=12-month implementation period; Post=12-month post-program completion period

All cost components were inflated to 2014 U.S. dollars using Medical Care Services of the Consumer Price Index (CPI) retrieved from U.S. Bureau of Labor Statistics.

Table 6. 3 Asthma-related expenditure per patient-year (n=1,683)

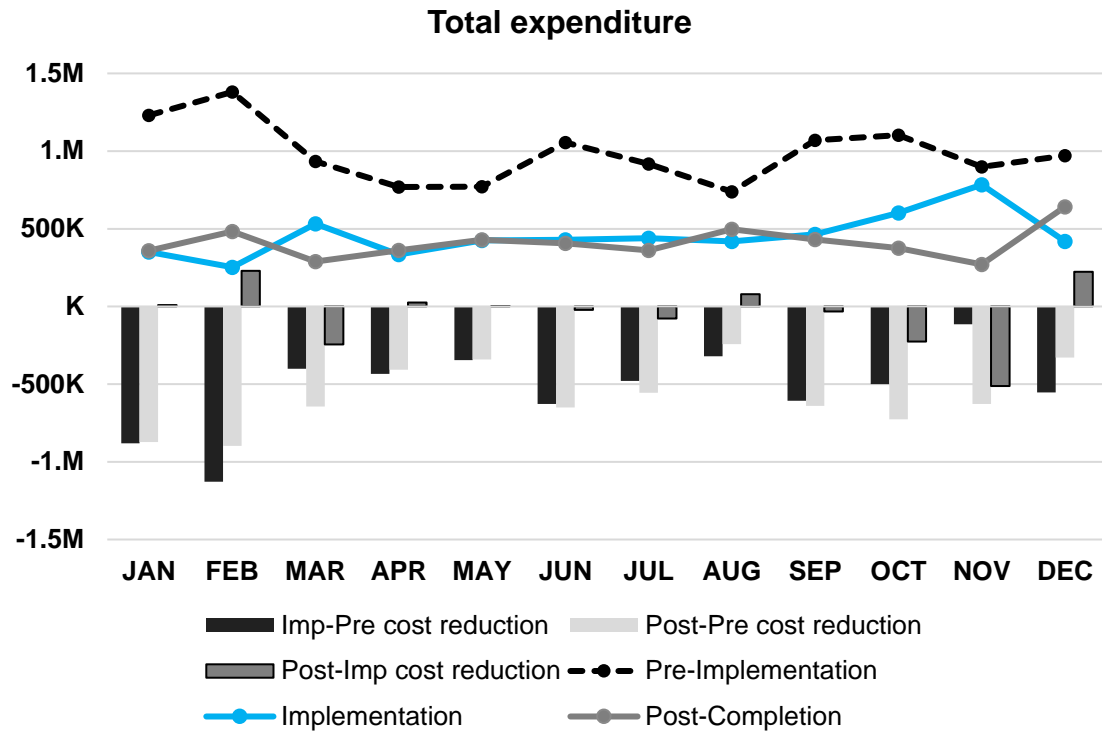
Health resource use	Average cost by study period (SD)			Average cost reduction (SD)		
	Pre-implementation Year 2012	Implementation Year 2013	Post-completion Year 2014	Δ Pre to Imp	Δ Pre to Post	Δ Imp to Post
Emergency room visit	\$268 (\$661)	\$99 (\$500)	\$82 (\$332)	-\$169 (\$667)	-\$186 (\$626)	-\$17 (\$498)
Hospital admission	\$3,463 (\$15,641)	\$1,870 (\$15,561)	\$1,659 (\$13,005)	-\$1,594 (\$16,820)	-\$1,805 (\$16,008)	-\$211 (\$14,030)
Physician office and outpatient visits	\$2,603 (\$6,137)	\$889 (\$2,960)	\$842 (\$2,887)	-\$1714 (\$5,820)	-\$1761 (\$6,097)	-\$46 (\$3,494)
Asthma medications	\$393 (\$981)	\$323 (\$963)	\$291 (\$858)	-\$70* (\$608)	-\$102* (\$646)	-\$32* (\$565)
Durable medical equipment	\$105 (\$854)	\$51 (\$773)	\$29 (\$399)	-\$54 (\$1024)	-\$75 (\$908)	-\$22 (\$760)
Other	\$201 (\$1,391)	\$6 (\$135)	\$10 (\$222)	-\$195 (\$1,385)	-\$191 (\$1,397)	\$4 (\$258)
Total	\$7,033 (\$19,258)	\$3,237 (\$16,545)	\$2,913 (\$13,702)	-\$3,795 (\$19,461)	-\$4,120 (\$19,080)	-\$325 (\$14,809)

SD=Standard deviation; Δ=Cost difference; Pre=12-month pre-implementation period; Imp=12-month implementation period; Post=12-month post-program completion period

All cost components in this study were inflated to 2014 U.S. dollars using Medical Care Services of the Consumer Price Index (CPI) retrieved from U.S. Bureau of Labor Statistics.

