ORIGINAL RESEARCH

Protocol for the asthma tools study: a pragmatic practice-based research network trial

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Background: Asthma is common among children, adolescents, and adults. However, management of asthma often fails to follow evidence-based guidelines. Control assessments have been developed, validated against expert opinion, and disseminated. However, in primary care, assessment of control is only one step in asthma management. To facilitate integration of the evidence-based guidelines into practice, tools should also guide the next steps in care. The Asthma APGAR tools do just that, incorporating a control assessment as well as assessment of the most common reasons for inadequate and poor control. The Asthma APGAR tool is also linked to a care algorithm based on the 2007 National Heart, Lung, and Blood Institute asthma guidelines. The objective of this study is to assess the impact of implementation of the Asthma APGAR on patient asthma outcomes in primary care practices.

Methods: A total of 1400 patients aged 5–60 years with physician-diagnosed asthma are enrolled in 20 practice-based research network (PBRN) practices randomized to intervention or usual care. The primary outcomes are changes in patient self-reported asthma control, asthma-related quality of life, and rates of exacerbations documented in medical records over the 18–24 months of enrollment. Process measures related to implementation of the Asthma APGAR system into daily care will also be assessed using review of medical records. Qualitative assessments will be used to explore barriers to and facilitators for integrating the Asthma APGAR tools into daily practice in primary care.

Discussion: Data from this pivotal pragmatic study are intended to demonstrate the importance of linking assessment of asthma and management tools to improve asthma-related patient outcomes. The study is an effectiveness trial done in real-world PBRN practices using patient-oriented outcome measures, making it generalizable to the largest possible group of asthma care providers and primary care clinics.

Keywords: asthma, asthma control, asthma management, primary care, pragmatic research, practice-based research, protocol

Introduction

Asthma affects as many as 18% of US children by the age of 18 years and 5% of adults, with another 5% of children and adults reporting exercise-induced asthma.[1–7] Asthma is the 15th most common condition seen by family physicians,[8] and the majority of the 11.9 million annual asthma-related medical visits are made to primary care physicians.[2,3,9–11] Asthma is associated with significant morbidity and mortality,[3,12–16] much of which could be prevented[17–19] by broader implementation of the four major tenets of the 2007 National Heart, Lung, and Blood Institute (NHLBI) asthma guidelines.[20–28] These tenets include accurate diagnosis, appropriate treatment, ongoing

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monitoring and assessment, and developing partnerships between health professionals and families.[29–34] Simple tools have been developed to monitor asthma control.[35–45] However, none of the control scores recommended in the US guidelines are linked to the next steps of asthma care.[7,21,43,46–49]

Asthma is a chronic inflammatory disease with overlying acute episodes of increased inflammation and bronchoconstriction.[18] Determining how to specify, address, and prevent the inflammation of asthma better is the major therapy question, while the translational question of most importance is how to facilitate, operationalize, systematize, and integrate guideline-directed care into everyday practice.[7,43,46–48,50,51]

Assessment of asthma "control" requires knowledge of the patient's symptom burden, eg, daytime and nighttime symptoms and need to modify activities. Primary care medical records consistently lack this information.[7,43,46,47,50,52] Existing highly promoted control assessments collect the information to assess control.[21,22,46,47,52] The control assessments leave the patient labeled as in or out of control and may predict future exacerbations, but provide no further guidance related to therapy. Primary care physicians need systems and tools to guide daily practice and not just to label or risk-stratify patients.

Therefore, asthma remains an important target for translational studies and testing of tools that facilitate all four of the NHLBI's major tenets of asthma care.[18] The Asthma APGAR system uses tools developed, validated, and demonstrated to work in primary care practices. This multicomponent system includes audit with feedback and patient-reported signs and symptoms, as well as information on adherence, triggers, and response to therapy in a system that allows flexibility and adaptability in implementation.[54,55] This clinical trial assesses the effectiveness of the Asthma APGAR system[54] in primary care, focusing on patient-oriented asthma outcomes. The trial is being done at community practice-based research network (PBRN) primary care sites to enhance the generalizability of the results while maintaining adequate internal validity.[56–60]

Materials and methods
Overview
This is a pragmatic, randomized, controlled effectiveness trial (Figure 1) of a practice system change for asthma evaluation and management and is now presently underway in 20 family medicine and pediatric practices (all members of the PBRN). Randomization was 1:1 (intervention to usual care) and stratified by residency status (yes or no) and type of practice (pediatric or family medicine practice). A total of 1400 patients are to be enrolled. The primary outcomes will be changes in self-reported asthma control, self-reported quality of life, and rates of asthma exacerbations documented by medical records. Secondary outcomes are care process measures, including documentation of asthma control, education on or review of inhaler technique, and assessment of adherence during clinic visits. Exploratory outcomes will be assessed using qualitative methods (semistructured interviews) to explore factors associated with the feasibility of implementing Asthma APGAR tools in the intervention practices.

