Title: Promoting Asthma Guidelines and Management Through Technology-Based Intervention and Care Coordination (PRAGMATIC)

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CONFIDENTIALITY STATEMENT

Promoting Asthma Guidelines and Management through Technology-Based Intervention and Care Coordination (PRAGMATIC)

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Background

Asthma disproportionately affects low-income and minority children residing in inner cities such as the Bronx, NY.[1, 2] Use of national guidelines reduces asthma morbidity by 70%[3]; yet, these guidelines are not consistently implemented.[4-11] For example, providers' failure to document symptom severity and control in the medical record can lead to inadequate prescription of controller medications.[42] Providers also often fail to assess patients' inhaler technique,[10] identify in-home exposures,[43] and evaluate asthma co-morbidities.[44-46] Asthma education and action plans are not consistently provided.[42, 47-49] System-level barriers found in our research include limited access to resources (e.g. sample MDI-spacers) necessary to follow the recommended care.[10] Provider-level barriers include lack of awareness, disagreement with the guideline recommendations, lack of self-efficacy for being able to carry out the best practice, low expectation that outcomes will improve, and external barriers such as time constraints during a visit.[6, 7, 10] Patient factors may affect adherence to preventive medications. Many parents have uncertainty about the effectiveness of medications, lack understanding about proper use of preventive medicines and administration devices, and have concerns about potential side effects.[37, 49, 50] Other factors, such as financial barriers and problems with access to care have also been reported.[51, 52] There are missed opportunities to improve asthma care within the context of the child's medical home, particularly during clinic visits that are not asthma-related.[26, 42, 53] A recent AHRQ review of interventions to improve provider adherence to national asthma guidelines concluded that systems-level interventions that address barriers and all the elements of the asthma care process (i.e., prescription of controller medication, environmental control practices, self-management education, documentation of severity and control) are needed.[9] Although interventions to improve provider adherence to asthma guidelines have been described,[12-24] few studies address translation of guidelines into routine care.[25, 26]

The proposed translational study builds on our experience evaluating a Multifaceted Prompting Intervention (MPI) in 12 urban clinics.[27] MPI uses guideline-based prompts at the time of an office visit to support providers' decision-making, increasing the likelihood that they will recommend corrective actions (i.e., preventive medication prescription) to improve asthma management. We found that MPI delivered at one visit led to improved preventive care and short-term clinical outcomes (defined as number of symptom-free days (SFDs)).[28] Although effective, this intervention must be modified in several ways to translate into practice.

Our earlier study found that one-time prompting did not improve long-term clinical outcomes, so support at multiple visits is warranted. Further, MPI was implemented by the research team to a sample of children with persistent asthma. Successful translation means that guideline-based care is delivered by providers and staff to all children with asthma, rather than just a research sample. The prompt was printed on paper, rather than delivered through the electronic health records (EHR), limiting wide-scale adoption. Further, the original study did not offer support for caregivers to follow through on providers' recommendations (e.g., filling prescriptions, ongoing self-management, medication adherence). Although providers are directly responsible for making healthcare recommendations to patients, delivery of guideline-based care requires all clinic staff to facilitate

communication, make changes to clinic work flow, and ensure patients and caregivers are able to follow recommended corrective actions. In order to translate MPI to pediatric practices, we will enhance it in several ways: (1) use clinic rather than research staff to facilitate assessment for prompts at every visit; (2) ensure prompting for guideline-based care for all children ages 2-12 with persistent or uncontrolled asthma, rather than just a research sample; (3) routinely deliver prompts to the provider via EHR; (4) offer telephone-based care coordination, education and support to children with the highest morbidity via a dedicated Outreach Worker (OW) to ensure recommendations are followed; and (5) provide practice-level supports (e.g. clinic champions, on-going performance feedback and participatory problem solving) to promote full adoption of guidelines. The enhanced MPI program **(eMPI)** consists of innovative multi-level and team-based strategies to enable providers to effectively and efficiently adopt asthma care guidelines.

We will conduct a cluster randomized trial comparing eMPI to enhanced usual care (eUC) in 22 Bronx practices serving over 5,000 children ages 2-12 years with persistent or uncontrolled asthma. Eleven eUC practices will receive guideline information and assess children's asthma severity and control, but active intervention components will not be provided. Practices will join the study in 4 waves over 4 years (4-6 practices per year). Including attendings and residents we anticipate enrolling an estimated 200 providers into the study.

Study Objectives

This study has the following objectives:

1. ***To test the impact of eMPI on provider adoption of asthma management guidelines***. The primary outcome is a clinic-level variable measured by the proportion of visits with ≥1 guideline-based corrective actions, as indicated in the EHR (i.e., controller medication prescription or adjustment, trigger evaluation). In this analysis we will include all patients ages 2-12 years with persistent or uncontrolled asthma (~5,000). **Hypothesis 1 (primary):** eMPI will improve provider adoption of asthma guidelines compared to eUC.

2. ***To determine whether consistent use of eMPI leads to both short- and long-term improvements in clinical outcomes***. Our main clinical outcome is improvement in SFDs. Since these data are not in the EHR, we will randomly sample 512 children's caregivers from eMPI and eUC practices. Caregivers will be interviewed every 3 months to examine short- (at 3 months) and long-term (at 6-12 months) change in SFDs. **Hypothesis 2a (secondary):** Short- and long-term improvements in SFDs will be greater in eMPI over eUC. **Hypothesis 2b (secondary)**: We also will assess if these improvements are mediated by corrective actions taken at the visit.

3. ***To evaluate the process of program implementation.*** We will apply the RE-AIM framework to address the intervention's Reach (the provider-level proportion of visits with corrective actions), Effectiveness (provider corrective actions and SFDs), Adoption (the pace and level of uptake of guidelines), Implementation (improvements in reach and effectiveness over successive waves), and Maintenance (sustainable use of guidelines). We will evaluate group differences in the extent of healthcare utilization and resources used (i.e., adherence to clinic follow-up visits, specialty referrals, emergency and in-patient care, OW referrals).

Study Overview

A. Study Design

Design Overview: We will conduct a 2-group cluster randomized trial comparing eMPI to enhanced usual care (eUC) in 22 Bronx practices serving over 10,000 children with asthma. The randomization will be at the practice level to avoid contamination. Each practice will be matched into 11 similar pairs based on size and type and then randomly assigned to either eMPI or eUC.

