Clinic-based vs home-based support to improve care and outcomes for older asthmatics
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Mount Sinai	Protocol Title:	Clinic-based vs. home-based support to improve care and outcomes for older asthmatics
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MSSM Protocol HRP-503a

This study is funded by the Patient-Centered Outcomes Research Institute (PCORI). PCORI has established a **two-staged** approach to its study development, implementation, and analysis of findings.

- In **Stage I**, we will include development of interventions, solidifying partnerships, IRB approval, and training of project staff. **Research activities in this Stage I will include:** conducting focus groups and one-on-one cognitive interviews with stakeholders to provide feedback on the intervention materials and on the content and flow of the EMR-based asthma decision support tool.
- In **Stage II**, we will conduct a 3-arm randomized controlled trial among elderly patients with poorly controlled asthma from the clinics of the Mount Sinai Hospital, Mount Sinai's St. Luke's-Roosevelt, and Institute for Family Health. Patients will be randomized to clinic- or home-based support programs or to a usual care control arm and will be observed for 12-months.

Brief Summary of Research (250-400 words):

We will compare the effectiveness of home-based vs. clinic-based care coordination and self-management support to improve asthma treatment and outcomes for older adult asthmatics from Latino and African-American communities. Older Latino and African-American adults with asthma have a disproportionately higher risk of poorer health and health outcomes resulting from their disease compared to whites. Several contributing factors include but are not limited to multiple morbidities, greater medication regimen complexity, limited health literacy and English proficiency, healthcare costs, and beliefs about medications and illness that affect medication use.

Clinics have successfully leveraged the electronic medical record (EMR) to improve asthma care by providers. Unfortunately, this clinician-centric strategy cannot compensate for the diverse demographic, psychosocial, health status and health systems challenges faced by older adults. However, two viable patient-centric strategies have emerged with great promise: **clinic-based care management support** led by a care coach, and **home-based patient/family support** led by a community health worker. At present, no study to our knowledge has directly compared these approaches for improving asthma care and outcomes for any adults, including the elderly.

In this study, we will compare these two patient-centric self-management support strategies, and couple them with clinician-centric, EMR-based clinician decision support to complete a 360^0 approach to improving asthma care and outcomes for older adults.

1) Objectives:

Our specific aims and hypotheses are:

Aim 1: To compare the effectiveness of clinic and home-based asthma care coordination and self-management support to improve care and asthma-related outcomes.

Hypotheses: Compared to usual care, patients receiving either clinic- or home-based support will:

1) have better asthma outcomes (control, quality of life, less need for urgent care)
2) have better asthma self-management (medication adherence, trigger avoidance, appointment keeping, use of action plans)

Aim 2: To identify subsets of individuals who will have greater benefit from home-based care coordination and self-management support compared to clinic-based support.

Hypothesis: Patients with more severe asthma and those at greater risk of missed clinic appointments because of physical or cognitive impairment and psychosocial issues (e.g., substance abuse, mental illness) will be more likely to benefit from the home-based intervention.

In **Stage I**, we will address these aims through future developing the intervention. We will conduct focus groups and one-on-one cognitive interviews with stakeholders to provide feedback on the intervention materials and on the content and flow of the EMR-based asthma decision support tool.

In **Stage II**, we will conduct a 3-arm randomized controlled trial among elderly patients with poorly controlled asthma from the clinics of the Mount Sinai Hospital, Mount Sinai's St. Luke's-Roosevelt and Institute for Family Health. Patients will be randomized to clinic- or home-based support programs or to a usual care control arm and will be observed for 12-months.

2) Background

IMPACT OF THE CONDITION ON THE HEALTH OF INDIVIDUALS

Asthma, Disparities, and Aging. African-Americans and Latinos, low-income individuals, and the elderly suffer disproportionately from asthma in the US. Physical factors like frailty and long term changes to the lung and immune system can contribute to poorer outcomes among older asthmatics. Much of asthma outcomes in the elderly are traceable to the care they receive and their ability to effectively manage their illness between medical visits. Compared with younger adult asthmatics, the elderly have more chronic illnesses and more complex medication regimens, and higher prevalence of depression and cognitive and functional impairments. They are also more likely to have low health literacy, fixed incomes and high healthcare costs, and less likely to have reliable social supports. Alone or in combination, these factors challenge the self-management skills of older adults.

POTENTIAL OF THE STUDY TO IMPROVE CARE AND OUTCOMES

Re-Thinking Asthma Interventions to Address Aging and Disparities. Numerous interventions to improve asthma outcomes across the lifespan - from young children, early adulthood, and onward have been extensively described. But very few have been specifically designed for older adults or comprehensively address the barriers to asthma control commonly found in the elderly. Current interventions fail to address the multiple needs of these complex patients as they seek to improve asthma care and outcomes. Moreover, they often provide patients with a broad understanding of asthma disease and its management with small benefit, rather than tailoring to the specific needs of the patient. Such broad-stroke, unfocused approaches may unduly complicate patient learning and distract attention from the key information and skills needed to improve asthma control, especially among older adults who are disproportionately affected by low literacy and cognitive limitations that further limit new learning and retention. Many published interventions also have patients spend time in lengthy training sessions or complete complex tasks thereby limiting opportunities for engagement as well as retention of information.

We have chosen to compare 2 promising mechanisms for engaging older adults in asthma care, improving their care, health and quality of life. The approaches take advantage of emerging models of care delivery, use of the practice-based care coordinator and the community health worker conducting home visits.