The intervention consists of a facilitated practice systems change to integrate the Asthma APGAR tools into daily management of asthma. The Asthma APGAR tools address five domains critical to the tracking, assessment, monitoring, and management of asthma (Table 1). The Asthma APGAR tools include: a five-question practice asthma care audit used to motivate, monitor, and report baseline asthma care processes (Figure 2); a patient-completed survey issued at all asthma visits to assess and track control as well as explore the most common reasons for lack of control (Figure 3A and B); and a care algorithm linked to the control, adherence, and trigger assessment using evidence from the 2007 NHLBI asthma guidelines (Figure 4). The algorithm incorporates both drug and nondrug management strategies, eg, stepped medication care, asthma education, and evaluation of inhaler technique. The intervention tools have been pretested and validated to change and sustain processes centered on the Asthma APGAR tools.[54] Use of the tools has been shown to facilitate guideline-adherent asthma care and should thereby improve patient outcomes.

Practices
The practices enrolled are members of the American Academy of Family Physicians National Research Network (http://www.aafp.org/nrn) or the American Academy of Pediatrics Quality Improvement Innovation Network (http://www.aap.org/en-us/professional-resources/practice-support/quality-improvement/Quality-Improvement-Innovation-Networks/Pages/Quality-Improvement-Innovation-Networks-QuIIN.aspx).

Inclusion criteria
- Practice located in a non-inner city or urban center with >250,000 population
- Practice includes 2–12 primary care clinicians
- Within the practice, 80% of all primary care physicians agree to participate in the project for three years
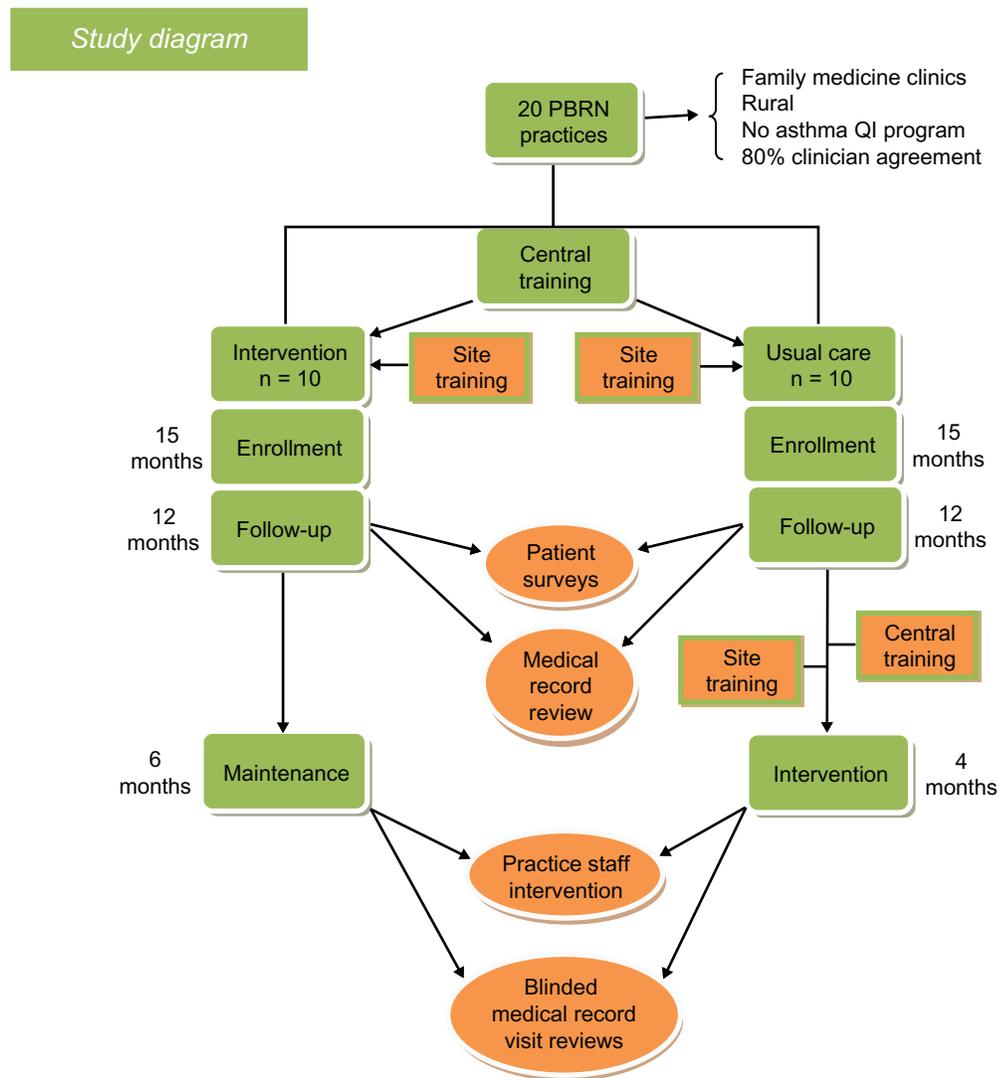
Figure 1 Study design.
Abbreviations: PBRN, practice-based research network; QI, quality improvement.