Provider adoption of guidelines and utilization of care in all patients (~5,000) ages 2-12 years with persistent or uncontrolled asthma from eMPI and eUC practices will be evaluated using EHR data and practice-based screening for asthma severity and control. We will also enroll a random subset of 512

caregivers of children with persistent/uncontrolled asthma from both study arms to systematically evaluate caregiver-reported child morbidity outcomes and obtain measures not available in EHR. These children will be enrolled at the time of the office visit and followed prospectively for 4 time points - 3, 6, 9, and 12 months after the initial visit - to assess clinical and process-focused outcomes.

B. Subjects and Setting

Outpatient practices (n=22) that are part of Montefiore Health System will participate in the study (see Letter of Support). These 22 practices are located throughout the Bronx, NY, represent different practice types, and have participated in several of our prior studies (Table 3). Though there were initially 22 proposed outpatient practices, two practices were closed, two practices (FCC-B and FCC-C) were combined as a single site given that they serve patients in the same facility, and one practice was excluded given no pairing available, resulting in a total n=18 participating outpatient practices. The number of children with asthma across practices (N=10,109) of whom we estimate ~ 50% (N=5,000) to have persistent or uncontrolled asthma is sufficient to meet our sample size needs. A subset of 512 children will be recuited over 4 years (~128 participants each year) to obtain clinical outcomes data that are not in the EHR.

Table 1. Primary Care Practices*

Site	Practice Type	Provider Type	# 2-12yr olds in practice	# 2-12yr olds with asthma	# visits for 2-12yr olds with asthma
Astor Avenue	NHC	Pediatrics	3,075	576	1,012
Bronx East	NHC	Pediatrics	4,775	884	1,516
Burke Avenue	NHC	Pediatrics/Family MD	1,102	117	196
Castle Hill	FQHC	Family MD	814	97	135
CFCC	FQHC	Pediatrics	5,791	1,144	1,824
CHCC	FQHC	Pediatrics	4,658	1,332	2,488
Co-op Bartow Ave	NHC	Pediatrics	2,485	634	1,059
Eastchester	NHC	Pediatrics	1,350	325	703
FCC - B	Hospital Clinic	Pediatrics	3,671	684	1,028
FCC - C	Hospital Clinic	Pediatrics	3,470	805	1,300
FHC	FQHC	Family MD	1,739	339	606
Grand Concourse	NHC	Pediatrics/Family MD	3,133	540	868
Grand UCC	NHC	Pediatrics/Family MD	2,950	235	262
HIP Cross County	NHC	Pediatrics/Family MD	3,058	272	385
MAP-8	Hospital Clinic	Pediatrics	2,935	631	1,551
Marble Hill	NHC	Pediatrics/Family MD	1,143	186	294
University Avenue	FQHC	Pediatrics/Family MD	1,697	344	645
Verde Clinic	NHC	Family MD	359	78	146
Wakefield	NHC	Pediatrics	354	309	600
West Farms	FQHC	Family MD	954	215	368
White Plains Road	NHC	Pediatrics/Family MD	1,204	174	273
Williamsbridge	FQHC	Family MD	1,059	188	308
TOTAL	-	-	51,776	10,109	17,567

FQHC=Federally Qualified Health Center; NHC=Neighborhood Health Center. *Number of patients seen between 1/1/14-12/31/14

Randomization: Prior to participant enrollment, each practice will be matched into 11 pairs based on size of the practice and provider type (Table 1). Practices will then be randomly selected within each pair as an eMPI or a eUC site. Practices will join in 4 waves over the course of 4 years (4-6 practices/year). Each practice will remain in the study for 24 months and receive $500 donation to thank them for participation.

Inclusion Criteria: The criteria listed below will apply to ~5,000 children from eMPI and eUC practices. We will obtain a waiver of consent to be able to review EHR data by practice.

(1) Physician-diagnosed asthma (based on EHR).

(2) Persistent or uncontrolled asthma as per clinic assessment. Based on NHLBI guidelines,[41] any one of the following: in past month, > 2 days/week with asthma symptoms, >2 days/week with rescue medication use, >2 days/month with nighttime symptoms, or ≥ 2 episodes in the past year that required systemic corticosteroids.

1) Mild persistent or more severe asthma severity, or poor asthma control (see definitions below). ***A different assessment of eligibility will be performed depending on whether or not the child has a current prescription for preventive asthma medication at baseline and parent reports its use. This is consistent with the EPR recommendations that make a strong distinction between classifying asthma severity (for children not using preventive medications) and assessing control (for children using preventive medications). If a child has used a preventive medication in the past, but reports no use of the medication in the prior 3 months, we will assess severity. This 3-month time frame is consistent with the length of "wash-out" time for inhaled steroids.***[152]
   a) ***Children not using a preventive medication at baseline***: Mild persistent to severe persistent asthma.[9,10] Any 1 of the following, during the prior 4 weeks (as defined by parent interview in the waiting room and EMR review):
      i) An average of >2 days per week with asthma symptoms
      ii) >2 days per week with rescue medication use
      iii) ≥3 nights per month awakened with nighttime symptoms
      iv) Minor limitation of activity
      v) >2 episodes of asthma during the past year that have required systemic corticosteroids
   b) ***Children using a preventive medication at baseline***: Poor asthma control. Any 1 of the following, during the prior 4 weeks (as defined by parent interview in the waiting room):

i) An average of >2 days per week with asthma symptoms
ii) >2 days per week with rescue medication use
iii) ≥2 nights per month awakened with nighttime symptoms
iv) Some limitation of activity
v) >2 episodes of asthma during the past year that have required systemic corticosteroids.

(3) Age 2 and 12 years, inclusive.

Additional inclusion criteria will apply to a subset of 512 of children whose caregivers will be interviewed to systematically evaluate experiences with the program and caregiver-reported morbidity outcomes:
(1) Caregiver is able to speak and understand either English or Spanish. Participants unable to read will be eligible as all surveys will be administered verbally by research personnel.
(2) Consent from the primary caregiver, caregiver permission for the child to participate as well as assent from the child (≥7 years). If there are eligible siblings, they will be enrolled if logistically possible.

Exclusion Criteria:
(1) The child has other significant medical conditions, such as congenital heart disease, cystic fibrosis, or other chronic lung disease, that could interfere with the assessment of asthma-related measures.