Clinic-Based Care Coordination and Self-Management Support (CC/SMS). Self-management support programs have been used extensively in primary care for several decades with important benefits, including for older adults. Mount Sinai Hospital (MSH) and The Institute for Family Health (IFH) have developed successful models of care coordination/self-management support based on the Chronic Care Model and others. At MSH, the Preventing Admissions Care Team uses care coordinators to provide patients with extensive self-management and social services support. This program has resulted in a 50% reduction in hospital readmissions among frequently hospitalized Medicare patients. MSH has also applied this approach to reducing ED revisits by older adults, and has created a team of care coaches in the primary care practices who use the same strategies toward the goal of improving diabetes care and outcomes. At IFH, a Chronic Care Model-based diabetes care management program resulted in a 22% reduction in HbA1c levels, a measure of diabetes control, indicating substantially improved diabetes control. IFH has also broadly and successfully implemented the Collaborative Care Model for depression management in primary care, again using care coordination and self-management support as a core element.

Community Health Worker Programs. Programs use community health workers (CHWs) to promote the well-being and improve the health of individuals with diseases like asthma, diabetes and hypertension by engaging the patient and their social supports, addressing barriers to care, and promoting self-management activities. CHWs are lay persons with limited training in self-management support for one or more conditions. They are typically

residents of the communities in which they serve. The American Public Health Association explains that CHWs develop trusting relationships with patients, social networks, and other community members and organizations that allow them to serve as influential healthcare liaisons to the community to improve health outcomes and self-management. The Institute of Medicine supported the use of CHWs to close the gap in the quality of care received by populations experiencing racial and ethnic disparities. CHW programs have a proven record of success for several chronic diseases. CHW programs have been effective for asthma. The literature on CHW interventions for asthma, however, focuses almost exclusively on pediatric populations. A major innovation of our study is the plan to adopt the CHW model for older asthmatics.

Comparing Home- and Clinic-Based CC/SMS. Our emphasis on comparing home versus clinic-based strategies is highly germane to older asthmatic patients, as both have legitimate strengths and weaknesses. Home-based interventions allow for patient engagement in a setting where the CHW can more directly and objectively determine asthma self-management concerns related to one's physical environment. In addition, elderly patients are often socially isolated and have fixed incomes, posing challenges for transport to and from the clinic. Further, with greater comorbidity, more frequent visits may not be as plausible. Yet there are negatives as well for home-based approaches; when outsourcing care coordination and self-management support services, there may continue to be a disconnect between these activities and clinical decision making and care since it is not based directly in the clinic itself. Furthermore, some patients may be less receptive to the intrusion of a home visit. For clinic-based care, the strengths of home-based interventions are the weaknesses here. Assessments and interventions are not tailored to one's living situation (i.e. avoiding triggers, helping patients organize and store medicine). At times follow-up may require phone calls rather than face-to-face meetings to reach patients. And collaboration between the care coach and PCP is greatly enhanced when the two work in the same location.

3) Setting of the Human Research

In **Stage I**, we will recruit stakeholders to participate in focus groups and cognitive interviews, and in Stage II we will recruit patients to participate in a 3-arm RCT. The research will take place at Mount Sinai Hospital, the Institute for Family Health, and Mount Sinai's St. Luke's-Roosevelt. At Mount Sinai Hospital, the participating site will be the Internal Medicine Associates (IMA) and Pulmonary clinic. Interviews with IMA stakeholders will be conducted in the Center for Advanced Medicine, 17 East 102nd Street, New York, NY, 10029. At St. Luke's Roosevelt Hospital, the participating sites will be University Medical Practice Associates (UMPA), 2771 Frederick Douglass Blvd., New York, NY 10039, and the St. Luke's Medical Group (SLMG), 1090 Amsterdam Ave., New York, NY, 10025, and the Pulmonary Clinic. At the Institute for Family Health (IFH), the participating sites will be at the Family Health Center of Harlem, 1824 Madison Ave, New York, NY, 10035 and the Walton

Family Health Center and Center for Counseling, 1894 Walton Ave, Bronx, NY, 10453.In stage II, patients will also be recruited from additional IFH sites: Sidney Hillman/Philips Family Practice, 16 E 16 St., New York, NY 10003, Amsterdam Center, 690 Amsterdam Av., New York, NY 10025, Mt. Hope Family Practice, 130 W Tremont Av., Bronx, NY 10453, Urban Horizons Family Health Center, 50-98 E 168th St., Bronx, NY, 10452, Stevenson Family Health Center, 731 White Plains Road, Bronx, NY 10473.

The following table describes the **Stage I activities**:

Stage I -- Research Activity	Subjects
30 Cognitive Interviews - One subject per interview - *Focus:* intervention protocols and materials	- Patients, caregivers, and clinicians (30 subjects total) - **10 subjects recruited from and invited to Mount Sinai** - 10 subjects recruited from and invited to IFH - 10 subjects recruited from and invited to SLR
9-12 Focus groups - 8 individuals per focus group - *Focus:* intervention protocols and materials	- Patients, caregivers, and clinicians (60 subjects total) - **20 subjects recruited from and invited to Mount Sinai** - 20 subjects recruited from and invited to IFH - 20 subjects recruited from and invited to SLR
9-12 Focus groups - 8 individuals per focus group - *Focus:* EMR-decision support tool	- Clinicians only (60 subjects total) - **20 subjects recruited from and invited to Mount Sinai** - 20 subjects recruited from and invited to IFH - 20 subjects recruited from and invited to SLR

The follow table describes **Stage II activities**:

Stage II -- Research Activity	Subjects
In-person Interview (at baseline)	- Patients - **175 subjects recruited from and invited to Mount Sinai** - 175 subjects recruited from and invited to IFH - 100 subjects recruited from and invited to SLR
Phone Follow up (at 3-months and 6-months)	
In-person Interview (at 12-months)	

4) Resources Available to Conduct the Human Research

Based on our estimation of 900 eligible patients from Mount Sinai. Approximately 9% (100/900) of eligible patients will need to be recruited in order to meet recruitment goals in Stage I. Approximately 20% (175/900) of eligible patients will need to be recruited to meet recruitment goals in Stage II.