- Practice has had at least 100 patients aged 5–60 years making asthma visits in past 12 months
- Practice agrees to recruit at least 70 patients with asthma over the 15-month enrollment period of the study
- Practice is willing to sign an individual investigator agreement with the American Academy of Family Physicians institutional review board or have an affiliation with a local institutional review board.

Table 1 APGAR domains: essential elements

A (**A**ctivity limitation)
P (**P**ersistence of symptoms, day and night)
G (Tri**G**ger identification)
A (**A**dherence to medications)
R (**R**esponse to therapy)

Exclusion criterion
- Practice has been involved in any formal asthma care improvement program during the previous three years.

Each practice signed a practice agreement attesting to the support of the practice leadership and acknowledging the $1300 per year they would receive based on attaining specific enrollment goals and copying and mailing of medical records goals. Practices were not and could not be blinded to their randomization status. However, the patients who are enrolled will not know the randomization status of the practice they attend.

Patients
Patients are recruited in two ways, ie, as they are seen in the enrolled practices for a patient visit or by identification from an asthma registry and an invitation to come for an asthma checkup

Asthma APGAR Audit instructions

Please answer the following questions by looking at all visits during the past 12 months that include any comments about asthma. Complete this form including information from all asthma visits during the year. Mark "yes" if the information is present at least once during the year reviewed.

1. Are activity limitations documented in the chart? **Yes   No   Unsure**

(Examples are missed work or school days, missed activities. A listing of "no problems" should be marked as "unsure")

2. Are comments about the frequency of symptoms during the previous 2–4 weeks documented in the chart?

   Daytime symptoms?   **Yes   No   Unsure**

(Examples include wheezing every day for past month, coughing spells one or two days each week, wheezing only with running)

   Night-time symptoms?   **Yes   No   Unsure**

(Examples, wakes every night coughing, awakes with wheezing once a week)

3. Are triggers mentioned or documented in the chart?   **Yes   No   Unsure**

(Examples, had problems around friends' cats, only problems happened when uncle who smokes came to visit, will have patient see allergist for evaluation)

4. Are the asthma medications (specific names and dosage) and frequency patient is actually taking them documented?   **Yes   No   Unsure**

(Examples, taking inhaler once a day = no, using beta agonist most days = yes, taking medications as prescribed above = unsure)

5. Are the responses to treatment clearly listed so that you could decide whether to make changes or leave therapy the same?   **Yes   No   Unsure**

(Examples, no wheezing when taking meds = unsure, a lack of any comments = no, wheezing only when playing soccer = yes)

Calculate the percent of yes answers for each of the 6 elements. For example of 20 charts, five have activity limitations documented (25% for the A element).

Figure 2 Asthma APGAR audit.

and enrollment in the study. The enrollment process is the same for patients in an intervention or a usual care practice.

Inclusion criteria
- Patient is aged 5–60 years
- Patient has a physician diagnosis of asthma and a current prescription for an asthma drug
- Patient or parent agrees to complete the five study packets (baseline, and at 6, 12, 18, and 24 months after enrollment) and allow review of the enrollee's medical record by the central study team members.