Additional exclusion criteria will apply to a subset of 512 children/caregivers as described above:
(1) No access to a telephone to conduct follow-up surveys.
(2) Children in foster care or other situations in which consent cannot be obtained from a guardian.
Based on our previous studies, we anticipate <10% of children will be excluded based on these criteria.

Screening: In 22 practices, clinic staff (RN/LPN) will ask caregivers of all children 2-12 years of age with asthma to complete a screening survey in EPIC Electronic Health Record (EHR) during the triage portion of their doctor visit. The screening survey questions follow national guidelines and will identify children with persistent or uncontrolled asthma (Appendix A).
Procedures for enrollment of a subset (n=512): Clinic staff will inform research team on days of recruitment to obtain consent and baseline assessment from a subset of children with persistent or uncontrolled asthma and their caregivers from whom additional morbidity measures (not present in the EHR) will be collected. Enrollment goals for each practice will be based on the number of children with asthma seen at the pracrice. Since enrollment will occur over an extended time period, we will block enrollment by site pair to assure an equal balance of children in each group for each seasonal time period. Research staff will be present in each clinic 2-3 days/week for recruitment, until monthly enrollment goals are met for that practice. We will review the practice's schedule the day before to determine if potentially eligible participants are scheduled for a visit. Research staff will call patients with asthma ages 2-12 years and ask families to come to their appointment with physician 30-60 minutes earlier to be screened by the nursing staff for asthma severity. If eligible, the caregiver/child will be informed about the study, undergo the informed consent process and complete baseline survey prior to seeing the physician. Recruitment goals will be reviewed weekly for each practice and adjustments of staffing made as needed. Days for recruitment will vary to ensure that patients of providers who are in clinic on certain days of the week are not over- or under-sampled (see Recruitment Protocol, Appendix A). Following informed consent/assent, research staff will conduct a 10-minute survey with the primary caregiver in the waiting room to obtain *baseline measures* of enrolled participants. All survey instruments will be available in English/Spanish and questions will be read aloud. Caregivers will be offered a private location within the waiting room to complete the survey. The baseline measures include standard demographic and health history variables, healthcare utilization, quality of life, beliefs about medication and adherence (Appendix A).

eMPI Intervention: The eMPI components are described in Table 4 and closely mirror implementation strategies recommended by the panel of experts in implementation science for development of a tailored multilevel strategy for implementation.[54] First, at every office visit, caregivers of children ages 2-12 years with persistent or uncontrolled asthma will be asked to complete a screening survey in EPIC Electronic Health Record (EHR) during the triage portion of their doctor visit (Appendix A). Clinic staff will review the answers with the caregiver and read the questions aloud as needed. Based on these responses, a prompt for both the provider and caregiver will be generated in EPIC EHR using a simple algorithm (Appendix B). The *provider prompt* will be delivered to the provider at each visit via EHR and include information on child's current level of asthma severity or control, controller medication use, exposure to triggers, and specific tailored recommendations for guideline-based preventive care (e.g. for persistent asthma without controller medication, the recommendation on the prompt will include starting controller medication).[41] For children with poor control despite being on controller medications, recommendation will include evaluation of inhaler technique and medication adherence, treatment and referral for evaluation of co-morbidities (e.g., referral to the Asthma Center for allergy and pulmonology consultations), "step-up" of medications, evaluation and counseling on triggers, and outreach worker referral (See below). The prompt will also include a recommendation for the provider to establish treatment goals with the patient and inquire about any caregiver's concerns. The prompt for the provider will be seen on the computer screen in EPIC EHR at the time of the visit allowing provider to check off the guideline-based recommended items discussed during the visit. The *caregiver prompt* will include immediate feedback on child's asthma severity/control with personally tailored information highlighting caregiver's goals and concerns. The prompt will include simplified recommendations for preventive care issues to discuss with the provider during the visit (e.g., to discuss triggers, medication concerns, need for asthma action plan (AAP) and medication administration form (MAF) for school). AAP and MAF are embedded into EPIC EHR patient chart and can be printed and given to patient to take home or to school. The caregiver prompt is based on the guideline recommendation to promote joint discussions about treatment plan and goals and will be printed for caregiver to bring to the visit. *Outreach worker* (OW)-delivered telephone-based care coordination and support will be provided by the bilingual (English/Spanish) OWs, lay people from the community who have asthma or a child with well-controlled asthma. OWs will become a practice-based resource. OWs will provide telephone-based care coordination, education and support to children who are already on controller medication but still have uncontrolled asthma and other barriers to guideline-based care (e.g., unable to fill a prescription, loss of medical insurance, poor medication adherence, gaps in caregiver knowledge despite provider education). The decision to refer family to OW service will be based on provider's assessment at any office visit. Providers will be prompted to make OW referrals for children with uncontrolled asthma as part of the guideline-based care. We estimate that 20% of children in each intervention practice will be referred to the OW. Providers will have a referral mechanism embedded within EHR to refer patients to the OW with suggestions on which children should be referred. OW training: OWs will be trained (4-weeks) by the PI (Reznik) and Co-Is (Rastogi, Jariwala) using evidence-based guidelines on asthma self-management skills, proper inhaler technique, triggers, medication use, goal setting and problem solving. The PI will oversee OWs with bi-weekly (and more often if needed) meetings to discuss cases/concerns and will listen to 20% of the recorded telephone calls to ensure the OWs deliver the sessions as intended. OWs role: OWs will help facilitate implementation of the guideline-based care prescribed by provider at the office visit. If referred to the OW at the initial visit, the first OW telephone call with the child's caregiver will occur within 2 weeks after the initial visit to determine any care coordination needs (e.g., assistance scheduling specialty appointments, inability to fill prescriptions) and then monthly, starting at 1-month post-initial visit for 6 months. If referred at the follow-up office visit, the same

TABLE 4. CORE ELEMENTS OF eMPI MULTI-LEVEL TRANSLATIONAL STRATEGIES

Direct Support for Providers' Delivery of Guideline-Based Care in Practice
- Caregiver waiting room assessment of asthma severity and control
- Provider prompts to deliver guideline-based corrective actions at every visit
- Caregiver prompts to encourage discussion with provider