Based on our estimation of 500 eligible patients from SLR. Approximately 10% (50/500) of eligible patients will need to be recruited in order to meet recruitment goals in Stage I.

Approximately 20% (100/500) of eligible patients will need to be recruited to meet recruitment goals in Stage II.

Key Personnel from Mount Sinai involved in the study:

Name	Department	Role
Alex Federman, MD, MPH	Medicine - General Internal Medicine	Principal Investigator
Juan Wisnivesky, MD, DrPH	Medicine - General Internal Medicine	Co-Investigator
Joseph Kannry, MD	Medicine - General Internal Medicine	Co-Investigator
Joel Erblich	Oncological Sciences	Co-Investigator
Jonathan Arend, MD	Medicine - General Internal Medicine	Significant Contributor
Victoria Wagner	New York State Department of Health*	Co-Investigator
Diane Hauser, MPA	The Institute for Family Health*$^{\Psi}$	Co-Investigator
Manmeet Kaur	City Health Works*	Significant Contributor
Tim Johnson	Greater New York Hospital Association	Significant Contributor
Virna Little, PysD, LMSW	The Institute for Family Health*$^{\Psi}$	Co-Investigator
Ray Lopez	Little Sisters of the Assumption*	Co-Investigator
Joseph Lurio, MD	The Institute for Family Health*$^{\Psi}$	Co-Investigator
Jennifer Mane	New York State Department of Health	Significant Contributor
Carla Nelson	Greater New York Hospital Association	Significant Contributor
Rosemary Obiapi	Union Settlement	Consultant
Michael Wolf, PhD	Northwestern University*‡	Co-Investigator
Edwin Young, MD	St. Luke's Roosevelt*$^{\Psi}$	Co-Investigator

**Partner organization (subcontracted)*

$^{\Psi}$Research compliance of study activities with IFH or SLR subjects will be monitored by the IFH or SLR IRBs, respectively.

‡Research compliance of study activities involving qualitative data analysis will be monitored by the Northwestern IRB.

Non-Key Personnel involved in the study participating in research activities with Mount Sinai and SLR subjects will be managed by the PI. Requisite certifications and records for these individuals will be included in the Regulatory Binder and Financial Conflicts of Interest will be reported on Sinai Central.

5) Study Design

a) Recruitment Methods

IDENTIFICATION OF HUMAN SUBJECTS (Patients, Caregivers and Clinicians):

Potentially eligible patients (Stage I and II) will be identified through queries of the clinical billing records systems (Cerner) at Mount Sinai and through EPIC and queries of eClinicialWorks at SLR (generated by Dr. Edwin Young). This application includes a Waiver of Authorization to access patient medical records at Mount Sinai and at SLR.

- **In Stage I,** the queries will identify patients ≥60 years with an asthma diagnosis, and will list their names, medical record numbers, date of birth, date and time of upcoming clinic appointment (within 4 weeks), address, phone number, and name of primary care provider. At Mount Sinai, these queries will identify patients ages ≥50 years.
- **In Stage II,** three queries will identify patients ≥55 years with an asthma diagnosis.

  - **POPULATION MANAGEMENT REPORT:** Query #1 will be a monthly report. At MOUNT SINAI, this report will be the primary method for recruiting asthma patients who access regular primary care and pulmonary services. We expect this query to identify patients with both controlled and uncontrolled asthma. The report will list patients' names, medical record numbers, social security numbers, date of birth, date and time of upcoming clinic appointment (within 4 weeks), address, phone number, and name of primary care provider. At ST. LUKE'S, this query will also be generated.
  - **ACUTE CARE REPORT:** Query #2 will be a daily report. At MOUNT SINAI, this report will be used to identify patients who were recently in the ED or hospital for an acute asthma attack. We expect this report to identify patients with uncontrolled or severe asthma. The report will list patients' names, medical record numbers, social security numbers, date of birth, address, phone number, oral steroid use, latest ED/hospital visit (in past 12 months) and name of primary care provider. At ST. LUKE'S, this query will not be generated.
  - **POINT OF CARE REFERRAL REPORT:** Query #3 will be a daily report. At MOUNT SINAI, this query will not be generated. At ST. LUKE'S, this report will be used as described in Stage I activities (see below) to assist PCPs with approaching patients.

At MOUNT SINAI:

We will obtain permission from physicians to recruit their patients. A request form will be distributed to physicians who see patients in IMA and pulmonary clinics. If we do not hear back by two weeks by email, mail, or fax, we will assume that we have permission to offer eligible patients the opportunity to participate in this study. Each physician will choose their preferred method of recruitment for their patients. Physicians will choose to:

a) Allow RAs to offer participation to all asthma patients under their care who are ≥50 years;
b) Require RAs to ask their permission by email or telephone on a patient-by-patient basis, or;
c) Prohibit study personnel from directly approaching patients under their care.

Eligible patients will also be identified from a previous study (NIH Grant#: R01HL096612; GCO#: 08-1084; HSM#11-00706). Patients previously enrolled in the aforementioned study indicated that they would like to be contacted to participate in future studies. A master list of these patients (name, medical record number, date of birth, address, phone number, and name of provider) will be generated for recruitment in this new study.

