Examining Home Visits from Community Health Workers to Help Patients Manage Asthma Symptoms

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Institution Receiving Award: Public Health—Seattle & King County
Original Project Title: Guidelines to Practice (G2P): Reducing Asthma Health Disparities through Guideline Implementation
PCORI ID: AS-1307-05498
HSRProj ID: HSRP20143417
ClinicalTrials.gov ID: NCT021906

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ABSTRACT

**Background:** A disproportionate burden of asthma is borne by racially and ethnically diverse groups with low income, disparities that are driven by social determinants of health. Little is known about the potential synergies between community health worker (CHW) home-visit services and planned, preventive asthma primary care visits (ie, enhanced clinical care).

**Objectives:** Public Health—Seattle & King County, in partnership with local clinics, health plans, other asthma experts, and patients, reviewed existing asthma clinical guidelines for incorporation into community and clinical asthma health care interventions. We then assessed the effectiveness of a CHW home-visit protocol compared with usual care focused on low-income and racially and ethnically diverse groups with asthma. This trial was nested in a feasibility study of a planned preventive asthma “enhanced clinical care” intervention among a nonrandomly selected group of “safety-net” clinics, where attempts were made to coordinate the CHW’s work with that of the clinical teams. This trial is known as Guidelines to Practice (G2P).

**Methods:** Participants were recruited over a 13-month period from 13 clinical sites, where patients were randomly assigned to receive CHW home-visit services or not. The participants were then followed for 12 months. The CHW intervention included 3 planned home visits covering asthma trigger reduction, education, self-management support, and goal setting. CHW services were provided in English, Spanish, or Somali. The enhanced clinical care intervention was implemented at 4 sites selected nonrandomly from the 13 sites. At each of these 4 sites, a “change team” was identified that consisted of a lead clinician and support staff. The intervention included a combination of quality-improvement tools delivered in a “change package” (ie, a group of specified preventive asthma health care elements, as described in detail in the Methods section) accompanied by training and support over the intervention period. An electronic health record (EHR) template focused on asthma guideline recommendations was developed and implemented to facilitate clinical decision support and interagency communication. For study participants assigned to both interventions (CHW and enhanced clinical care), efforts were made to coordinate care between the CHW and practice team, communicating through in-person meetings, phone conversations, and the EHR asthma template common management page once it was enabled.

The purpose of the study was to assess the impact of the CHW intervention and the feasibility of coordinating this intervention with the clinical teams trained to provide enhanced, preventive asthma care. This represents a change in the original study design, which included assessing the health impact of the enhanced care intervention. Instead, we describe the enhanced care intervention as a feasibility study, which we decided upon for 2 main reasons: (1) The sample of enhanced care clinical teams was chosen nonrandomly, a change from the proposed randomized factorial design; and, (2) the full rollout of the preventive care processes that comprised the enhanced care intervention was incomplete at the end of the study timeline. Thus, we abandoned the original 2×2 factorial design and simply compared study
participants randomly assigned to receive CHW home-visit services with those who were not randomly assigned to receive them.

Primary outcome measures included self-reported asthma symptom-free days, Asthma Control Test (ACT) score, and Asthma-Related Quality of Life Questionnaire (AQLQ) score. Secondary outcome measures included nights awakened due to asthma, asthma-related urgent care use (combining hospitalization, emergency department visits, and unscheduled clinic visits), β-agonist use, oral steroid use, and school days or workdays missed. Sources included a pre-post patient survey; home environmental checklist; and midpoint interviews with CHWs, clinic staff, and health plans. The results reported below were based on a multivariate model using all participants and across both intervention groups (ie, CHW and enhanced care).

**Results:** Our 551 participants with uncontrolled asthma included low-income patients aged 5 to 75 years. In total, 53% were adults, and 47% were children; 77% were non-White; and 88% were renters. There were 273 patients randomly assigned to receive CHW services and 278 who were not. There were 285 patients who received clinical care at 4 practices nonrandomly chosen to deliver enhanced asthma care and 266 patients who received care at 9 practices delivering usual asthma care. This resulted in 4 groups: group 1 (usual care) included 133 patients, group 2 (enhanced clinical care) included 145 patients, group 3 (usual care plus CHW intervention) included 133 patients, and group 4 (dual intervention: enhanced clinical care plus CHW) included 140 patients.

There were statistically significant CHW intervention effects on all outcomes, including the primary outcomes of asthma symptom-free days (mean, 1.27-day improvement; 95% CI, 0.2-2.4), ACT score (1.2-unit improvement; 95% CI, 0.3-2.1), and AQLQ score (0.39-unit improvement; 95% CI, 0.2-0.6). However, the differences in ACT and AQLQ scores did not meet the published standards for the minimal clinically important difference (MCID) for asthma care. Evaluation of the feasibility study was impeded by the lack of reliable process measures from the clinical sites and delays in implementing the enhanced asthma health care intervention within the study time frame. We obtained results from qualitative interviews of the clinicians and support staff at the enhanced asthma health care sites and the medical directors from both involved federally qualified health center (FQHC) practice networks. Key themes expressed by the clinic teams and medical directors were a generally positive attitude toward the G2P and the enhancements in asthma care as a result of the enhanced asthma health care intervention, which are further elaborated in the Results section.

**Conclusions:** We demonstrated statistically significant improvements across 8 health outcomes among patients randomly assigned to receive CHW services vs usual care. However, 2 of the 3 primary outcome measures, ACT and AQLQ scores, failed to meet the published MCID in this hard-to-reach population. Both care teams and CHWs reported that coordinating planned asthma care with the CHW’s work was both feasible and acceptable.

**Limitations:** The study had 9 main limitations: (1) The 4 enhanced clinical care intervention clinics were not chosen randomly. (2) The uptake of the clinic-based Planned Asthma Change Package by providers beyond the identified change team (ie, practice-wide spread) took longer
than anticipated. The desired enhanced asthma health care changes continued to be implemented beyond the study intervention period at the 4 enhanced care sites as well as at the 9 usual care sites, which also received enhanced asthma health care training at the conclusion of the intervention period. (3) We have not been able to obtain valid care metrics from the EHR for closer inspection of care received by patients. (4) The 12-month end point CHW evaluation visit was, at times, difficult to complete within the study time frame, thereby introducing a potential seasonal bias to our outcome measures. (5) Most of the CHW staff had years of experience in delivering home visits, so our findings may not be generalizable to a newly hired CHW staff. (6) The CHW staff did most of the data collection, introducing potential bias in outcomes assessment. (7) There was relatively little communication between the CHWs and the enhanced care practice teams. (8) A nonrandomly chosen portion of patients receiving CHW services also received care at the 4 enhanced care practices, confounding the CHW intervention results. (9) We abandoned the results of the enhanced vs nonenhanced clinic groups because of the study design flaws.
BACKGROUND

Over 25 million adults and children in the United States have asthma, affecting 19 million adults (7.7% of total population) and 7 million children (9.5%). After plateauing in the early 2000s, the prevalence of asthma is currently increasing by an average 1.5% per year. Most people with asthma report that it is not well controlled. Asthma attacks result in almost a half million hospitalizations and over 2 million emergency department (ED) visits annually. The disease carries a national economic burden of $56 billion per year.

Asthma Health Inequities

The disproportionate burden of asthma is borne by racial and ethnic minorities and low-income populations. These associations are persistent and profound. For example, during the study year (2010) those identifying as Black with asthma are 3 times as likely as those identifying as White to have an ED visit (18.4% vs 6.1%, respectively) and more than twice as likely to be hospitalized (2.8 % vs 1.3%, respectively).

Asthma prevalence is higher among low-income populations: 11.2% among those with incomes below poverty level compared with 7.3% for persons with incomes at least 200% of the poverty level. Poverty, in turn, is associated with other social and environmental determinants of health—such as substandard housing and air quality—that affect asthma morbidity directly or indirectly.

Providing the right assessment and treatment at the right time is essential to asthma management. Even if ideal clinical care is provided, it is often not enough to solve the complex collection of barriers and causes of asthma morbidity. Social and environmental determinants can negatively affect morbidity even if optimal medical care is delivered. Community health workers (CHWs) who employ a home-visit model are typically lay workers from the community served. To directly address such determinants, CHW interventions have been successfully used to pick up where clinical care leaves off. A focus on indoor environmental trigger identification and reduction and a means of directly addressing other social determinants are also often needed. A multifactorial problem requires a multifaceted solution.
Asthma Health Care Guidelines

Most people with asthma can control their illness if the National Asthma Guidelines are followed. Despite the availability of guidelines, implementation of them by both health care providers and people with asthma is limited. For example, among children who had been hospitalized ≥2 times over the previous year, only 32% had taken maintenance controller medications. Among providers, only 16% of primary care practitioners adhered to guidelines for asthma action plans and 10% for spirometry. Low-income, less-well-educated, and racially/ethnically diverse populations are even less likely to receive or use appropriate asthma medications, have continuity of care, have a written asthma plan, and receive pulmonary function testing.

The Chronic Care Model

The Chronic Care Model (CCM) provides a guide for improving chronic disease care by using a coordinated, team-based approach to consider the multiple needs of patients that extend beyond the traditional medical system. According to the CCM, interrelated areas can create higher-quality patient-provider interactions and, ultimately, patient care. Practice change involved the CCM elements of delivery system design, information system support, and decision support. Delivery system design was created by establishing a system of planned preventive asthma health care visits, with a frequency reflecting the severity of the patient’s asthma, and incorporating point-of-care spirometry, skin testing for airborne allergen sensitization, and teaching about asthma medications and delivery devices. Information system support involved the development and implementation of a preventive asthma template incorporated into NextGen, the electronic health record (EHR) system used by both federally qualified health centers (FQHCs) participating in the enhanced care feasibility study. The EHR also provided decision support by imputing asthma severity and control levels based on symptom frequency, lung function, and asthma exacerbation history, guiding the clinician to the proper treatment step according to the National Asthma Guidelines. CHWs also play an important role in deploying the CCM elements—specifically, for self-management support and linking community resources, 2 other aspects of the CCM.
The Dilemma Faced by People Who Need to Make Choices When They Are Uncertain About the Outcome

This dilemma is well summarized as the “tyranny of the urgent.” Disefranchised people with asthma often have to contend with competing priorities such as food, clothing, and shelter. Until these basic needs are met, it is often unrealistic to expect a patient to deal with something seemingly less urgent, such as daily inhaled corticosteroid use, even if the patient recognizes that the medication may decrease daily symptoms and the likelihood of future exacerbations. Inhaled corticosteroids, a mainstay of asthma treatment, require weeks of regular use to provide a benefit, which makes adherence to a good treatment plan all the more challenging. Addressing social determinants that are barriers to preventive asthma care (and/or facilitators of asthma morbidity) needs to be part of a holistic solution.

Providers also contend with a work environment of ongoing urgency. Safety-net primary care practices are busy places and the first source of care for acute illness, including asthma exacerbations, as well as infectious illnesses and trauma. Fifteen-minute acute visits are frequently the norm in this setting, a time frame incompatible with the needs of planned preventive visits for asthma. Although there is a functioning preventive care visit schedule (e.g., the well-child visit schedule), this does not include a chronic illness focus. As a result, planned preventive chronic illness care is often missing in the primary care setting.