Asterisks indicate statistical significance of a Wilcoxon Signed Ranks Test at a significance level of 0.05.

Figure 6. 1 Costs for emergency room visits and inpatient stays per month and cost reduction using pre-implementation period as a reference



(All costs were expressed in 2014 U.S. dollars.)

Table 6. 4 Respiratory-related costs by types of health resource use (n=1,683)

Health resource use	Costs of the attributed 1,683 patients (% of the total cost)			%Cost difference		
	Pre-Implementation Year 2012	Implementation Year 2013	Pre-Implementation Year 2012	Δ Pre to Imp	Δ Pre to Post	Δ Imp to Post
Emergency room visit	\$544,228 (3.7%)	\$171,209 (3.0%)	\$139,359 (2.6%)	-68.5%	-74.4%	-18.6%
Hospital admission	\$6,961,205 (47.7%)	\$3,215,432 (56.2%)	\$3,052,788 (57.7%)	-53.8%	-56.1%	-5.1%
Physician office and outpatient visits	\$5,549,554 (38.1%)	\$1,616,490 (28.3%)	\$1,469,276 (27.8%)	-70.9%	-73.5%	-9.1%
Prescription	\$661,344 (4.5%)	\$543,869 (9.5%)	\$489,785 (9.3%)	-17.8%	-25.9%	-9.9%
Durable medical equipment	\$424,379 (2.9%)	\$161,574 (2.8%)	\$122,769 (2.3%)	-61.9%	-71.1%	-24.0%
Other	\$442,444 (3.0%)	\$12,036 (0.2%)	\$16,243 (0.3%)	-97.3%	-96.3%	35.0%
Total	\$14,583,154 (100.0%)	\$5,720,610 (100.0%)	\$5,290,220 (100.0%)	-60.8%	-63.7%	-7.5%

Δ=Cost difference; Pre=12-month pre-implementation period; Imp=12-month implementation period; Post=12-month post-program completion period

As additional analyses, this table reports annual health care costs per study period of different types of health resource use due to respiratory-related conditions among 1,683 patients with asthma.

All cost components in this study were inflated to 2014 U.S. dollars using Medical Care Services of the Consumer Price Index (CPI) retrieved from U.S. Bureau of Labor Statistics.

Chapter 7: Discussion

7.1. Summary of study results

7.1.1. Summary of the first-manuscript results

This manuscript examined the effect of ECPA on six asthma guideline-based performance measures collected from a chart review in each health center at three different points in time. Before ECPA was implemented, at least 75% of the participating centers reported less than half of their patients having documentation for the following guideline-based components: ACT, pulmonary function testing, asthma education, and asthma action plan. While at least 50% of the participating health centers at baseline had no patients whose ACT was documented, the rate was dramatically improved during the implementation and post-implementation phases. At the end of the ECPA implementation, at least 50% of the centers reported 79% of their patients having the ACT documentation.

The results of ECPA effectiveness from generalized linear mixed models (GLMM) showed statistically significant improvement in all performance measures at the ECPA completion, compared to pre-implementation of ECPA. The GLMMs also showed statistically significant improvement in all performance measures at 6-month post-program completion, compared to pre-implementation of ECPA.

Regarding the change in the measures from program completion to 6-month post-program completion, results showed significant improvement in the rate of documenting asthma controller medication prescription among participating health centers (rate ratio from a complete case analysis=1.387; 95% CI 1.254, 1.534). Nonetheless, the rate of documenting pulmonary function testing at 6-month post-program completion decreased

by 25% compared with program completion (rate ratio from a complete case analysis=0.750; 95% CI 0.655, 0.860).

The overall improvement in asthma guideline-based performance measures provides support for the effectiveness of ECPA on the provider- and facility-level outcomes. The quality of asthma care among participating health centers with varying structural practice settings was suboptimal prior to the ECPA implementation. Results presented in the first manuscript provided strong evidence for an effective asthma quality improvement model that can be replicated in diverse health centers to improve asthma quality metrics among asthma care providers.

7.1.2. Summary of the second-manuscript results

The objective of this manuscript was to estimate the effect of ECPA on alleviating the rates of ER visits and hospital admissions during the 12-month program implementation and 5-month post-program completion periods. By utilizing administrative claims data, this manuscript attributed 1,828 patients with asthma to 15 health centers from the first and second cohorts. Cohort 1 comprised 92.1% of the patients (1,121 from Illinois, 498 from New Mexico, and 64 from Oklahoma). The mean age of patients from both cohorts was 30.5, with New Mexico having the highest average age (mean=42.3). All Texas patients were less than 18 years old. Fifty-five percent of the included patients were female.