At ST. LUKE'S ROOSEVELT:

There will be two methods in which recruitment will occur in the Internal Medicine and Pulmonary clinics.

In the first method:

1) A list will be generated from an eCW query to identify patients with asthma who are 55years and older.
2) The RA will pre-screen the list for potentially eligible patients on eCW.
3) The RA will then email the providers of potentially eligible patients asking permission to approach them.
4) The RA will then approach the patient during their scheduled visit and introduce the study and administer the eligibility screener to those interested in participation.

In the second method:

1) A list will be generated from an eCW query to identify patients with asthma who are 55 years and older.
2) The RA will pre-screen the list for potentially eligible participants on eCW.
3) The RA will then email the providers of potentially eligible participants and request permission to send a letter on their behalf describing the study. We will only send a recruitment letter to those patients the provider recommends for the study.
4) The RA will then send the recruitment letter #1 where patients are provided with a phone number to opt in and hotline number to opt out.
5) If the study team did not hear from the patients after 10 days, recruitment letter #2 will be sent. This letter states that a member of the study team will call them in 10 days if we do not receive an opt out call from them.
6) Patients who do not opt-out after 10 days will be contacted by the RA to introduce the study.
7) Patients who speak with the RA on the telephone will be screened for eligibility.

Potentially eligible caregivers (Stage I only) will be identified from our eligible patient lists. At Mount Sinai, we will ask patients if they have a caregiver and if we may contact them to participate in Stage I of the study. At St. Luke's Roosevelt, we will provide patients with a letter to give their caregiver. The letter to their caregiver will have an opt-in hotline.

Potentially eligible clinicians (Stage I only) will be identified from clinical practices participating in this study.

RECRUITMENT OF HUMAN SUBJECTS (Patients, Caregivers and Clinicians):

In **Stage I**, we will recruit stakeholders to participate in focus groups and cognitive interviews. In **Stage II**, we will recruit patients to participate in a 3-arm RCT. In both stages, we will approach participants as described below:

- **Patients** (Stage I and II)– RAs at Mount Sinai will recruit patients from Mount Sinai (physician-approved) and SLR (release form provided) by sending them a recruitment letter. The recruitment letter will have an opt-out hotline number to call. Ten (10) days after the recruitment letter, an RA will approach the patient over the telephone. RAs

will use a recruitment script. If PCP approaches a patient about the study in a clinic appointment and the patient is interested in meeting with the RA in-person, the patient will be offered the opportunity to complete the eligibility screener that same day and bypass the recruitment letter and ten day waiting period.

- **Caregivers** (Stage I only)– RAs will ask eligible patients if they have a caregiver, and if we may approach their caregiver for participation in one of these focus groups or cognitive interviews as well. Caregivers will be approached over the telephone. RAs will use a recruitment script. At SLR, we will provide a letter for the patient to provide to the caregiver. The letter will include an opt-in hotline.
- **Clinicians** (Stage I only)– The PIs will make announcements at faculty meetings, staff meetings, and send out Division-wide recruitment emails. Clinicians will be invited to contact RAs if interested in participating.

In **Stage I**, RAs will schedule interested subjects for either a focus group session or cognitive interview. On the day of a focus group session or cognitive interview, the RA will meet with the subjects to administer the informed consent procedure. In **Stage II**, RAs will administer the eligibility screen and schedule the baseline research visit at the patient's preferred location (in the clinic or in the patient's home). The RA will call to confirm the baseline research visit 1-2 days in advance.

Note: No identifiable information beyond what is listed in the Waiver of Authorization will be automatically collected from the potential subjects prior to them being consented. If the potential subject decides not to sign informed consent, they will be asked to verbally give permission for de-identified information to be recorded in order to keep track of whether subjects who decide not to participate are different from those who decide to participate. They will be clearly told that this is optional and that if they refuse, it will have no bearing on their medical care. They will be told that the de-identified information we would like to record is the following: gender, age (not date of birth), race, and ethnicity. In the unlikely event that anyone is older than 89 years, they will be categorized as '90 or older' rather than specifying the age.

While this application and protocol seeks approval for conducting the study at Mount Sinai and SLR sites, IFH recruitment procedures are as follows:

Epic queries will identify potentially eligible patients; Epic reports will list their name, medical record number, date of birth, date and time of upcoming clinic appointment (within 4 weeks), address, phone number, and name of primary care provider. We will obtain permission from physicians to recruit their patients (see Letter request at Attachment A.) A request form will be distributed to physicians who see patients at the study sites. Each physician will choose their preferred method of recruitment for their patients. Physicians will choose to:

a) Allow RAs to offer participation to all asthma patients under their care who are over age 55;

b) Require RAs to ask their permission by email or telephone on a patient-by-patient basis, or;

c) Prohibit study personnel from directly approaching patients under their care.

