PCORI RESEARCH PLAN

Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report in developing their Research Plan.

RESEARCH STRATEGY

(Use continuation pages as needed to provide the required information in the format shown below. Limit 15 pages for this section. Refer to the PCORI Application Guidelines for additional guidance.)

Part A: Background and Significance

Mouse over each criterion for a short description of each. Refer to the PCORI Application Guidelines for additional information.

Impact of the Condition on the Health of Individuals and Populations (Criterion 1)

Asthma is an inflammatory lung disease that affects people of all ages and has significant morbidity and mortality. In the US, asthma affects over 26 million people and has experienced a concerning increase in overall prevalence[1,2]. Despite evidence that this disease can be managed on an outpatient basis, the burden of asthma remains high, and this condition alone is responsible for 2 million Emergency Department (ED) visits, 439,000 hospitalizations, and 3,000 deaths every year[3]. In addition to having a detrimental affect on health utilization, asthma negatively impacts patients' quality of life. Over 20% of all asthma patients miss at least one day of work or school every year, and twice as many asthma patients rate their health as poor compared with the general population[4]. There are also marked disparities in asthma outcomes for vulnerable populations. For example, African American children with asthma have triple the rates of their white counterparts in hospitalizations and ED utilization, and their mortality rates are almost five times higher than white children[5].

Poor outcomes and disparities for patients with asthma persist despite advances in medical knowledge. For example, the use of self-management tools and shared decision making (SDM) has produced notable positive changes in asthma outcomes[6,7]. Indeed, the research team leading this proposal also led the Asthma Comparative Effectiveness (ACE) Study funded by the Agency for Healthcare Research and Quality (AHRQ) to create a Toolkit to assist providers with implementation of a SDM approach to asthma care that would be effective in everyday practice[8]. Initial results from this study show that use of the Asthma SDM Toolkit is associated with improved outcomes in medication adherence and a reduction in utilization of acute care services.

Unfortunately, uptake of many proven new approaches such as the Asthma SDM Toolkit can be slow because of the gaps in our understanding of how best to disseminate evidence into everyday practice. Indeed, dissemination of information and interventions into practice has been highlighted as a key national priority by the Agency for Healthcare Research and Quality (AHRQ) and the Institute of Medicine (IOM)[9,10]. To address potential problems with the spread of new practices like SDM, the ACE study also piloted two different means of dissemination across almost 80 primary care practices. From this experience our team identified the following steps to test best practices for dissemination that will be used for this study. These steps include: (1) clearly define current dissemination methods and their impact; (2) identify and test novel methods for dissemination; (3) outline the underlying theoretical framework supporting current and novel dissemination mechanisms; (4) use a real world laboratory of primary care practices to test dissemination methods; (5) fully evaluate the impact of dissemination methods using quantitative outcomes data (ED, hospital, outpatient clinics, and pharmacies) as well as quantitative data collection to assess provider and patient satisfaction with dissemination methods and to solicit feedback for process improvement.

The study of dissemination methods is relatively new. Known barriers to dissemination include: heterogeneous patient and provider populations, limited support staff, lack of clinic resources, pressure on practices to improve efficiency, and the complexity of electronic medical record (EMR) systems. The most common type dissemination is the traditional model, (active diffusion), which does not adequately overcome these barriers. This process includes exposure to academic detailing by subject matter experts, journal publications, didactic presentations, and educational material distributed in paper and on-line formats[11,12].

The ACE study provided initial data on a novel mechanism for dissemination (described below, Page 5) that is based on the use of key principles of community-based participatory research (CPBR) to engage practice stakeholders and patients. The ACE study showed that this approach, termed Facilitator Led, participant OWned dissemination (FLOW) has greater facility for dissemination into real world practice settings than traditional methods. However, more rigorous testing of the FLOW dissemination process is required to determine its true utility.

Although the existing body of knowledge on dissemination methods is still developmental, practice-based research networks (PBRNs) have been identified as an ideal laboratory to test dissemination methods[13,14]. This study will occur within a well-established consortium of four PBRNs called the North Carolina Network Consortium (NCNC) that has been actively funded by AHRQ since 2005. The network includes diverse practices that range in size, location, practice type, and the race/ethnicity of their patients. Each member PBRN has extensive research experience and knowledge regarding how to work closely with practices to study interventions and to maintain the fidelity of their deployment[8].

To fully evaluate the effectiveness of a dissemination strategy across the full continuum of care, it is essential to collect data from both the providers and payors for evaluation. For this study, the team has closely partnered with the NC Medicaid network to design the initial study and to share data required for the evaluation. NC Medicaid has targeted asthma as a priority condition, and they will be a key partner in this project assisting with practice identification, recruitment, and evaluation.

The research team for this proposal is ideally suited to test a novel means of dissemination (FLOW) developed in an AHRQ funded study. We will work in partnership with a state-wide consortium of established PBRNs and the NC Medicaid network partners to implemented the intervention in real world practices and evaluate its impact using both payor and provider data. Qualitative data will be collected to assist in understanding barriers to implementation, to ensure that patients feel that they are partners in the development of the asthma care plan, and to improve the FLOW implementation over time. Data collected during the study and assessment of the impact of the dissemination strategies will allow the team to develop a theoretical framework to better describe the underlying mechanism supporting practice change.

Summary: Asthma is a common disease that affects people of all ages and has significant morbidity and mortality. Poor outcomes and health disparities related to asthma result in part from the difficulty of disseminating new evidence and paradigms of care delivery such as SDM into clinical practice. This study will evaluate a novel mechanism for dissemination of an evidence-based SDM Toolkit for asthma care in primary care practices. The study is ideally suited to study dissemination methods because it will leverage a partnership between an established consortium of PBRNs and an advanced Medicaid Network.

Innovation and Potential for Improvement through Research (Criterion 2)

Innovation #1: New Approaches are Needed to Improve the Care of Patients with Asthma. The need for research to improve asthma treatment and management has been identified as a national priority by the Institute of Medicine (IOM) and AHRQ.[15,16] This has also been recognized at the state level secondary to the high prevalence, burden of suffering, and disparities that exist in NC for this condition. In response, NC Medicaid has identified asthma as a top priority condition for 2013. A potential solution to improving asthma outcomes is the use of patient-centered approaches like Shared Decision Making (SDM). This approach to care was identified by both the IOM and PCORI as an important new means of improving patient outcomes.[17,18] In the SDM process, patients and their health care providers are engaged jointly in making decisions about medical tests and treatments. The research team for this proposal was funded by AHRQ to build, disseminate, and evaluate a novel Asthma SDM Toolkit – The Asthma Comparative Effectiveness Study[8]. The Toolkit development was completed in 2010, and has been in evaluation for 2 years. Initial results from this study show marked improvement in patient adherence to medications, deceases in asthma exacerbations, and decreases in utilization of the ED and hospital for asthma care[19]. This study will continue to evaluate the Asthma SDM Toolkit in a wide array of practices across NC while testing a new method of dissemination.

Innovation #2: New Methods are Needed to Disseminate Information and Better Paradigms of Care Delivery into Practice Because practice adoption of SDM requires varying degrees of practice level systematic change, the research team for the ACE study used key principles of community-based participatory research (CBPR)[20] to involve providers and patients in the development of the Facilitator-Led Participant OWned (FLOW) approach to dissemination. The participatory process, Toolkit, and FLOW approach to dissemination are described in greater detail in the following sections. In this initial ACE study, FLOW was used for dissemination into six pilot sites, while a traditional dissemination process was used in over 70 control sites. Preliminary findings show that FLOW sites had a greater uptake of the SDM Toolkit with all six FLOW sites using the full Toolkit, while none of the traditional dissemination sites were able to take on this complex practice change. This preliminary work suggests that the novel FLOW dissemination methodology can provide an ideal approach to spread new paradigms of care into real world clinical practices.

Innovation #3: Collaboration between a large, well-established research network consortium and a state-wide Medicaid network to implement and evaluate new methods of asthma management and dissemination. The science behind patient-centered approaches to care and evaluation of methods of dissemination is still in its infancy. The infrastructure of community and stakeholder partnerships that we have built for this proposal provides a laboratory ideally suited for the proposed study. The consortium of four experienced research networks provides the critical research infrastructure that will allow us to use rigorous research methodology evaluate the impact of the FLOW dissemination approach as well as the asthma SDM Toolkit itself on asthma related outcomes. In addition, the seasoned research teams from the networks will ensure that there is fidelity in the intervention roll out and data collection. Finally, the inclusion of the statewide Medicaid network has allowed for initial identification of practices. Perhaps more importantly, working with the Medicaid network for data sharing will allow the research team to use standardized data from the practices to fully evaluate the impact of the intervention on patient oriented outcomes including health services utilization and medication adherence.

A.2.1: Development of Asthma SDM Toolkit

This study will disseminate the Asthma SDM Toolkit developed by the research team as part of the Asthma Comparative Effectiveness (ACE) study funded by AHRQ. The development team, which has been using community-based participatory research (CPBR) techniques for the past decade, drew upon this experience when developing the Asthma SDM Toolkit[13,21-27]. The development process included patients and providers as partners in every step of development other than the initial study design. Of particular importance, the team used regular qualitative process assessment to engage participants and to get feedback from all partners to improve the development process itself.[28,29] The objective of involving patient and provider stakeholders early in the process was to develop an intervention that was not only effective, but also able to be readily disseminated into practice. Indeed, previous research suggests that implementation success is maximized when there are coordinated efforts to encourage participation, promote action, create supportive systems, and monitor and provide feedback on progress[11,12,30].

The Asthma SDM Toolkit that will be used in the current study was based upon the Better Outcomes for Asthma Treatment (BOAT) study[31]. This study was the first to demonstrate the effectiveness of SDM to improve medication adherence and disease outcomes for asthma patients in a research setting[31]. Our research team utilized the results from the BOAT study to create an Asthma SDM Toolkit that could be implemented in everyday practice. The participatory process for development occurred over a 6 month period and consisted of the following steps: (1) formation of a patient and provider advisory board; (2) a qualitative assessment of baseline asthma management strategies using focus groups consisting of both providers and patients; (3) identification of provider champions; (3) training of the advisory board and champions on the BOAT materials; (4) creation of the new Asthma SDM Toolkit designed for implementation into practice; (5) development of a dissemination strategy, FLOW; (6) deployment of the new Toolkit into practice; (7) regular qualitative assessment of providers and patients exposed to the Toolkit to collect feedback; and (8) evaluation of the impact of the Toolkit deployment on process measures and patient oriented outcomes. Of note, the advisory board and practice champions were regularly exposed to the qualitative assessments that were collected. Patients almost universally provided positive feedback that helped providers to better understand the impact of the Toolkit and to sustain their engagement. In addition, the advisory board was asked to regularly provide feedback on the research process in a setting without the research team members in attendance. The data was de-identified and presented back to the research team to help improve the research process.

This participatory approach culminated in the Asthma SDM Toolkit that will be deployed in this project (see appendix 1). This SDM Toolkit includes: (1) a tool to assess baseline asthma control; (2) a guide for eliciting the patient's goals for treatment priorities; (3) asthma educational materials; and (4) a tool to guide the negotiation process to jointly develop a treatment regimen that accommodates the patient's goals and preferences. At the conclusion, an asthma action plan is provided. The Toolkit and a training video can be found at: http://www.dicksoninstitute.com/FamilyMedsTools/.

A.2.2: Development of the Facilitator-Led participant OWned (FLOW) Approach to Dissemination

Adoption of the SDM process into a practice requires provider buy-in and practice flexibility[32]. Key barriers to implementation and sustainability include provider beliefs, attitudes, and motivations[33].

The ease of dissemination depends not only on provider/staff-level attributes but also clinic-level attributes such as practice culture[34] Typical barriers to adoption perceived by providers include, time constraints concern that SDM may not be applicable to their practice's patient population because of the patients' limited education or a preference that all medical decisions should be made by their physician[32,35,36]. However, providers tend to feel that incorporating SDM into their practices will improve patient outcomes and satisfaction with their care[35,36].

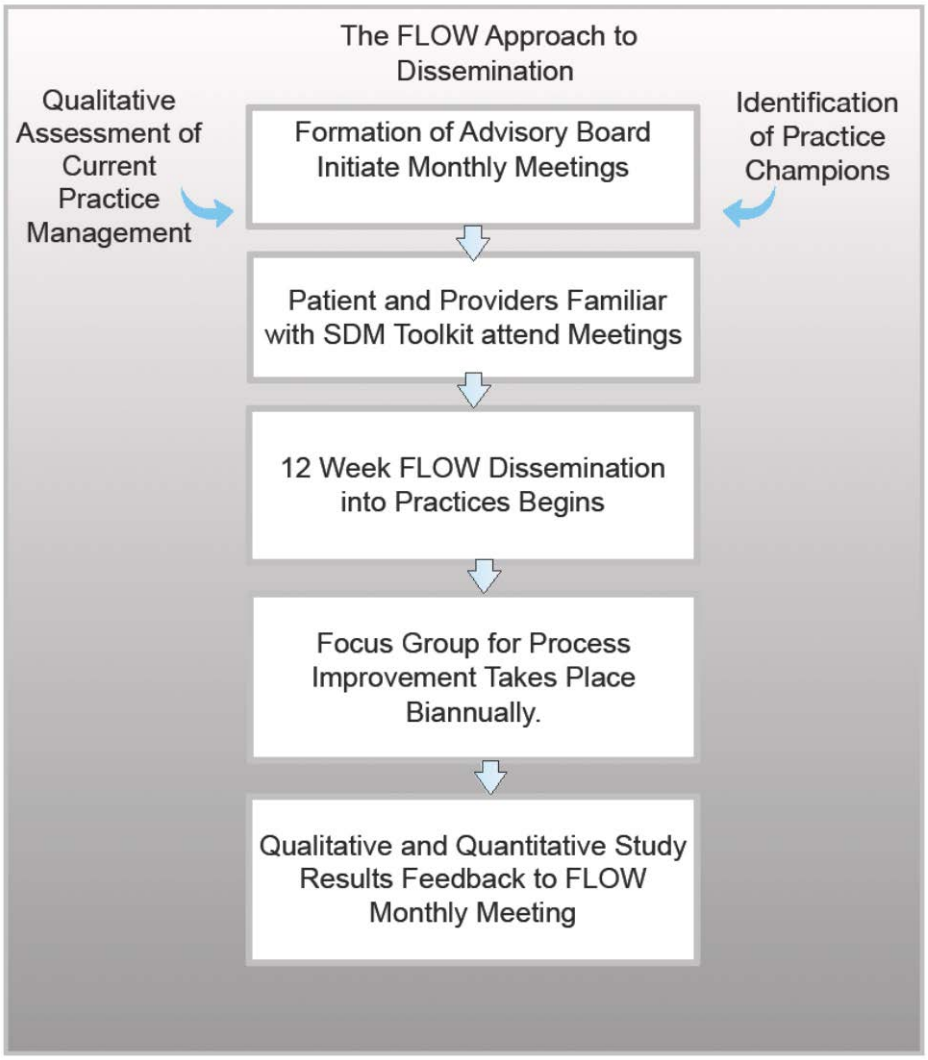


Figure 1. The Flow Approach to Dissemination

Recognizing the existence of perceived barriers to SDM adoption, the second phase of development of the Asthma SDM Toolkit involved using the participatory approach to design an innovative method for disseminating the Toolkit into real-world practices. The same team of providers, clinic staff, and patients helped to develop a strategy that incorporated a practice facilitator. The facilitator worked with each practice to individually tailor the Toolkit into the practice's unique circumstances, while maintaining key elements that were felt to be essential to the SDM process. The FLOW approach includes the following steps: (1) *Qualitative assessment of the way providers currently manage asthma (both providers and their patients are included in these sessions)*. This process allows providers to learn more about opportunities for improvement in the way they care for asthma patients, and to hear directly from