Graphic presentation of the data demonstrated a clear reduction in the combined number of ER visits and hospital admissions, the number of ER visits alone, and the number of hospital admissions alone after ECPA was implemented. After adjusting for seasonality, patients during the 12-month ECPA implementation and 5-month post-

program completion periods were significantly less likely to experience either ER visits or hospitalizations, ER visits alone, or hospitalizations alone, compared to the patients during the 12-month pre-ECPA implementation period. To illustrate, ER visit occurrence during the 5-month post-program completion period was reduced by 55.7% with a rate ratio of 0.443 (95% CI 0.350, 0.562). When using the 12-month program implementation period as a reference, patients in the 5-month post-program completion period showed a significant 27.8% lower ER visit rate only (RR=0.728; 95% CI 0.562, 0.942 p-value 0.0158).

This manuscript also included results from sensitivity analyses to evaluate a sustainable effect of ECPA on potentially preventable health events. Exclusively focusing on the 1,683 patients from the first cohort, the results from GLMMs pinpointed the significant improvement in the rates of combined ER and hospital admission events and ER visits alone during the 12-month post-ECPA completion period, compared to the 12-month ECPA implementation period. The rate ratios were 0.875 (95% CI 0.770, 0.994) and 0.757 (95% CI 0.633, 0.905), respectively.

The manuscript results suggest a translational effect of ECPA, where the improvement in asthma care processes occurred at the health center level, on potentially avoidable health events at the individual level. ECPA expansion in other health-center settings should be espoused among decision makers to consequently enhance patient outcomes. The results of this manuscript, together with the ECPA implementation framework that has been clearly described and is ready to be replicated, supported ECPA's effectiveness, compared to other downstream interventions where the quality improvement efforts have to be allocated directly to patients.

7.1.3. Summary of the third-manuscript results

The third manuscript focused on the effect of ECPA on asthma-related health care costs among patients who received asthma care from participating health centers in the first cohort. The manuscript utilized a pretest-posttest, quasi-experimental design to reveal the effect of the program on asthma-related costs.

Total annual asthma-related health care costs to the included 1,683 patients were reduced from \$11,836,254 in the pre-implementation phase to \$5,448,481 and \$4,902,218 in the implementation and post-program completion phases, respectively (about 50% cost reduction). In connection with potentially preventable health care costs, asthma-related ER visit and hospital admission costs decreased at least 60% and 45%, respectively when using the 12-month pre-implementation period as a reference.

Evaluating monthly patterns of total health care costs due to asthma, costs during the pre-implementation months were higher than the costs in the same month during the implementation and post-program completion periods.

Results from GLMMs showed the beneficial effect of the ECPA implementation on total annual asthma-related health care costs due to asthma. The ECPA implementation was associated with a 56.4% reduction in total health care costs (95% CI -60.7%, -51.8%).

This manuscript provides further support for the hypothesis that asthma quality improvement efforts at the health center level through ECPA were associated with a substantial reduction in total asthma-related health care costs measured at the patient level. These findings provide evidence that ECPA can alleviate financial burdens on patients with asthma and their health insurers.

7.2. Implications of the dissertation

This dissertation assembled evidence for the implementation of a quality improvement program at the practice level that could result in improving both asthma guideline-based performance measures and asthma outcomes at the patient level. Thus, the dissertation offers both clinical and policy implications.

With respect to clinical implications, the results of this dissertation can be used to build a national model for asthma care in community settings. Despite the fact that the CDC's NACP (CDC, 2013) has provided financial funding for a variety of activities concentrated on surveillance, intervention, partnerships, and evaluation, the implementation of quality improvement initiatives for patients with asthma at the community level has lacked standardization. No standard framework has directed the development of asthma care processes to ensure high-quality care. The results from this dissertation fill this gap by demonstrating that ECPA is an effective quality improvement program that improves both asthma quality measures and patient-focused asthma outcomes. The results provide additional evidence for the significance of promoting change at the health center level. Thus, this dissertation serves as an example of using an evidence-based quality improvement program that was successfully executed in diverse geographical states to develop a standardized model for improving asthma care processes in real-life practice settings.