Systematic Reviews or Other Pertinent Literature Documenting Evidence Gaps

A review of single-component interventions to improve asthma outcomes shows that while some are effective, effect sizes tend to be modest. A larger impact may be realized by combining interventions. Multicomponent interventions have employed combinations of information, education, clinic redesign, decision support, and/or audit or feedback. Although some multicomponent interventions have shown beneficial effects on guideline implementation and a few on health outcomes, most have employed relatively weak study designs, such as pre-post comparisons without control groups. It remains uncertain which combination of interventions is most effective, feasible, and acceptable. These studies have largely focused on providers. A recent review concluded that the strength of evidence is
insufficient to low and that more rigorous studies are needed to explore this promising approach.\textsuperscript{20} Much remains to be learned about multicomponent interventions.

Often, different relevant components exist across different agencies. Systems theory suggests that considering the interactions of the multiple factors, interventions, and organizations that influence adoption of guidelines will help researchers design more effective and integrated approaches.\textsuperscript{37-39} Because system-based approaches have the potential for broader impact, evaluating a multilevel systems intervention based on current evidence-based single- and multicomponent interventions is necessary.

**Main Research Question**

We studied whether CHW home-visit services result in better health outcomes in patients with asthma compared with no home visits. We also studied the feasibility and acceptability of coordinating CHW services with primary health care teams that participated in an enhanced clinical care (preventive asthma care quality improvement [QI]) intervention.

In our original proposal to PCORI and in our original draft final research report (DFRR), our study was initially presented as a 2×2 factorial design comparing 4 groups: usual care, enhanced clinical care, usual care plus CHW, and dual intervention (enhanced clinical care plus CHW). Based on feedback from DFRR reviewers and our own internal discussions reflecting on how the study was actually carried out, we decided to fundamentally change how we report our findings. We now present the study as a prospective randomized controlled trial (RCT) of the CHW intervention. The enhanced care intervention was reframed as a feasibility study, and the rationale for this change is presented in the Methods section of the abstract. Patients from all participating clinics (enhanced care clinics and usual care clinics) were randomly assigned to CHW vs no CHW. This is described further in the Methods section.

The primary hypotheses of this study, therefore, were that CHW home visits would improve asthma care and outcomes and that these services could be successfully coordinated with primary care teams providing enhanced preventive asthma care.
Significance and Potential Impacts of the Research as Envisioned at the Time of the Award

At the time of the award, we envisioned the following impacts on the various stakeholders involved:

1. Patients will experience better health and improved quality of life (QOL), less disruption of personal and family activities by asthma, greater skills and autonomy in managing asthma, and improved communication with their providers.

2. Clinicians will increase their asthma management skills, increase efficiency when addressing asthma, gain tools for asthma management, enhance relationships with patients through improved communication, improve quality metrics, and reduce health inequities.

3. Health plans will see improved quality metrics, gain access to on-the-ground information about members, be able to connect with hard-to-reach members, and reduce health inequities.

4. Our local community organizations (eg, public health department) will be able to better control asthma at the population level, strengthen partnerships with the health care system, sustain current asthma-control efforts, and reduce health inequities.
PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

The Guidelines to Practice (G2P) study used a combination of stakeholders and participation methods that were unique to the project conducted. However, it is important to consider the stakeholder development and involvement in a long history of the health department’s work on community-based asthma programs and research. Below, we discuss the history of stakeholder engagement through the work led by the Public Health—Seattle & King County (PHSKC) health department in asthma, the organization of stakeholder engagement specific to the G2P project, and how engagement evolved throughout project planning and implementation, participant enrollment, and evaluation.

Asthma Stakeholder Engagement Since 1997, Before PCORI Funding

Using community-based participatory research approaches, Dr Jim Krieger and PHSKC engaged stakeholders in the design of a CHW home-visit model to help low-income families reduce exposure to environmental asthma triggers. The first project was an NIH study called “Healthy Homes I,” which started in 1997. This project demonstrated that CHWs were indeed effective in reducing trigger exposure and improving asthma outcomes. The next step was to expand the scope of home visits to include other aspects of asthma self-management support, including proper use of medications and accessing medical care for asthma. The Healthy Homes II project was implemented by PHSKC under the oversight of a newly formed local Allies Against Asthma coalition. Embedding the Healthy Homes II project in the coalition fostered links between home visits and clinical care.

The coalition included schools; public health and housing agencies; academic institutions; hospital systems; community clinics; and other health providers, residents, and community organizations. The goals identified in the coalition’s efforts were to (1) increase asthma self-management and the control of the home environment, (2) improve guideline-based clinical care, (3) increase education throughout the community, and (4) increase the coordination and sharing of consistent information across sites. Programming included the CHW model, clinical quality improvement (CQI), work with childcare and school-based health care, and home-improvement/weatherization programs. The work and mission in this past
programming is similar to the work performed to this day by PHSKC, though it now operates within a more mature and robust system focused on communication and coordination of care with clinical teams.

In the following years, the partnerships established through the Allies Against Asthma coalition have supported a series of projects supported by large grants (mostly federal) to further develop and study the effectiveness and cost-effectiveness of home-based CHW interventions to support asthma self-management and improve asthma outcomes. Each grant opportunity enabled the PHSKC asthma program to partner with a variety of providers serving low-income, uninsured, and Medicaid clients. For example, our Breathe Easy Homes project integrated CHW home visits into the development of asthma-friendly, low-allergen housing.

**G2P Stakeholder Engagement for Proposal Development and Planning**

In preparation for the application for the PCORI-targeted funding award for asthma, the regional stakeholders were consulted individually to determine whether a CHW model coordinated with asthma care teams and across frontline providers was possible or appropriate. The largest FQHC networks in King County, Medicaid managed care organizations, and regional asthma experts were part of this process. Although these organizations had strong relationships with PHSKC and separate relationships with each other, these project partners were newly convened to discuss improvements in asthma care. The process entailed pulling data, identifying the patient populations that would be served, and assessing the feasibility of care teams at multiple sites for collaboration.

To learn from patients similar to those who would participate in G2P, we held a 2-hour discussion on September 4, 2013, with 6 adults who either had asthma or were caregivers of children with asthma. The discussion focused on which outcomes of asthma management they valued, what helped control asthma, and which barriers affected their control of asthma. We have also hosted discussion groups that addressed the same topics as well as suggestions for research design. The following key themes emerged:
1. Outcomes of importance are decreasing symptoms; disruption of family activities; missing school, work, and other activities; and worry about child’s health.

2. Patients and caregivers want to know how asthma works and the latest information about controlling it (medications, trigger reduction).

3. Caregivers fear adverse effects of long-term medication use.

4. It is costly and challenging to eliminate triggers in the home. Support—both education and resources—is needed.

5. Stress, from daily events and extraordinary life changes, makes it hard for many patients to manage their asthma.

6. Patients would like providers to receive more education about up-to-date treatment of asthma.

7. Providers should conduct in-depth interviews of patients and develop a plan for asthma management.

8. Asthma educators should be persons with asthma.

9. Follow-up communication (telephone, newsletters, internet messaging), ongoing self-management support, and providing newly emerging information would be helpful after initial education is complete.

G2P Stakeholder Engagement in the Conduct of the Study

Patients and other stakeholders played important roles in G2P design and implementation, and they participated in the research team (including 2 patients and 1 caregiver). The project initiation included a patient advisory group and senior advisory group. We planned to continue these groups as structured engagement opportunities by including ongoing stakeholder input. In addition, routine (monthly) consultation began with a local community advisory board (noted below as project partners). This board was also part of the planning phase for further refinement of study methods and measures to ensure buy-in, feasibility, and cultural appropriateness (for both patient and provider cultures). We used community-based participatory research methods developed by Dr Krieger and others as a framework for engagement.
During implementation, stakeholders participated in project monitoring and oversight. During the analysis and dissemination phase, they participated in interpretation of data, preparation of manuscripts and reports, and other dissemination activities.

**G2P Stakeholder Engagement Through the Enrollment and Analysis Period**

The core component of our patient and stakeholder engagement was primarily centered on the research team, which included 15 to 20 participants, with representatives from all stakeholder groups at all times. This was called the Project Partners team. The Project Partners team was a balanced set of all stakeholders that met monthly for 1.5 hours. The patient advisory and senior advisory groups were contacted as needed when there were enough materials for their review. There were difficulties in scheduling and low reengagement with these groups; however, we found the consistency of attendance by the Project Partners team and the quality of engagement sufficient to broadly represent our community of patients and stakeholders. The Project Partners team consisted of the following stakeholder groups:

1. Research team (5 members): principal investigator (PI) and analysts
2. CHW program team (2 members): program manager and program nurse
3. Investigators (2 members): participant subject matter experts from a regional QI organization and clinical systems
4. Clinics (4 members): medical directors and quality managers from the 2 FQHCs
5. Health plans (2-3 members): senior managers of care management programs
6. Patients (2-3 members): adult patient with asthma and caregiver of a child with asthma

We also held weekly meetings with G2P CHWs that included representatives from the research team and visitors across the broader stakeholder set. These weekly meetings had 2 standing agenda items: (1) clinical review of home-based services and (2) continued professional development and training on the protocols. From an engagement standpoint, these meetings brought routine feedback from patients’ homes and clinical connections. The CHWs served as a collective patient perspective, enabling us to gain real-time feedback on how...
the intervention was performing. Over the entire intervention period, regularly reviewing feedback from over 500 homes on a weekly basis as a whole team brought the vast diversity of patient and community experiences and obstacles to light. In addition, these weekly meetings enabled the CHWs to process these heartening and difficult experiences in a collaborative environment that was supportive and enriching.

In summary, both the monthly Project Partner meetings with the broad stakeholder group and the weekly meetings with the core CHW team provided an essential mix of ongoing engagement and feedback that kept the program current, relevant, and connected to the communities that we served. We experienced significant difficulty convening the patient advisory group and senior advisory group as often as originally proposed. The patient advisory group did reconvene at the study recruitment midpoint. In considering the logistical difficulty and the needs of the project, we felt the project had substantially fulfilled the roles through our local advisory group of stakeholders and experts and the collective patient voice that our CHWs supplied.
METHODS

Study Overview

PHSKC, in partnership with local health clinics, health plans, and other health experts, implemented a 2-year clinical trial to assess the effectiveness of a CHW home-visit intervention in patients with asthma. Each participant had a clinical home in 1 of 2 FQHCs that participated in the project—Neighborcare Health (NCH) and HealthPoint (HP). Study participants were randomly assigned at the patient level to receive or not receive the CHW intervention, and then divided into 4 groups based on randomization and the clinic in which they received care: group 1 (usual care), group 2 (enhanced clinical care), group 3 (usual care plus CHW intervention), and group 4 (dual intervention: enhanced clinical care plus CHW). We briefly provide a general overview of each of these groups here, along with more detailed description throughout this section.

Group 1: Usual Care

This group received asthma care as typically provided at their clinical sites. They received no enhanced asthma health care training during the intervention period, and they did not receive CHW home-visit services (i.e., no change from status quo ante).