patients about their expectations for asthma management; (2) *Exposure to a patient and provider champion that have utilized the SDM Toolkit and seen improvements in their symptoms/outcomes*. This is an informal 1 hour session where providers can ask questions about the process and learn more about the benefits of implementation prior to training. During the session a local practice provider and patient champion are identified; (3) *The facilitator joins the practice for one hour each week to train all staff on different components of the SDM process over a 12 week period.* Training includes exposure to videos showing providers using the SDM technique as well as opportunities for the team members to practice SDM; (4) *Every six months, members of the practice staff including providers and patients will be asked to participate in a focus group soliciting feedback on the SDM process.* They will be asked about how the implementation of SDM within their practice could be improved; (5) *Qualitative and quantitative data will be collected from practices and provided back to the practices for review.*

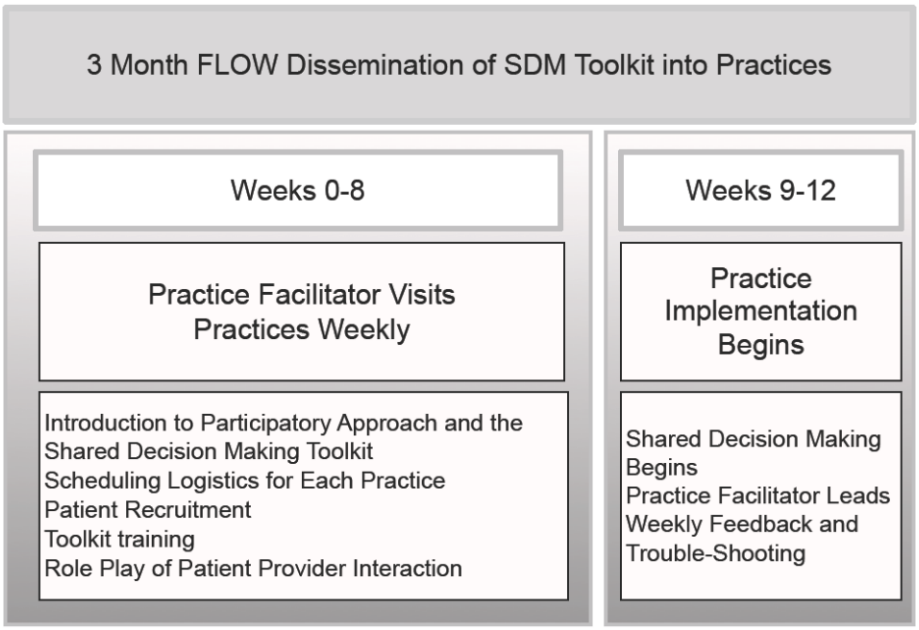


Figure 2. FLOW Dissemination

During the pilot study, this FLOW approach has led to effective dissemination of the Asthma SDM Toolkit at six diverse practices in 3 specialties (Family Medicine, Internal Medicine, and Pediatrics).

A.2.3: Patient Oriented Outcomes from the Asthma SDM Toolkit and FLOW Approach to Dissemination. Of the clinics that initially participated in FLOW, 100% (6/6) fully implemented the Asthma SDM Toolkit, and all clinics continue to use the Toolkit to date. After one year, of the 125 patients who received the SDM intervention, 91% reported that their visit involved a shared decision about asthma treatment (Figure 3). 79.3% reported that their influence on the treatment decision was equal to that of the provider. Furthermore, focus groups show that patient/parent participants felt involved in the decisions about their/or their children's asthma treatment. Additionally, FLOW dissemination results from the ACE Study show that compared with control, there was a decline in ED and inpatient visits**,** increased medication adherence for Medicaid patients, and increased appropriate care measures for asthma care.

Although the team has seen successful uptake of the SDM intervention during the FLOW pilot study, a larger more rigorous study is needed to fully evaluate the effectiveness of a FLOW approach when compared to traditional dissemination (active diffusion). In this proposed study, we will leverage an innovative partnership between the NC Medicaid Network and the state-

wide consortium of Practiced Based Research Networks (NCNC) to identify best practices for dissemination of the proven Asthma SDM Toolkit.

The hypothesis to be tested in the current proposal is: T**he FLOW approach to practice level dissemination is superior to the traditional (active diffusion) dissemination approach.**

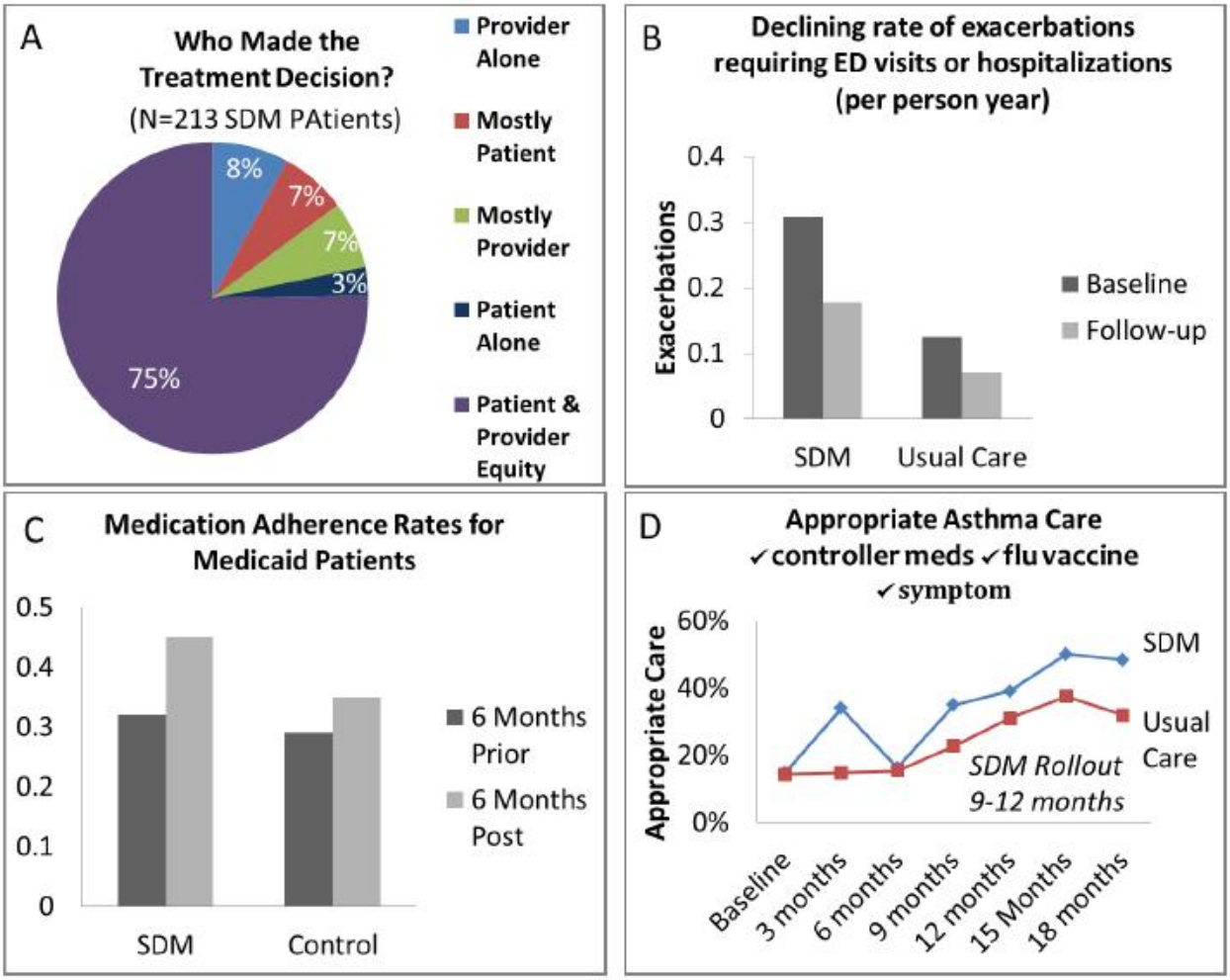


Figure 3. Preliminary FLOW dissemination results from ACE Study. **A** ~90 percent of patients equally or partially shared in the decision about their treatment. Compared with control, there was **B** a decline in ED and inpatient visits**, C** increased medication adherence for Medicaid patients, and **D** increased appropriate care measures for asthma care.

If proven to be successful during this study, our partners at NC Medicaid have committed to use FLOW to disseminate the Asthma SDM Toolkit to the 298 practices that they have identified for this study as having a higher than average volume of asthma patients (e.g. over 100 asthma patients with Medicaid Figure 8). The PBRNs will also use the FLOW infrastructure evaluated in this study to further disseminate the Asthma SDM Toolkit to other, non-Medicaid, practices within their networks. Furthermore, given the pragmatic design of the trial, and the expected generalizability of the results, the PBRNs can leverage the FLOW process to test dissemination related to best practices for care of patients with other chronic diseases, such as diabetes. If this novel approach to dissemination is found to be effective and

generalizable, proven therapies and novel patient centered care approaches like SDM can be efficiently implemented in practices across the US, which will have broad and significant implications for improving patient outcomes and the quality of care.

Summary: This study will evaluate a novel dissemination process (FLOW) to spread an Asthma Shared Decision Making Toolkit to practices within a Medicaid network using a consortium of practice-based research networks (NCNC). The knowledge gained from this proposal and the partnerships formed between practice-based research networks and NC Medicaid will facilitate widespread dissemination to almost 300 practices.

Impact on Health Care Performance (Criterion 3)

Shared Decision Making (SDM) is an example of a new approach to care delivery that has been shown to improve patient knowledge/satisfaction as well as disease outcomes[37]. However, despite evidence of its effectiveness, SDM has not been widely disseminated into practice. This is likely because SDM is a new paradigm for many providers who were trained to use a more unidirectional decision making process. In addition, SDM requires more time and often requires the involvement of a team-based approach to care delivery. The complexity of SDM can be daunting for providers who have difficulty seeing the immediate benefit of adopting more patient centered approaches to care.

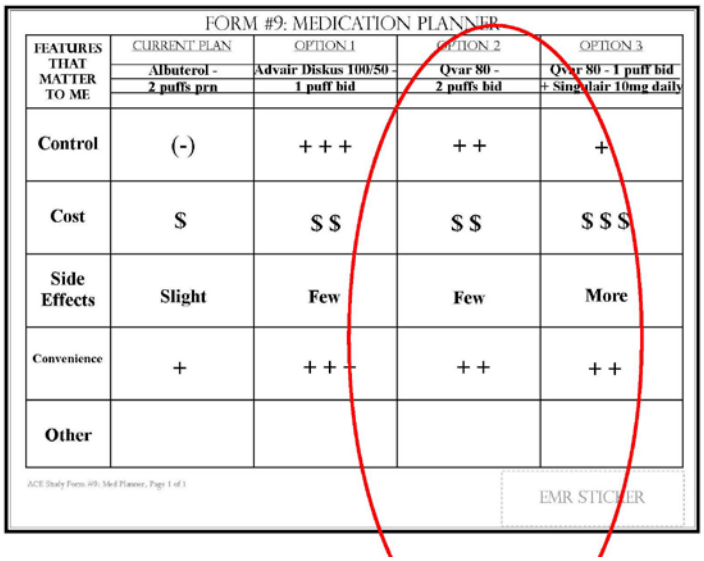
Developing mechanisms of dissemination that overcome these barriers is essential for new paradigms in care delivery like SDM to be adopted more broadly. Once FLOW has been used to spread the SDM paradigm into the clinical setting for one disease (in this case asthma), it is conceivable that providers will change their approach to providing care for other chronic conditions.

Part B: Relevance to Patients (Criterion 4)

Additional Information

B.1. Relevance to Patients for SDM:

The proposed study will evaluate a novel approach to dissemination, a need that was identified and further defined by a group of patients and key stakeholders participating in our the Asthma Comparative Effectiveness (ACE) Study. An advisory board that included patients, which was developed for this AHRQ study, was instrumental in the development of the intervention and dissemination methodology for this proposed study. Having a patient voice in the development and oversight of the Asthma SDM Toolkit design is critical to its successful implementation, and ensures that the study outcomes (asthma exacerbations and ED/hospital utilization) are of importance to patients, as well as providers and members of the research team.


FORM #9: MEDICATION PLANNER

FEATURES THAT MATTER TO ME	CURRENT PLAN	OPTION 1	OPTION 2	OPTION 3
	Albuterol - 2 puffs prn	Advair Diskus 100/50 - 1 puff bid	Qvar 80 - 2 puffs bid	Qvar 80 - 1 puff bid + Singulair 10mg daily
Control	(-)	+ + +	+ +	+
Cost	$	$ $	$ $	$ $ $
Side Effects	Slight	Few	Few	More
Convenience	+	+ + +	+ +	+ +
Other				

EMR STICKER

Figure 4. Medication Decision Planner

In addition to patient involvement in development and oversight of the ACE study, our team actively sought to get feedback from patients that were enrolled in the study itself. This was achieved by collecting surveys (Appendix 3) and qualitative data from patient focus groups. The survey results and analyzed qualitative data were shared with the providers who were using the Toolkit to promote continued engagement and uptake by the provider and practice.