Enhancements to Increase the Feasibility and Sustainability of eMPI
- Waiting room assessment for the prompts on Tablet PCs
- Physician prompts in Electronic Health Record (EHR)

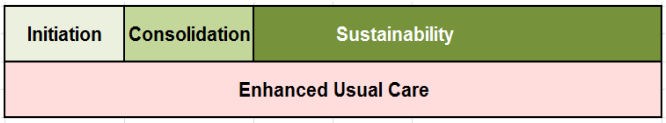
Involving Clinic Staff in Promoting and Supporting Use of Guidelines
- Regular staff administer and survey information for prompts
- Outreach Worker-delivered care coordination and support to ensure recommendations are followed by patients

Building Accountability and Commitment to Guideline-Based Care
- Designation of clinic champion to lead practice change
- Designation of Practice Advisory Board to monitor and guide change

Promoting Providers' Understanding, Acceptance and Use of Guidelines
- Interactive seminars about asthma guidelines, pocket cards with guidelines
- Ongoing feedback about performance improvement
- Identification of barriers to guideline use and eMPI implementation
- Ongoing sharing of best ideas and solutions to overcome barriers

schedule of OW calls will apply. OWs will use evidence-based educational materials that were previously adapted to the needs of our community, and focus on helping parents develop 6 key asthma management behaviors as per NHLBI guidelines[41] and our prior research using OWs: (1) Asthma control monitoring, (2) Identifying and minimizing exposure to triggers, (3) Effectively using controller medications, (4) Using quick-relief medications, (5) Using an asthma action plan, and (6) Effectively working with the child's physician and schools on optimizing asthma care. The decision to work on specific behaviors will be tailored to caregiver needs expressed at the provider visit and based on caregiver's concerns and goals identified by the caregiver prompt. During the telephone calls, OWs will also assist with patient care activities (e.g., scheduling appointments, refer to community services for Integrated Pest Management provided by the NYC Department of Health, smoking cessation programs (NYS Smokers' Quitline), free legal services and existing on-line resources) and share information with the provider and other members of the clinical team via EHR if any concerns about patient or caregiver arise during the telephone encounters (e.g., caregiver does not have prescription for medication, child seen in ED or hospitalized). The OWs will use a Microsoft Access database to record call frequency, length, and notes taken. These calls will last ~30 minutes. OWs will also send text messages, if preferred by the caregivers, to remind about clinic appointments or schedule follow-up telephone calls.

Translational Process within eMPI Clinics: At each intervention clinic, there will be three phases of eMPI translation into routine practice: 1) *initiation* (3 months, intense support provided), 2) *consolidation* (3 months, support available), and 3) *sustainability* (18 months, support as needed). During the *initiation* phase, the goal will be to introduce eMPI to the practice. First, we will partner with a *clinic champion,* a practice physician who will also serve on our *Practice Advisory Board*. The Board will consist of ≥ 2 physicians, 1-2 nurses, 1-2 front desk and administrative staff. The Board will meet monthly during the initiation and consolidation phases to review the study protocol as it relates to the practices, discuss any provider-reported barriers to implementation and identify solutions to address these barriers using a collaborative problem solving approach. These Boards will capitalize on already existing and engaged groups created by the Bronx Ongoing Pediatric Screening in the Medical Home (BOPS) program described in the Preliminary Studies section. To initiate the planning process, we will ask Board members to complete the RE-AIM planning tool[96] to highlight any concerns or barriers to implementation. We will engage providers in a practice improvement process by having the clinic champion discuss feedback received from individual providers and solutions at the regular clinic meetings. We will provide the champion with a tool, updated monthly, to record identified barriers to guideline implementation and ways to address them. We will also collect baseline information on provider corrective actions in EHR; assess provider self-efficacy, provider-caregiver communication, and provider competencies in guideline-based care using a validated survey (Appendix A). During month 1 of the initiation phase, we will provide *practice-level support* (e.g., pocket cards with guidelines, brief interactive seminars, local asthma resources; Appendix C) to the practices to assist providers in implementing the asthma management outlined in the NHLBI guidelines[41] and to help remove practice and provider-level barriers to guideline implementation.[7, 10] The interactive seminars, developed using principles of physician behavior change[97] and led by the PI (Reznik) and co-Is (Rastogi, pulmonologist and Jariwala, allergist), will generate enthusiasm around prompting and empower providers to implement desired changes. The seminars will include an overview of guideline-based asthma care and orientation to the prompts, resource guides and the feedback charts. At the end of the seminar, a brief needs assessment survey will be done, and additional resources will be provided based on the needs of the individual practices. Providers will receive continuing education credit for their participation. These sessions will be coordinated by each practice's champion. We will also provide *practice-level feedback*. eMPI practices will receive monthly feedback during the initiation phase on the proportion of visits with appropriate guideline-based preventive actions, and the proportion of patients meeting goals of therapy (limited symptoms, no ED visits/hospitalizations). The feedback will be delivered to the champion who will then share it with the rest of the providers. The information will be presented graphically with other intervention practices displayed by a code for comparison. A Quality Control Tool will be used to measure and assess nurse adoption of the asthma severity/control screening. Research staff will observe nursing staff at least once during the



implementation period as they conduct the severity/control asthma screening, make note of their screening practices and provide feedback to the nursing staff and the clinic champion. During the consolidation phase, we will continue to work with site champions and practices to ensure eMPI is implemented as intended and provide support on addressing barriers or concerns. Major activities during this time will include on-going monitoring of all aspects of eMPI, feedback to sites about their performance, identification of barriers and needed resources, and Board meetings to address these impediments. Given the COVID-19 pandemic, as of March 2020, Board meetings have been restricted to telephonic or video conference call only. We will finalize a sustainability plan with each practice to ensure on-going use of guidelines. During sustainability phase, we will observe practices' continued use of guideline-based care. During this time, we will not provide regular consultations or support, but will be available to address questions and concerns that arise. This will allow us to monitor how much outside help sites require to sustain eMPI. We will provide feedback at the practices' request. We expect that eMPI practices undergoing our translational program will increase guideline-based care during a 3-month initiation period and subsequent 3-month consolidation period, and will maintain these gains over an 18-month sustainability period.

Enhanced Usual Care (eUC) Practices will receive a review packet of the NAEPP guidelines[41] and educational resources for families. Children will be assessed for asthma severity and level of control at each visit as best-practice care, but active intervention components will not be provided.