Group 2: Enhanced Clinical Care (Usual Care Plus Enhanced Preventive Asthma Changes)

The multifaceted enhanced clinical care intervention targeted primary care teams to improve the quality of asthma care through CQI training. The 4 intervention practice locations were chosen by leadership from the respective FQHC networks to participate in this intervention based on an identified clinical champion at each site and perceived readiness to change. This experience included training in the use of a new preventive asthma care EHR template and a review of the asthma guidelines, with a focus on establishing a patient’s asthma severity and control. During the 2-year intervention period, monthly meetings were held at 1 FQHC site (1 of 4 intervention sites) and attended by the PI (J.S.) and a QI consultant (Jeff Hummel, MD). The other FQHCs (3 of 4 intervention sites) supported enhanced care changes...
internally and participated in twice-yearly meetings with the PI (J.S.) to review progress, reinforce training principles, identify best practices, and troubleshoot barriers. Leadership at both the HP and NCH FQHCs assigned a champion to oversee progress and help troubleshoot barriers. The intervention followed a Planned Asthma Change Package (see “Planned Asthma Change Package” section), a set of 10 specific processes to deliver planned preventive asthma care. The CQI training was delivered via in-person workshops and an evidence-based online spirometry training and feedback program ([www.spirometry360.org](http://www.spirometry360.org)\(^60,61\)). Thus, the nonrandom half of patients receiving CHW services also received their care at 4 practices trained to deliver enhanced asthma care. This exposure to enhanced asthma care confounds the results of the CHW vs non-CHW comparison.

**Group 3: CHW Intervention (Usual Care Plus CHW Home Visits)**

Patients randomly assigned to the CHW intervention received 3 planned home visits, which included a protocol-driven home environmental assessment, indoor trigger reduction, self-management support, goal setting, and improvement of patient-provider interaction. CHWs all received training in preventive asthma management, recognition of impending exacerbations, and clinical supervision from the PI (J.S.) as well as training in motivational interviewing techniques, links to clinical and community resources, and standardized asthma protocols led by staff at PHSKC. As described, this group was not exposed to enhanced asthma care during the intervention period.

**Group 4: Dual Intervention (Enhanced Clinical Care Plus CHW Visits Plus Efforts to Coordinate Care Between the Practice Team and CHWs)**

Patients from enhanced clinical care sites and randomly assigned to the CHW intervention received both sets of services. Attempts were made to coordinate care between CHWs and practice teams. Modes of communication toward this coordinated care included phone calls; in-person CHW visits to the practice site; and, once completed and approved by the FQHCs and PHSKC, messaging through the NextGen preventive asthma module, built specifically for this project.
There was a 13-month recruitment period and a 12-month intervention period for each enrolled study participant.

Our study population of 551 participants included those identifying as Black, Hispanic/Latino, and other low-income patients who had asthma and were aged 5 to 75 years, and it included 3 language groups: English, Spanish, and Somali. Primary outcome measures included self-reported asthma symptom-free days, Asthma Control Test (ACT) score, and Asthma-Related Quality of Life Questionnaire (AQLQ) score. Secondary outcome measures included nights awakened because of asthma, asthma-related urgent care use with hospitalization, ED visits, unscheduled clinic visits combined, β-agonist use, oral steroid use, and school days or workdays missed. Data were collected between 2014 and 2017, and sources included a pre-post patient survey; home environmental checklist; and midpoint interviews with CHWs, clinic staff, and health plans.

Study Design

This study used a prospective randomized control design of CHW home-visit services vs not (usual care). As described previously, patients were recruited from a nonrandom selection of clinics from 2 FQHC networks either receiving a CQI intervention to enhance preventive asthma care (enhanced clinical care) or not. Thus, the study was designed to measure the health impact of the CHW home-visitor model while concurrently assessing the acceptability and feasibility of coordinating CHW experiences from home visits with the preventive asthma care delivered by the intervention practices. The phone case managers from both involved health plans participated in an asthma clinical in-service (enhanced health plan).

Study Setting

The study participants were recruited from those receiving primary care across 2 FQHC systems in 1 of 13 clinics. The participants must also have been enrolled in Medicaid. The partner organizations were chosen for having the highest volume of patients with uncontrolled asthma in King County based on preliminary data sharing and assessment.
The CHW intervention occurred at the homes of the study participants. NCH and HP (the participants’ clinical homes) are the 2 largest networks of FQHCs in King County. NCH had all 8 of its clinics participate in the G2P study. All the NCH clinics are within the Seattle city limits. HP had 5 (Auburn, Federal Way, Renton, SeaTac, and Tukwila) of its 12 clinics participate in the G2P study. All the HP clinics are in King County. The clinics that participated are all located in south King County, along the Interstate 5 corridor. Seattle, particularly south Seattle, and south King County are well documented to have higher morbidity and mortality across multiple health indicators (including asthma) and greater health disparities, which is why these clinic locations were a focus for this project.

Participants

The population of focus was patients with asthma from participating clinics who met the inclusion and exclusion criteria.

Inclusion Criteria

1. Patient receives primary care provision at NCH or HP (2 FQHC primary care networks) with 13 different regional clinic sites
2. Enrolled in either Community Health Plan of Washington or Molina Medicaid health insurance plan
3. Patient has a diagnosis of asthma, with asthma not well controlled or very poorly controlled per Expert Panel Report 3 (EPR-3) criteria at phone screening
4. Between 5 and 75 years of age at enrollment at phone screening
5. Residence in King County
6. Primary language is English, Spanish, or Somali

Exclusion Criteria

1. Patient is planning to leave King County within the next 12 months.
2. Household appears to be unsafe for visit by a CHW.
3. Patient has coexisting medical conditions that make asthma control a low priority for patient management, that confound outcome measurement, or that preclude participation in self-management (eg, stage II-IV congestive heart failure; dementia; uncontrolled psychosis; chronic obstructive pulmonary disease [COPD]; or other chronic pulmonary conditions such as cystic fibrosis, idiopathic pulmonary fibrosis, lung cancer, or pulmonary arterial hypertension).

4. Patient was enrolled in another asthma research study at the time of phone screening.

**Recruitment**

Participants were recruited from NCH and HP clinics. We obtained patient lists from the clinics and health plans for recruiting patients into the study. Patient lists from the 2 sources were merged, deduplicated, and screened based on study enrollment eligibility. A list for screening phone calls was then generated. The list was then stratified into the CQI enhanced clinical care intervention and nonenhanced control clinics based on nonrandom clinic designation.

We divided the 2 stratified lists into biweekly batches and sent an initial invitation letter signed by the medical director of each potential participant’s primary care clinic. In the letter, the patients were introduced to our study and encouraged to participate. If they wished to opt out and did not want to receive a phone call from the study, they were given the option to mail back an opt-out card.

Two weeks after the invitation letters were mailed, we started to conduct phone-screening interviews for recruitment. During the phone-screening interview, once the potential participant had been found to be eligible, project staff scheduled an appointment for a home visit during which informed consent was obtained. In addition to completing the baseline interview questionnaire, a home-assessment walk-through was conducted to assess in-home environmental asthma triggers. At the end of this baseline home visit, based on age and asthma control level, the patients were randomly assigned to either the CHW group or the non-CHW control group.
The CHWs, with the assistance of research study staff, performed most of the recruitment activities and all of the enrollment and exit surveying. The CHWs and staff were trained by PhD-level staff health-services researchers in proper research practices, including informed consent, standard survey delivery methods, and the importance of objective and thorough data collection. The CHWs’ research activities were supervised with support from the evaluation team. Periodic observational audits were performed for quality assurance.

Randomization and Masking

Study participants were randomly assigned to having a CHW intervention or no CHW intervention. Among the 13 clinics, 4 clinics were designated as the enhanced care clinics. This designation was based on the judgement of each FQHC’s medical director, who identified and communicated with the clinicians who expressed willingness to serve as clinical champions and to lead change teams at the 4 enhanced asthma health care sites, as described in the “Nonrandomized Clinics” section. The remaining 9 clinics were labeled “nonenhanced clinics.” For the CHW intervention, all participants were included to be randomly assigned to either the CHW intervention group or the control group using a permuted block design, with varying block sizes in 4 age- and asthma-control-level strata (children vs adults and not well controlled vs very poorly controlled). Sequence numbers and group allocations were programmed into the DatStat software (R1 RCM, Inc) that housed the electronic survey data-collection form. The DatStat randomization system revealed the randomization outcome only after the final baseline survey was submitted and uploaded to the system. Therefore, the randomization assignment was known to the participant and surveyor only at the end of the survey data collection and after informed consent and enrollment. After that point, the participant and all study staff knew to which study group the participant had been randomly assigned. The nature of the intervention made it impossible to mask participants and staff to study group assignment. The study staff, CHWs, and investigators were masked to the study outcomes. The study outcomes were reported to the data safety and monitoring board (DSMB) 5 months before the end of the study, at which point the active period of the intervention had concluded. Those attending the DSMB meeting and who saw these early results, including the PI, CHW program manager, and
lead evaluator, did not inform anyone outside the DSMB meeting, which may have theoretically introduced unconscious bias. However, those attending the meeting did not inform anyone else.

Nonrandomized Clinics

The medical directors for these clinic systems, in collaboration with clinicians at their practice sites, chose a convenience sample of clinics for the enhanced clinic intervention based on their judgement of clinic readiness, capacity for an additional QI project, and the availability of a clinician who was enthusiastic about assuming the role of asthma care champion. The clinics chosen for the enhanced clinic intervention were Columbia City, High Point, and Rainier Beach for NCH and Federal Way for HP.

Interventions and Controls

The CHW intervention activities were designed to be conducted during the first 4 months of the 12-month study enrollment period. The enhanced care clinics began their clinic intervention before the first study participant enrollment and continued to develop and spread their QI program throughout the duration of the research period.

CHW Intervention

The CHW intervention is described briefly at the beginning of this section, under the “Study Overview.” In our hiring of CHWs, we emphasized shared life experiences. In total, 3 of 4 CHW staff either had asthma themselves or had a family member with asthma. The fourth CHW had 8 years of experience providing asthma home visits. The CHWs also provided patient self-management support to participants or their caregivers through phone communications. The intervention protocols, CHW training, and program supervision have been described in our previous studies. In taking on this new study, the program protocols were updated and combined to make the program accessible to all age groups.

The CHW made an initial assessment visit and 3 follow-up educational visits 0.5, 1.5, and 3.5 months later. This sequence was based on evidence from our previous studies. At the initial
visit, the CHW collected baseline data and conducted a home environmental assessment using our home environmental checklist. At follow-up visits, the CHW worked with each participant to develop a tailored set of actions to reduce asthma triggers, learned about patient challenges and concerns, reviewed progress on implementing the self-management plan, provided targeted education to help with plan implementation, revised self-management goals as the participant progressed, and made referrals to community resources. The CHW reviewed the participant’s use of medications, observed and taught inhaler technique and self-monitoring, reviewed the asthma action plan with the participant and encouraged its use, encouraged follow-up with medical care, improved patient-provider interaction by advising on effective communication strategies, helped participants develop strategies to organize their self-management resources and activities, and encouraged receipt of immunizations. In addition to scheduled visits, the CHW worked with participants on an as-needed basis via telephone or additional home visits (though atypical). A different CHW then called the participant at 10 months and scheduled an exit survey. For participants <18 years of age, the CHW worked with both the child and the caregiver.