Moreover, this dissertation contributed to health policy research by supplying an analytical framework for a health care intervention that was executed in different settings at different points in time. The Agency for Healthcare Research and Quality (AHRQ) has inaugurated quality indicators, including preventable ER visits, to quantify the performance

of health systems (Agency for Healthcare Research and Quality, 2015). However, no best-practice guidelines have been developed to facilitate the assessment of real-world programs that have been implemented in multiple settings with multiple timelines. Policy makers may inevitably face difficulties determining if real-life interventions are effective and worth replication on a broader scale. This dissertation offered an analytical cornerstone for the evaluation of health care programs in practical settings and provided an answer to two fundamental policy questions: how to determine if an investment at the patient care delivery level enhances chronic illness care; and, how to evaluate whether the investment results in improving patient-focused and clinically meaningful health care outcomes and costs. Therefore, this dissertation has a potential policy impact not only for patients with asthma but also patients with other chronic illnesses who struggle with potentially preventable health events.

7.3. Strengths of the dissertation

This dissertation has several strengths. First, the study combined two data sources: asthma guideline-based quality measures extracted from a patient chart review process and administrative claims data. The data sources have enabled the investigation of the ECPA effect at the practice and patient levels. The complementary data components have strengthened the study validity and ensured their applicability for decision makers. As previously mentioned, decision makers often face difficulties in adjudicating an effective program with limited funds (Dilley et al., 2012); the supportive results of the two data sources could provide them with needed evidence to adopt the effective ECPA program in other settings.

Second, this dissertation employed proper statistical approaches to managing missing data from a retrospective chart review. Multiple imputation was conducted to create completed datasets. The analysis results from the GLMMs of each dataset were combined to generate a single inference. The results from the complete case and multiple imputation analyses were parallel, validating the conclusion regarding ECPA's effectiveness.

Third, superior to previous quality improvement efforts, where many studies followed the outcomes up to 12 months after the programs were executed, this dissertation utilized the 3-year continuous administrative claims data of patients receiving asthma care from the first cohort. The data comprised 12-month before the program was implemented, 12-month during the program implementation, and 12-month post-program completion. The improvement in the outcomes after the program was completed showed a sustainable effect of ECPA on potentially preventable health services use and asthma-related costs.

Fourth, this dissertation employed a quasi-experimental design using health centers and patients as their own control. This design is beneficial because all non-time varying variables remained stable throughout all study periods. Thus, these non-time covariates did not confound the statistical estimates.

Fifth, the analyses of the third manuscript were not affected by seasonality. Seasonality has been recognized as a common confounding factor in asthma research. However, the third manuscript focused on the 3-year continuous administrative claims data of patients receiving asthma care from the first cohort. Each year the seasonality pattern is relatively stable. Thus, in using the same 12 month periods for each period, we did not need to account for seasonal variation.

Last and most importantly, the results of this dissertation emphasized the importance of cross-sector partnerships in advancing asthma care in practice. ECPA was a quality improvement initiative generated by the ALAUM and a private insurance company. This multi-sector collaboration has brought the effective, guideline-based quality improvement program to the forefront. The collaboration demonstrated a mutually beneficial investment that proliferated better health outcomes among patients with asthma.

7.4. Limitations of the dissertation

This dissertation demonstrates several strengths with solid methodologies. However, it also has several limitations. The limitations are disaggregated into three components: limitations due to study design, limitations due to the use of a retrospective chart review, and limitations due to the use of administrative claims data.

7.4.1. Limitations due to study design

The first limitation is due to the self-controlled design of this study. The same group of health centers and patients before the ECPA implementation was used as a comparison group. We had no control over the secular trend occurrence, so it is possible that improvement in the outcomes would have appeared with or without the ECPA implementation (Wells et al., 2017). Nonetheless, the trends of asthma ER and hospital admissions events have been stable from 2001-2010 (Moorman et al., 2012; Nath & Hsia, 2015). Graphic presentation of asthma-related ER visits and hospital admissions from the second manuscript also substantiated the unchanging trend of the two health events over repeated observations prior to the ECPA implementation. Hence, it is unlikely that the

secular trend would impact the results of this dissertation. Further, the use of the ITS in the second manuscript offered a statistically sound and recommended approach in analyzing data from real-life programs that lack a comparison group.

7.4.2. Limitations due to the use of a retrospective chart review

Data used in the first manuscript had been collected previously. The quality of the data could affect the study results. A retrospective chart review is susceptible to inconsistency between medical record reviewers (Matt & Matthew, 2013). Likewise, participating health centers might have falsely reported clinic-based performance measures to reflect an improvement in their settings. Although no verification of the chart audits was processed at each center site, a standardized chart audit tool for the clinic measures was provided to all centers with assistance of ALAUM state program managers to ensure the methodological attainment of data collection.

Additionally, missing data on clinic-based performance measures occurred in this study. The staff members were required to engage in the data collection process and serve their patients at the same time. Due to the competing demands (Glasgow & Emmons, 2007), the clinic staff might have not been able to collect the clinic-based performance measures. Nevertheless, multiple imputation was selected to account for the missing data issues.