Exclusion criteria
- Patient or parent is unable to read or speak English
- Patient has a concomitant diagnosis of cystic fibrosis, chronic obstructive pulmonary disease (COPD), or other chronic lung disease.

Children younger than 5 years of age are excluded to avoid the problem of diagnostic uncertainty often found in preschool children.[61,62] Adults over 60 years of age were also excluded because of concerns about COPD that has been misdiagnosed as asthma.[63] Treatment for cystic fibrosis, COPD, active tuberculosis, or other chronic lung disease is significantly different from that recommended for asthma, and inclusion of these patients could confound our results. Spirometry is not required because it is unlikely to be available in most of the primary care practices enrolled and because most asthma seen in primary care is diagnosed on the basis of symptoms and response to therapy.[64–66]

Study procedures
Site training

Two members from each practice (a lead study physician and a lead nurse) were brought together at a central site to intro-

A

A = Activities	P = Asthma plan
P = Persistent	L = Lung function
G = triGGers	U = Use of inhaler
A = Asthma medications	S = Steroids
R = Response to therapy	

APGAR PLUS

Please circle your answers:

A **1. In the past 2 weeks, how many times did any breathing problems (such as asthma) interfere with your ACTIVITIES or activities you wanted to do?**

   Never   1–2 times   3 or more times

P **2. How many DAYS ☼ in the past 2 weeks did you have shortness of breath, wheezing, chest tightness, cough or felt you should use your rescue inhaler?**

   None   1–2 DAYS   3 or more DAYS

3. How many NIGHTS ☾ in the past 2 weeks did you wake up or have trouble sleeping due to coughing, shortness of breath, wheezing, chest tightness or get up to use your rescue medication?

   None   1–2 NIGHTS   3 or more NIGHTS

G **4. Do you know what makes your breathing problems or asthma worse?**

   Yes   No   Unsure

- **Please circle things that make your breathing problems or asthma worse:**

   Cigarettes   Smoke   Cold air   Colds   Exercise   Dust   Dust mites

   Trees   Flowers   Cats   Dogs   Mold   Other: _____

- **Can you avoid the things that make your breathing problems or asthma worse?**

   Seldom   Sometimes   Most of the time

A **5. List or describe medications you've taken for breathing problems or asthma in the past 2 weeks: Remember you may use Nasal, Oral, or Inhaler medications.**

Breathing or asthma medication	When taken?		Reasons for taking medication:	Reasons for not taking medication:
	☐ Daily	☐ As needed		
	☐ Daily	☐ As needed		
	☐ Daily	☐ As needed		
	☐ Daily	☐ As needed		

R **6. When I use my breathing or asthma medicines I feel:**
   Worse   No different   A little better   A lot better

Figure 3 (*Continued*)

B

A = Activities **P** = Persistent **G** = triGGers **A** = Asthma medication **R** = Response to therapy	

For clinician use:

P = Asthma plan **L** = Lung function **U** = Use of inhaler **S** = Steroids

Activity follows up questions:
- What have you given up due to asthma?
- What would you like to do that you can't, because of asthma?

Persistence follow up questions:
- Has the frequency and severity of your daytime symptoms been similar over the last 2 months?
- Has the frequency and severity of your nighttime symptoms been similar over the last 2 months?

Medication follow up questions:
- Would you like to know the difference between rescue and controller medication? *Y/N/Unsure*

- Do you have or use a rescue medication? *Y/N/Don't know*
    - Show me medication or describe it.
    - How often do you use your rescue medication?

- What do you do when you feel you need a rescue medication? _____

- Do you have or use a prevention medication? *Y/N/Don't know*
    - Show me medication or describe it.
    - How often do you use your prevention medication?

- Demonstrate inhaler technique.

- Does the cost of your treatment affect your taking/buying asthma medication? *Y/N/Unsure*

Response follow up questions:

- Do you think your asthma therapy helps? *Y/N/Unsure*

- How often do you have to refill your rescue inhaler?