The quantitative and qualitative results from the pilot study have also shown that the Asthma SDM Toolkit addresses key questions that are central to patient centered outcomes research. These questions include: “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me? What are my options and what are the potential harms and benefits of those options? What can I do to improve the outcomes most important to me?

How can clinicians and the care delivery systems they work in help me make my best decisions about my health and health care?” For example, after exchanging information about the patient’s assessment of his or her disease, goals, and preferences, the patient and provider work through the patient’s needs related to cost, convenience, and side effects for their medication choices (Figure 4 Medication Planner). This approach creates a framework that guides a dialogue between patient and provider, resulting in a two way discussion of the best evidence based options available for asthma care.

The current proposal will engage patients at all stages of the research process through the following three mechanisms. **First**, patients were involved in the development of this proposal. The research question underlying this study was born out of discussions at the NC Medicaid stakeholder meeting and guidance on the proposal was solicited from patients at the monthly meetings of the advisory board developed for the pilot ACE study. **Second**, the actual subject of the dissemination strategies, the Asthma SDM Toolkit, is built on the tenets of patient involvement in care decisions and inclusion of patient goals and preferences in the development of treatment plans. **Third**, a primary outcome of the study is the patient’s perception of shared decision making having taken place during his or her visit for asthma care.

B.2. Relevance to Patients of the FLOW Dissemination Process:

The FLOW dissemination approach is of particular relevance to patients, because patients helped to develop the approach and are included as part of the dissemination process as well. The FLOW approach includes the following five steps: (1) Targeted providers and their patients take part in a short focus group that asked providers to share how they currently manage asthma and asks patients to share perceptions about how their asthma is being managed by the provider. The goal of this step is to help patients and providers identify gaps in the way asthma is currently managed in the practice; (2) A provider and patient champion that have familiarity with the asthma SDM Toolkit come to the practice to share their experience with the providers in the practice. The goal of this step is to demonstrate that the SDM Toolkit can be implemented and can provide a better solution for managing asthma than the current state. In addition, a local provider and patient champion are identified in this step. These champions will become members of the advisory board and will be the first members of the practice to use the Toolkit; (3) A practice facilitator will come to the practice to train providers and staff one hour per week over a 12 week period of time. The training usually occurs over lunch (depending on provider preference). The goal of this step is to train the practice team on all elements of the SDM Toolkit; (4) Staff and patients participate in a focus group soliciting feedback on the implementation of SDM every six months. The goal of this step is to collect data that can be used by the advisory board and research team to improve the overall process; and (5) The analyzed and de-identified qualitative and quantitative data collected from practices during implementation is provided back to the practices for review. The goal is for the members of the

practice to share as partners in the discovery of new information and to use the feedback to improve the implementation of the SDM Toolkit themselves.
Finally, patients from each practice in the FLOW dissemination approach will be invited to be participants in the practice adoption and roll out of the Asthma SDM Toolkit by serving on an advisory board (see Stakeholders Section for details). Particular attention to the expertise provided by these patients will be maintained throughout the entire research process to ensure that dissemination is patient centered and sustainable.

Part C: Approach (Rigorous Research Methods) (Criterion 5)

Mouse over each underlined subheading for a short description of each. Refer to the PCORI Application Guidelines for additional information.

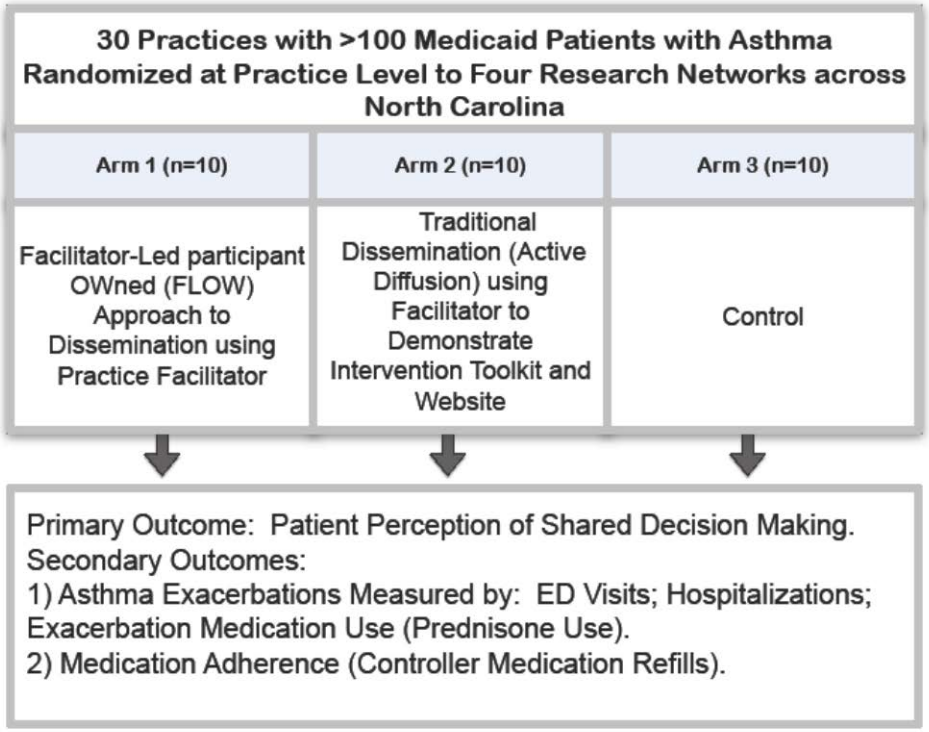


Figure 5: Study design

This study is designed to address the clear need expressed by patients, providers, and national groups for solutions to improve outcomes for patients with asthma care.
The question that will be addressed by this study is: **What dissemination strategy most effectively increases practice level adoption of SDM?** This question will be addressed using a statewide randomized controlled trial that will compare the effectiveness of the FLOW Approach to Dissemination to a traditional dissemination approach (active diffusion), and a control.

Research Question **The research question is: What dissemination strategy most effectively increases practice level adoption of a shared decision making approach to asthma management?** Adoption will be evaluated by measuring the level of patient involvement in the decision making process, qualitative assessments from patients and providers, and outcomes measures including medication adherence and asthma exacerbations. This study will include 30 primary care clinics located in eastern, southwestern and central North Carolina. Clinics will be randomized to one of three study arms: (1) Facilitator-Led participant OWned (FLOW) Approach to Dissemination; (2) Traditional dissemination (active diffusion) with facilitator exposure; and (3) Control / No active dissemination.

Choice of comparators This study will compare the effectiveness of three alternative approaches to dissemination of an evidence based Asthma SDM Toolkit that is designed to

improve patient/caregiver participation in care decisions and improve patient-oriented outcomes.
Arm 1: The FLOW Dissemination Method. This approach to dissemination allows clinics some freedom to tailor the SDM Toolkit and training process for their specific environment and patient population while maintaining fidelity of certain key elements that are felt to be essential for success. The expertise of the trained Practice Facilitator will help guide the process of implementation at the practice level.
Arm 2: Traditional Dissemination (Active Diffusion). The most commonly used dissemination technique is active diffusion, which includes didactic presentations, academic detailing, exposure to journal publications and subject matter experts, and educational material distribution. We have defined this type of dissemination, "traditional dissemination". For the purpose of this study, practices randomized to traditional dissemination will receive a lunchtime presentation by a physician champion / subject matter expert on shared decision making. The presentation will gives an overview of the Asthma SDM Toolkit, access to the internet link with additional information, and a copy of all printed materials associated with the Toolkit.
Arm 3: Control. A third group will be randomized into an arm with no formal dissemination. This arm will receive information only through passive exposure to the concepts of shared decision making. This would include introduction to the SDM concepts through the media, conferences, or social networks. Having this control in place will allow the research team to isolate the effect of both the FLOW approach and the traditional approach to dissemination.

Choice of study design

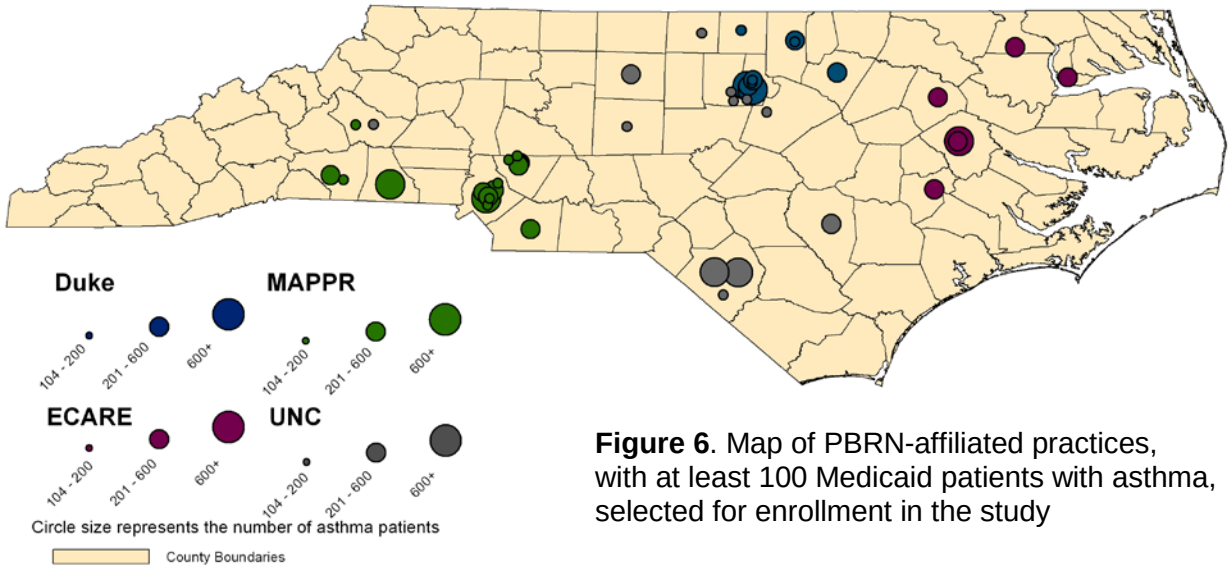


Figure 6. Map of PBRN-affiliated practices, with at least 100 Medicaid patients with asthma, selected for enrollment in the study

The 2 year study will use a randomized controlled design. Randomization will occur at the practice level. Thirty diverse primary care clinics located across North Carolina will be equally randomized into one of three study arms: (1) FLOW Dissemination, (2) Traditional Dissemination (active diffusion), and (3) Control. The randomization will be stratified by participating PBRNs (Figure 6) to ensure relatively equal geographical distribution. The practice was chosen as the unit for randomization because dissemination generally happens on a practice level. Prior experience from the pilot study also revealed that patient-level randomization causes difficulty for providers to adhere to the protocol.
Recruitment: Practices will be eligible for participation in the study if they have over 100 active Medicaid patients in their panel with the diagnosis of asthma. The Medicaid Network's

Informatics Center has identified 298 practices meeting this criterion for this study (Figure 8). The 30 practices will be recruited by the four PBRNs either from practices within their existing network or practices within an appropriate geographically defined area. Each PBRN has identified appropriate practices (Figure 6) which have already expressed interest in being part of this study during the preparation phase. For example, within the MAPPR network, University Pediatrics, has provided a letter of support for this project. Each PBRN will be responsible for recruiting two or three practices per arm for a total of 6 or 9 practices per PBRN and they will be responsible for the recruitment and oversight of a Practice Facilitator. As the lead group, MAPPR, will be responsible for hosting a centralized training and ongoing continuing education for the PBRNs' Practice Facilitators.

Applicability of study findings to broad populations This study is designed to test a dissemination strategy across the state of North Carolina. The Medicaid network and PBRN partnership are vested in providing statewide improvements in outcomes for patients with asthma. Therefore, after study completion, the PBRN consortium is prepared to assist the statewide Medicaid network to train all of the 298 eligible practices across the state in the use of the Asthma SDM Toolkit (Figure 8). Furthermore, while this study examines approaches to dissemination for an intervention specific to asthma within a high risk Medicaid population, it is designed to have broad generalizability to change the care delivery paradigm for patients with chronic diseases besides asthma

Choice of outcomes

Success of the dissemination process will be determined by looking at process and outcome measures collected at the patient and clinic level. The primary outcome will be the patient's perceptions of their care and changes in their health status using a patient survey (Appendix 3) and qualitative data collection. (Table 1 below includes a list of outcomes and data sources). Outcomes were selected with guidance from patients and stakeholders to ensure they are patient-oriented and obtainable through the unique partnership with the NC Medicaid network. Additional measures that will be evaluated to determine the success of dissemination will be based on indicators of poor asthma control including: ED and hospital utilization; medication adherence; oral prednisone use; and beta-agonist use.

Patient and Provider Level Data:

Patient level data will be collected using patient and provider focus groups. Focus groups will be performed with consented patients (or their parents for children under age 17) and providers from each PBRN throughout the study. Focus group analysis from patients and providers will provide additional rich information on the quality of the SDM experiences and the Toolkit dissemination process. For this analysis, existing Focus Group guides that were developed during the stake-holder meetings for the pilot study will be used. These guides have been used with success to effectively obtain needed qualitative data during the development phase of the SDM intervention (see Appendix 2 for focus group guide).

The focus groups will take place in the two arms of the study that use the dissemination. Each focus group will have between 8-10 participants and will occur at 12 months after the study begins and at the completion of the study.