In addition, CHWs provided a full set of supplies and resources to help participants reach the self-management goals set for home environmental changes and medication adherence. These included allergen-impermeable bedding encasements for the participant’s bed, a “green” cleaning kit, a peak flow meter, an inhaler holding chamber, and plastic medication boxes. CHWs assisted caregivers unable to encase the mattress on their own. A low-emission (high-efficiency particular air [HEPA]) vacuum was provided to each household, as well as food storage containers to curtail current or future pest infestations. HEPA air filter purifiers were provided to participants exposed to pets and tobacco smoke. CHWS provided instructions and demonstrations of use for all supplies and resources. All participants received low-literacy educational materials collected into an asthma resource guide in English and Spanish. These materials were not translated into Somali.

We continuously assessed CHW fidelity to protocols. The CHWs were supervised by a general program manager, and they were further supported by a team that included a program
public health nurse, the study PI, and a motivational interviewing specialist. These 3 individuals would routinely accompany a CHW on home visits to assess their quality and fidelity. To provide structured feedback on program fidelity, the support team followed a visit review template that has been used in previous studies that looks holistically at the CHW’s performance on protocols as well as the ability to engage with the participant. The support team expected to review at least 1 home visit per month for each CHW. The support team gave the CHWs one-on-one feedback and broached topics in our weekly clinical meetings, which enabled the team to share and learn from each other. In addition to providing a forum for clinical case review with the study PI (a clinician), the public health nurse, and the program manager, these meetings were supplemented with regular reviews of the protocols and trainings on new community and clinical resources that became available. We also provided 30- to 60-minute monthly motivational interviewing refreshers and quarterly half-day motivational interviewing trainings.

**Enhanced Clinical Care Interventions**

The enhanced clinical care intervention activities were conducted at the clinic setting with the primary care providers and the asthma management team. For the study participants in group 4 (dual intervention), the CHWs attempted to provide feedback to the primary care providers about the patient’s asthma control, adherence, and home asthma triggers.

The enhanced clinical care intervention followed the Planned Asthma Change Package to support the design of a planned, preventive asthma health care visit between the primary care team and the patient. The change package is listed below, followed by more detailed steps taken in the enhanced clinical care intervention.

**Planned Asthma Change Package**

1. Planned, preventive asthma health care visits, with frequency based on asthma severity:
   a. Intermittent asthma: annual visits
   b. Mild persistent asthma: 2 times a year
   c. Moderate persistent asthma: 3 times a year
d. Severe persistent asthma: 4 times a year (often shared with a specialist)

2. Spirometry performed

3. ACT administered

4. Severity assessment performed (spirometry, ACT, steroid burst history)

5. Control assessment (spirometry, ACT, steroid burst history)

6. Objective measure of allergic sensitivity

7. Flu vaccination in past year

8. Appropriate prescribing of controller medications:

   a. Any level of persistent asthma should be associated with a controller medication prescription (almost always inhaled corticosteroids)

9. Written asthma action plan created, reviewed, or updated

10. Communicate and coordinate care with CHW

   **Clinic team and system redesign.** The care teams (provider, medical assistant, primary care nurse, and patient services representative) reevaluated their roles in providing asthma care using the planned visit CCM framework and CQI methods to provide enhanced previsit assessments, focused clinical encounters, and expanded postvisit options. Clinics formed teams and facilitated regular QI and continuous improvement events such as Plan-Do-Study-Act cycles and rapid process improvement workshops, such as a current state–to–ideal state mapping exercise.

   Each enhanced care clinic had a provider champion. The champion promoted the use of a planned asthma health care model through the implementation of the Planned Asthma Change Package, modeled and encouraged use of the asthma template in the NextGen EHR, served as an on-site consultant for asthma management, and participated in monthly planning and learning sessions.
**Spirometry and allergy testing.** Practice teams participated in the Spirometry 360 online training and feedback program. Spirometry 360 is a comprehensive, interactive, and evidence-based online training program and feedback system that allows test administrators and clinical interpreters to master spirometry.\(^{60,61}\) Following training, clinics continued to submit spirometry tests for quality monitoring and feedback throughout the study period.

MAs and primary care nurses at intervention clinics learned how to perform limited-panel allergy skin prick testing (recommended by the EPR-3) to test the airborne allergens most commonly associated with asthma so that this information could be obtained for patients without their traveling to a specialist’s office. Skin testing and immunoglobulin E (IgE) testing have similar sensitivity and specificity profiles, and skin testing is less expensive than IgE testing. Skin testing enables point-of-care teaching, rather than relying on phone follow-up in a population where that is not always feasible. The use of a disposable 10-prong multitest unit for a limited panel of airborne allergens commonly associated with asthma in the Pacific Northwest was found to be technically straightforward, and it was deemed feasible and acceptable by participating providers. The use of IgE testing was encouraged for any food allergy testing, less common airborne allergen testing, or because of patient or provider preference for other reasons.

In addition to the remote Spirometry 360 program, training in both spirometry and allergy scratch testing using the multitest unit was accomplished or reinforced through hands-on workshops led by Jim Stout, MD. Ongoing monthly feedback on spirometry test quality was provided through the Spirometry 360 program.

**Staff education.** The Physician Asthma Care Education (PACE) program was updated to reflect current asthma guidelines and offered to providers at all intervention clinics. Staff at intervention clinics participated in small-group case-based learning sessions led by study investigators. The topics included review of guidelines; skill building in asthma diagnosis; severity and control assessment; use and maintenance of devices, such as metered dose inhaler holding chambers; spirometry performance and interpretation; communicating with patients;
cultural variation in asthma beliefs; and assessing patient treatment preferences. Special attention was placed on training in patient-centered approaches to care, including motivational interviewing, shared decision-making, and communication skills. The Spirometry 360 program was also part of the provider education intervention.

**EHR optimization for audit, feedback, and decision support.** A preventive asthma template for the NextGen EHR was developed and enabled to support clinical workflows in the enhanced clinical care teams. Several revisions to the EHR were piloted on a small scale, modified based on feedback from care teams about usability, and implemented on a wider scale. The EHR analytics functionality was promoted for care team feedback.

**Reporting.** In collaboration with the investigative team, clinics were asked to produce regular action reports for care team members and outcomes reports for QI and the research team. The study team requested that these reports display practice quality metrics over time in the form of run charts, and they used them to compare progress with benchmarks and other intervention clinics. This goal was only partially realized.

**Coordinated Communications Plan**

A subcommittee of the research team with representatives from each stakeholder group developed a common set of guidelines and a common asthma management plan to be used by the CHW, clinician, and case manager.

**Implementing a common asthma management plan via paper and the clinic EHR system.** The common asthma management plan was eventually located in the NextGen EHR system, the shared communications and records platform for this project.

**Coordination and communication across settings of care through the EHR system.** Once developed, care team members in the intervention clinics used NextGen to share information about patients. Through HIPAA business associate agreements, CHWs were trained to access the EHR using remote, Citrix-based access and to receive accounts with role-
based access. A dashboard summarizing each patient’s clinical care and status enabled easy access to key information for team members.

NextGen also served as a secure messaging and posting platform, enabling care team members to share information and coordinate care. Urgent issues detected by the CHW were communicated by telephone by the project manager or public health nurse to clinic staff.

**Usual Care Control**

Health plans offered usual care activities through phone-based care management programs for all study participants.

*Enhancing case management.* Plans used materials that were updated based on G2P common guidelines and standardized case management protocols that case managers adhered to. Case managers at both health plans received a presentation on preventive asthma care. CHWs would interact with case managers, as needed, for those participants assigned to a CHW. Health plan representatives actively participated in monthly stakeholder meetings and met one-on-one routinely with G2P investigators.

*Monitoring medications.* Plans were initially asked to implement pharmacy claims-based systems to monitor reliever and controller fills. In the original proposal design, project partners were supposed to receive alerts of potential rescue inhaler overuse or controller underuse. The pharmacy claims system and its communication to the practices was not developed, so this goal was not realized.

Finally, clinics serving as usual care controls were offered all of the training and QI elements at the end of the intervention period.

*Measurements.* The ACT was used for adults and children aged ≥12 years, answered by the patient.$^{64}$ For children aged 5 to 11 years, the Childhood Asthma Control Test (C-ACT) was used, in which 4 questions were answered by the child and 3 questions were answered by
the caregiver. In the final model, ACT and C-ACT scores were standardized into the same scale, and then combined into a single measure.

For asthma-related QOL (range, 1-7) in adults, the interviewer-administered the mini-AQLQ. For children aged 12 to 17 years, the Pediatric-AQLQ (PAQLQ) was used and answered by the patient. For children aged 5 to 11 years, the PAQLQ was used but was answered by the caregiver. In the final model, the AQLQ and PAQLQ scores were combined.

**Sample Size and Power Calculation**

We calculated a sample size of 550 participants to finish, with 500 staying until the end of the study. Table 1 shows the power the study had to detect minimal clinically important differences (MCIDs) for the primary outcomes, with \( \alpha \) set at .05 (2 sided) for each of the 2 main effects (CHW intervention and enhanced clinical care intervention groups). Standard deviations are based on our prior work or the literature. A sample size of 250 participants per group for each of the main effects provided power of 0.96 to 1.0. If the sample size were reduced to 125 per group to the 2 main effects, the power would have been between 0.81 and 1.0. We originally targeted for the larger sample size to provide enough power to find moderate interaction effects between the 2 intervention main effects (CHW × enhanced clinical care).

**Table 1. Sample Size Calculations**

<table>
<thead>
<tr>
<th>Variable</th>
<th>MCID 63-64</th>
<th>SD</th>
<th>Power with n = 250 participants/group</th>
<th>Power with n = 125 participants/group</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT/CC-ACT</td>
<td>3.0</td>
<td>5.0</td>
<td>1.000</td>
<td>0.997</td>
</tr>
<tr>
<td>Mini-AQLQ</td>
<td>0.5</td>
<td>1.4</td>
<td>0.961</td>
<td>0.806</td>
</tr>
</tbody>
</table>

Abbreviations: ACT, Asthma Control Test; AQLQ, Asthma Quality of Life Questionnaire; C-ACT, Childhood Asthma Control Test; MCID, minimal clinically important difference.

**Reach, Effectiveness, Adoption, Implementation, and Maintenance**

The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework was used to identify the key dimensions that influence the success of intervention activities in practice and clinical settings (Table 2).\(^40\) Attainment of RE-AIM dimensions is
discussed throughout the Results section of this report and was tracked using outcomes data and interviews with clinicians, medical directors and staff, CHWs, and intervention participants.
<table>
<thead>
<tr>
<th>RE-AIM dimension</th>
<th>Measured by</th>
<th>What we learned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reach</strong> the intended population</td>
<td>• Participation rate among those eligible</td>
<td>• Understand why patients chose or chose not to participate (generalizability)</td>
</tr>
<tr>
<td></td>
<td>• Representativeness of participants compared with nonparticipants based on demographics</td>
<td></td>
</tr>
<tr>
<td><strong>Effectiveness</strong> of intervention activities</td>
<td>• Impact on asthma-related health outcomes and QOL</td>
<td>• What was most or least helpful to patients and how it increased/decreased effectiveness</td>
</tr>
<tr>
<td><strong>Adoption</strong> of intervention by staff, settings, and institutions</td>
<td>• Characteristics of settings participating vs not participating</td>
<td>• Representativeness of the settings adopting the intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Factors influencing whether settings or providers adopted intervention</td>
</tr>
<tr>
<td><strong>Implementation</strong> consistency, costs, and adaptations</td>
<td>• Fidelity to intervention protocols</td>
<td>• Differences in implementation by different settings or staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Facilitators and barriers to implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Adaptations that make intervention easier to deliver</td>
</tr>
<tr>
<td><strong>Maintenance</strong> of intervention activities</td>
<td>• No. of settings where intervention components will continue</td>
<td>• Challenges of implementation without funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Priority elements that will continue</td>
</tr>
</tbody>
</table>

Abbreviations: G2P, Guidelines to Practice; QOL, quality of life; RE-AIM, reach effectiveness, adoption, implementation, and maintenance.
Time Frame for the Study

The designated study period was 12 months between the baseline interview date and the exit interview date. All intervention activities were expected to be conducted during this time period. Because of scheduling difficulties for the exit interviews, however, the study period for some participants deviated from the designed length of 12 months.