Following approval by the PCP, patients will receive a letter about the research study and an upcoming call from the RA. The letter will have a toll-free telephone number patients can call to opt-out of the study. The RA will phone patients who have not opted out after 10 days. The RA will describe the study, recruit, screen for asthma control and eligibility, and schedule a baseline research interview.

b) Inclusion and Exclusion Criteria

PATIENTS: Inclusion Criteria: we will include English and Spanish speaking adults ages ≥55 years (≥50 years at Mount Sinai for Stage I only) who have a physician diagnosis of asthma. **Exclusion Criteria:** COPD or other chronic lung condition, ≥15 pack-years

CAREGIVERS: Inclusion Criteria: we will include English and Spanish speaking adults ages ≥21 years who provide formal (≥6 continuous months) or informal care to an older adult (age ≥60 years) with a physician diagnosis of asthma. **Exclusion Criteria:** n/a

CLINICIANS: Inclusion Criteria: we will include English speaking clinicians from participating clinics (adults ages ≥21 years). **Exclusion Criteria:** n/a

c) Number of Subjects

In Stage I, a total of 150 subjects (patients, caregivers, providers) will be recruited to participate in focus group sessions and/or cognitive interviews. We will recruit 100 subjects from the IMA clinic and 50 subjects from the UMPA and SLMG practices at SLR. In Stage II, a total of 405 patients will be recruited for this study. We will recruit 175 patients from the Mount Sinai Hospital's IMA and Pulmonary clinics, 175 from all aforementioned sites at the Institute for Family Health, and 100 patients from the Mount Sinai's St.Luke's Roosevelt UMPA, SLMG, and 59th Street practices.

d) Study Timelines

The duration of **Stage I** is 8 months. The duration of **Stage II** is 2 years and 4 months. Patients will be followed from the time of consent from baseline through the 12-month follow up.

e) Study Endpoints

Stage I activities are estimated to close on 11/30/2014. Stage II activities are estimated to close on 12/30/2017. We will follow patients for one year (12 months) or until death. We will continue to track patients throughout hospitalizations or after withdraw from the either study arm.

f) Procedures Involved in the Human Research

STAGE I. ***Focus Groups and Cognitive Interviews. (Months 0-8)***

We will conduct focus groups and cognitive interviews with patients, caregivers, and clinicians. We expect to conduct 30 cognitive interviews with stakeholders on the intervention protocols and materials, 9-12 focus groups on this same topic and 8-10 interviews with clinicians focusing on the EMR-decision support tool. Team members will compare notes after conducting two interviews at each site and will revise the protocols, materials, and EMR-screen shots before proceeding to the next round of interviews. Interviews will continue until no further substantive changes are required. We will reimburse subjects $25 in cash. The table below describes the topics to be discussed in the interviews. At the end of each focus groups or cognitive interview, we will ask participants to complete an Information Sheet. The Information Sheet for patients/caregivers asks about gender, age, race, ethnicity, educational attainment, income, English ability, and age the patient was first told they had asthma. The Information Sheet for providers asks about their gender, role in the clinic, clinical training, work domain, what electronic medical records they have used in the past. The sheet also asks them to rate their knowledge and skills in managing asthma in adults, how helpful Epic is in helping them to manage their patients with asthma, and provide any suggestions for what features could be added to Epic to help them to better manage their patients with asthma.

Research Activity	Topics
30 Cognitive Interviews - One subject per interview - *Focus:* intervention protocols and materials - Patients, caregivers, and clinicians	- Intervention materials - Clinical protocols - EMR-content and programming - Research data collection - Assembly of materials - Creation of manuals
9-12 Focus groups - 8 individuals per focus group	- Asthma symptoms and how they affect your life - Roles and responsibilities of the care coach

- *Focus:* intervention protocols and materials - Patients, caregivers, and clinicians	- Clinical intervention protocol – i.e., calls vs. visits, length of calls and visits, optimum number of reminders - Best practices for notifying patients about disease belief misconceptions - Review of optimum patient education materials
9-12 Focus groups - 8 individuals per focus group - *Focus:* EMR-decision support tool - Clinicians only	- Information required for a patient assessment - Decision support tool - Other support tools to model - Overall program

STAGE II. ***Randomized Controlled Trial. (Months 9-36)***

ACC AND CHW ASTHMA PROGRAM DETAILS. The ACC and CHW programs for asthma CC/SMS will have the same objectives and provide the same general services. The primary difference will be the location, home or office, in which the bulk of services are provided, and the attendant advantages and disadvantages these locations present. **Note:** the ACC and CHW programs will be developed from existing, successfully operating programs at IFH and MSH, and in the East Harlem and South Bronx communities.

- **Training.** During this **Stage I** there will be a brief orientation to the study for all clinical and non-clinical staff in the participating clinics. The project manager will train the four RAs in all study protocols. The RAs will have appropriate Human Subjects Training Program certification. Our team of experts (Asthma Social Workers, Care Managers, General Internists, and Pulmonologists) will train the ACCs and CHWs. All protocols and materials will be carefully reviewed. A pulmonologist and asthma social worker (overseen by Dr. Wisnivesky) will conduct the asthma trainings, which will cover basic disease processes and the role of allergens and other triggers, symptom and severity assessments (ACT and peak flow), medications and other management strategies, medication adherence and other self-management behaviors (action plans, trigger avoidance, appointment keeping, etc.). Mr. Lopez will lead training on home assessment, with a discussion on performing the assessment by patient self-reports (germane to the work of the ACC). Dr. Little will lead the training on chronic illness management (e.g., methods to support adherence, motivational interviewing) and principals of care coordination, and Dr. Baum will supplement this with information and methods relevant to the CHW and home-based support. We will include some existing CHWs and CCs for this study, thus limiting additional training to asthma-specific management, basic management of other chronic conditions, and the program protocols. Trainings will include role playing and interviews with actual patients. Complete training will be approximately 60 hours. During **Stage II**, ACC/CHWs will be supervised at regular intervals of program implementation to ensure fidelity to program protocols and to reinforce learning.

RESEARCH COMPONENT DETAILS. We will conduct a 3-arm, patient-randomized pragmatic clinical trial following older adults with uncontrolled asthma for up to 12 months. We will register the trial at ClinicalTrials.gov.