Table 1. Measures for assessment of changes in patient asthma outcomes

Outcome	Data Source	Study Arms and Networks	Collection Frequency	References
Patient Perception of Shared Decision Making	Survey Question "Who made the decision today?" collected via index cards at Arm 1 and 2 Practices	Arms 1, 2, 3	Collected Bimonthly	Wilson et al.[7]
Asthma Emergency Department Visits	Medicaid claims via CCNC Informatics Center, CHS Asthma Comparative Effectiveness Research Database	Arms 1, 2, 3	Quarterly	D'Souza et al.[34] Smith et al.[35] Press et al.[33] American Healthways[36]
Asthma Hospitalization Rate	Medicaid claims via CCNC Informatics Center; CHS Asthma Comparative Effectiveness Research Database	Arms 1, 2, 3	Quarterly	Press et al.[33] American Healthways[36]
Controller Medication Use	Medicaid claims via CCNC Informatics Center	Arms 1, 2, 3	Quarterly	American Healthways[36]
Beta Agonist Overuse	Medicaid claims via CCNC Informatics Center	Arms 1, 2, 3	Quarterly	Anis et al.[37] Hong et al.[38]
Exacerbation Requiring Oral Steroid	CHS Asthma Comparative Effectiveness Research Database and Medicaid claims data	Arms 1, 2, 3	Quarterly	Halterman et al.[39] Espinoza et al.[40]

Additional focus groups will occur once every 12 months to evaluate the monthly SDM meetings and to obtain feedback about the study and dissemination process itself. A focus group guide for these sessions has been previously developed by the research team and can be found in the appendix. Providers will be asked to provide feedback about their perceptions of the study and its impact on their ability to receive or provide high quality asthma care. For the SDM monthly call-in focus group, we will solicit critical feedback about the project to be used for process improvement. Focus group data will be analyzed and provided back to all participating practices and the research team. Data from focus groups will be identified only by practice and no individual data from the focus groups will be collected.

Analytic Methods

General

Bivariate comparisons between study arms will be conducted using Chi-square test for proportions and t-tests (for two group comparisons) or analysis of variance for means, for each of the six outcome measures. Changes over time will be assessed using regression models including the outcome measure as the dependent variable and study arm, time, and a study arm x time interaction term as independent variables to assess differences by intervention and whether changes over time vary by intervention. Analysis over time will employ generalized estimating equations to address correlation between measures at the same practice[46]. We

hypothesize that patients in arm 1 (FLOW approach to dissemination) will be more likely to share in their treatment decision compared to patients in arm 2 (traditional dissemination through active diffusion). Also, we hypothesize that clinical outcomes in arm 1 will show greater improvement than arms 2 or 3. Analysis will be conducted using SAS (version 9.3).

Avoidance of bias

Selection bias may arise in this study because of self-selection. During recruitment, we will approach practices that meet inclusion criteria and determine their interest in participating in a study to improve the quality of asthma care. Practices that agree to participate may be different from those that choose not to participate. However, the nature of the project requires willingness to participate and therefore results should be generalizable to practices with similar motivation. We will randomize practices to each study arm to limit bias associated with practice characteristics and type of intervention received.

The outcome measure of asthma exacerbation resulting in emergency department visit or inpatient admission or prednisone prescription will be determined using Medicaid claims data with primary diagnosis of asthma (ICD-9 code 493). Misclassification may occur from coding errors, but should be non-differential and not vary between study arms since a single source of data will be used for all outcomes. National surveillance studies[2] and intervention studies[7,47] have applied asthma ICD-9 codes to administrative data with useful interpretation of outcomes.

Study population

The proposed study will take place in 30 NC Medicaid practices with representation across the state. The inclusion criteria are that practices must be: (1) located in NC and (2) have greater than 100 active patients with a diagnosis of asthma (seen within last 12 months). Of the 1600 practices serving NC Medicaid patients, 298 meet the inclusion criteria (Figure 8). For this study, data collection and analysis will include all Medicaid patients diagnosed with asthma and who are registered as patients within one of the 30 randomized practices. Patients with a diagnosis of Chronic Obstruction Pulmonary Disease (COPD) are excluded. The NC Medicaid population includes low-income children, parents, seniors and individuals with disabilities. In 2011, NC Medicaid covered approximately 1.5 million non-elderly individuals with a racial breakdown of 43% White, 35% Black, and 14% Hispanic (http://www.statehealthfacts.org/profileind.jsp?ind=158&cat=3&rgn=35). NC Medicaid practices are located in each of NC's 100 counties, thus the population is geographically heterogeneous with both rural and urban representation.

Sample size

Clinics will be randomized to one of three study arms. The primary outcome measure for dissemination will be patients' surveys and qualitative data. In addition, we will examine the number of asthma patients with exacerbations before and after the intervention and between each study arm. Exacerbations will be defined as ED visits, or hospitalizations with a primary diagnosis of asthma (ICD-9 code of 493) or a prednisone prescription in the outpatient setting. The primary analysis will compare the number of patients with exacerbations at follow-up between arms 1, 2 and 3. Based on data from our pilot study, we anticipate a 7% decline (from 16% to 9% over 24 months) in the number of patients with asthma exacerbations. Our primary hypothesis is that the FLOW approach will result in greater improvements in patient outcomes compared to traditional dissemination (active diffusion) and control. To achieve 80% power to detect a 7% decline in exacerbation rates over a 24 month period, each study arm will require 10 practices with a minimum of 50 asthma patients per practice[48]. Given variable visit frequencies and show rates for patients, we included only practices with greater than 100 asthma patients. This conservative approach will ensure that the requisite 50 asthma patients per practice will be exposed to the SDM intervention during the study period.

Part D: Inclusiveness of Different Populations (Criterion 6)

North Carolina has a population of 9.5 million making it the 10th most populous state. Of these 9.5 million, 900,000 are diagnosed with asthma. NC has large populations of both African Americans (22%) and Latinos (~10%), with the latter population growing rapidly, primarily by immigration. It also has two geographically distinct Native American populations – the population found in Robeson County has strong practice representation in one of our consortium PBRNs.

NC Medicaid works with 1600 practices across NC's 100 counties to serve over 1.5 million low-income and disabled patients. Many of these 1600 practices are active participants in practiced based research networks that make up the NCNC consortium, which collectively represents 318 practices in 52 NC counties (Table 3).

Table 3. Practice-Based Research Networks in the North Carolina Network Consortium

Network Name	Director(s) Institutional affiliation	Total # of Practices	Brief description, types of Practices, Population
Mecklenburg Area Partnership for Primary-care Research (MAPPR) Lead contract	Michael Dulin, MD, PhD Hazel Tapp, PhD Andrew McWilliams, MD, MPH Carolinas Healthcare System (CHS) (Charlotte, NC)	85	Lead for Proposal Practices affiliated with a large hospital-system, (CHS) Pediatrics, Internal Medicine, Family Medicine Population: urban and rural; all ages, African American and Latino
UNC Affiliated Networks: North Carolina Family Medicine Research (NC-FM-RN) North Carolina Multisite Adolescent Research Coalition for Health (NC-MARCH) subcontract	Katrina Donahue, MD, MPH Jacquie Halladay, MD, MPH Tamera Coyne-Beasley, MD, MPH University of North Carolina at Chapel Hill (Chapel Hill, NC)	114	Statewide primary care network Pediatrics, Internal Medicine, Family Medicine Population: Native American, urban and rural; African American and Latino, all ages
Duke Primary Care (PCRC) subcontract	Emmanuel Walter, MD, MPH Duke University (Durham, NC)	34	Duke Health affiliated practices: Internal Medicine, Family Medicine and Pediatrics Population: all ages
Eastern Carolina Association for Research and Education (E-CARE) subcontract	Paul Bray, MA Vidant Health Eastern Carolina University	85	Practices affiliated with a large hospital-system: Pediatrics; Internal Medicine; Family Population: all ages, rural health, large African-American population

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING PLAN

(Use continuation pages as needed to provide the required information in the format shown below. Limit 2 pages for this section. Mouse over each underlined subheading for a short description of each. Refer to the PCORI Application Guidelines for additional information.)

Replication of Research Findings

Within the first 12 months of the study we will develop and provide a complete, final study protocol. The protocol will contain a list of the 30 selected practices and the arms the practices are randomized into. The study population will be described in terms of number of asthma patients at each site together with other available demographics such as age, gender, race. Also included will be:

1. The finalized primary and secondary hypothesis. We hypothesize that clinical outcomes in Arm 1 will show greater improvement than Arms 2 and 3. We also hypothesize that patients in Arm 1 (FLOW dissemination) would be more likely to express that they shared in their treatment decision compared to patients in Arm 2 (traditional dissemination through active diffusion).
2. Finalized methods of dissemination, including rollout plans and asthma Toolkits. The current version is available at: https://www.dicksoninstitute.com/FamilyMedsTools/
3. All outcomes measured (see Table 1).
4. All focus group discussion guides that are developed (see appendix for current guide).
5. The full analysis plan.

The trial will be registered at www.clinicaltrials.gov.

Reproduction of Research Findings (Data Sharing Plan)

Note: The requirement for a data-sharing plan applies only to studies that are requesting funding at a level greater than $500,000 in direct costs in any project year. The data sharing plan must:

- *State that a complete, cleaned, de-identified copy of the final dataset used in conducting the final analyses will be made available within nine months of the end of the final year of funding.*
- *Propose a method by which investigators will make this dataset available if requested.*
- *Propose a budget that would cover costs of data sharing if requested.*

Not Applicable

DISSEMINATION AND IMPLEMENTATION ASSESSMENT

Governance Plan

The novel infrastructure of community and stakeholder partnerships that we have built provides a laboratory ideally suited for the proposed study, as well as subsequent dissemination. Relationships with community practices and patient advisory boards will define the success of patient oriented research. This project is unique in that these relationships already exist and have been strengthened over years by the consortium's four experienced PBRNs. Our consortium of PBRNs called NCNC has a history of successful collaborations for grant submissions, studies and convening annual statewide meetings for practices and patients. In preparing this grant, the consortium leadership have engaged network practices and patients, held regular monthly phone meetings, and convened face to face planning conferences to jointly draft the proposal concept and define the roles and responsibilities of each PBRN, investigators, and Practice Facilitators (Table 2 below). The research team has also strategically partnered with NC Medicaid from the early stages of generating this proposal, allowing the research team to identify practices, access patient level data, and ensure that the FLOW process is applicable to the stakeholder that will ultimately adopt the FLOW approach.

During the study period, the consortium will continue monthly meetings to evaluate the progress and process of the study. Practice staff, providers, and patients within the FLOW arm will be invited to participate. The monthly meeting format is based on the successful SDM Stakeholder meetings used in the AHRQ ACE Study. Grounded in the principles of equitable participation and open communication, the group first establishes clear and operational group goals, operating rules, roles, and responsibilities. Decisions that are key to the study process including design, process, outcomes, and data analysis will be discussed and made by the advisory board. In the FLOW arm, practice level decisions will be made by the stakeholders in the individual practices through a process guided by the Practice Facilitators. Community based participatory research (CBPR) and group dynamic literature demonstrates that conflict is not only inherently a part of CBPR, but also a necessary component of group development[49,50]. We have found in our previous success with CBPR and community advisory boards when conflict is welcomed and addressed successfully, resultant decisions are more creative and effective. We explicitly discuss conflict resolution methods early on with open, transparent discussions about important dimensions such as project direction, finances, expectations, and roles.

Resource Sharing

Each PBRN has budgeted funds for participating practices and patients within their networks. Patients who are involved in stakeholder meetings and focus groups will be compensated for their time and expertise through merchandise gift cards. Each practice will be allocated funds that can be used at their discretion; however, the research staff will provide examples of asthma related supplies that the funds may be used for, such as spirometers.

Table 2. Governance Plan: Key Personnel, Roles and Responsibilities

	Name	Role	Responsibility
Key Personnel Research Staff MAPPR	Hazel Tapp, PhD	Principle-Investigator	Oversee all aspects of the study
	Mike Dulin, MD, PHD	Investigator	
	Andy McWilliams MD MPH	Investigator	
	Yhenneko Taylor, MS	Data Manager	Quantitative data management, Data analysis, Statistical Analysis,
	Tamara Alkhazraji	Project Coordinator	Coordination of IRB, data collection, research team communication
	Lindsay Kuhn	Lead Practice Facilitator	Training of practice facilitators; lead training day; coordinate all training phone-calls and follow-ups
	Kelly Reeves	Practice facilitator CHS	Practice facilitator CHS
	Diane Derkowski	Patient Stakeholder	Patient input on all aspects of the study
NCNC Networks	Jacquie Halladay MD	Investigator	Oversee all aspects of the study at UNC
	Walter Emmanuel MD	Investigator	Oversee all aspects of the study at Duke
	Paul Bray MS	Investigator	Oversee all aspects of the study at ECU
	TBD	Practice facilitator UNC	Rollout of study dissemination arms
	TBD	Practice facilitator ECU	
	TBD	Practice facilitator Duke	
Medicaid CCNC networks	Tyana Summers	Data manager	CCNC medicaid outcomes data. Data collection and management. Previously described outcomes data reported quarterly to MAPPR
	Stacy Warren	Coordinator	
Stakeholder Group for Dissemination study advisory board	All Investigators and practice facilitators as listed above	Investigator/Practice Facilitator	Monitoring all aspects of dissemination rollout; engaging all practices and disseminating the asthma shared decision making toolkit
	Diane Derkowski	Patient stakeholder	Patient stakeholder; monitor project conduct and input on all aspects of project
	Lisa Hubert	Policy maker Carolinas Healthcare System	Dissemination policy within Healthcare System
Shared decision making stakeholder group for Participatory arm *Monthly*	All Investigators and practice facilitators above	Investigator/Practice Facilitator	Workgroup meets to jointly discuss practices enrolled in participatory arm of the study. Purpose is to troubleshoot project progress from individual practices perspectives, discuss and share barriers and facilitators to dissemination of the SDM toolkit in these practices.
	Diane Derkowski	Patient Stakeholder	
	Patient Representatives	Multiple Patients CHS UNC ECU Duke	
	Practice Champion Representatives	Multiple Providers/staff CHS UNC ECU Duke	
Community Care of North Carolina Asthma Stakeholders Work Group *bimonthly*	Marian Earls	Physician chair	Workgroup meets to analyze trends around asthma care; determine feasibility of interventions; review asthma related resources; identify challenges and barriers to improving outcomes; and identify and disseminate sustainable best practices for asthma care throughout the state. Study progress and results will be discussed biannually to this group for input and with a view to future dissemination through the CCNC networks
	Quality Improvement Coaches	Multiple people From 14 CCNC networks	
	School Nurses	Multiple people From 14 CCNC networks	
	Policy Makers	Medicaid North Carolina	
Mecklenburg County Asthma Coalition *quarterly*	Andrew Harver	Chair, Mecklenburg County Asthma Coalition	The coalition organizes various community initiatives throughout the year including a free annual "Asthma Health Fair" at the University of North Carolina, Charlotte. Study progress and results will be discussed biannually to this group for input and with a view to dissemination through MCAC community initatives.
	Providers (nurses and physicians)	Local Healthcare systems	
	Hazel Tapp	Researcher, at large board member	
	Patients / Caregivers	Board members	
Elizabeth Family Medicine (EFM) Patient Advisory Board	Patients	30 Patients of EFM	Patients give feedback on delivery of care and research activities at Elizabeth family medicine. Study progress and results will be discussed biannually to this group for input from a general patient population.
	Dr Dael Waxman	Provider	
	Will Fields	Manager	
MAPPR Shared Decision making group	Providers / staff from 6 SDM operating practices	SDM toolkit experts	Ongoing shared decision making support group involving 6 practices with active SDM. Study progress and results will be discussed biannually to this group for input and feedback from practices already using the asthma SDM toolkit.
	Hazel Tapp	Researcher	
	Lindsay Kuhn	Practice facilitator	

REFERENCES CITED

(Use continuation pages as needed to provide the required information. Do not exceed 10 pages.)