7.4.3. Limitations due to the use of administrative claims data

Administrative claims data used in the second and third manuscripts were subject to limited reliability owing to their original reimbursement purposes (Hashimoto, Brodt, Skelly, & Dettori, 2014; Johnson & Nelson, 2013); the degree of clinical details is somewhat restricted (Johnson & Nelson, 2013). For instance, administrative claims data

do not contain essential asthma clinical information, such as forced expiratory volume in the first second (FEV1) measured through a pulmonary function test by spirometry (Giannini et al., 1997), which is used to establish asthma severity. Without the lung function record, we could not determine the asthma severity of each included patient. Although this clinical variable is lacking, it does not affect the statistical inference of this study due to its non-time varying nature.

Administrative claims data are dependent on medical coding, which has been criticized for potential coding errors that could lead to misclassification of asthma and other comorbidities. In addition, medical coders from different clinical settings may have inconsistencies in how they interpret billing code systems (Tyree et al., 2006). Minor clinical occurrences could have been ignored because coders perceived them to be of nonclinical importance (Hashimoto et al., 2014). It is also possible that coders may choose particular codes to maximize provider reimbursement, resulting in unrepresentative health care costs (Riley, 2009).

This study used the provider tax identification numbers of participating health centers to identify patients to be attributed to the centers. Some clinic locations shared the same identification number. This study could not attribute patients to the specific location and could not include the location data as a random intercept.

Last, this study had access to administrative claims data from one private insurance company only. There were some participating health centers where none of their patients had health coverage through the private company. Additionally, some participating health centers, such as mobile clinics and school-based health centers, were financed differently and did not submit claims for reimbursement. Therefore, patients who

received asthma care from those centers could not be included, and the ECPA effect among these centers could not be determined.

7.5. Recommendations for future research

This study has provided insights into the effect of ECPA on clinic-based performance measures, potentially preventable asthma-related health resource use, and asthma-related health care costs. However, this study has not addressed other vital measures. Additional research efforts could further investigate the ECPA effect on other patient outcomes, including: asthma-specific quality of life scores e.g. St-George Respiratory Questionnaire (Jones, Quirk, & Baveystock, 1991); the Asthma Quality of Life Questionnaire (Juniper et al., 1992); and generic quality of life instruments, such as SF-12 (Ware, Kosinski, & Keller, 1996); days of restricted activity; school days missed; and days absent from work.

A qualitative evaluation of ECPA should be considered to better understand the implementation of ECPA in practice settings. For instance, semi-structured interviews could be undertaken with medical directors of health centers that were eligible to participate in ECPA but chose not to. The interview would provide insights into the challenges that the practices had in deciding whether they should engage in the quality improvement efforts. Furthermore, in-depth interviews could be carried out with health center staff who championed ECPA. The qualitative results would offer a deep understanding of the enablers and constraints to implementing the quality improvement program. Such precious information would provide opportunities for improving ECPA.

Future research could also investigate if improving asthma guideline-based care among health center providers would result in the improvement of prescribing patterns of asthma medications. This study found that the annual costs of asthma medications significantly decreased after the ECPA implementation. This finding raised broader questions about whether ECPA also optimized pharmacological treatment among patients with asthma by reducing unnecessary use of SABAs. Due to the limited information about pharmacy-based claims, the question remains unaddressed.

Based on further internal analyses of this dissertation, future work could examine whether a decrease in the number of physician office and outpatient visits due to asthma has resulted from optimal asthma control among participating patients. This dissertation explored a reduction in the number of physician office and outpatient visits and found that the combined number of both types of visits decreased from 5,406 times/ year in the pre-implementation phase to 3,303 times/ year in the implementation period, and to 3,746 times/ year in the post-program completion period (38.9% and 30.7% reduction, respectively).

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Appendix

Appendix 1: IRB exempt study notification



Sirikan Rojanasart <rojan003@umn.edu>

1506E74041 - PI Rojanasart - IRB - Exempt Study Notification

1 message

irb@umn.edu <irb@umn.edu>
To: rojan003@umn.edu

Mon, Jul 20, 2015 at 8:36 AM

TO : carls007@umn.edu, rojan003@umn.edu,

The IRB: Human Subjects Committee determined that the referenced study is exempt from review under federal guidelines 45 CFR Part 46.101(b) category #4 EXISTING DATA; RECORDS REVIEW; PATHOLOGICAL SPECIMENS.

Study Number: 1506E74041

Principal Investigator: Sirikan Rojanasart

Title(s):

Asthma Health Outcomes Achieved with a Clinic-Based Quality Improvement Program

This e-mail confirmation is your official University of Minnesota HRPP notification of exemption from full committee review. You will not receive a hard copy or letter. This secure electronic notification between password protected authentications has been deemed by the University of Minnesota to constitute a legal signature.