- **Recruitment.** (*Procedures are described in detail above in #5a.*) Patients will be identified from several EMR reports. Following approval by the PCP, patients will receive a letter about the research study and the upcoming call from the RA. The letter will have a toll-free telephone number to enable patients to call and opt-out. The RA will phone patients to describe the study, recruit, screen for asthma control and eligibility, and schedule for a baseline research interview. All research interviews will take place at the preferred location of the patient (in the clinic or in patients' home).

- **Randomization.** After the RA has completed the baseline research interview, the PM will access a dedicated website that implements the algorithm to obtain the assignment. The PM will notify the ACCs or CHWs that a new patient is assigned to their respective intervention arm. Randomization to the study arms will be made with a 1:1:1 scheme using a dynamic algorithm to minimize imbalance between treatments with respect to important covariates including site and level of asthma control (not well controlled vs. very poorly controlled as per NAEPP guidelines). A minimization technique will be employed (i.e., allocation is assigned to the arm that minimizes an imbalance score calculated based on site and asthma control). **Please note:** at the end of the 12-month study period, patients assigned to the usual care arm will be given the option to meet with a clinic-based care coach.

- **Measures.** Baseline and 12-month interviews in person, 3-month and 6-month interviews by phone.

Outcome	**Measure**	**Comments**
Asthma control	ACT	Baseline, 3M, 6M, 12M
Pulmonary function	FEV1; FEV1/FVC (hand-held device)	Baseline, 12M
Asthma related QoL	Mini-AQLQ	Self-report measure - Juniper (1999); Baseline, 3M, 6M, 12M
Resource Utilization	Urgent clinic visits, emergency department visits, and hospitalizations	1) Self-report (Baseline, 3M, 6M, 12M) 2) New York State SPARCS registry (12 mos preceding enrollment, 12 mos post-enrollment)
Asthma Management behavior: Medication Adherence	Medication Adherence Report Scale (MARS)	10 item self-report measure – Cohen (2009); Baseline, 3M, 6M, 12M
	Also working on obtaining pharmacy claims	

Asthma Management behavior: Inhaler Technique	MDI and DPI inhaler technique	RA observation on placebo device using validated checklist - Manzella (1989); Baseline, 12M.
Asthma Management behavior: Self-Monitoring	Asthma action plan use; Peak Flow Meters	Self-report: Action Plan (y/n), Peak Flow (y/n) Peak Flow Frequency of Use; Baseline, 3M, 12M
Trigger Avoidance	Individual Items	Self-report: allergy cover use, household pets, exposure to cigarette smoke in the home, washing bed sheets in hot water, cleaning dust in home; Baseline, 12M
Environmental Exposure	Urban Environment and Childhood Asthma assessment	Baseline and 12 months
Appointment Keeping	Appointment keeping	Chart review of kept and missed clinic appointments; 1 year before baseline – 12M
Patient Perspectives of Services	CAHPS/HCAHPS	Modified Subscales: Perceived trust, Your Care from Nurses. Overall rating of intervention (Scale 1-10) Baseline, 3M, 12M
Programs expectations/Exit Survey	See attached questionnaire	Exit survey at 12M.

Other Measures	Items	Comments
Sociodemographics	• Age • Sex • Race/ethnicity • Education • Income • Insurance type	Interviewer administered at baseline
Social support	• Marital status • Number of household occupants • Lubben social support scale	Interviewer administered at baseline, 12 months
Health literacy	• Newest Vital Sign (NVS)	Baseline
Asthma history	• Age of onset • Intubations • Current asthma medication use	Interviewer administered at baseline
Smoking history	• NHANES items	Interviewer administered at baseline, 12 months
Cognitive function	• Montreal Cognitive Assessment (MoCA)	Interviewer administered at baseline
General health	• SF-1 general health measure	Baseline, 3, 6, 12 months
Co-Morbidities		From EMR abstraction at baseline
Medications currently used		From EMR abstraction at baseline
Depression	• NIH PROMIS Measures for Depression	Interviewer administered at baseline, 6, 12 months
Anxiety	• NIH PROMIS Measures for Depression	Interviewer administered at baseline, 6, 12 months
Physical functioning	• Activities of daily living • Instrumental activities of daily living	Lawton and Brody

- **Statewide Planning and Research Cooperative System (SPARCS) Data.** The researchers will also access data on patients' healthcare use (including: hospitalizations or emergency department visits at hospitals other than Mount Sinai) from the New York State Department of Health's SPARCS data. Please note that all the SPARCS data collected is for research purposes only, and not clinical care.

- **Assessment of Acceptance and Implementation of Intervention.** In the final stages of the program, we will perform qualitative and quantitative assessments of provider acceptance, use, and implementation of the EMR-based decision support and tools,

provider experience communicating with ACCs and CHWs and vice versa, and patient experiences.

Qualitative assessments will involve one-to-one, semi-structured, exploratory interviews. Interviews will be 45 minutes and conducted on an ongoing basis until we have reached saturation for identified themes. We anticipate requiring up to 10 interviews each at site and will divide them evenly among clinicians and patients. Participants will be compensated for the time they spend participating in qualitative interviews. Dr. Wolf is an expert in qualitative research and will lead this effort following well-established methods.

Quantitative data will also be collected from stakeholders via written questionnaires. Among patients, at month 12 we will assess: general helpfulness of the program for improving their health (rated on a scale of 1 to 10), and trust in the ACC or CHW, measured with adapted items from the CAHPS. Among all clinicians in the participating sites, at study month 30 we will assess general helpfulness of the program for improving their patients' health, trust in the ACC or CHW, quality of the communication with the ACC/CHW, helpfulness of EMR-based support tool and barriers to using it. We will further assess clinicians' use of the decision support tool through electronic inquiries of the EMR. These will include the proportion of encounters in which the PCPs used the decision support tools, what elements they used or actively disregarded, and when they were used. Assessments of ACC activities will include reviews of their documentation on a random selection of 20 cases for each ACC and CHW beginning in study month 25. These will include the number and frequency of contacts per patient, the duration of visits and calls, the number of calls required to make contact with a patient for each planned encounter, the number of missed and kept scheduled in-person meetings, the number and subject of topics addressed during in-person encounters, and the frequency of documented exchanges between the ACC/CHW and PCP. The RAs will use a standardized chart abstraction form.