Provide a list of references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication); the article title; and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Refer to the PCORI Application Guidelines for additional information.

1. Akinbami L. Asthma prevalence, health care use, and mortality: United states 2005-2009. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics 2011.
2. Akinbami LJ, Moorman JE, Bailey C, Zahran HS, King M, Johnson CA, Liu X. Trends in asthma prevalence, health care use, and mortality in the United States, 2001-2010. National Center for Health Statistics Data Brief 2012:1-8.
3. Trends in Asthma Morbidity and Mortality: American Lung Association, Epidemiology and Statistics Unit, Research and Health Education Division; 2012.
4. Meltzer EO, Blaiss MS, Nathan RA, Doherty DE, Murphy KR, Stoloff SW. Asthma burden in the United States: results of the 2009 Asthma Insight and Management survey. Allergy Asthma Proc 2012;33:36-46.
5. Flores G, Bridon C, Torres S, Perez R, Walter T, Brotanek J, Lin H, Tomany-Korman S. Improving asthma outcomes in minority children: a randomized, controlled trial of parent mentors. Pediatrics 2009;124:1522-32.
6. van der Meer V, Bakker MJ, van den Hout WB, Rabe KF, Sterk PJ, Kievit J, Assendelft WJ, Sont JK, Group SS. Internet-based self-management plus education compared with usual care in asthma: a randomized trial. Ann Intern Med 2009;151:110-20.
7. Wilson SR, Strub P, Buist AS, Knowles SB, Lavori PW, Lapidus J, Vollmer WM. Shared Treatment Decision Making Improves Adherence and Outcomes in Poorly Controlled Asthma. Am J Respir Crit Care Med 2010;181:566-77.
8. Tapp H, Hebert L, Dulin M. Comparative effectiveness of asthma interventions within a practice based research network. BMC health services research 2011;11:188.
9. For the Public's Health: Investing in a Healthier Future: Committee on Public Health Strategies to Improve Health; Board on Population Health and Public Health Practices; Institute of Medicine; 2012.
10. US Department of Health and Human Services, Agency For Healthcare Research and Quality. American Recovery and Reinvestment Act Investments in Comparative Effectiveness Research for Dissemination, Translation, and Implementation. In; 2010.
11. Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. Lancet 2003;362:1225-30.
12. Grol R, Grimshaw J. Evidence-based implementation of evidence-based medicine. Jt Comm J Qual Improv 1999;25:503-13.
13. Tapp H, Dulin M. The science of primary health-care improvement: potential and use of community-based participatory research by practice-based research networks for translation of research into practice. Exp Biol Med (Maywood) 2010;235:290-9.

14. Peterson KA, Lipman PD, Lange CJ, Cohen RA, Durako S. Supporting better science in primary care: a description of practice-based research networks (PBRNs) in 2011. J Am Board Fam Med 2012;25:565-71.
15. Initial National Priorities for Comparative Effectiveness Research. In: Institute of Medicine, Report Brief; 2009.
16. National Healthcare Disparities Report, 2010 Chapter 5. Patient Centeredness. Agency for Healthcare Research and Quality. U.S. Department of Health & Human Services, 2010. (Accessed at http://www.ahrq.gov/qual/nhdr10/Chap5.htm.)
17. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Social science & medicine (1982) 1997;44:681-92.
18. Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. Social science & medicine (1982) 1999;49:651-61.
19. Tapp H, Taylor Y, Kuhn L, Dulin M. Evaluating Asthma Management in primary care: Impact of the chronic care model and shared decision making on outcomes for poorly controlled patients with asthma. . In: North American Primary Care Resaerch Group Annual Conference. New Orleans, LA; 2012.
20. Israel B, Eng E, Schulz A, Parker E. Methods in Community-Based Participatory Research. San Francisco: Jossey-Bass; 2005.
21. Dulin MF, Ludden TM, Tapp H, Smith HA, de Hernandez BU, Blackwell J, Furuseth OJ. Geographic Information Systems (GIS) demonstrating primary care needs for a transitioning hispanic community. J Am Board Fam Med 2010;23:109-20.
22. Dulin MF, Ludden TM, Tapp H, Blackwell J, de Hernandez BU, Smith HA, Furuseth OJ. Using Geographic Information Systems (GIS) to understand a community's primary care needs. J Am Board Fam Med 2010;23:13-21.
23. Dulin MF, Tapp H, Smith HA, Urquieta de Hernandez B, Furuseth OJ. A community based participatory approach to improving health in a Hispanic population. Implement Sci 2011;6:38.
24. Dulin MF, Tapp H. Communities matter: the relationship between neighborhoods and health. North Carolina medical journal 2012;73:381-8.
25. Ponomarenko N, Tapp H, Taylor Y, Dulin M. The impact of shared decision making on emergency and impatient costs for patients and hospitals within Carolinas Healthcare System, North Carolina USA. . In: Annual Primary Care Conference: Royal College of General Practitioners and the Society for Academic Primary Care. Glasgow, United Kingdom; 2012.
26. Tapp H, Kuhn L, Alkhazraji T, Ludden T, Mohanan S, Dulin M. A Participatory Approach to Developing a Shared Decision Making Intervention for The Treatment of Asthma In: North American Primary Care Research Group 2011; Banff, Alberta; 2011.
27. Tapp H, Philips S, Waxman D, Alexander M, Brown R, Hall M. Multidisciplinary Team Approach to Improved Chronic Care Management for Diabetic Patients in an Urban Safety Net Ambulatory Care Clinic. Journal of the American Board of Family Medicine 2012;25.
28. Tapp H, Alkhazraji T, Kuhn L, Mohanan S, Courtlandt C, DeSantis A, Matkins P, Wade K, Hebert H, Dulin M. Using a Participatory Approach to Developing a Shared

Decision Making Intervention for Asthma. In: AHRQ National Practice Based Research Network Conference; 2011; Bethseda, MD; 2011.
29. Tapp H, Davis C, Smith H, Tyson A, Brucato J, Hernandez B, Mowrer L, Jilg A, Dulin M. Evaluation of Partnerships and Group Participation among a Transdisciplinary Community Based Participatory Research Team. American Public Health Association Annual Meeting,Washington DC. In; 2011; 2011.
30. Gross PA, Greenfield S, Cretin S, Ferguson J, Grimshaw J, Grol R, Klazinga N, Lorenz W, Meyer GS, Riccobono C, Schoenbaum SC, Schyve P, Shaw C. Optimal methods for guideline implementation: conclusions from Leeds Castle meeting. Medical care 2001;39:II85-92.
31. Wilson SR, Strub P, Buist AS, Knowles SB, Lavori PW, Lapidus J, Vollmer WM, Better Outcomes of Asthma Treatment Study G. Shared treatment decision making improves adherence and outcomes in poorly controlled asthma. American journal of respiratory and critical care medicine 2010;181:566-77.
32. Legare F, O'Connor AM, Graham ID, Saucier D, Cote L, Blais J, Cauchon M, Pare L. Primary health care professionals' views on barriers and facilitators to the implementation of the Ottawa Decision Support Framework in practice. Patient Educ Couns 2006;63:380-90.
33. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. The Milbank quarterly 2004;82:581-629.
34. Aarons GA, Sawitzky AC. Organizational Culture and Climate and Mental Health Provider Attitudes Toward Evidence-Based Practice. Psychol Serv 2006;3:61-72.
35. Frosch DL, Moulton BW, Wexler RM, Holmes-Rovner M, Volk RJ, Levin CA. Shared decision making in the United States: policy and implementation activity on multiple fronts. Z Evid Fortbild Qual Gesundhwes 2011;105:305-12.
36. Grimshaw JM, Eccles MP, Walker AE, Thomas RE. Changing physicians' behavior: what works and thoughts on getting more things to work. J Contin Educ Health Prof 2002;22:237-43.
37. Mullan RJ, Montori VM, Shah ND, Christianson TJ, Bryant SC, Guyatt GH, Perestelo-Perez LI, Stroebel RJ, Yawn BP, Yapuncich V, Breslin MA, Pencille L, Smith SA. The diabetes mellitus medication choice decision aid: a randomized trial. Arch Intern Med 2009;169:1560-8.
38. Press VG, Pappalardo AA, Conwell WD, Pincavage AT, Prochaska MH, Arora VM. Interventions to improve outcomes for minority adults with asthma: a systematic review. J Gen Intern Med 2012;27:1001-15.
39. D'Souza WJ, Te Karu H, Fox C, Harper M, Gemmell T, Ngatuere M, Wickens K, Crane J, Pearce N, Beasley R. Long-term reduction in asthma morbidity following an asthma self-management programme. Eur Respir J 1998;11:611-6.
40. Smith S, Mitchell C, Bowler S. Standard versus patient-centred asthma education in the emergency department: a randomised study. Eur Respir J 2008;31:990-7.
41. American Healthways and Johns Hopkins Consensus Conference. Standard outcome metrics and evaluation methodology for disease management programs. Disease Management 2003;6:121-38.
42. Anis AH, Lynd LD, Wang XH, King G, Spinelli JJ, Fitzgerald M, Bai T, Pare P.

Double trouble: impact of inappropriate use of asthma medication on the use of health care resources. Cmaj 2001;164:625-31.
43. Hong SH, Sanders BH, West D. Inappropriate use of inhaled short acting beta-agonists and its association with patient health status. Curr Med Res Opin 2006;22:33-40.
44. Halterman JS, Szilagyi PG, Fisher SG, Fagnano M, Tremblay P, Conn KM, Wang H, Borrelli B. Randomized controlled trial to improve care for urban children with asthma: results of the School-Based Asthma Therapy trial. Arch Pediatr Adolesc Med 2011;165:262-8.
45. Espinoza-Palma T, Zamorano A, Arancibia F, Bustos MF, Silva MJ, Cardenas C, De La Barra P, Puente V, Cerda J, Castro-Rodriguez JA, Prado F. Effectiveness of asthma education with and without a self-management plan in hospitalized children. J Asthma 2009;46:906-10.
46. Zeger SL, Liang KY, Albert PS. Models for longitudinal data: a generalized estimating equation approach. Biometrics 1988;44:1049-60.
47. Cloutier MM, Hall CB, Wakefield DB, Bailit H. Use of asthma guidelines by primary care providers to reduce hospitalizations and emergency department visits in poor, minority, urban children. J Pediatr 2005;146:591-7.
48. Hayes RJ, Bennett S. Simple sample size calculation for cluster-randomized trials. International journal of epidemiology 1999;28:319-26.
49. Forsyth D. Group Dynamics. Belmont, CA: Wadsworth, Cengage Learning; 2009.
50. Johnson D, Johnson F. Joining together: Group theory and group skills. Upper Saddle River, NJ: Pearson Education; 2009.
51. Lillie-Blanton M, Anthony JC, Schuster CR. Probing the meaning of racial/ethnic group comparisons in crack cocaine smoking. Jama 1993;269:993-7.

PROTECTION OF HUMAN SUBJECTS

(Use continuation pages as needed to provide the required information. For detailed instruction, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form, as found on the National Institutes of Health (NIH) website. Do not exceed 5 pages.)

This proposal was developed with ongoing discussion with the Carolinas Healthcare System IRB. Each PBRN will require approval from their own IRB's to enroll practices and randomize each practice to control or intervention. There are no known additional risks for patients in any of the three arms of the trail.

This study involves a quality improvement type initiative involving the implementation of a shared decision making Toolkit for patients with asthma. This evidence-based intervention has been safely used before in an IRB approved study at the Kaiser Permanente system, throughout California, and also IRB approved by Carolinas Healthcare System's institutional IRB to be performed within six practices at Carolinas Healthcare System. In general, involving patients in shared decision making is widespread and accepted as posing no additional risk to the patient. This intervention is developed around the 2007 asthma guidelines published by the American Heart and lung association using the step up step down standard accepted guidelines. All medication options that that the patient may be prescribed as part of shared decision making are those considered to be appropriate options for treatment of the severity of disease determined by the provider. The shared decision made by the patient and clinician regarding medication choices considers what medications are available for this severity level of asthma. Among these options no one treatment is known to be vastly superior to another and the decisions around which is the best medication for each individual vary depending on personal preferences, levels of comfort and dexterity with asthma medication delivery systems and lifestyle choices of the patients. Allowing the patient to share in the decision is much more likely to improve the adherence to the medication and therefore considered a way to reduce potentially life-risking exacerbations known to occur with asthma. We therefore consider there to be no known risk to the patient associated with using this intervention.

The outcome data collected from this study will mostly be de-identified practice level data. Identified data from Medicaid and Carolinas Healthcare Systems databases will also be used. The primary risk associated with this study would be a breach of confidentiality or patient anonymity if unauthorized access to the research data occurs. To counter this risk, all study data will remain protected with paper documents being stored in a locked office accessible only to the research team. All electronic data will remain on password protected computer servers. Confidentiality of participants will be strictly maintained and where possible direct identifiers will be removed.

Focus group participants will be consented using standard IRB procedures. A complete waiver of consent will also be requested for focus groups if it is felt by individual PBRNs that the consent process would negatively impact participation. In this case, participants would be read an IRB approved verbal consent reviewing risk and benefits, and no direct identifiers would be collected. All participants will receive information in Spanish and English explaining the project, their role in the study, information to be collected, and contact numbers for the research team and IRB. All tools will be approved by the IRB prior to the initiation of the study.