- Which ones help?
    - Avoiding triggers? *Y/N*
    - Rescue inhaler? *Y/N*
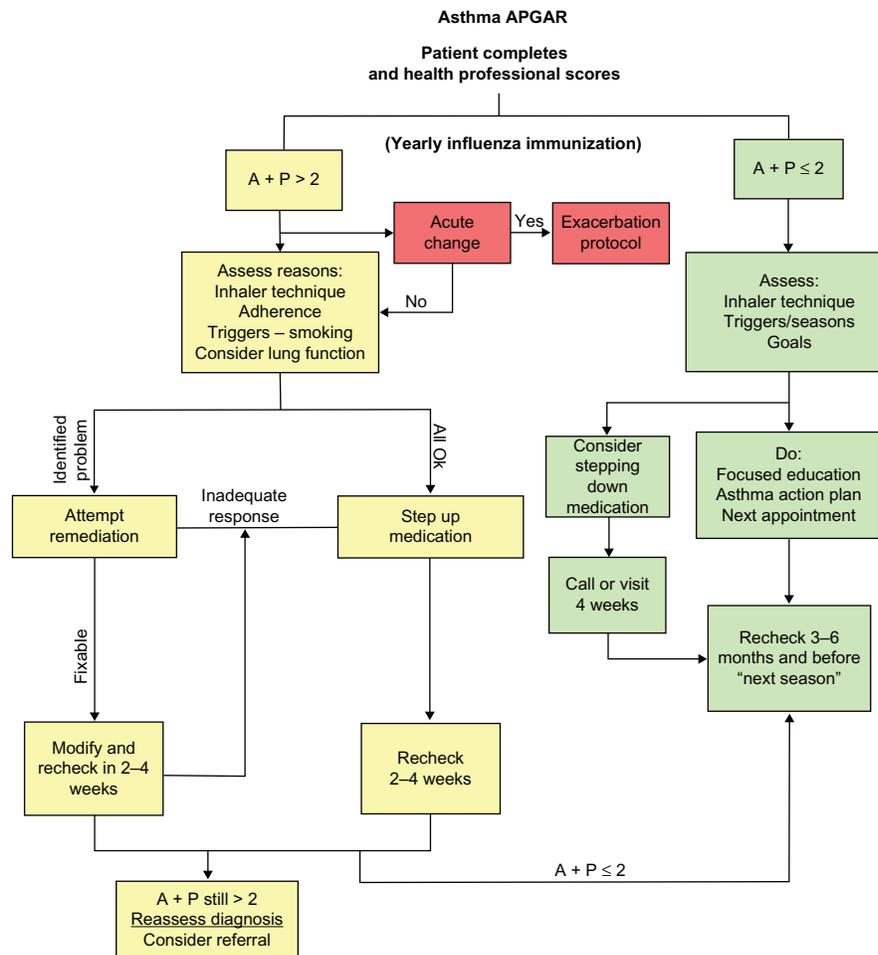   - Preventive medicines? *Y/N*
- What else helps your asthma?_____

Figure 3 Asthma APGAR Plus. (**A**) Front and (**B**) back of questionnaire.

duce the study procedures to all sites and the Asthma APGAR system to the intervention sites. Training on the study procedure lasted eight hours, beginning with a short overview of the 2007 NHLBI asthma guidelines. The remainder of the day focused on methods to identify asthma patients for potential enrollment, informed consent, tracking forms to assess enrollment and refusal rates, and methods (e-faxing and faxing) used to send study data to the central site. An opportunity to complete the required human subjects training was included.

The intervention site training continued with six hours of work on the next day. That time was used to introduce the Asthma APGAR tools and to discuss and demonstrate how they could be integrated into daily asthma care. Interaction methods included case presentations, discussion, and interactive brainstorming of ways to facilitate use of the Asthma APGAR. Because implementation of the intervention includes some flexibility, time was spent working with each practice team individually to discuss practice-specific implementation. Each team was provided with an arm-specific slide presentation designed to be used by the team leaders at an all-practice local study training session. The slides included a shortened version of the information presented during central

Algorithm

Asthma APGAR

**Patient completes
and health professional scores**

(Yearly influenza immunization)

A + P > 2

Acute change —Yes→ Exacerbation protocol

No

Assess reasons:
Inhaler technique
Adherence
Triggers – smoking
Consider lung function

A + P ≤ 2

Assess:
Inhaler technique
Triggers/seasons
Goals

Identified problem

All Ok

Inadequate response

Attempt remediation

Step up medication

Consider stepping down medication

Do:
Focused education
Asthma action plan
Next appointment

Fixable

Call or visit 4 weeks

Modify and recheck in 2–4 weeks

Recheck 2–4 weeks

Recheck 3–6 months and before "next season"

A + P ≤ 2

A + P still > 2
Reassess diagnosis
Consider referral

Figure 4 Asthma APGAR algorithm.
Abbreviations: A, activities; P, persistence.

training. The principal investigator for the study attended all of these local training sessions by telephone conference call to lend support and answer questions.