Outcomes Assessment. Follow-up assessments for 512 participants will be conducted by interviewers blinded to the treatment allocation at 3, 6, 9, and 12 months. Outcome measures will be assessed by telephone interview, and EHR data will be reviewed for all patients with asthma in both study arms. Given the minimal risk of survey questions and the importance of having full datasets for study analyses, in the case that study personnel are unable to reach the caregiver who signed consent at enrollment (after multiple phone attempts, letters, home visits, and scheduled appointment outreach), we will proceed to obtain verbal consent and survey data from another caregiver who is aware of the enrolled child's history with asthma. These caregivers include the other parent, guardian, grandparent, aunt, or uncle. Name and contact information of the alternate caregiver will have been provided at enrollment by the caregiver who initially signed consent.

Measures: The following measures are organized by clinic-, provider- and patient-level variables.

Clinic-Level Variables

The ***primary outcome*** is a clinic-level variable measured by the proportion of visits with ≥1 guideline-based corrective actions. To calculate this proportion, the denominator will include only the visits by patients aged 2-12 years with persistent or uncontrolled asthma at the time of visit. We will obtain these data from the EHR at baseline, monthly during the initiation phase (to provide feedback to eMPI practices) and every 3 months thereafter for 24 months. Corrective actions include: (1) prescription of a new preventive asthma medication; (2) increase in dose of a preventive medication (for children already on preventive medication); (3) evaluation and counseling regarding triggers; (4) treatment of co-morbid conditions (e.g., sinusitis, allergic rhinitis, obesity); (5) referral to an allergy or pulmonary specialist. We will consider children receiving any of these guideline-based preventive care measures during the visit as having a corrective action (as not all actions may be necessary for each patient), and also will consider each component of preventive care separately. We collected prospective data on most items included in the corrective action definition in our prior work.[28, 98] Additional corrective actions include recommendations for a follow-up visit specifically to discuss asthma, referrals made to OW, and provision of an asthma action plan or school medication administration form.
Covariate: Practice characteristics will include practice size (small, medium, large), practice type (hospital-based practice, Federally Qualified Health Center, neighborhood health center), and patient mix (pediatrics, adult/pediatrics), involvement of support staff in the delivery of preventive asthma care, practice-level changes (e.g., new asthma-related initiatives in the practice). We will obtain this information from the existing database of practices and from interviews with the physician champion and office administrator at each practice.

Provider-Level Variables

Potential Mediators: **1) Provider Competencies:** We will assess a) provider's asthma practices (frequency of assessing patient symptom severity, treatment adherence, and use of guideline-consistent care),[99, 100] and b)

frequency of use of communication and education strategies contained in the Physician Asthma Care Education (PACE) physician survey.[101] **2) Provider/Caregiver Communication:** We will ask providers in all practices to complete a brief survey at the beginning (during initiation) and end of the study (during sustainability phase). The survey is adapted from the PACE[102] assessment and includes questions about asthma care practices and communication with families. The providers will also be asked if they have been involved in other quality improvement or educational efforts on asthma care. Survey link will be sent to providers electronically.

Covariate: We will collect data on provider type (MD, PNP, PA), the level of training (resident or attending), specialty (family medicine or pediatrics), and if the visit's provider was the child's primary care provider. We will obtain this information from the chart review, caregiver interview for a subset of patients and provider survey.

Patient-Level Variables

Clinical/Functional Outcomes will be collected from caregivers of 512 children (Table 5).

Table 5. Measures	Measurement Strategy	Time of Administration
Clinical/Functional Outcomes		
Asthma Symptoms	Caregiver report on SFDs, ACT,[105] NHLBI guidelines[41]	Baseline; 3, 6, 9, & 12 months
Healthcare Utilization	Caregiver interview on health care contacts; EHR data	Baseline; 3, 6, 9, & 12 months; chart review
Quality of Life	Caregiver interview – Juniper Scale[106]	Baseline; 3, 6, 9, & 12 months
Functional Severity	Caregiver interview – Child Health Survey for Asthma[107]	Baseline; 3, 6, 9, & 12 months
Medication Beliefs/Adherence	Caregiver interview – Horne Scale[108]	Baseline; 3, 6, 9, & 12 months
SFDs=Symptom-Free Days; ACT=Asthma Control Test; EHR=Electronic Health Records		

1. Asthma Symptoms: We will assess number of symptom-free days (SFDs) ***(secondary outcome measure)*** at baseline, 3 months to determine short-term effectiveness of the intervention, and at 6, 9, and 12 month follow-up evaluations to assess long-term intervention effects. This outcome measure is consistent with the symptom monitoring recommended by the national guidelines and has been suggested as a useful endpoint for pediatric asthma studies.[103, 104] Caregivers will be asked to report the number of days their child experiences *no* symptoms of asthma (defined as 24 hours with no coughing, wheezing, chest tightness, or shortness of breath) in the past 2 weeks. We will also assess asthma control with the Asthma Control Test.[105]

2. Healthcare Utilization: Caregivers will report child's healthcare utilization at baseline and each follow-up. In addition, EHR data will be reviewed at each follow-up to assess for office visits (acute and routine), emergency department visits and hospitalizations. We will also evaluate healthcare utilization outcomes from the EHR data review for all patients with persistent or uncontrolled asthma (~5,000) across practices.

3. Quality of Life: Quality of life will be measured at baseline and each follow-up using Juniper's Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ).[106] The PACQLQ is a standard instrument used to assess the quality of life of caretakers of children with asthma, and provides a quantitative score that reflects answers to questions about the burden of caring for a child with asthma.[106]

4. Functional Severity: Functional limitations of the child will be assessed at baseline and each follow-up evaluation using a subscale from the Children's Health Survey for Asthma.[107] The child activity subscale includes 5 items on limitations to the child's activities due to asthma (Cronbach's alpha .87-.89).

5. Beliefs about Medications and Adherence: We will use the 10-item Horne's Beliefs about Medications Questionnaire (BMQ).[108] Five questions assess parent's views about the necessity (alpha=.80) and five measure parental concern about their child's medications (alpha=.75). The 4-item Adherence Scale[108] measures parent-reported medication adherence using a 5-point Likert scale (alpha=.60-.83).