Among the 551 participants, 484 completed the exit interview. For these 484 participants, the study period ranged between 10 and 25 months, with a median of 12 months: 32% participated for between 10 and 12 months (ie, ending up to 2 months before the 12-month point), 52% participated for 12 to 14 months (ie, up to 2 months after the 12-month point), and 95% participated for <3 months after the targeted 12-month point. An adjustment was made midcourse to avoid delays in completing the exit survey, initiating exit survey scheduling at month 10 to reach finalization in the 10- to 14-month window. Figure 1 shows the overall study design. Because asthma symptoms tend to vary by season, it is important to measure baseline and exit symptoms and control level in the same season. Of the 484 participants with an exit interview, 339 (70%) were interviewed in the same season (December-February as winter, March-May as spring, June-August as summer, and September-November as fall). Both seasonality and time difference from the targeted 12-month end point were considered (Figure 2).
Figure 1. Trial of CHW Intervention

Figure 2. Time Between Baseline and End Point Interviews, Control and Intervention Groups

Abbreviation: CHW, community health worker.

aOne bar equals about 30 days.
CHW home visits were expected to occur at 0.5, 1.5, and 3.5 months after the baseline date. The sequence and timing were chosen based on previous evidence produced by our research team in showing the effectiveness of a CHW intervention. Of the 273 participants in the CHW group, 269 (98.2%) received at least 1 CHW visit, and 81.0% received 3 visits, while 5.5% had only 1 visit. Five participants (1.8%) did not receive any visits.

Data Collection and Sources

The baseline survey was conducted by a CHW, almost always in the home of the study participant (or occasionally at the clinic or a mutually convenient location). To compensate participants for their time, we offered them a $25 gift card to complete the baseline survey. For those randomly assigned to the CHW intervention, the same CHW who had done the baseline survey made 3 follow-up educational home visits at 0.5, 1.5, and 3.5 months after the baseline visit. The CHW also worked with participants as needed by telephone or through additional home visits. At 10 months, all participants (both of the randomized study groups) were contacted again for tracking, to inform them about the exit interview, and to complete scheduling within a month of their exit due date. The exit survey was completed by a different CHW than the one completing the baseline or home visits in an effort to control for some biases. There were a few exceptions when the original CHW was required to complete both the baseline and the exit interviews based on participant mistrust of being introduced to new staff or because of a lack of English-language fluency (only 1 CHW spoke Somali). A $25 gift card was provided for completing the exit interview. For the control group, after completing the exit interview, an educational home visit was provided, during which a HEPA vacuum cleaner and cleaning supplies were provided. In general, all participants who were not reached through standard follow-up by phone and mail were left open and eligible to complete an exit questionnaire until the research data set was officially closed to begin analysis.

Analytical and Statistical Approaches

For each of the primary and secondary outcome variables, we analyzed the independent effects of the 2 study interventions (CHW intervention and enhanced clinical care intervention) and their potential interaction using a mixed-effects regression model, controlling for
prespecified covariates (baseline measure of the outcome, age, sex, race, and education, controlling for confounding) and clinic as the random effect term to control for potential cluster effects (see Table 3). We also included an interaction term for the 2 interventions, CHW study group, and clinic type (enhanced clinical care vs no enhanced clinical care). Because no interaction was found, the interaction term was removed from the final models.

The primary analysis was intention to treat. We used multiple imputation\textsuperscript{42} to adjust for missing data in the outcome measures for participants with missing exit interviews. Analysis based on multiple imputation can properly account for statistical uncertainty resulting from missing data under the assumption of missingness at random.

For confirmatory and descriptive heterogeneity of treatment effect analysis, the main subgroups included CHW intervention and enhanced clinical care intervention (main effects). Because of operational challenges associated with the enhanced clinical care intervention (eg, staff turnover, shifting agency priorities), participants in the intervention clinics had varied exposure to different intervention elements due to differences in clinic EHR and/or asthma champion/team rollout and implementation inconsistencies. Process measure data obtained from the EHR underwent a head-to-head comparison with measures collected by independent record review by the chief medical officer at one of the practice networks. Correlation was poor enough to question the validity of the EHR-derived data. Accordingly, we abandoned the planned process measure analysis that was to be based on data collected from the EHR. This was an attempt to measure the elements of our Planned Asthma Change Package, described previously. We also did a Holm-Bonferroni correction to adjust for multiple comparisons (ie, multiple primary and secondary outcome variables).\textsuperscript{43}

Also, for measures with different instruments for adults and children (ACT, AQLQ) in addition to pooled analysis, we ran analyses separately for children and adults.
Table 3. Study Outcomes\textsuperscript{a}

<table>
<thead>
<tr>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcomes</strong></td>
</tr>
<tr>
<td>Symptom-free days in the past 14 d\textsuperscript{b}</td>
</tr>
<tr>
<td>ACT score\textsuperscript{b}</td>
</tr>
<tr>
<td>AQLQ and PAQLQ</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
</tr>
<tr>
<td>Nocturnal awakening/past 14 d\textsuperscript{b}</td>
</tr>
<tr>
<td>Asthma-related urgent care use in the past 12 mo</td>
</tr>
<tr>
<td>β-agonist use in the past 14 d\textsuperscript{b}</td>
</tr>
<tr>
<td>Oral steroid use in the past 12 mo</td>
</tr>
<tr>
<td>Missed school days or workdays in the past 14 d</td>
</tr>
</tbody>
</table>

Abbreviations: ACT, Asthma Control Test; AQLQ, Asthma Quality of Life Questionnaire; PAQLQ, Pediatric Asthma Quality of Life Questionnaire.
\textsuperscript{a}All measures are based on patient self-report (for children aged 5 to 11 years, the PAQLQ was answered by the caregiver).
\textsuperscript{b}Measures for assessing asthma control and severity that are included in the National Heart, Lung, and Blood Institute EPR-3 guidelines (https://www.nhlbi.nih.gov/files/docs/guidelines/04_sec3_comp.pdf).

Changes to the Original Study Protocol

We initially proposed using a 2×2 factorial design, assessing outcomes for both a CHW intervention and a clinic intervention. As pointed out by reviewers, the clinic intervention group was not randomly assigned. Furthermore, full implementation of the practice change elements during the time frame of the 2-year intervention period proved unfeasible without considering the time needed for such preventive changes in asthma care to change clinical outcomes. Furthermore, we were unable to use the preventive asthma EHR template to gather process measures as originally planned. Lack of information further undermined our ability to demonstrate changes in the process of asthma care. As first mentioned at the end of the Background section, we now describe the study as an RCT of the CHW intervention, and a feasibility study of the enhanced asthma care clinic intervention.

We originally proposed comparing asthma-related urgent care use (ie, hospitalization and ED visits) across a representative sample of Medicaid enrollees not exposed to the
intervention that could serve as a control for usual care. The rationale for this exercise was the concern that preventive change elements (the content of enhanced clinical care) might organically diffuse from intervention to control sites. Indeed, we became aware of this occurring in some instances. For example, there was an increase in use of written asthma action plans at control sites, which may have been the result of increased awareness of this tool across the FQHC network. Furthermore, the preventive asthma EHR template was made available system-wide, and although control sites received no training or communication regarding its existence, we were informed by the FQHC networks that there was some use of this template beyond the intervention sites. We decided not to pursue comparing asthma-related urgent care use for several reasons. The relevant outcomes would all need to be claims based. The definitions for asthma-related urgent care use vary across data sources between patient self-report and claims coding to asthma diagnosis and services. We have run these data (not shown) and did not feel confident that a true comparison could be made. Additional concerns include the inability to confirm that all patients in the study or across the Medicaid population had full coverage for the entire study period. Medicaid claims data may also under-report asthma-related events because of Medicaid/Medicare dual coverage and gaps in Medicaid coverage.

The clinics individually approached the enhanced practice transformation, which led to individualized developments. Such work is to be expected of CQI in a pragmatic trial. We describe these developments here because although they were not explicitly designed, they contributed to successful integration:

1. Although not part of the original plan, our proposed practice changes were championed by internal facilitators employed by NCH and HP, respectively, who were responsible for monitoring and supporting the Planned Asthma Change Package. At 1 practice network, a clinician played this role, and at the other, a nonclinician administrator. In both cases, these individuals were effective internal change agents with whom we worked closely. In our experience, an individual appointed by clinic network leadership and charged with monitoring and mentoring process change for the enhanced care intervention was more impactful than those of us from outside the system attempting to serve in this role. These internal change agents produced a level of organizational accountability from the change teams that our team could not. Additionally, support from an individual
who knows the internal workings and people in a specific clinic system appeared to be a
more effective way to promote change than our outside team could provide.

2. Although not requested by the study team, clinical champions at both intervention clinic
agencies independently developed workflow diagrams regarding the clinical approach to
participants based on the type of visit (ie, planned asthma visit vs asthma being
discussed in the context of a visit for another reason). Without collaboration, these
diagrams were remarkably similar.

Because of a recruitment lag, we added 3 control clinics that were not exposed to the
enhanced care intervention during the study period to meet our study sample targets. These
clinics were additional sites from HP. The clinics neighbored those areas already served,
encompassing a similar geography and patient mix.

As mentioned previously, the EHR-based process measure dose analysis had to be
abandoned because of data validity concerns.

The study was overseen by the University of Washington IRB, which reviewed and
approved standard modifications and annual status reports. There were no major modifications
or concerns.
RESULTS

Participants

We contacted 1495 potentially eligible participants, of whom 415 (28%) were not eligible for the study, 413 (28%) declined to participate, 116 (8%) were eligible but were not enrolled, and 551 (37%) were enrolled. Of the 415 who were not eligible, 278 reported no asthma or did not have frequent enough asthma symptoms, 43 had moved or planned to move outside King County, 28 had other serious medical conditions that were not suitable for participation, 20 were not in a participating clinic, 19 had a language barrier, 17 were not insured by Medicaid, and 10 were homeless.