Implementation at intervention sites

Based on experience from previous work, introduction of the Asthma APGAR system in the intervention practices was accompanied by "motivational" work to improve practice engagement in the project. Each practice's current asthma care was evaluated using the Asthma APGAR audit which assesses the presence or absence of documentation in selected medical records of the elements required to evaluate asthma control (Figure 2).

These audit data were summarized, graphed, and presented to the entire practice staff as part of the local study training led by the site lead physician and nurse as described above. One goal of the sessions was to help the practices assess the strengths and gaps in asthma care before initiating the study. Strengths were discussed first.

By including discussion of what the practice does well, discussion appeared to begin more readily than when focusing first on gaps. When discussing gaps, invariably one or two clinicians pointed out they had done much more than was documented. These comments facilitated discussion on the purpose of the information documented in the medical record and its use, not only at the current visit but also during future visits to assess changes in asthma status over time. Guided discussion also addressed the potential value of the Asthma APGAR data elements (Figure 3A and B) in identifying reasons for inadequate control, such as the role of triggers, adherence, and medication failures in asthma control.

Introducing a new tool into practice requires planning and often trial and error. All intervention practices were allowed a six-week period to adapt implementation of the Asthma APGAR into their practice before adding the additional burden of patient enrollment. No specific study visits are required in this pragmatic trial. When patients do visit the clinic for any reason, they receive the patient Asthma APGAR survey.

The Asthma APGAR information is used and documented as the physician/clinician chooses during each visit.

A coordinator from the central study team is assigned to each practice as the practice liaison. The liaison interacts with the site nurse leader weekly during the early implementation phase and then biweekly or as needed throughout the rest of the study.

Usual care group

After returning home from central training, the usual care study leaders also provide a short education session for their practice members. The focus of the education session is "whole practice participation" in identifying patients eligible for enrollment and assuring that all practice staff are aware of the study. As in the intervention program, no visits or visit frequency is dictated by the study. All care decisions are at the discretion of the physician/clinician and patient. Usual care sites are also assigned a liaison from the central study team to work with the local sites on patient enrollment.

Patient-reported outcomes

Patient or parent subjects are asked to complete five survey packets at baseline and at 6, 12, 18, and 24 months after enrollment. Each packet includes the Patient Assessment of Chronic Illness Care (PACIC), the Asthma Quality of Life Questionnaire/Pediatric Asthma Quality of Life Questionnaire (AQLQ/PAQLQ), the Asthma Control Test (ACT), Asthma APGAR patient questions, and a group

of health care utilization questions (Table 2). The initial packet also includes demographic data. To facilitate continued participation in the study, a central site coordinator calls each enrolled person (or parent) within 72 hours of signing the informed consent.

Practice process data

Medical record data are required to measure practice asthma care processes and to assess asthma exacerbation rates. All data abstraction is done centrally. Inter-rater reliability testing will be accomplished within each site and across sites and must remain at 90% or greater. This will be done by abstraction of the same record by multiple abstractors across and within sites. If agreement is lower than 90% for at least five major items within the abstraction, additional training and testing will be undertaken.

Fidelity measures

Translational and effectiveness studies differ from efficacy and traditional randomized controlled trials in that no central study staff are present in the study practice sites. Therefore, it is important to have some measure of how well the intervention is actually implemented, ie, a study fidelity metric. In this study, uptake of the intervention is assessed using mixed methods, including semistructured interviews with the lead physician and nurse at the study site and medical record review at the end of the study period to assess documentation of use of the Asthma APGAR tools.

Exploratory data concerning barriers and facilitators

The central site staff will conduct interviews to collect information on use of the Asthma APGAR tools. Each interviewee will be queried regarding barriers and facilitators of the Asthma APGAR implementation.

Data analysis

The patient data will be summarized and presented in both graphic and tabular form, separately by site and pooled intervention versus control. The primary patient-oriented outcomes will be analyzed using linear mixed effects or generalized linear random effects models, with random mean terms for patient and practice, and fixed-effect terms for patient age and gender, and a fixed-effect term for the intervention. For these patient outcomes, the random effects for practices are likely to be important, given that there are likely to be fairly large differences in patient characteristics across different practices.