The study number above is assigned to your research. That number and the title of your study must be used in all communication with the IRB office.

If you requested a waiver of HIPAA Authorization and received this e-mail, the waiver was granted. Please note that under a waiver of the HIPAA Authorization, the HIPAA regulation [164.528] states that the subject has the right to request and receive an accounting of Disclosures of PHI made by the covered entity in the six years prior to the date on which the accounting is requested.

If you are accessing a limited Data Set and received this email, receipt of the Data Use Agreement is acknowledged.

This exemption is valid for five years from the date of this correspondence and will be filed inactive at that time. You will receive a notification prior to inactivation. If this research will extend beyond five years, you must submit a new application to the IRB before the study's expiration date.

Upon receipt of this email, you may begin your research. If you have questions, please call the IRB office at (612) 626-5654.

You may go to the View Completed section of eResearch Central at <http://eresearch.umn.edu/> to view further details on your study.

The IRB wishes you success with this research.

We value your feedback. We have created a short survey that will only take a couple of minutes to complete. The questions are basic, but your responses will provide us with insight regarding what we do well and areas that may need improvement. Thanks in advance for completing the survey. <http://tinyurl.com/exempt-survey>

Appendix 2: IRB acknowledgment of the change in protocol request



Sirikan Rojanasart <rojan003@umn.edu>

IRB Acknowledgment of Change in Protocol Request

1 message

irb@umn.edu <irb@umn.edu>
To: rojan003@umn.edu

Thu, Sep 15, 2016 at 3:27 PM

TO : carls007@umn.edu, rojan003@umn.edu, The IRB has reviewed and acknowledged your change in protocol for the study listed below:

Study Number: 1506E74041

Principal Investigator: Sirikan Rojanasart

Title(s):

Asthma Health Outcomes Achieved with a Clinic-Based Quality Improvement Program

Your study was determined previously to be exempt from IRB review in one of the following categories 45 CFR 46.101(b):

#1 INSTRUCTIONAL STRATEGIES IN EDUCATIONAL SETTINGS.

#2 SURVEYS/INTERVIEWS; STANDARDIZED EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR.

#3 PUBLIC OFFICIALS; SURVEYS/INTERVIEWS; OBSERVATION OF PUBLIC BEHAVIOR.

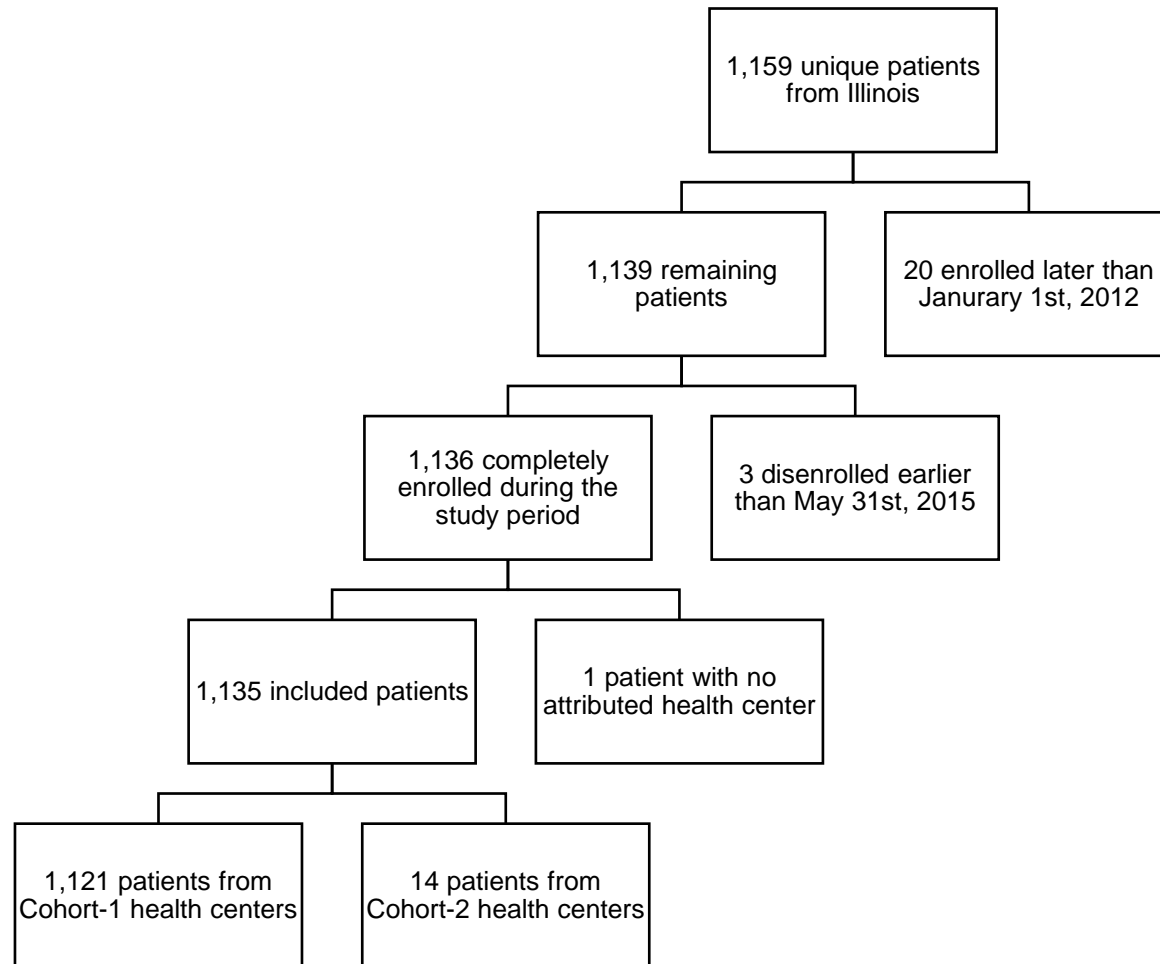
#4 EXISTING DATA; RECORDS REVIEW; PATHOLOGICAL SPECIMENS.