Of the 551 participants enrolled, 273 were randomly assigned to receive CHW services and 278 were not. There were 285 patients who received clinical care at 4 practices nonrandomly chosen to deliver enhanced asthma care and 266 patients who received care at 9 practices delivering usual asthma care. This resulted in 133 participants being assigned to group 1 (usual care), 145 to group 2 (enhanced clinical care), 133 to group 3 (usual care plus CHW intervention), and 140 to group 4 (dual intervention: enhanced clinical care plus CHW). Exit interviews were completed by 484 (88%) participants, with 236 (86%) in the CHW intervention group and 248 (89%) in the non-CHW control group; concurrently, 253 (89%) were from enhanced clinics, and 231 (87%) were from nonenhanced clinics. These details are further shown in Figure 3.

Of the 67 participants who did not complete the exit interview, 42 were lost to follow-up, 23 were unable to schedule the exit interview when the study was closed, and 2 refused to continue the study during the intervention year.

Based on intervention assignment, there are 4 nonoverlapping study subgroups (group 1 = non-CHW/nonenhanced clinic, group 2 = non-CHW/enhanced clinic, group 3 = CHW/nonenhanced clinic, and group 4 = CHW/enhanced clinic). Figure 3 shows the study flow. Although we know which clinics the participants were assigned to, we do not know whether the
participant received the full enhanced clinical care intervention, and these cells have been left blank (*) in the diagram for that reason.

**Figure 3. G2P CONSORT Study Flow Diagram**

<table>
<thead>
<tr>
<th>Group</th>
<th>Grp 1</th>
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Abbreviations: CHW, community health worker; G2P, Guidelines to Practice; Grp, group; NA, not applicable.

*Grp 1 = non-CHW/nonenhanced clinic, Grp 2 = non-CHW/enhanced clinic, Grp 3 = CHW/nonenhanced clinic, Grp 4 = CHW/enhanced clinic.

*Limited data available, unable to report.

**Baseline Characteristics**

Table 4 presents the demographics and asthma control level at enrollment by study group for the 551 participants. Of those 551 participants, 53% were adults and 47% were children; 77% were non-White, and 88% were renters. Two-thirds had very poorly controlled asthma, and 42% had had at least 1 hospitalization or ED visit for asthma during the 12 months before enrollment. There were some significant differences at baseline between the study...
groups. Between the enhanced and nonenhanced clinics, a significantly higher percentage of participants from enhanced clinics were Black or were patients at NCH. The mean asthma symptom-free days at baseline was significantly lower among participants in the CHW group and in the nonenhanced clinic group than with their corresponding counterparts. Compared with those who completed the exit interview, participants who did not complete the exit interview were more likely to speak English or to be a patient at NCH.
<table>
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<th>Nonenhanced</th>
<th>Exit done</th>
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<td>70</td>
<td>67</td>
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<td>37</td>
<td>32</td>
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<td>Aged 18-74 y (n = 292)</td>
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<td>74</td>
<td>72</td>
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<tr>
<td>Aged 5-11 y (n = 172)</td>
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<td>4.4</td>
<td>4.6</td>
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<td>4.5</td>
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<tr>
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<td>4.9</td>
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<td>5.1</td>
<td>4.9</td>
<td>5.0</td>
<td>5.3</td>
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<tr>
<td>Aged 18-74 y (n = 292)</td>
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<td>5.4</td>
<td>5.5</td>
<td>5.5</td>
<td>5.5</td>
<td>5.5</td>
<td>5.6</td>
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<td><strong>Urgent health care use, mean</strong></td>
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<td>2.2</td>
<td>2.6</td>
<td>2.1</td>
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<td>2.3</td>
<td>2.9</td>
<td>2.6</td>
<td>2.9</td>
<td>1.7</td>
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<td>Aged 18-74 y (n = 292)</td>
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<td>2.1</td>
<td>1.4</td>
<td>1.8</td>
<td>1.6</td>
<td>1.7</td>
<td>1.8</td>
</tr>
<tr>
<td><strong>Had hospitalization or ED visit for asthma, %</strong></td>
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<td>40</td>
<td>44</td>
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<tr>
<td>Aged 18-74 y (n = 292)</td>
<td>39</td>
<td>44</td>
<td>35</td>
<td>33</td>
<td>46</td>
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<td>33</td>
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</tbody>
</table>

Abbreviations: ACT, Asthma Control Test; AQLQ, Asthma Quality of Life Questionnaire; C-ACT, Childhood Asthma Control Test; CHPW, Community Health Plan of Washington; CHW, community health worker; ED, emergency department; HP, HealthPoint; NCH, Neighborcare Health.

aThe difference between the groups is statistically significant (P < .05) between enhanced clinic intervention groups.
bThe difference between the groups is statistically significant (P < .05) between exit interview completers and noncompleters.
cFor either adults or parents of children.
dThe difference between the groups is statistically significant between CHW intervention groups.
Primary and Secondary Outcomes

We aimed to examine the independent effects of CHW and enhanced clinical care interventions as well as their joint effect (interaction of CHW and clinic type). We conducted intention-to-treat analysis using multiple imputations for the 67 participants with missing outcome data. Table 5 shows the unadjusted difference as well as the mixed-model results in the outcome measures between the intervention group and the control group at exit interview for both the CHW intervention and the enhanced clinic intervention. The enhanced clinic intervention showed no statistically significant effect on any outcome measured. We detail the results of the randomized CHW intervention below.

CHW Intervention

Among the mixed-effect models for all the outcome measures, none of the interaction terms between the CHW intervention and the enhanced clinic interventions was statistically significant, implying that outcomes were not further improved among the subset of patients receiving CHW services who also received asthma care at 1 of the 4 enhanced care clinics. One possible explanation is a low intervention effect of the enhanced clinical intervention, where an unknown number of study participants received enhanced asthma care in both the CHW and non-CHW intervention study groups. As a result, the interaction term was removed from all the mixed-effects regression models. The intervention effects for the CHW intervention and the enhanced clinic intervention were evaluated in the same model, adjusting for prespecified potential confounding factors at baseline, including the outcome measures at baseline, age, sex, race/ethnicity, and education level as well as the clinic cluster effect among the 13 participating clinics.

The prespecified primary outcomes include asthma-related symptom-free days during the past 2 weeks, ACT score during the past 4 weeks, and AQLQ score during the past week.

Based on the final model, although there were statistically significant CHW intervention effects on asthma symptom-free days (mean, 1.27-day improvement), ACT score (1.2-unit
improvement), and AQLQ score (0.39-unit improvement), these differences in ACT and AQLQ scores did not meet the published standards for an MCID.

The CHW intervention effect was also statistically significant on all of the 5 secondary outcome measures. In particular, nocturnal awakening because of asthma during the previous 2 weeks was 1.22 nights fewer in the CHW intervention group than in the control group; asthma-related urgent care use during the previous 12 months was 0.63 fewer events in the CHW intervention group than in the control group.

To control for multiple comparisons, we performed the Holm-Bonferroni correction separately for the 3 primary outcome measures and the 5 secondary outcome measures (Table 3). After the correction, the intervention effects for all 3 primary outcome measures remained statistically significant. For the 5 secondary outcome measures, however, only nocturnal awakening and missed workdays/school days remained significant.
Table 5. End Point Intervention Outcomes for the CHW Intervention

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<th>CHW intervention</th>
<th>Enhanced clinic intervention</th>
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<tr>
<td></td>
<td>Unadjusted mean (SD)</td>
<td>Adjusted difference</td>
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<td>CHW</td>
<td>Non-CHW</td>
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<tr>
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<td>16.9 (5.0)</td>
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<tr>
<td>AQLQ/PAQLQ score</td>
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<td>5.1 (1.4)</td>
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<td></td>
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<tr>
<td>No. of nocturnal awakening nights</td>
<td>2.5 (3.9)</td>
<td>3.8 (4.9)</td>
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<tr>
<td>Urgent-care use</td>
<td>1.1 (2.7)</td>
<td>1.7 (3.5)</td>
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<tr>
<td>β-agonist use</td>
<td>3.6 (4.7)</td>
<td>4.6 (5.4)</td>
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<tr>
<td>Oral steroid use</td>
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<td>0.5 (1.3)</td>
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<tr>
<td>No. of missed workdays/school days</td>
<td>0.6 (2.1)</td>
<td>1.1 (2.8)</td>
</tr>
</tbody>
</table>

Abbreviations: ACT, Asthma Control Test; AQLQ, Asthma Quality of Life Questionnaire; C-ACT, Childhood Asthma Control Test; CHW, community health worker; ENH, enhanced; MCID, minimal clinically important difference; PAQLQ, Pediatric Asthma Quality of Life Questionnaire.

Unadjusted mean is for participants in the study group who completed the exit interview. The MCID for the ACT/C-ACT is 3.0 and for AQLQ is 0.5.

P value remains significant after Holm-Bonferroni correction.
Heterogeneity of Treatment Effects

To examine the heterogeneity in the CHW intervention effect, we examined the interaction term between each of the 3 primary outcome measures and asthma control level at baseline, adults vs children, age groups, sex, race/ethnicity, and education level in separate mixed models. The only significant interaction term was age group on ACT score, in which those aged ≥65 years had a significantly higher coefficient. Stratified analysis showed that for participants <65 years of age, the CHW intervention coefficient was 0.8 (95% CI, −1.0 to 1.8) and $P = .093$. For participants aged ≥65 years, the coefficient was 3.0 (95% CI, 1.5-4.7) and $P = .000$, suggesting that the intervention was more effective among older participants. None of the other variables examined for any of the primary outcome measures showed a significant interaction.

Process and Feasibility Evaluation

As part of the midpoint evaluation, we conducted interviews with staff involved in the delivery and management of asthma care for G2P. This involved one-on-one interviews with the medical directors of the participating clinics and representatives from the 2 participating health plans. The medical directors and health plan representatives were integrally involved in developing and implementing the G2P care and intervention activities. Questions asked of them included their assessment regarding changes in administrative burden and processes of care related to asthma as a result of G2P; scalability; and how/what kind of information is conveyed between the clinics, health plans, and CHWs. We also conducted group interviews with the asthma clinic teams at HP and NCH and with the CHWs based at PHSKC. The purpose of these interviews was to gather feedback on how well asthma processes were being rolled out and received by study participants and to identify areas for technical assistance, suggestions for improvements, and ways to integrate enhanced asthma care into existing processes.

Interviews were analyzed using thematic analysis, a widely used form of qualitative analysis. Thematic analysis requires that the researchers read each transcript and begin to record themes (or patterns of responses) within the transcribed data. Themes are recurring comments that are identified across data sets (in this case, qualitative transcripts) that are
associated with a specific research question (eg, CHW communication with clinic staff). We looked for consistency—the equivalent of interrater reliability—between the 2 qualitative researchers to reduce errors in thematic analysis and assigned codes. Each researcher read through each of the transcripts and coded relevant themes that followed the content of the interview questions. For example, we coded all interview responses regarding CHW communication with clinic staff to identify recurring experiences and descriptions of the type and quality of the interactions.

Key themes expressed by the clinical teams and medical directors were a generally positive attitude toward G2P and enhancements in asthma care as a result of G2P. Some clinicians said that they were already implementing aspects of the Planned Asthma Change Package, such as asthma education, but the intervention brought components together in a more cohesive, systematic way. Apart from frustrations regarding technical issues with the EHR template and spirometry setup, clinic staff expressed the value of integrating spirometry into asthma health care visits and using the output as a visual tool in conjunction with an action plan to explain progress and next steps to patients. The primary benefits noted by staff at both clinics were improved integration of the asthma action plan into the clinical encounter, training in and regular use of spirometry, and inclusion of CHWs in patient care. Staff provided suggestions for improvements in timing of trainings (eg, spirometry, allergy testing), troubleshooting equipment, and EHR template interface use. One challenge noted was staff turnover. Staff also expressed a need for clarity of expectations for each role within G2P to allow for an improved transfer of information about the study and its expectations for new staff.