Participants will be given an opportunity to decline further involvement at any time and/or to have their data
removed from the study if possible (data collected without identifiers will remain).

The immediate significance of this project is the potential to enhance health outcomes for patients living with

asthma in our community. The long-term benefit will depend upon the sustainability and success of the
interventions. However, the potential direct benefits of this project for the participants outweigh potential risks.

Inclusion of Women and Minorities

This study will involve participation of patients with asthma. As a practice-wide implementation, we assume that all patients with asthma visiting the practice during the time of the study will be exposed to the shared decision making approach. Participants will therefore represent the community asthma population as a whole. We expect a slight overrepresentation of African-american and Native American patients given the prevalence of asthma in these community members. All age groups, women and minorities are included in the study.
There will also likely be a slight overrepresentation of women given their propensity for asthma. We expect approximately 25% African American, 10% Hispanic, 69% Caucasian and 55% Women.

Inclusion of Children

Children will be included in this study as asthma is an important disease in pediatric populations, and there is a large potential benefit for this population if improved interventions and systems of care can be provided. Again, potential benefit is thought to be greater than potential risk. The primary risk for pediatric patients would be accidental disclosure of their medical information. The entire research team is trained in HIPPA and Good Clinical Practices (GCP) and will take all reasonable precautions to prevent data disclosure. Practices will be provided the option to withdraw from the study and will be mailed information about the risk and benefits of participating as well as the contact information for the PI and IRB.

Study Title: Comparing Traditional and Participatory Dissemination of a Shared decision Making Intervention

Total Planned Enrollment: 4,500

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	247	203	450
Not Hispanic or Latino	2228	1822	4050
Ethnic Category: Total of All Subjects *	2475	2025	4500
Racial Categories			
American Indian/Alaska Native	50	40	90
Asian	50	40	90
Native Hawaiian or Other Pacific Islander	3	2	5
Black or African American	619	506	1125
White	1757	1437	3145
Racial Categories: Total of All Subjects *	2475	2025	4500

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

CONSORTIUM/CONTRACTUAL ARRANGEMENTS

(Use continuation pages as needed to provide the required information. Do not exceed 5 pages.)

Use this section to further describe the research projects of the subcontracts and explain the strengths that the partners bring to the overall project.

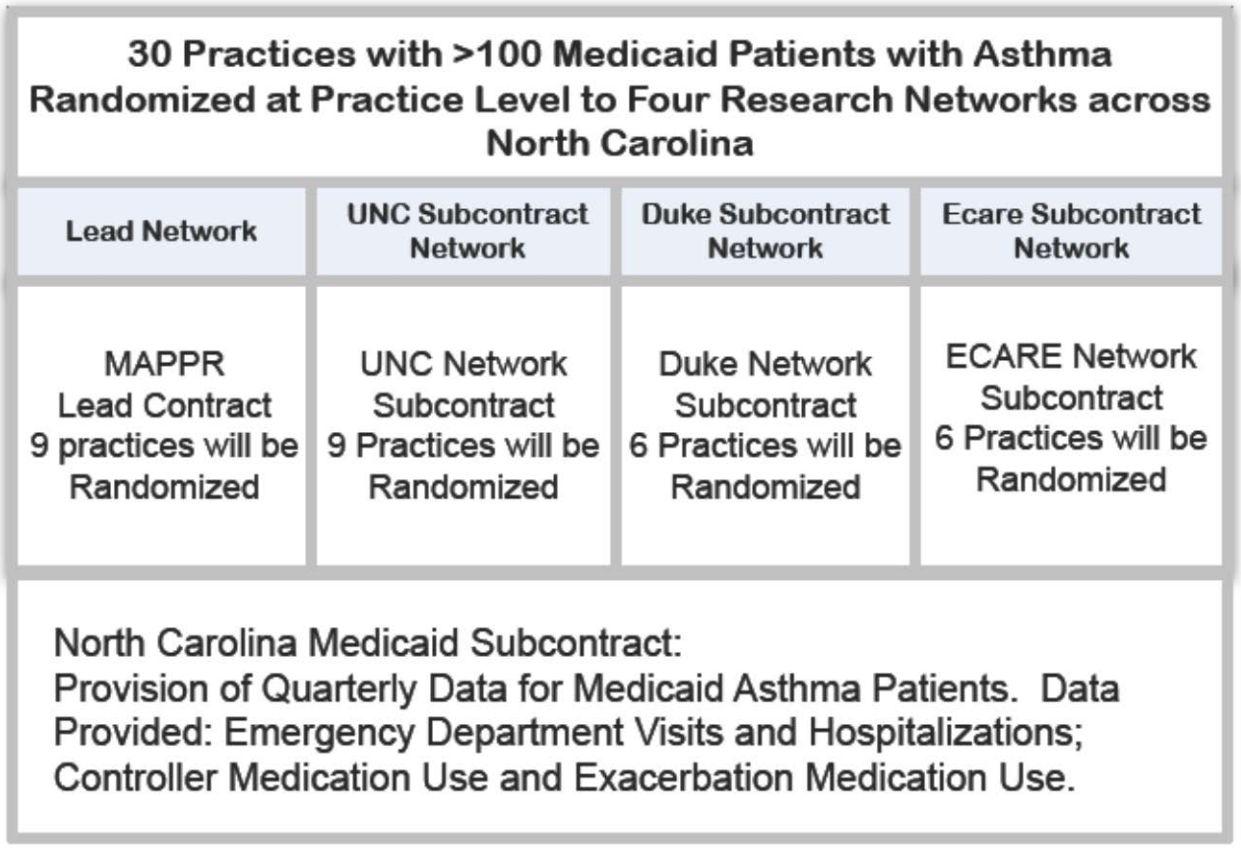


Figure 7. Overview of Subcontracts

This project will have four subcontracts. The subcontracts are three Practice based research networks (PBRNs) (of the four PBRNs involved, Table 3) and North Carolina Medicaid (NC Medicaid). Briefly, each of the three PBRNs will join with MAPPR to give four networks recruiting practices for randomization into the three arms of the project (Figure 5).

Although the existing body of knowledge on dissemination methods is still developmental, practice-based research networks (PBRNs) have been identified as an ideal laboratory to test dissemination methods[13,14]. This study will occur within a well-established consortium of PBRNs called the North Carolina Network Consortium (NCNC) that has been actively funded by AHRQ since 2005. The network includes diverse practices that range in size, location, practice type, and the race/ethnicity of their patients. Each member PBRN has extensive research experience and knowledge on how to work closely with practices to study interventions and the fidelity of their deployment. The mission of NCNC is to work to address

pressing questions related to the delivery of primary care health services and the management of primary care problems. The secondary mission is to build collaborative, cooperative organizations with expanded capabilities to carry out statewide and national research related to the delivery of primary care services and the improvement of population health.

1) UNC- Networks

a) North Carolina Family Medicine Research Network (NC-FM-RN)

The NC-FM-RN was founded in 2000 by Leigh Callahan, PhD and Philip Sloane, MD, MPH initially to study complementary and alternative medicine use by primary care patients with arthritis. The recruitment was structured in way to establish a statewide family practice-based research network (PBRN), with the goal of being a permanent resource for research. NC-FM-RN has addressed chronic conditions, preventive health behaviors, preventive care, mental health symptoms, racial differences in health, complementary osteoporosis screening, sleep problems, end of life decision-making. Funding for the NC-FM-RN has come from the CDC, AHRQ, the NIA, NIAMS, Kate B Reynolds Foundation and the Robert Wood Johnson Foundation.

Initially, 14 practices were purposively selected within 6 strata, so as to insure they would represent the 3 geographic areas of the state (west, central, east) and both rural and urban locations within these areas, and so that the study could selectively enroll practices with high proportions of minorities. More practices were added in 2004, 2005, 2006 to recruit specific minorities (Latinos and American Indians) and to increase the number of practices within an hour or two of Chapel Hill (to better facilitate more intensive research efforts, such as clinical trials). NC-FM-RN also recruited and maintained a cohort of 5,000 adults from participating practices who provided data on their personal health and consented to be approached in future studies and were followed every 1-2 years.(Sloane 2006) The cohort allowed for regular connection with the practices, the exposure students in practices and the collection of pilot data for numerous studies.

In 2007, NC-FM-RN led the development of NCNC for the Master Task Order for the Agency for Healthcare Quality and Research. In the last 5 years, through NCNC, NC-FM-RN brought together and conducted collaborative research with the state networks in this proposal.

NC-FM-RN has worked with many investigators. Recent topics include:

- CDC funded study examining the comparative effectiveness of a combined lifestyle and medication intervention to reduce cardiovascular research
- R-01 from NHLBI to assess the reproducibility and clinical implications of masked hypertension.
- Collaboration with NC State colleagues on an NIH grant examining the issues in development of an open source electronic health record.
- Collaboration with UNC Center for Health Promotion and Disease Prevention, along with E-CARE in a NHLBI funded Center for Health Disparities on projects to improve cardiovascular outcomes in practices and communities by combining a collaborative practice learning approach as well as using Community-Based Participatory Research methods.
- CDC funded study and collaboration with E-CARE practices in a collection of biological specimens from patients with Southern Tick-Associated Rash Illness in order to understand this rare and not-well understood tick borne illness.
- NIA funding examining new technologies to examine older patient communication in offices
- Quality improvement collaboratives in prevention, health behaviors and hypertension.
- AHRQ R18 examining the adoption and process of transformational change in terms of the patient centered medical home.

- Consulting on a recently awarded U grant 'NC GENES' where they will assist this group with the development of facilitate the application of clinically applicable genetics within the Practice Based Research Network (PBRN) framework, the first of this type of "Genomics" PBRN.

b) NC Multi-site Adolescent Research Consortium for Health (NC MARCH)

NC MARCH, an affiliate network of NCCHRN, is a state-wide network (founded in 2005) representing adolescent health clinics. It includes all three high-volume, free-standing teen-only clinics in the state (Wake Teen [Raleigh], Wilmington Health Access for Teens [Wilmington], and Teen Health Connection [Charlotte]), plus 51 School-Based Health Centers (SBHCs) across the state, all of which belong to the North Carolina Association of SBHCs. There is wide variation in scope of services and resources at these SBHCs. In 2006 NC MARCH received a PBRN-development R03 from AHRQ, was a founding member of the NCNC task order grant.

2) Duke Primary Care Research Consortium (PCRC)

The PCRC, established in 1997, is an established primary care research network for academic, community, Veterans Affairs (VA), and managed-care practices within the Duke University Health System and surrounding communities. PCRC includes 34 pediatric, family medicine, and internal medicine-focused practices across 8 counties in North Carolina; it is co-directed by Dr. Rowena Dolor (a general internist) and Dr. Emmanuel (Chip) Walter (a pediatrician). PCRC practices include more than 150 primary-care clinicians and provide care for more than 250,000 patients. A major emphasis of the PCRC has been the conduct of clinical trials in participating practices. The PCRC is a founding member of NCNC Master Task Order grant. Since 1997, PCRC has participated in over 70 studies including RCTs, surveys, focus groups, chart reviews and QI research. Examples include:

- Randomized trial of SSRI Treatment (RTI and Lilly)
- Take care of your Blood Pressure (NHLBI)
- Communicating Health, Analyzing talk (NCI)
- MTM study on improving drug safety and effectiveness (AHRQ)
- Nurse administered self-management intervention for diabetic/hypertensive patients (NIDDK)
- Teen CHAT: Improving physician-adolescent communication about healthy weight (NHLBI)
- Primary Care Interventions for managing osteoarthritis (NIAMS)
- Prevention of Influenza in Infants by immunization of household contacts (CDC U01)
- Prospective Multi-center imaging study for evaluation of chest pain (NHLBI)

3) Eastern Carolina Association for Research and Education (E-CARE)

E-CARE, founded in 2008, is a network of practicing clinicians in eastern North Carolina formed to ask and answer clinical and organizational questions central to primary health care. E-CARE involves eastern North Carolina community-based clinicians and their staffs in activities designed to understand and improve primary care. E-CARE strives to link relevant clinical questions with research methods in community settings to produce valid scientific information. Relevant questions re identified by both community-based clinicians and E-CARE coordinators. E-CARE is sponsored by the Department of Family Medicine, Brody School of Medicine, East Carolina University. Funding for E-CARE has come from NHLBI, RWJF, NC CTSA and DHHS. Studies include:

- RWJF project examining an educator coaching model of expanded care
- Collaboration with UNC Center for Health Promotion and Disease Prevention, along with NC-FM-RN in a NHLBI funded Center for Health Disparities on projects to improve

cardiovascular outcomes in practices and communities by combining a collaborative practice learning approach as well as using Community-Based Participatory Research methods.

- NC TraCS pilot to examine the dissemination of teleretinal imaging to limit disparities in diabetes retinopathy in rural North Carolina

4) NC Medicaid

The North Carolina Medicaid System is one of the most successful in the country in terms of providing high quality of care at a low cost.[51] NC Medicaid is targeting asthma as a priority condition, and is a key subcontract for this project assisting with practice identification, recruitment, evaluation and long-term dissemination. In improving asthma care, NC Medicaid faces the challenges inherent to caring for a vulnerable population in diverse practice settings, which often results in wide variations in care consistency and quality. Through their informatics center NC Medicaid has data-base storage capacity for data collection around asthma outcomes. They have an extensive database of asthma specific information that will be made available for this study (see letter of support Annette Dubard). This asthma database excludes COPD diagnosis and contains all the outcome elements described above in the research plan required for this study. Practices will be eligible for participation in the study if they have over 100 active Medicaid patients in their panel with the diagnosis of asthma. The Medicaid Network's Informatics Center has identified 298 practices meeting this criterion for this study (Figure 8). Eventually, dissemination to 1600 Medicaid practices across North Carolina is envisioned.