- **Retention Materials.** We will send winter holiday postcard to study participants. The card will thank them for their participation, letting each enrolled/consented person know that we appreciate their time and effort.

g) Specimen Banking

Not applicable.

h) Data Management and Confidentiality

In **Stages I and II**, each subject will tracked using an Access database. Identifiers and other related information for coordinating research activities (recruitment outcome, research interview call log and interview visit schedule, etc.) will be password

protected and kept on the secure Mount Sinai network drive. Only the PI, project manager, and RAs will have access this database.

Subject	Identifiers in database
Patient	name, MRN, address, phone number, DOB, (social security number, insurer, and beneficiary ID in Stage II only for NYS data on resource utilization)
Caregiver	name, address, phone number, DOB
Clinician	name, address, phone number, email address, job title, DOB

Security Measures: Several methods will be employed to reduce the risk of breach of confidentiality. A study identification number will be assigned to each subject in the study. The research data collected and stored will have the study identification number and no other identifying information on it. Research data (hard copies) will be stored in a locked file cabinet where the project manager's office is located in the Center for Advanced Medicine (CAM) Building at 17 East 102nd Street, New York, NY, 10029. The consent forms and the de-identified study data will be kept in a separate locked file cabinet at the same location. Using this method, if someone were to gain illegal access to the locked filing cabinet with study data, they would have no way to link this data to any identifying information.

Audiotape data access will be limited to only the PI, project manager, RAs and DSMB representatives. The RAs will set up and collect the audio-recordings at each taped session. The recording will be brought from the session directly to the project manager's office at Mount Sinai. It will be stored in a locked cabinet in the project manager's office. Data will be downloaded weekly from the recording device will be kept on the project manager's computer using an encryption software (TrueCrypt) to further ensure the safety of the audiofiles. De-identified transcripts will be sent to one of our partner organizations (Northwestern University, Chicago, IL) for coding and analysis.

i) Provisions to Monitor the Data to Ensure the Safety of subjects

The Data Safety and Monitoring Plan (DSMP) for **Stage I** activities is described below. The Data Safety and Monitoring Board (DSMB) for the study will be formed before the RCT begins in **Stage II**.

Data Safety and Monitoring Plan

A) Monitoring Entity: Dr. Federman will be responsible for the data safety and monitoring for the entire study; he will also oversee the safety and monitoring of data collected at ISMMS. Dr. Lurio will be responsible for the safety and monitoring of data collected at IFH.

Data collected at ISMMS and IFH will be sent for transcription. Transcribed focus groups will be sent to and summarized by Northwestern University. Dr. Wolf will oversee the data safety and monitoring of the data at Northwestern University.

B) Procedures for Monitoring Study Safety: 1) Safety reviews: The principal investigator will review the safety and progress of this study on a monthly basis. 2) Annual review: The principal investigator will review this protocol on a continuing basis for subject safety and include results of the review in the annual progress reports submitted to the safety officer and the Institutional Review Board. 3) Annual report: The annual report will include a list of adverse events. The annual report will address: a) whether adverse event rates are consistent with pre-study assumptions; b) reason for dropouts from the study; c) whether all participants met entry criteria; d) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and e) conditions whereby the study might be terminated prematurely. 3) Institutional Review Board review: The Institutional Review Board will review each protocol annually for safety.

Dr. Federman will be responsible for monitoring and reporting safety data from all study sites (ISMMS, IFH, and Northwestern University). Dr. Lurio will supervise the collection and reporting of safety data for all participants enrolled at IFH. Adverse events will be reported to the ISMMS and IFH IRBs. Additionally, safety data from IFH will be sent to ISMMS monthly. These data will be summarized individually and then combined with Mount Sinai data for reporting to the IRB and PCORI as necessary. Safety data from both study sites will be discussed monthly during study meetings with investigators from all study sites. We have used similar procedures in our prior studies conducted at ISMMS, IFH and Northwestern University.

In addition, we will use encryption software (Truecrypt, TrueCrypt Foundation) to protect all electronic audio data collected at ISMMS. Audio files from ISMMS and IFH will be sent for transcription and the transcripts will be sent to Northwestern University. Northwestern will serve as the Data Coordinating Center.

j) Withdrawal of Subjects

Patients are withdrawn from the study when they are found to be ineligible or become ineligible after enrollment. When patients are withdrawn, they are still followed up with research interviews, and also with the intervention (if the subject had been randomized to an intervention arm), but their data is later on excluded from analysis.

6) Risks to Subjects

Participation in the study poses minimal risk of psychological, social and economic harm. Informing subjects in advance that they may decline to answer any question asked during the interview will mitigate any risks associated with expressing their opinions (e.g., feeling uncomfortable). They will also be assured they can terminate their participation in the study at any time without penalty.

Greater than minimal risk is expected for subjects in the RCT. Participants enrolled into the intervention arms of this study are expected to benefit, having better asthma control. While participants in the usual care arm of this study may not benefit directly from their participation, we anticipate results from this study to benefit future patients by expanding research on comprehensive models of chronic care, including the multidisciplinary management of chronic diseases and the medical home concept.