With respect to the health plans, the representative indicated that G2P enabled them to build on existing practices and momentum around improving asthma care. Both plans already had set referral plans for asthma patients. However, they indicated a desire for more opportunities to share information with clinics about additional resources available to patients with asthma. They also expressed appreciation for the value added by CHWs in providing
preventive asthma care. One plan conducted an informal cost assessment and found that their asthma patients who had an assigned CHW showed improvements in health and lower costs.

Despite the appreciation the clinic and health plan staff had for the CHWs and their work, there was relatively limited direct communication between CHWs and clinics or health plans. Both the clinics and CHWs provided suggestions on how to improve communication between them regarding patients, including CHWs joining asthma clinic team meetings, as appropriate, and CHWs using the EHR to provide helpful notes to providers.

Several of the recommendations presented during the in-depth interviews included a need for increased CHW–clinic-health plan communication frequency and effectiveness. For example, both CHWs and clinic staff noted that CHWs could be better incorporated into asthma clinic visits. It was agreed that clinics would invite CHWs periodically to attend clinic team meetings. CHWs noted that they could find ways to better inform the clinics about the environmental and social factors affecting patient health based on what they were hearing during home visits and that this would require more frequent communication with the clinic liaison. Toward the latter part of the G2P study, staff and CHWs focused on increasing opportunities for this type of 2-way communication through the EHR common management template as well as via phone calls and direct visits. Although EHR communication was demonstrated to be feasible by the end of the intervention period, establishing these communication channels took longer than anticipated for various reasons. Finally, health plans met with CHWs to communicate what they had to offer to G2P participants in an effort to assist CHWs in accurately relaying this information to patients.

Following the CHW focus group, the evaluators summarized and shared key themes and concerns from the discussion with PCORI staff. Staff outlined action steps they would take to address CHW concerns and suggestions. For example, CHWs requested additional information about why certain questions on the home environmental checklist were being asked so they could better respond to patients’ concerns about the questions. Project staff reviewed the purpose of the questions with CHWs, such as knowing whether a particular participant would benefit from weatherization or mold remediation. CHWs mentioned that they would find it
helpful to have clear information about what health plans offer in terms of resources (eg, assistance with case management or relocation expenses) so they could share this with clients.

In response to this request, G2P staff developed a written resource clarifying the types of resources or assistance that health plans could offer their patients. In addition, CHWs wanted more education and information about certain home environmental triggers, such as mold.

Project staff arranged for a presentation from staff in environmental health at PHSKC to discuss mold remediation and code enforcement and to answer related questions. These types of midcourse corrections strengthened the project and demonstrated openness among program staff to CHW suggestions.

RE-AIM

Referring back to Table 2, Table 6 outlines lessons learned from our study within the RE-AIM framework.
Table 6. RE-AIM Framework: Lessons Learned

<table>
<thead>
<tr>
<th>RE-AIM dimension</th>
<th>Measured by</th>
<th>Examples of what we learned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reach the intended population</strong></td>
<td>• Participation rate among those eligible</td>
<td>• We achieved a high response rate (75% agreed to participate) and a low attrition rate; there were no significant demographic differences between participants and nonparticipants.</td>
</tr>
<tr>
<td></td>
<td>• Representativeness of participants compared with nonparticipants based on demographics</td>
<td></td>
</tr>
<tr>
<td><strong>Effectiveness of intervention activities</strong></td>
<td>• Impact on asthma-related health outcomes and QOL</td>
<td>• Participants identified CHWs, health education, home cleaning information, and assistance with medications as some of the most helpful elements of the project in controlling asthma.</td>
</tr>
<tr>
<td><strong>Adoption of intervention by staff, settings, institutions</strong></td>
<td>• Characteristics of clinics participating in enhanced care vs not participating</td>
<td>• The 4 intervention clinics (settings) were not chosen randomly, eliminating our ability to compare outcomes and reframing this intervention as a feasibility study.</td>
</tr>
<tr>
<td><strong>Implementation consistency, costs, and adaptations</strong></td>
<td>• Fidelity to intervention protocols</td>
<td>• For enhanced clinic activity implementation, clinic staff identified operational challenges, such as staff turnover; shifting agency priorities; and varied exposure to different intervention elements because of differences in clinic EHRs, asthma team rollout, and implementation inconsistencies.</td>
</tr>
<tr>
<td></td>
<td>• Variations in clinic EHRs, asthma team rollout, and implementation inconsistencies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The “Implementation of Study Results” section describes, in detail, the set of recommendations for increasing fidelity to intervention protocols.</td>
<td></td>
</tr>
<tr>
<td><strong>Maintenance of intervention activities</strong></td>
<td>• No. of settings where intervention components will continue</td>
<td>• Although intervention clinics indicated interest in continuing clinic and practice enhancements, it is too early postfunding to assess the depth and breadth of maintenance.</td>
</tr>
<tr>
<td></td>
<td>• CHWs received additional gap funding (secured by G2P staff) to continue their efforts on asthma education and outreach.</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CHWs, community health workers; EHRs, electronic health records; G2P, Guidelines to Practice; QOL, quality of life; RE-AIM, reach, effectiveness, adoption, implementation, and maintenance.
DISCUSSION

Context for Study Results

The major goal of this study was to test the health impact of an asthma CHW home-visit model in a prospective RCT and to assess the feasibility of coordinating this CHW intervention with a clinical team trained to deliver planned, preventive asthma care. We demonstrated statistically significant improvements across multiple other health outcomes among patients randomly assigned to receive CHW services, findings that have been demonstrated in prior studies. However, scores on 2 of the 3 primary outcome measures, the ACT/C-ACT and the AQLQ/PAQLQ, failed to meet the published MCIDs in this hard-to-reach population.\(^{63,64}\)

Despite limitations in delivering and measuring the enhanced clinical care intervention, coordinating CHW and clinical services was both feasible and acceptable. At the end of the intervention period, the CQI component of this intervention was still gaining momentum and, in some cases, continues to do so.

Evidence for the CHW and Clinic Interventions

The CHW model provides an effective, culturally competent approach to delivering skills training to help people with asthma achieve illness control, including asthma knowledge, medication use, and trigger reduction. This model is well suited to our ethnically diverse, low-income population.\(^{14-18,44-49}\) Systematic reviews of home-based multitrigger, multicomponent interventions for asthma demonstrate strong evidence of their effectiveness.\(^{54-57}\)

The evidence for clinic-focused interventions was recently summarized in a systematic review released in May 2013.\(^{58}\) The largest effect sizes with the strongest supporting evidence were found for decision support, audit and feedback, and clinical pharmacist support. The CCM is also a widely used approach to redesign. A recent study found a strong, dose-dependent association between the degree of model implementation and patient adherence to inhaled corticosteroids.\(^{59}\)
Generalizability of the Findings

We demonstrated an improvement in some asthma health outcomes among patients randomly assigned to the CHW home-visit intervention, a finding that has been demonstrated in prior tests of the model.

Our CHW home-visit model appears to be generalizable to low-income populations with asthma in urban or suburban settings of King County, Washington, and may be generalizable to other urban/suburban communities in the United States. However, our community has had significant interest over 2 decades in working together to deliver an asthma CHW intervention and may represent a best-case scenario. As such, the statistical differences we demonstrated may not be demonstrable in other settings with new or still-maturing programs.

In summary, the model has been shown to improve some health outcomes in people with asthma, and it warrants consideration at multiple levels, such as clinic systems and managed care organizations, particularly those serving Medicaid clients. The health impact of a fully implemented coordinated care model (CHW plus prepared clinical team) warrants further study. Once established, however, the coordinated CHW/practice model was feasible and well received by practice stakeholders at the conclusion of the intervention period. Though implemented late in the intervention, the preventive asthma EHR template then served as a communication tool between the CHW and provider teams. Both HP and NCH continue to implement the planned asthma health care model throughout their organizations, facilitated through use of this EHR tool. Bridge funding from the Kaiser Family Foundation enabled a feasibility study of provider-initiated referral of poorly controlled asthma patients (aged 5-75 years) for CHW home-visit services, including written feedback to the referring provider. This program has proven to be both feasible and highly used by both primary care and specialty providers.

Our coordinated CHW model is generalizable to low-income populations with asthma in the urban or suburban settings of King County, Washington. The increased travel resources required for CHW home visits in remote or rural settings would also increase the cost of the intervention.
Implementation of Study Results

As mentioned previously, the coordination of enhanced clinical care and CHW home-visit services was feasible and well received, continues to be implemented at both NCH and HP, and required navigating a variety of challenges. When implementing this model in additional clinic systems, there are several lessons learned to carry forward:

1. An explicit plan should be developed for within-practice implementation of a preventive Planned Asthma Change Package (ie, a set of preventive care processes) that targets all of a practice’s patients with poorly controlled asthma, not just those seen by the core “change team.” Once this change team is delivering planned asthma care, there are different approaches to accomplishing the aim of scaling planned preventive asthma care to all patients seen at a practice that has multiple providers. For example, the change package could be disseminated to all provider teams at the practice. Alternatively, ≥1 provider teams, as a subset of the practice, could be charged with providing planned, preventive asthma care, with the potential to expand preventive care to patients with other chronic conditions.

2. Practice teams need to be prepared for integrating their planned care with the home-visit services of CHWs. This involves setting clear expectations regarding EHRs or other modes of communication (establishing to whom, how, when, and why these communications are made) and expectations for feedback between the provider team and the CHW.

3. CHWs, in turn, also need clear expectations for communication with the provider team, appropriate supervision and mentoring regarding messages delivered, training in the use of the particular EHR system or other communication method (eg, secure email or faxes) used by the clinic system, and proper clearances for having limited access to their patients’ records. In our case, the CHWs had access to 2 pages in the preventive asthma template: (1) the common management plan page (see the “Process and Feasibility Evaluation” section) for communication between the CHW and provider teams and (2) the airborne trigger exposure page, enabling entry of findings from their home environmental assessment, 1 part of the home-visit protocol.

4. Explicit plans for use of a preventive asthma template for the practice EHR system should be made. Capabilities should include decision support, population-level monitoring and metrics, and the template’s use as a referral and communication tool for the CHWs. In our opinion, this is the only way to fully integrate planned care for asthma or any chronic condition. If being built from scratch, as in our case, there should be
explicit plans for revision cycles. For these inevitable upgrades, input should be sought from both provider teams and CHWs, their supervisors, and other users. Staff should receive proper training and hands-on practice before going live with new templates, both initially and ongoing, fully anticipating staff turnover and software revision cycles.

5. In our experience, our proposed practice changes were incorporated more smoothly when an internal facilitator employed by NCH and HP became responsible for monitoring and supporting the proposed practice changes. At 1 practice network, a clinician played this role, and at the other, a nonclinician administrator. In both cases, these individuals were effective change agents with whom we worked closely.