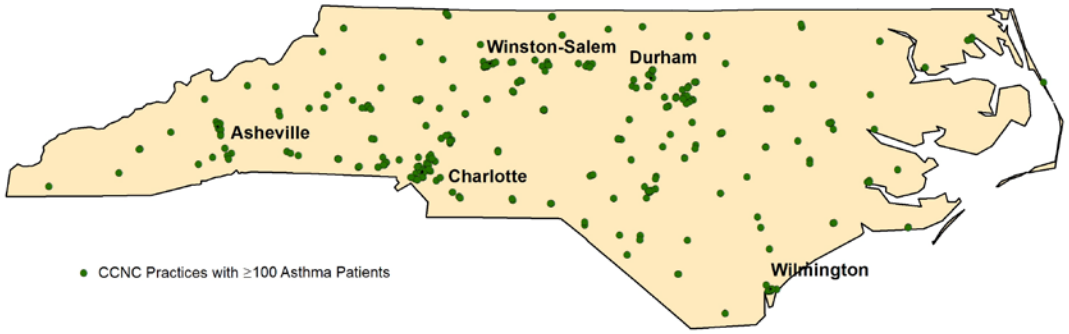


Figure 8. North Carolina Medicaid Practices with ≥ 100 Patients with Asthma

PROJECT PLAN AND TIMELINE

(Use continuation pages as needed to provide the required information. Do not exceed 5 pages.)

Provide a project plan with accompanying timeline for completion of the research project within the project duration being requested. There is no required format for this plan, but a timeline or Gantt chart is appropriate. Required components include a list of major activities, milestones, and deliverables (including interim deliverables) and estimated dates for each. The project plan must include at least one deliverable or interim deliverable to be submitted to PCORI during each 12-month period of the project. Refer to the PCORI Application Guidelines for additional information.

The proposed study will span three years and is divided into three distinct Phases: Phase 1 Initiation; Phase 2 Implementation; and Phase 3 Analysis and Reporting. Each Phase involves specific tasks, patient and provider engagement, and submission of deliverables to PCORI.

Phase 1 Initiation:

During Phase 1 the research team will focus on finalizing the study protocol, hiring necessary staff, training the staff, practice recruitment, and randomization. During the first month, the research team will hold an initial planning conference to be held at the CHS Department of Family Medicine (CHS DFM). At the conference, all the research staff and investigators from each of the four PBRNs will gather to review the research strategy, roles and responsibilities, and timeline. Following the planning conference, each PBRN will ensure approval of the project with their respective institutional review board. Also, each PBRN will hire a Practice Facilitator. The Practice Facilitators from each PBRN will travel to CHS DFM for training on the Asthma SDM Toolkit and the FLOW approach to dissemination.

During the early part of this phase, the Co-investigators at each PBRN will begin practice recruitment. Each PBRN has a pre-specified number of practices they are responsible for recruiting, as is identified in the sub-contracts. Once 30 practices have been recruited, the practices will be randomized to one of the three study arms. The randomization will be centralized and performed through blinded procedures by staff at the CHS Dickson Analytic group. After randomization, details of the practices and demographics of the patients will be assimilated into the finalized protocol. The finalized protocol will then be delivered to PCORI.

Phase 2 Implementation:

The first component of Phase 2 is to work with the practices that are randomized to the FLOW dissemination arm to identify practice champions. Champions are identified amongst providers, staff, and patients. The champions will partner closely with the Practice Facilitator and help the practice adopt the Asthma SDM Toolkit.

During the 12 week roll-out of the Asthma SDM Toolkit, the Practice Facilitator will meet at the practice with all staff, providers, and patient representatives on a regular basis. The practice, led by the champions, will then proceed with the following FLOW steps: (1) qualitative assessment of the way providers currently manage asthma (both providers and their patients are included in these sessions). This process allows for providers to learn more about opportunities for improvement in the way they care for asthma patients and to learn from patients directly about their expectations for asthma management; (2) exposure to a patient and provider champion that have used the SDM Toolkit and seen improvements in their symptoms/outcomes. This is an informal one hour session where providers can ask questions about the process and learn more about the benefits of implementation prior to training. (3) The Practice Facilitator joins the

practice for one hour each week to train all staff on different components of the SDM process over a 12 week period. Training includes exposure to videos showing providers using the SDM technique as well as opportunities for the team members to practice SDM; (4) Every six months members of the practice staff including providers and patients will be asked to participate in a focus group soliciting feedback on the SDM process and asking about how to improve the implementation of SDM within their practice; (5) qualitative and quantitative data will be collected from practices and provided back to the practices for review.

During the early part of Phase 2 Implementation, the Practice Facilitator will provide the practices in the Traditional Dissemination arm with a "lunch and learn". The lunch and learn will focus on explaining the Asthma SDM Toolkit and providing suggestions for implementation. At the conclusion of the lunch and learn session the practices will be given printed and electronic copies of all the Asthma SDM Toolkit materials.

Throughout Phase 2 Implementation, patients, providers, and staff in the FLOW approach arm will be actively engaged with monthly phone conference calls. Additionally, ongoing surveys will be conducted of patients in all three arms to determine their level of involvement in asthma care decisions (Appendix 3). Interim progress reports will be created and delivered to all stakeholders and PCORI.

Phase 3 Analyses and Reporting

During Phase 3, the implementation of the Asthma SDM Toolkit will conclude, and a final round of patient surveys will be collected. The research team and Practice Facilitators will conduct focus groups consisting of providers, staff, and patients from practices in each of the three arms. The focus groups will help describe the dissemination process and perceptions of the Asthma SDM Toolkit itself from the perspective of the stakeholders themselves. Also from the focus groups, patients will provide additional qualitative assessments of their perceived involvement in the asthma care decision-making process (the study's primary outcome). At quarterly time intervals, NC Medicaid will provide the research team with data related to the study's asthma related outcomes. During Phase 3, that data will be analyzed, combined with qualitative data analyses, and synthesized into a format that can be reported back to practices, other stakeholder groups, PCORI and ultimately published. At the conclusion of this phase, practices in the control arm will be offered the chance to be guided by the Practice Facilitators through adopting the Asthma SDM Toolkit, using whichever dissemination method (FLOW or traditional) that was shown to be most effective in the study.

	2012								2013												2014								2015			
	Year 1												Year 2												Year 3											
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Study Activities	*Practice Recruitment/Randomization & Rollout*												*Data collection & Focus Groups*												*Continued Data collection/Analysis/ Dissemination*											
Phase 1: Initiation																																				
NCNC Research Team Planning Conference	X																																			
NCNC Research Team Meetings		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
IRB- CHS primary and then all sites	X	X	X																																	
Subcontract Preperation and Execution	X	X	X																																	
Practice Facilitator Trainings		X	X	X	X	X	X																													
Recruitment of Clinics				X	X	X	X																													
Randomization of Clinics				X																																
Deliverable to PCORI: Finalized Protocol							X																													
Phase 2: Implementation																																				
Identify PracticeChamptions				X	X	X	X																													
Rollout to FLOW Practices (Arm 1)								X	X	X																										
Focus Groups with FLOW Practices											X					X						X						X					X			
Rollout to Traditional Dissemination Practices (Arm 2)								X												X												X				
FLOW Workgroup Meetings					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Patient Survey Data Collection at FLOW, Traditional and Control Practices							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X								
Deliverable to PCORI: Interim Progress Reports												X																								
Practice faciliatator follow up training calls	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X								
Year two Rollout Refresher to All Arm 1 and 2 Practices																		X																		
Phase 3 Analyses and Reporting																																				
Patient Focus Groups- all three arms (FLOW, Traditional, Control)																																				
Data collection from Medicaid- all three arms (FLOW, Traditional, Control)			X			X			X			X			X			X			X			X			X			X			X			
Data analysis																																		X	X	
Deliverable to PCORI: Final Report																																				X
Asthma SDM Toolkit Dissemination to Control Practices																															X	X				
Interim Reports to Stakeholder Groups																																				
NC Medicaid Asthma Workgroup				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Mecklenburg County Asthma Coalition	X					X						X						X						X						X						X
MAPPR SDM Group	X					X						X						X						X						X						X
Elizabeth Family Medicine Patient Advisory Board	X					X						X						X						X						X						X
Mecklenburg County Asthma Coalition Asthma Fair									X												X												X			
Statewide Dissemination Forum																																				X

APPENDIX

(Use continuation pages as needed to provide the required information. Note that the Appendix is optional.)

Appendix 1

FORM #1: PATIENT INFORMATION FORM

ASTHMA BOTHER

QUESTION	PROBE	NOTES
• How much does asthma get in the way in terms of your daily living - for example, does it affect your daily life?	❑ Activity level ❑ Work and/or home life ❑ Relationships with friends/family ❑ Finances ❑ How you see yourself ❑ Anything else?	
• Of these things you just mentioned, what bothers you the most or what would you most like to change?		
• How long have you had asthma?		• Years _____

SYMPTOMS

QUESTION	PROBE	NOTES
• In the past 4 weeks, did your asthma wake you up at night (including asthma-related coughing)?	• [If yes] How often?	• Awakened at night? ❑ Y ❑ N • Frequency or # of times? _____
• In the past 4 weeks, did you miss any normal daily activity because of your asthma?	• [If yes] How often?	• Missed daily activity? ❑ Y ❑ N • Frequency or # of times? _____
• How often do you experience episodes in which your asthma is especially bad (we call these asthma exacerbations, attacks, or flares)?		
• Have you ever had to go to the ER or an urgent care during an asthma attack?	• [If yes] When was the last time?	
• Have you been hospitalized because of your asthma?	• [If yes] When was the last time? • Have you ever been intubated (had a breathing tube inserted)?	
• Do you experience a cough with your asthma?	• [If yes] How often? • What is the cough like?	
• How well-controlled do you think your asthma symptoms are?	GO TO **FORM #2: HOW WELL CONTROLLED IS YOUR ASTHMA** AND HAVE PATIENT INDICATE WHERE THEY THINK THEIR CONTROL IS BY MOVING THE ARROW.	

Form completed by: _____
Date: _____

EMR STICKER

ACE Study Form #1: Pt Info Form, Page 1 of 4

CHRONIC RHINOSINUSITIS:

- Do you usually have a stuffy, runny, or plugged nose for much of the year? Y ☐ N ☐
- Do you often have itchy, watery eyes? Y ☐ N ☐
- Do you have drainage in the back of your throat (post-nasal drip) most of the year? Y ☐ N ☐
- Has your health care provider told you that you have chronic sinus problems or allergies? Y ☐ N ☐
- When you have a head cold, do your nasal symptoms usually last for 3 months or more? Y ☐ N ☐
- Are you unable to smell scents? Y ☐ N ☐

Y _____

GERD:

- Do you have heartburn or indigestion? Y ☐ N ☐
- Does food sometimes come up in the back of your throat (regurgitation)? Y ☐ N ☐
- In the past 4 weeks, have you had coughing, wheezing, or shortness of breath that was not relieved by taking albuterol? Y ☐ N ☐

Y _____

MEDICATION USE: SHOW ASTHMA CONTROLLERS/RELIEVERS POSTERS

What are your CURRENT PRESCRIPTIONS for asthma? Let's start with albuterol.

For each medication:

- ☐ How many puffs/pills are you supposed to take each time?
- ☐ How often is it supposed to be taken?
- ☐ How many days did you take it last week?
- ☐ How many puffs/pills do you usually take?
- ☐ How do you think this medication works for your asthma?

Show me how you use your inhaler?

[Examine technique using appropriate "Skills Checklist" on the last page. Note errors, but do no correct. Provider will review in detail and give patient handouts.]

☐ **Med 1** ALBUTEROL Rx: _____

days taken last week _____
Usual # of puffs _____
How patient thinks it works: _____

☐ **Med 2** _____ Rx: _____

days taken last week _____
Usual # of puffs _____
How patient thinks it works: _____

☐ **Med 3** _____ Rx: _____

days taken last week _____
Usual # of puffs _____
How patient thinks it works: _____

☐ **Med 4** _____ Rx: _____

days taken last week _____
Usual # of puffs _____
How patient thinks it works: _____

EMR STICKER

QUESTION	PROBE	NOTES
• Many people have a hard time taking their controller medication on the prescribed schedule. • How often do you miss taking a dose of your controller medication(s)? [State name(s)]	• What is the reason? [Examples: forgetting, being too tired or busy, deciding not to]	
• Almost everyone tries cutting back on their controller medications at some point, or they don't take them as often or in the amount their doctor prescribes. • What situations have led you to decrease your controller medications in the past?	• What happened? • Did you continue taking a decreased amount or stop altogether? • How did that work out?	
• Have you tried taking more of your controller medications than what was prescribed by your doctor?	• What led you to do this? • What happened when you did it?	
• What asthma medications have you tried in the past that you feel did not help or that caused you problems?	• What happened when you took them? [Probe if reported problems are unlikely to be attributed to the medication] • What did you do about that? • Did any other asthma medications give you problems?	
• How do/would you feel about taking asthma controller medications on a regular basis?	• Are there any other things that might bother you about taking asthma medications every day?	
• What are the worst things about taking asthma medications every day? • Do you believe that taking controller medications more regularly would make any difference in your asthma?	• [If no] Why not?	
• Are you concerned about side effects of any asthma medications?	• What are you concerned about? [Probe further if side effects mentioned have not been documented]	
•	•	

EMR STICKER

ALTERNATIVE TREATMENTS

QUESTION	PROBE	NOTES
• Have you ever tried anything other than prescription medications to help with your asthma? For example: ☐ Vitamins ☐ Herbs ☐ Acupuncture ☐ Deep breathing yoga ☐ Seeing a chiropractor ☐ Anything else?	• [For each] Did it help your asthma? • Do you think any of these things were helpful in reducing your asthma symptoms? • [If no] Do you have any thoughts on why this didn't work for you?	
• Did you add this/these treatments to your prescription medications or did you try to use them as an alternative to taking medication?		

ENVIRONMENTAL TRIGGERS

QUESTION	PROBE	NOTES
• Are there different times of the year that your asthma is better or worse?	• When is it worse?	Worse at times? ☐ Y ☐ N When? _____
• Are there certain things in your surroundings that you know affect your asthma?	• [If yes] Can you give an example?	
• What changes have you made in your surroundings in order to avoid your asthma symptoms?	• Has that been helpful?	
• Are there changes that you think you should make that you haven't decided to or haven't been able to do yet?	• What are they? • What gets in the way of these changes?	