Covariates:

1. Demographic Variables will include child's age, gender, race, ethnicity, medical insurance, and caregiver's education level. We will use standardized questions from the national child health surveys to obtain these data.

2. Medical Variables will include birth history (prematurity), duration of asthma diagnosis and history of allergies (e.g., allergic rhinitis, seasonal allergies) or eczema.

3. Caregiver Depression: Caregiver depression has been shown to affect adherence to care plans, communication and child's asthma outcomes.[109, 110] We will assess maternal depression using a validated Patient Health Questionnaire 9 (PHQ-9).[111]

Potential Mediators:
1. Caregiver/Provider Communication: We will use 5 communication items from the PACE Parent/Caregiver Questionnaire[102, 112] to assess caregiver's perception of their communication with the provider. Items are scored on a 6-point Likert scale (Don't know, Strongly Agree-Strongly Disagree).
2. Self-Efficacy: We will assess caregiver self-efficacy in communication with their child's provider using the validated Perceived Efficacy in Patient-Physician Interaction questionnaire (PEPPI).[113-115]

RE-AIM Measures: We will use RE-AIM framework[93] to evaluate the translational process: (1) the provider-level proportion of visits with corrective actions (*Reach*); (2) the impact of the intervention on provider delivery of guideline-based care (corrective actions taken at the visit) and SFDs (*Effectiveness*); (3) the pace and level of uptake of guidelines and changes in service utilization (*Adoption*); (4) improvements in reach and effectiveness over successive waves (*Implementation*); and (5) continued use of guidelines and sustainability of strategies by practices in order to facilitate dissemination to other clinical settings (*Maintenance*). We will be completing post-study qualitative interviews with approximately 125 clinic stakeholders (e.g. advisory board members, physicians, medical directors, nurses, and administrative personnel) from both eMPI and eUC practices to further evaluate the process of program implementation. Individual interviews will be completed through Zoom audio conference call, where clinic stakeholders will answer questions related to their clinic's culture, asthma management workflows, and barriers and facilitators to program implementation. The interviews will be audio-recorded and transcribed verbatim for further qualitative analyses.

Analysis of qualitative data: Transcribed interviews will be imported into the NVivo qualitative data software to assist with data organization. Qualitative data will be analyzed according to the concepts of grounded theory. Codebooks will be developed in an iterative fashion. Coders will independently code the first 3 transcripts, meet to compare codes, and then alter or add codes as necessary. After this, a codebook will be created to include definitions, rules, and examples for each code. The coders will then code all subsequent transcripts and revise the codebook as necessary to incorporate new codes or refine existing codes. The constant comparison method will be used to determine if there are any patterns or themes by provider/stakeholder characteristics.

Summary of Analytic Plan:
We will use graphical and numerical summaries to describe the outcomes at each assessment point. If distributional assumptions for particular statistical procedures are violated, appropriate transformations will be made or non-parametric tests will be used. All primary and secondary analyses will follow the intent-to-treat principle; all participants will be analyzed in the group to which their clinic was assigned irrespective of their post-randomization behavior, and all participants will be analyzed using multiple imputation techniques. Hypothesis-driven comparisons will be made with control of the type I error rate at 0.05 (two-sided).
Preliminary Analysis. We will examine data for out of range values. Descriptive statistics will be generated regarding practice characteristics such as size (small, medium, large), practice type (hospital-based practice, Federally Qualified Health Center, neighborhood health center), and patient mix (pediatrics, adult/pediatrics) to help to understand the sample as well as the generalizability of study findings. We will determine whether there are differences at baseline between the eMPI and eUC providers and patients in demographics and background characteristics. This will include analogs of t-tests (or Wilcoxon rank sum tests) for continuous variables and chi-square (or Fisher's Exact) tests for categorical variables adjusted by generalized estimating equation (GEE) methods for the clustering induced by providers within clinics.

Aim 1. ***To test the impact of eMPI on provider adoption of asthma management guidelines***.
The ***primary outcome*** is a clinic-level variable measured by the ratio of number of visits with ≥1 guideline-based corrective actions to the number of visits by patients aged 2-12 years with persistent or uncontrolled asthma at the time of visit. The *primary null hypothesis* is that there is no difference between eMPI and eUC clinics in the mean proportion of visits where the necessary corrective actions were taken. To test this null hypothesis, we will use a matched-pairs randomization (or permutation test) at the 0.05 two-tailed level of

significance. The permutation test will account for the fact that clinics (rather than providers) are randomized and that the randomization will be performed within clinic pairs. Each pair of clinics will produce a matched difference in the proportions of corrective actions, and under H_0 the randomization can be viewed as attaching a random plus or minus sign. Thus there will be 2^{11} = 2,048 possible signed permutations, allowing a two-tailed p-value as significant as 2/2,048 < 0.001 (if all 11 pairs show a greater proportion of corrective actions taken by the eMPI practices). Assuming no important practice characteristics are significantly out of balance (at two-tailed p<0.01), the permutation test will comprise the primary analysis. If any important clinic characteristics are significantly imbalanced at p<0.01, we will adjust for such variables in a linear regression model and report the adjusted intervention coefficient as the primary result. We will also examine for a clinic-size (or provider-type) by intervention interaction. If not significant at the 5% level, the above approach will be used to provide the primary results. If significant, we will attempt to identify factors that affect the primary outcomes and might differ between clinics (or provider types). If including such factors removes the interaction, we will quote the adjusted intervention effect from the model including such factors. If not, we will quote two intervention effects (for large and small clinics) leaving the interaction unresolved.

Power Analysis. We conservatively estimate that the mean difference between eMPI and eUC clinics in the proportion of visits where the necessary corrective actions were taken will be at least 25 percentage points. To express this as a standardized effect size, we assume the standard deviation of the paired differences in the proportion of corrective actions will be no more than 0.2, based on several mock data sets generated by the investigators reflecting their clinical experience and best estimates. We present one generated data set in Table 6 for illustration. This hypothetical data set has an average matched difference in proportions of 0.246 (about 25 percentage points) with standard deviation 0.142 (14.2 percentage points). Our assumption of a standard deviation of 0.2 or 20 percentage points is thus about 50% larger than in this illustrative example.