#6 TASTE TESTING AND FOOD QUALITY EVALUATION.

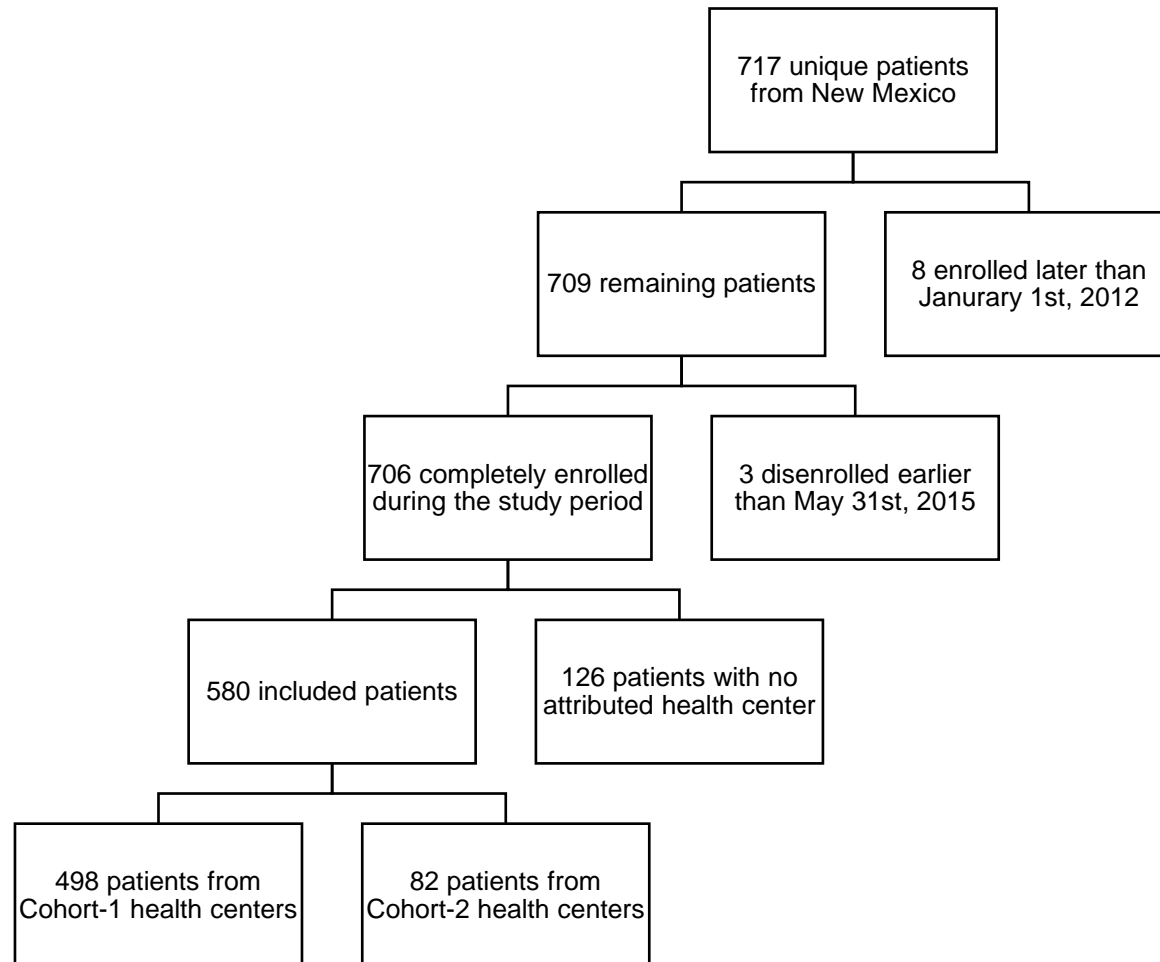
The changes you have proposed do not alter your exempt status. No action is needed at this time