Efforts at further elucidating and promulgating this model are underway. As mentioned, both NCH and HP continue dissemination of planned asthma care throughout their primary care sites and school-based clinics.

Historically at the PHSKC asthma CHW program, patients have been recruited for CHW home-visit interventions by study staff, drawing from practice- or plan-generated lists. For real-world implementation, identification of patients eligible for CHW services needs to be driven by clinicians, including primary care providers, specialists, emergency medicine physicians, and hospitalists. A bridge grant from the Kaiser Family Foundation of Washington enabled us to explore different models of clinician-driven referrals for CHW home-visit services. The goal of this project, called Clinic Home Connections, was to assess how different safety-net practice settings seek and coordinate a CHW home-visit model for asthma care. We established working relationships with primary care sites, specialists, and hospitalists.

Washington State is the recent recipient of a Section 1115 Medicaid waiver, 5 years of federal support to waive current reimbursement rules and test new models of care. Based on our PCORI-funded work, we proposed building a system of CHWs to deliver home visits and coordinate their care with practice teams, serving patients with 4 chronic conditions in 2 bundles: (1) asthma and COPD and (2) cardiovascular disease and diabetes.

Working in real-world clinical systems brings a variety of challenges and barriers. The so-called tyranny of the urgent has been discussed previously. Additional examples include the competing needs of patients with other acute or chronic illnesses; expectations for patient
volume (visits are often 15 minutes); frequent staff and provider turnover (estimated annual turnover is 25% at one of the clinical networks we worked with); and frequent lack of support beyond the clinical setting, such as support for informatics, data management, and technical assistance.

Subpopulation Considerations

As mentioned in the Background section, the prevalence and morbidity burden of asthma is disproportionately borne by low-income and racially/ethnically diverse populations, differences that are persistent and profound. Poverty, in turn, is associated with other social determinants of health, such as substandard housing and air quality, that affect asthma morbidity directly or indirectly.

Certain populations, particularly lower-income groups and communities of color, may struggle to meet basic needs that compete with prioritizing their own or their child’s asthma care. Given that our study sample was limited to participants receiving Medicaid, study participants either had low income and/or were receiving disability payments. In addition, the vast majority of participants were non-White (approximately 77%), with a quarter of participants needing non–English-language CHW supports (19% Spanish, 8% Somali). Qualitative data from participating clinical staff and medical directors highlighted the added value they observed among study participants from culturally and linguistically tailored asthma education; service referrals; social support provided by CHWs; and the improved processes of planned, preventive asthma care within their clinic systems.

Our study population lived in substandard housing conditions more often than not. Our CHW staff were able to provide services in 3 languages, English, Spanish, and Somali. Although the intervention is tailored to patients’ specific life circumstances, there are many common intervention goals. One goal involves identifying and fixing or mitigating these indoor environmental problems, including advocacy with landlord involvement, when indicated. The 3 CHW home visits each typically last between 1 and 2 hours. Taking the time for teaching, self-management support, coaching about how to have a productive clinic visit, setting goals for behavior change, and addressing other competing life issues are key goals of the CHW
protocols. These CHW intervention components directly address the root causes of asthma health care disparities.

Study Limitations

There were 9 main limitations with the study’s interventions.

1. Because the clinics were chosen nonrandomly by leadership, efforts made by the change teams in our practice sample may not be generalizable to all practices without a clinical champion who is enthusiastic about asthma-focused practice change. In addition to having an enthusiastic champion, clinics were chosen that had the support of the site medical director and were not struggling with acute staffing shortages, high staff turnover, or known internal conflicts and therefore were stable enough to accommodate the major effort in practice change that the Planned Asthma Change Package required.

2. The uptake of the Planned Asthma Change Package by providers beyond the identified change team (ie, practice-wide spread) took longer than anticipated. Embedding the practice changes, including completion of the EHR asthma template, was incomplete at the time that the study ended.

3. We have not been able to obtain care metrics from the EHR system for closer inspection of which care elements were received by which participants. Working in real-world clinical systems brings a variety of challenges and barriers. Examples include the competing needs of patients with other acute or chronic illnesses; expectations for patient volume (visits are often 15 minutes); frequent staff and provider turnover; and frequent lack of support beyond the clinical setting, such as support for informatics and technical assistance.

   Fundamentally, QI teams like ours from an outside organization are guests in a busy house. Everyone involved has to make accommodations when implementing significant practice changes, goodwill needs to be preserved, and gentle persistence must be applied consistently. For these reasons and others, QI efforts typically take longer than anticipated.

4. Seasonality is a well-recognized issue for asthma health services research. The competing challenges faced by this hard-to-reach population played out in our attempts to schedule exit interviews within the specified time frame. Of participants who completed the study, 70% were interviewed in the same season that they began
participating in the study. The 30% who were not may have introduced a seasonal bias to our results.

5. As mentioned in the “Generalizability of the Findings” section, our community has had significant interest over 2 decades in working together to deliver an asthma CHW intervention and may represent a best-case scenario. As such, the effectiveness we demonstrate may not be demonstrable in other settings with new or still-maturing programs.

6. The CHW staff did most of the study recruitment and data collection. Many researchers prefer to have specific staff deliver the intervention and to have other research project staff more objectively collect the baseline and exit surveys to minimize bias. Our approach of using the CHWs in this process is consistent with our previous studies. There are some potential biases, which can go in multiple directions. Here we consider a few. The CHWs perform most of the recruitment screening calls. Their innate ability to build trust and work across cultures may result in a wider range of study participants than a more typical research approach would. The CHWs were intensively trained in research practices and delivery of standard measures. Data collection was supervised and audited for quality control. Although the baseline survey was less likely to be biased, we sent a different staff member or CHW to the exit interview whenever possible.

7. There was relatively little communication between the CHWs and the enhanced care practice teams, despite our attempts to promote this communication.

8. A nonrandomly chosen portion of patients receiving CHW services also received their care at the 4 enhanced care practices, thereby confounding the results of the CHW intervention.

9. Finally, we abandoned the results of the enhanced vs nonenhanced clinic groups because of the study design flaws reported earlier.

Future Research

Methods for coordinating the asthma CHW home-visit model into other clinical systems of care is of great interest, and it is the current focus of our ongoing research. The goal of our Kaiser Family Foundation bridge project, Clinic Home Connections, was to gain an understanding of how different practice settings refer to and coordinate care with a CHW
home-visit model for asthma care. We received referrals from a variety of safety-net primary care sites, 1 hospital, and 1 asthma specialty clinic.

We are also interested in ways to prepare the CHW model for greater dissemination and scaling. The Medicaid waiver work mentioned previously may bring the challenge and opportunity to develop, test, and integrate a CHW model specifically for 3 other target conditions beyond asthma: COPD, diabetes, and cardiovascular disease.
CONCLUSIONS

We found a statistically significant CHW intervention effect across 8 health outcome measures (3 primary and 5 secondary), although the size of the differences in 2 primary outcomes (ACT and AQLQ scores) failed to meet the MCIDs published in the literature. The coordinated CHW/enhanced clinical care model, once established, was feasible and well received by practice stakeholders. More work needs to be done to fully understand the barriers and potential benefits of this coordinated care model.

The CHW model has a well-established evidence base and has already been replicated in other US cities based on the protocols developed through PHSKC, which are publicly available on the PHSKC website (https://kingcounty.gov/depts/health.aspx). Our findings and these resources should be useful to any decision-makers in search of a way to better treat patients with uncontrolled asthma, particularly those living in poverty. Interested stakeholders may include leaders and policy makers from local and state health departments, Medicaid health plans, and school districts.

Once enabled, the preventive asthma EHR template, which served as a communication tool between CHW and provider teams in the G2P study, should be replicated in other EHR systems. Both HP and NCH continue to implement the planned asthma health care model throughout their organizations, facilitated through use of the planned asthma EHR template. The Kaiser Family Foundation bridge grant, mentioned previously, enabled us to explore different models of clinician-driven referrals for CHW home-visit services, a fundamentally different approach from our typical recruitment by study staff.

Consideration should also be given to the challenges and time needed to conduct practice-based QI work.
REFERENCES


RELATED PUBLICATIONS

ACKNOWLEDGMENTS

The core of this programming and work was done by CHWs who, if evenly spread, met with a new participant in their home every other day of their workday for 2 years. However, that does not speak to the volume of repeated visits, phone calls, clinic visits, and other efforts these women put into supporting the care of the study participants and their families. The work is difficult, engaging with people in new environments through all sorts of obstacles, including traffic, weather, long days, and long weeks. Michelle Di Miscio, Joyce McCraney, Safia Mohammed, and Maria Rodriguez provided continuous service, with no turnover and tireless efforts to make this all possible. The work is both physically and emotionally demanding. Thus, second to the CHWs, we must thank Penny Brewer, who provided professional development training on motivational interviewing but, more importantly, made sure that self-care was always an essential component of our work. In addition, Shannon Roosma-Goldstein, RN, was instrumental in providing clinical supervision and continued support for the team. Without the commitment of these 6 individuals, the intervention and improved health outcomes would not have been possible.

Countless others who provided care in the clinics and at the health plans may not receive recognition for the important work they did to contribute to asthma care throughout this program and its continued implementation in the workflows at our stakeholder organizations. We thank their medical directors, QI managers, and asthma champions, but there are so many other primary care team members and health plan care managers who need to be acknowledged; unfortunately, we are unable to do that individually.
APPENDICES

Appendix A. Glossary

ACT – Asthma Control Test
AQLQ – Asthma Quality of Life Questionnaire
C-ACT – Childhood Asthma Quality of Life Questionnaire
CCM – Chronic Care Model
CHW – Community Health Worker
CQI – Clinical Quality Improvement
DSMB – Data Safety Monitoring Board
EHR – Electronic Health Record
FQHC – Federally Qualified Health Center
HEPA – High-Efficiency Particulate Air
MCID — Minimal Clinically Important Difference
PACE — Physician Asthma Care Education
PAQLQ— Pediatric Asthma Quality of Life Questionnaire
PHSKC— Public Health Seattle King County
Appendix B. Planned Asthma Change Package

1. Planned, preventive asthma visits, frequency based on severity: (EHR)
   Intermittent: Annually
   Mild persistent: Twice a year
   Moderate persistent: Three times a year
   Severe persistent: Four times a year (often shared with a specialist)

2. Spirometry performed (Claims, EHR) (PROCESS AND OUTCOME MEASURE FOR RUN CHART)

3. Asthma Control Test (ACT) performed (PROCESS AND OUTCOME MEASURE FOR RUN CHART)

4. Severity assessment performed (EHR) (Spirometry, ACT, steroid “burst” history)

5. Control assessment (EHR) (Spirometry, ACT, steroid “burst” history)

6. Objective measure of allergic sensitivity (Claims and EHR)

7. Flu vaccine in past year. (Claims)

8. Appropriate prescribing of controller meds:
   Any level of persistent asthma should be associated with a controller medication prescription (almost always inhaled corticosteroids) (EHR)

9. Written asthma action plan created, or reviewed, or updated (EHR)

10. Communication with Community Health Worker (CHW) as needed. (EHR)
Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgment:
Research reported in this report was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#AS-1307-05498). Further information available at: https://www.pcori.org/research-results/2013/examining-home-visits-community-health-workers-help-patients-manage-asthma