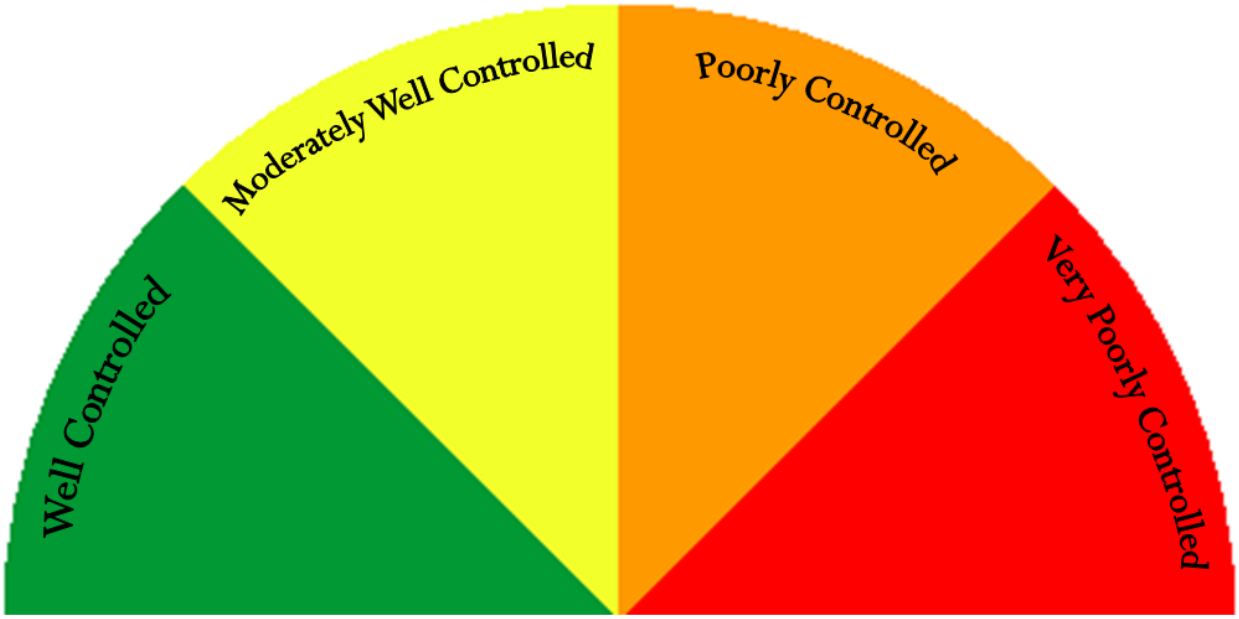
- Are you a smoker?
- [If yes] Have you tried to quit?
- I will give you some information on programs to help people quit and I want to encourage you to take advantage of them. This is particularly important because you have asthma.

☐ Check box indicating that you have recommended cessation and provided handout resources for smokers.

EMR STICKER

ACE Study Form #1: Pt Info Form, Page 4 of 4

FORM #2: HOW WELL CONTROLLED IS YOUR ASTHMA?



ACE Study Form #2: Control Dial Page 1 of 1

FORM #3: ASTHMA TREATMENT GOALS

- Activities:

_____

_____

_____

- Other Concerns:

_____

_____

_____

MEDICATION PREFERENCES

❑ Control Over Inflammation and Symptoms

_____

_____

❑ Side Effects

_____

_____

❑ Cost

_____

_____

❑ Convenience

_____

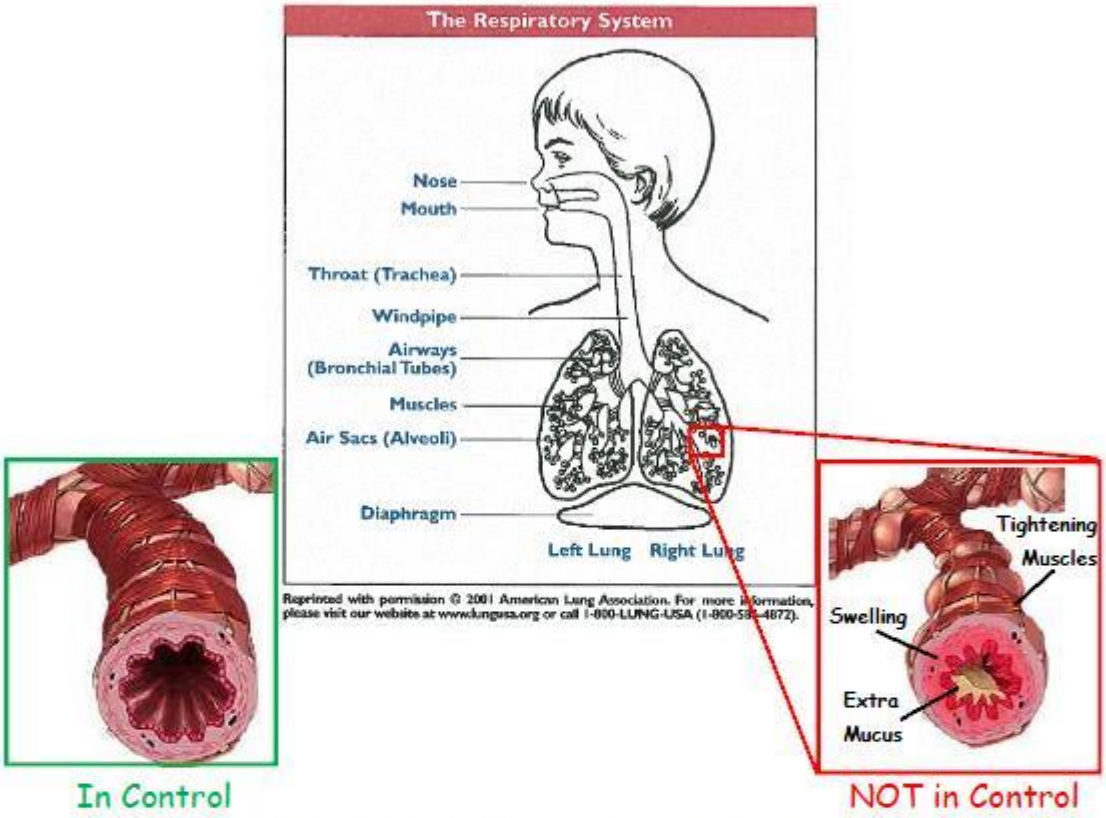
_____

❑ Other

_____

_____

Form #4: Facts About Asthma



Asthma is a disease of the airways in your lungs. When someone with asthma breathes in one of their "triggers," it causes their airways to get smaller. Doctors call this "bronchospasm." This makes it harder to breathe and can lead to an asthma attack.

3 main things cause the airways to get smaller:

Swelling/Inflammation

Extra Mucus

Tightening Muscles

There are 2 types of Asthma Medications

Controller

- **These medicines are <u>taken every day</u> to prevent and control asthma symptoms.**
- **They do NOT relieve symptoms once they start.**
- **Controllers work slowly over time to decrease <u>swelling</u> and <u>extra mucus</u> in your air tubes.**

- ☑ Swelling/Inflammation
- ☑ Extra Mucus
- ☐ Tightening Muscles

Examples:


Symbicort


Asmanex Twisthaler

Singulair


Advair Diskus


Advair HFA


Qvar

Pulmicort Respules


Flovent HFA


Pulmicort Flexhaler

Rescue

- **These medicines are <u>only taken when you have symptoms</u> to relieve asthma symptoms right away.**
- **Rescue medicines relieve the <u>tightening of muscles</u> around your air tubes.**
- **Tell your doctor if you use these more than 2 times a week. You may need a stronger controller medication.**

- ☐ Swelling/Inflammation
- ☐ Extra Mucus
- ☑ Tightening Muscles

Examples:


Generic Albuterol

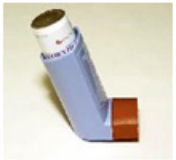

Ventolin HFA


Albuterol Nebulizer Solution

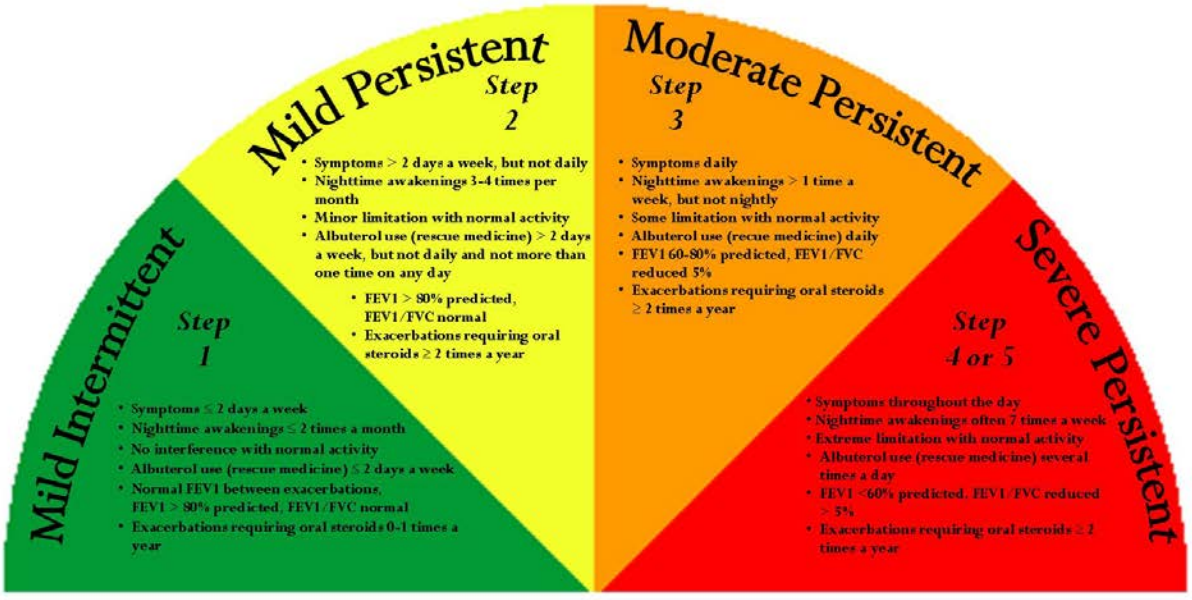

Proventil HFA


ProAir HFA

Xopenex Nebulizer Solution


Xopenex HFA

FORM #7: HOW SEVERE IS YOUR ASTHMA?



Use this dial for patients NOT on controller medication to initiate treatment
≥ 12 Years Old

ACE Study Form #7: Dial with Descriptors Page 1 of 1

FORM #9: MEDICATION PLANNER

FEATURES THAT MATTER TO ME	CURRENT PLAN	OPTION 1	OPTION 2	OPTION 3

ACE Study Form #9: Med Planner, Page 1 of 1

EMR STICKER

Appendix 2: FOCUS GROUP GUIDES

HOW THE STUDY WORKS

The approach of this study is exploratory focus groups. A focus group is a small group of people (between 6-8) who get together and provide answers and opinions to a few questions asked by a member of the research team. If you agree to participate in this study, the research leader will ask you some questions about you or your child's most recent visit to the doctor for your or your child's asthma within the past six months. For example, we will ask you if you and your provider have discussed your medications and their possible side-effects and if you helped to come up with an asthma treatment plan that is ideal for you or your child. The focus group will last approximately one hour.

PRELUDE

This research study is being done to learn more about how to manage asthma. We are interested in understanding how healthcare providers and patients talk about asthma and asthma treatment plans. We would like for you to think about a visit you had with your healthcare provider within the past six months for your asthma and respond to the following questions.

(1) ASSESSMENT

We would like to begin our discussion by talking about some basic things that may or may not have been talked about during your last asthma visit.

QUESTION (1):

When you were at your visit with your provider what was discussed as far as a plan to improve your asthma?/Did you and your healthcare provider come up with a plan of what you can do to improve your asthma?

PROMPTS

- Is this something that you would like for your provider to go over with you?
- What kind of things did you come up with to improve your asthma?

QUESTION (2):

When meeting with your provider, what sorts of things did you discuss? Who initiated these discussions?

PROMPTS

- Did you discuss any problems you may be having?
- What about side effects?
- Have there been any improvements or setbacks?

(2) SHARED DECISION MAKING

Next, I would like for us to talk about some of the decisions that you and your healthcare provider made about your asthma treatment.

QUESTION (3):

What sort of goals around your asthma care did you and your healthcare provider talk about?

PROMPTS

- Can you share some of those goals with us today?
- Why are these goals important to you?
- Can you think of any goals that you believe are important for your asthma management?
- Do you feel like you helped to make the decisions about your asthma care?
- What did you think about the length of the visit?
- Did you complete a health questionnaire like this (show questionnaire)>
- How useful did you feel the health questionnaire was?
- Did it help you to think differently about your asthma?
- In comparison with previous visits with your doctor around your asthma, what do you think about this last visit?
- Is there anything that you would change about this visit?

QUESTION (4):

What choices were you given to decide on for your asthma treatment?

PROMPTS

Can you think of any choices that you would like to be given regarding the treatment of your asthma?

QUESTION (5):

What did you and your provider talk about in reference to your values, opinions, traditions, and culture? Were these things taken into consideration when your provider recommended asthma treatments?

PROMPTS

- Can you share with us an example of how your asthma treatment was sensitive to your values, opinions, traditions, and culture?
- What can be done in the future to take this into account?

(3) END RESULTS

Now we would like to talk about other aspects of your visit that are important. Specifically, we would like for you to think of the actual asthma treatment plan that you went over with your provider/patient.

QUESTION (6):

When meeting with your provider how did you plan ahead for difficult times? And did you talk about how to best take care of your asthma during those times?

PROMPTS

Do you ever discuss what to do regarding events such as seasonal variations, cold weather, smoke in a room, perfumes, etc?

QUESTION (7):

Does the treatment plan that was discussed seem like something that you can do in daily life?

PROMPTS

- Exactly what about the treatment plan is the part that seems most manageable for every day asthma management?
- What things would you need to include in the asthma treatment plan to make it something that can be done on a daily basis?

QUESTION (8):

Was a copy of your asthma treatment plan given to you?

PROMPTS

- Was the form filled out by you, your healthcare provider, or by both?

(4) CONCLUSION

Finally, let's talk about your asthma care management.

QUESTION (9):

What has been negative and what has been positive about your asthma treatment?

Appendix 3: Patient Perception of Shared Decision Making

Tell Us About Your Asthma Meeting

Who made the decision in your meeting with the care manager about what your asthma treatment would be?

□ I alone made the decision

□ I mostly made the decision, and the provider played a small role in the decision- making

□ The provider and I participated equally in making the decision

□ The provider mostly made the decision, and I played a small role in the decision-making

□ The provider alone made the decision