Please do not hesitate to contact the IRB office at [612-626-5654](tel:612-626-5654) or irb@umn.edu if you have any questions.

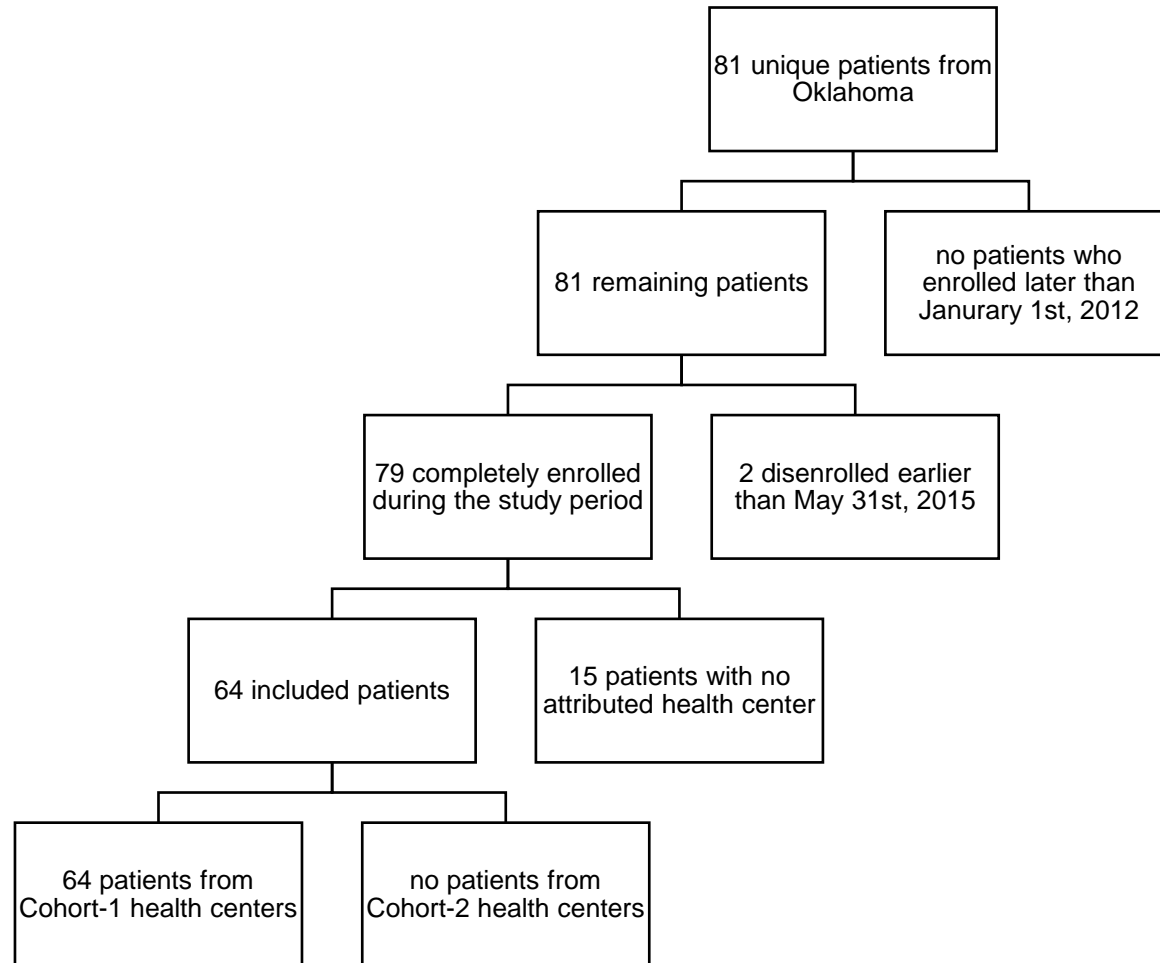
Appendix 3: Patient flowchart of included patients from Illinois



Appendix 4: Patient flowchart of included patients from New Mexico



Appendix 5: Patient flowchart of included patients from Oklahoma



Appendix 6: Patient flowchart of included patients from Texas