There always exists, the potential for loss of private information; however, there are procedures in place to minimize this risk. Procedures include: regular quality control data checks, encryption of data, and adherence to the ISMMS policy on data safety and transfer.

7) Provisions for Research Related Injury

This research involves minimal to no risk for subjects. The investigators on this project will make themselves available to meet with any participants expressing medical or psychological distress while being interviewed.

In order to reduce the risk of subjects:

1. *Psychological distress may be provoked by issues discussed during the intervention sessions.*
   In order to reduce the risk of subjects becoming psychologically distressed, subjects will be asked at the time of consent to inform a member of the research staff if at any point during the study they feel that participating in the research is causing them undue distress. Subjects will also be clearly instructed at each study visit that they are free to discontinue their participation in the research project at any time and that this will have no consequences at all for their continued medical care. *Additionally*, if study personnel find that the subject requires referral for mental health services (e.g., suicidal ideation) during the course of the intervention, the study personnel will contact the subject's PCP directly to arrange for referral to mental health services. The IMA clinic has mental health professionals in place to address any distress that is brought on during the interview questions. The costs associated with these services will be included as a part of usual care in IMA.
2. *Violation of participant confidentiality is always a potential risk in research where identifiable data is collected.*
   We have measures and protocols in place to deter the loss of identifiable data. See #5h.

8) Potential Benefits to Subjects

While subjects may not benefit directly from their participation, we anticipate results from this study to benefit future older asthmatic patients by improving standard care and physician-patient communication about asthma. Clinician subjects may help improve their work environment by assisting with the design and enhancement of the EMR decision support tools to be available to clinic staff in **Stage II** of the study.

9) Provisions to Protect the Privacy Interests of Subjects

Subjects will be informed that their data is confidential. Subjects may stop participation at any time or skip any question if he/she feels uncomfortable.

Throughout the study, steps will be taken to ensure the privacy of participants. The research personnel will not provide details of study to subjects in public waiting areas but will instead disclose details in one of the private exam rooms of the clinic. The research personnel will communicate with subjects through the contact numbers they provide and will not reveal PHI in voicemail messages.

To ensure that subjects feel at ease throughout the interviews and intervention sessions, the research personnel will remind the subjects that if at any point he/she becomes frustrated or does not wish to answer a particular question or participate in an activity or discussion, he/she does not have to do so. In addition, the research personnel will give opportunities for breaks throughout the interviews and sessions.

10) Economic Impact on Subjects

Not applicable.

11) Payment to Subjects

Subjects enrolled in **Stage I** study activities (focus groups, cognitive interviews) will be reimbursed for their time and effort at each interview with $25 in cash ($25 total). Participating SLR staff will not receive monetary compensation; they will be provided with refreshments at the session. Subjects enrolled in Stage II study activities (research interviews at baseline, 3-months, 6-months, and 12-months) will be compensated for their time and effort at each interview.

Subject	Research Interview	Payment	Form of Payment
Patient	baseline	$ 25	cash at close of interview
	3-month	$ 10	money order mailed within 2 weeks
	6-month	$ 15	money order mailed within 2 weeks

	12-month	$ 25	cash at close of interview

12) Consent Process

Waiver of HIPAA Authorization: Waivers of HIPAA Authorization from both Mount Sinai and SLR are requested to identify subjects (patients) prior to enrollment into the study.

Waiver of Written Documentation of the Consent Process (Mount Sinai Focus Groups only): A waiver of written documentation of the consent process is requested for the focus group participants. The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure. The research presents than minimal risk of harm to subjects. The research involves no procedures for which written consent is normally required outside of the research context.

The only record linking the subject and the research would be the signed document. The group will be consented together and each participant will be afforded the opportunity to step aside from the group to ask questions.

Setting: Consent will be obtained in a private room at one of the participating Mount Sinai practices or in the patient's home.

Process: We will follow the Informed Consent Process Standard Operating Procedure (SOP) as described in the PPHS document HRP-090. Informed consent will be viewed as a process, i.e. at several times during review of the IRB approved consent document, the subject will be asked to explain in his/her own words what his/her understanding of the consent. This will enable the research personnel to enter into a dialogue with the subject and ensure that the subject understands that he/she is free to withdraw at any time without penalty. Information will be provided to the subjects in terms that they can fully understand. There will be no exertion of any overt or covert coercion. The consent document is written in language that the potential subject can understand. Subjects will be asked to explain the purpose of the study and the expectations of their participation in their own words. They will be encouraged to ask questions prior to giving consent. Prior to signature of the informed consent document we ask the research patient to complete a set of questions designed to assess the patient's essential understanding of the information contained in the informed consent document and given during the informed consent process.

13) Process to Document Consent in Writing

We will use the PPHS consent template.

14) Vulnerable Populations

Include	*Exclude*	*Vulnerable Population Type*
	✓	*Adults unable to consent*
	✓	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	✓	*Wards of the State (e.g. foster children)*
	✓	*Pregnant women*
	✓	*Prisoners*

15) Multi-Site Human Research (Coordinating Center)

Northwestern will serve as the Data Coordinating Center for Stage I activities. Audio files from ISMMS, SLR and IFH will be sent for transcription and the transcripts will be sent to Northwestern University.

16) Community-Based Participatory Research

Not applicable.

17) Sharing of Results with Subjects

Not applicable.

18) IRB Review History

19) Control of Drugs, Biologics, or Devices

Not applicable.

20) Control of Drugs, Biologics, or Devices

Note: The IDS has its own forms that must be completed and a review process that must be followed before the IDS representative will sign off on Appendix B for submission to the PPHS.