Table 2 Variables, instruments, and links to study aims

Aim and outcome	Instruments	Source of data
Patient outcomes		
Asthma-related quality of life	AQLQ	Patient/parent
Asthma control	ACT	Patient/parent
Exacerbations	Number per year	Medical record and patient/parent
Chronic care approach	PACIC	Patient/parent
Maintenance	Use of APGAR	Medical records
	Use of algorithm	Medical records
Barriers		
Number of new systems	PPC	Key staff
Types of new systems	PACIC	Key staff
Implementation issues	Surveys and interviews	Key informants
Fidelity measures		
Reach of patient APGAR	Both by medical record review	Both by medical records
Reach of algorithm		

Abbreviations: PACIC, Patient Assessment of Chronic Illness Care; AQLQ, Asthma Quality of Life Questionnaire; ACT, Asthma Control Test; PPC, Practice Process Content.

Whenever patient-reported outcomes are used, some level of nonresponse is expected. To minimize the number of records excluded from analysis, we will use multiple imputations to fit missing responses. Results of the multiple imputation analysis will be compared with an analysis of complete data; if results differ, both will be presented.

The ACT and AQLQ/PAQLQ scores are reasonably Gaussian, and we will fit linear models for them. For asthma exacerbations and number of missed work/school days, we will fit generalized mixed linear models with a random effect term to adjust for differences between practices. A significant coefficient for the intervention term will be interpreted as indicating an intervention effect. For assessment of exacerbations (requiring short bursts of oral steroids), data are only relevant for those visits dealing with exacerbations. Therefore, for this measure, analysis will be restricted to those visits where that treatment is appropriate.

Information from visits will be compared between intervention and control practices starting at three months, to allow a run-in period for the intervention to be implemented. Per-practice rates for each of these procedures will be computed both before (baseline data) and after the three-month run-in period (study period), and will be presented in both graphic and tabular form. The hypotheses for the five measures will be tested through logistic regression with random effects (generalized linear mixed models), with random mean terms for patient and practice, fixed-effect terms for patient age and gender, and a fixed-effect term for the intervention. Baseline data obtained from both the intervention and control practices will be included in the models, but the visit-specific value for the intervention term will be 0 (not intervention) for these records, because at that time the intervention would not yet have been implemented. Inclusion of baseline data will allow good estimation of practice random effects, and will adjust for differences not accounted for by randomization. A significant coefficient for the intervention term will be interpreted as evidence of an intervention effect.

The number of asthma-related practice systems in place for each practice will be assessed at time 0 and at 24 months using the PACIC modified for asthma care. In each of the six domains, three clinically important types of system will be identified, so the number of new systems could range from 0 to 18. The within-practice number of new systems will be computed by subtracting the number of systems in place at study completion from baseline, and will be compared across practices using the Wilcoxon rank-sum test. The PACIC is a patient visit-level measure that we are using to quantify the practice-level intervention effect.[67] Its

distribution is approximately Gaussian, and we will fit a linear random effects model, with random mean terms for patient and practice, fixed-effect terms for patient age and gender, and a fixed-effect term for the intervention. Inclusion of the baseline data will allow good estimation of the practice random effects, and will adjust for differences not accounted for by randomization. A significant coefficient for the intervention term will be interpreted as evidence of an intervention effect.

Analysis of the key personnel interviews will be descriptive and exploratory. We will attempt to identify any unanticipated barriers and facilitators to implementation. In addition, the interviews will provide information about underused or ineffective systems.

Sample size

We will enroll approximately 1400 patients, averaging 70 per practice. In our study of post-partum depression[40] we were able to attain 12-month response rates better than 60%; this group of asthma patients is likely to be less mobile, and we believe that assuming a 60% complete response is conservative. Based on simulated data with 840 subjects, we estimate that we will have over 80% power to detect a change in exacerbation rate from 12% to 8%, and over 90% power to detect a difference between a mean of 5.0 versus a mean of 4.0 missed work/school days. For the AQLQ/PAQLQ, the overall score is approximately Gaussian with a standard deviation of about 0.8;[68] we will have approximately 80% power to detect a mean difference of 0.15. A difference of 0.5 represents an important clinical change for an individual.[69]