Table 6. A Mock Data Set

Clinic Pair	1	2	3	4	5	6	7	8	9	10	11
Proportion Difference	.25	.10	.20	.50	.00	.25	.30	.40	.10	.30	.30

The standardized effect size is therefore 0.25/0.20 = 1.25. Approximating the power of the permutation test by that of a paired t-test with 10 degrees of freedom, a sample size of 11 clinics per arm will yield a non-centrality parameter of $1.25\sqrt{11} = 4.15$, providing more than 95% power to detect a standardized effect size of 1.25 or more. The detectable effect size at 80% power is a mean difference 17.8 percentage points between eMPI and eUC practices. Even if the true standard deviation of the matched differences in proportions were as large as 0.281, we would still have 80% power to detect a 25 percentage point mean difference.

Aim 2. ***To determine whether consistent use of eMPI leads to both short- and long-term improvements in clinical outcomes***. In this Aim, we will compare the change from baseline to each of the follow up (FU) time points (i.e., 3, 6, 9, and 12 months) in number of SFDs between eMPI and eUC patients using intent-to-treat principles. We will employ the generalized linear model (GLM) with identity link function for this comparison. The analysis model is of the form $EY_{ij}=\alpha+\beta I_i+\sum\gamma_j T_{ij}+\sum\delta_j I_i T_{ij}$, where for subject i Y_{ij} is the number of SFDs for at time j, I_i denotes group indicator for eMPI group (vs. eUC), and T_{ij} is the indicator for time at FUj evaluation (vs. baseline). The regression coefficient δ_j corresponding to the group-by-time interaction term estimates the difference in average change of SFDs at FUj evaluation vs. baseline, comparing eMPI to eUC groups, and thus represents the effect of intervention on the SFDs. We will use generalized estimating equations (GEE) methodology to account for within-subject correlation due to multiple assessments for the same subject as well as the within-provider and within-practice correlations due to cluster sampling. We will also determine whether or not the corrective actions taken mediates the effect of intervention on outcomes; we will use the test of joint significance of the 2 paths involving a potential mediator, which best balance Type I error and statistical power.[116] A variable M will be declared a mediator only if both the test of the regression coefficient of the explanatory factor X on the mediator *and* the test of the coefficient of the mediator on the outcome variable Y controlling for X are significant at level alpha = 0.05, 2-tailed. This approach allows for partial mediation which we fully expect to occur. In subsequent analyses we will estimate the indirect path effect with 95% confidence intervals using the asymmetric distribution of products method.[116] Further exploration of causal mediation will

follow the methods of Imai et al.[117, 118] We will also examine whether the effect of intervention on SFDs is mediated by provider competencies, provider/caregiver communication or caregiver self-efficacy.
Missing data: Every effort to retain participants in the study will be exerted in order to avoid bias due to attrition. For those individuals who refuse continued participation, we will document reasons for study discontinuation and Rubin's multiple imputation method[119] with 5 repeated imputations will be employed to impute the missing endpoint for conducting the intent-to-treat analysis.

Power Analysis. With a recruitment of 512 participants at baseline, we anticipate a final sample of 460 participants with complete data for the primary analysis assuming no more than 10% attrition at 12 month evaluation. This estimate of attrition rate is conservative based on our prior experience. To account for the intra-cluster correlation due to cluster sampling, we estimate that an intra-provider correlation coefficient is no greater than 0.03 from our prior studies. Although the intra-practice correlation coefficient should be smaller than intra-provider correlation coefficient, we conservatively used the same value (i.e., 0.03). Under the above assumption, with 230 participants per group, we will be able to provide 80% power to detect a standardized effect size of $\geq$0.29 in change of number of SFDs. Even if actual attrition is greater than we expect (e.g.,15%), the detectable standardized effect size will only increase slightly to 0.30. Further, as we will impute missing data using informative covariates for the primary analyses, the power to detect such effects will be >80%.

Aim 3. ***To evaluate the process of program implementation:*** In order to evaluate the potential for dissemination of this primary care intervention, we will report specific summary measures recommended by the RE-AIM[93] framework. We will compare the provider-level proportion of visits with corrective actions taken by the eMPI providers to that of eUC providers using the same analytic approach stated in Aim 2 (*Reach*). We will evaluate the impact of eMPI on guideline-based corrective actions and symptoms (*Effectiveness*). We will qualitatively describe problem solving progress that occurs in each practice as part of process of improvement, by coding the specific barriers that arise during implementation and are collected by clinic champions, and the solutions that eMPI practices identify (*Adoption*). We will report consistency with which participants in the intervention arm receive the protocol through EHR data, practice observations of the process of implementation and data collected from OW contacts with participants. Additional measures of implementation of eMPI include 1) caregivers' completion of severity/control assessments at the visit; 2) provider and caregiver receipt of prompts; 3) providers' documentation of asthma discussion *(Implementation)*. We will use provider survey responses to evaluate the extent to which each intervention component was continued or modified post-study and sustained effects on the primary outcome (*Maintenance)*. Using EHR records of 5,000 children across all four waves of translation, we will determine if eMPI practices will (a) reach successively higher levels of guideline-based care, (b) achieve that level more quickly, and (c) sustain use of guidelines for 18 months. The analytic approach to address this will involve a statistical model with the main effect of intervention condition, time (which represents the level of Implementation), and the indicators of waves (which will allow us to evaluate sustainability), plus all the two-way and three-way interactions. We expect to see specific three-way interaction effects involving trends in rates of guideline-based care over 24 months, with an ever steeper linear increases and less pronounced downturns seen from wave to wave, in eMPI practices vs. eUC. Guideline-based care is intended to ensure that children receive needed services in a more timely fashion. We will examine patterns of utilization by children in both groups using the EHR, including adherence to clinic visits, specialty referrals, emergency and in-patient care, and OW referrals.

1. Compensation

Caregivers will receive $20 at baseline, 3, 6, and 9 months follow-up, and $30 at 12 months follow-up. In cases where caregivers are unreachable after multiple call attempts, we will offer an additional $10 gift card incentive in an effort to obtain accurate contact information and complete pending follow up surveys. If caregivers are still unreachable after these efforts, we will attempt to meet at the caregiver's home or in the community to complete the respective survey, obtain accurate contact information, and provide their compensation. Given the COVID-19 pandemic, as of March 2020, home visit and appointment outreach efforts have been restricted, focusing only on telephonic outreach to complete follow up surveys. In addition, each of

the 22 practices will be given a donation of $500.00 to thank them for their participation. This participation will include providing space for research assistants to speak with families. Practice staff will also assist research staff with printing schedules and identifying families for enrollment. Providers will also be asked to complete three brief surveys: baseline, 1, and 2 year follow-ups.