Discussion

Effectiveness and PBRN translational studies are different from efficacy studies and clinical trials based at academic centers.[58–60,70–75] Not only is the subject and goal usually different, but the study design must be built around the strengths and weaknesses inherent in doing research in a real-world practice. In national studies, it is rarely feasible to send research coordinators or facilitators to each of the study sites on a repeated basis.[57,76] Therefore, the study must be designed in a manner that allows the study personnel to carry out the study with limited use of practice resources. This difference is highlighted in the sections on study and intervention implementation. The all-practice meetings led by the two practice leaders are supported heavily by the central team, and include development and dissemination of pre-prepared educational slide programs and handouts, the simple practice audit, and a proven format in which to present the

audit data. Telephone support from the principal investigator and the central site lead study coordinator demonstrates the central team's commitment to provide help at each stage of the study.[77] The provision of a study liaison for continuity of contact has resulted in local sites identifying with their liaison and funneling their questions and concerns through a single individual. Making sure that all interactions with practices are at all times convenient for the practices not the principal investigator or central study team is necessary to engage the local sites. Unlike many large clinical trials, there can be no expectation that a PBRN study comes ahead of any clinical or practice issue. Familiarity with practice flow and challenges in sites similar to those enrolled in the study facilitates discussion and keeps expectations of the central site in line with those of the enrolled sites. Certain issues can be anticipated in all PBRN studies, and are discussed in the following sections.

Time pressures

Time pressures will be an issue for these practices. Meetings with the central study staff will be held by distance interaction (telephone or web-based) at a time that is convenient for the practice. Each practice will be paid $1300 in each of the study years. This will not cover their time or effort, but does serve to recognize the important contributions of the practice. We will limit staff time away from or interference with patient care as far as possible.

Practice politics

It can be difficult to engender open and honest discussion in some practices or suggest that baseline care is not of the highest quality. To avoid including practices with no hope of collaboration, we will query each practice about previous attempts at practice change and ask for assurance that at least 80% of their primary care physicians are committed to this study.

Reluctance to use asthma guidelines

The Asthma APGAR is designed to make it feasible to use the guidelines in practices that have previously been unable or unwilling to do so.

Lack of resources to make practice changes

We anticipate that our concepts and tools will minimize such difficulties and may even make the care of asthma easier in these practices.

Failure to institutionalize changes

Many previous quality improvement efforts have suffered from the mentality of "fix it and move on", that often results in a decline in practice systems or process improvement and potentially in the quality of care. We will test the level of the Asthma APGAR's sustainability and practice institutionalization by including a maintenance phase, which is similar to the intervention phase but without support or calls from the central site staff.

This study has limitations that must be recognized in its initial design and goals. The study will occur in practices that do not have the research personnel usually associated with a randomized controlled trial. This is an advantage for generalizability of the results, but might be viewed as a limitation by those only familiar with trials of efficacy conducted in carefully controlled environments. With careful monitoring, frequent contact, and collection of fidelity data, PBRNs have been shown to be capable of producing reliable and accurate effectiveness results.[57] Asthma is defined clinically, and no pulmonary function data are required. Many of the enrolled practices do not have experience with spirometry testing. This is comparable with the 40%–60% of all primary care practices in the US that do not use spirometry on a regular basis. Other researchers, such as Juniper[39] and Nathan et al,[37] have found that assessment of asthma control and patient outcomes is possible without pulmonary function testing. This study will be generalizable to the defined asthma population of most primary care practices. Outcomes assessment will rely heavily on patient self-reporting of asthma control and asthma-related quality of life. Not all patients will return the surveys containing this information. However, with good follow-up, response rates should be in the range of 65%–75%. The rate of exacerbations will use medical records data which may not fully reflect patient-reported symptoms; however, it is a very good resource for identifying prescribed medications, ie, oral steroids, which is what we are using to define significant asthma exacerbations.

Summary

Asthma continues to be associated with preventable morbidity and mortality that could be lowered through more consistent delivery of guideline-compliant care in primary care practices. This project uses patient outcomes to test the effectiveness of the Asthma APGAR system and tools developed in collaboration with practicing family physicians and their staff members. The patient asthma APGAR guides collection of the important information required to assess asthma control and the results are linked to action items in the care algorithm. The project uses the available evidence about translating research into practice, including addressing motivation, the process of change, and development of a systemic care process tailored to rural practices. The intervention is simple, requires limited investment of

time or money on the part of the practice, and is therefore likely to be feasible for broad dissemination in the future.

Acknowledgment

Disclosure

The authors report no conflicts of interest in this work.

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