There is no cost to those who participate in this study. The participants and their insurance company will be responsible for the cost of all standard of care office visits and medications. This intervention is meant only to help assure that appropriate medications are prescribed and national asthma guidelines are followed.

2. Safety or Risk

The study proposed should pose minimal risk to the participants, with the primary concern for loss of confidentiality. To minimize this risk, all records will be kept strictly confidential as required by the policies and procedures of the Montefiore Medical Center where data are collected, processed, or reported. Any significant concerns will be relayed promptly to the study coordinator, the principal investigator, the NHLBI, and the Institutional Review Board. During follow-up, all children with persistent symptoms or poor control will be referred to their primary care provider for care. The primary care provider or the family can discontinue the child's participation at any time during the study.

3. Data Storage and Confidentiality

Recruitment, Informed Consent, and Confidentiality: Human subjects' rights will be protected as explained in the consent form used for the study. The Institutional Review Board (IRB) will review all protocol and informed consent documents and research will be carried out only after proper approval from the IRB. Written consent will be obtained prior to the initiation of any research evaluations from the subset of 512 participants. Informed consent will be obtained from all potential subjects by a researcher trained and certified in human subjects protection. The informed consent process will detail the potential benefits of participating in the research as well as the potential risks of the intervention. Assent also will be obtained from children in the program who are 7 years of age and older. Subjects will be informed that they may choose not to answer any of the questions on the surveys and that they may withdraw from the study at any time without negative consequences. Strict confidentiality will be maintained throughout the study. The data will be stored in password protected computers and locked file cabinets in a study office, and only the researchers or their associates will have access to these data.

We will obtain a waiver of consent to be able to review de-identified EHR data by practice to identify the proportion of visits with $\geq$ 1 guideline-based corrective actions (clinic-level variable). These data will be obtained on a clinic-level without identifying specific patients.
To obtain a waiver of consent, the following criteria will be met (45 CFR 46.116(d):
(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Protection against Risk:
During recruitment, parents will be offered private areas in the waiting room to conduct informed consent and baseline assessments. For confidentiality protection, the identity and personal information of each subject will be used only for purposes of this study and will only be accessed by appropriate study personnel. For specific analyses, files consisting of pertinent data from the individual records will be formed from the base data file. All data will be held confidentially and stored in locked files, accessible to authorized staff and investigators only.

Any parent indicating high risk for depression during a follow-up interview will be referred to their primary care provider or mental health provider present in each clinic, and will be sent a summary of community resources available for care. Additionally, parents will be informed of emergency resources at the time of the telephone interview, including lifeline, social work supports, and 911. This mechanism is being used in our current

school-based study, is approved by our institutional review board, and has been well received by parents.
Additional Measures to Protect the Data:

We will take additional measures to minimize the risk of breaching the confidentiality of data. These include but are not limited to the following:

- Electronic firewalls
- Audit trails
- Disaster prevention and recovery plans
- Systems certification
- All research personnel take yearly HIPAA training

Identity of participants will not be revealed in the presentation or publication of any results from the project. All personnel working on the project will be regularly educated about the importance of strictly respecting participants' rights to confidentiality.

Data and Safety Monitoring Plan

Data Quality Monitoring

Baseline data forms will be completed electronically by research staff on Tablet PCs in the waiting room. All survey data collected on the Tablet PCs are entered using data entry forms created by Adobe Creative Suite 3 software, which allows for integration with secure data entry forms to an off-site server. Asthma severity and control assessment and data necessary for generation of the prompts will be entered into each patient's EPIC Electronic Health Record (EHR). For the safety of private subject information, no data will be stored on the Tablet PCs. For the 4 follow-up telephone interviews, data will be collected using RedCap database. Pre-intervention training of study staff will be conducted to increase knowledge about asthma, asthma medications, and other important information in order to reduce the number of "real-time" data collection errors. Through this training, staff will note any inconsistencies in parent reported data and will discuss them with the parent at the time of the interview.

A separate team of researchers will perform all follow-up interviews and follow-up data management. This group will work independently from the "enrollment team" and thus will be able to perform blinded assessments of outcomes. Randomization information will not be included with any follow-up materials in order to assure blinding of outcome assessment.

Once data have been collected, simple range checks as well as cross-form validation checks will be performed to ensure the accuracy and completeness of the data. A list of all data checks performed will be maintained and any errors detected by this method will be noted. In addition, data forms, valid informed consent documents for each enrolled patient, and supporting source documentation materials will be reviewed by the data analysts for accuracy. Required regulatory documents (IRB approval, updates to the protocol, data monitoring documents) will be maintained by the study coordinator. All events during the course of the trial including study enrollments, adverse events and study terminations will be reported to the study coordinator (see safety section below).

Safety Monitoring Plan

Potential risks related to participation in this study are minimal since surveys are administered and information is relayed to caregivers and providers during the time that children will be receiving care at their primary care office. No medications or investigational treatments are given as part of this study. Any significant adverse events will be flagged by the follow-up team and relayed promptly to the study coordinator, the principal investigator, the child's primary care provider, and the Institutional Review Board within 24 hours. We plan to hold monthly research review meetings with the study team to provide monitoring to ensure subject safety as well as treatment integrity. Any child experiencing an exacerbation or persistent symptoms at the time of an assessment will be referred to their primary care provider. All records will be kept strictly confidential as required by the policies and procedures of the Albert Einstein College of Medicine /Montefiore Medical Center

where data are collected, processed, or reported. The family can discontinue their participation at any time during the study.

4. Potential Benefits

There are potential benefits of this intervention. Children obtaining care from the eMPI practices may have improved care due to the use of prompts and telephone-based care coordination, education and support provided by the Outreach Worker to help promote discussion of the child's asthma, provide recommendations for asthma care and promote full adoption of asthma guidelines. In addition, both groups may benefit by having the asthma guidelines reinforced with all practices, and providing resources for physicians. All families will receive multiple phone calls in order to assess the child's symptoms. It is possible that an increased awareness of symptoms and enhanced communication with the primary care provider will occur, and will result in reduced morbidity for these children.

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