ADAPT–NC

Asthma Dissemination Around Patient-centered Treatments in North Carolina

Comparing Traditional and Participatory Dissemination of a Shared Decision Making Intervention

Manual of Operating Procedures

Version 2.0

March 7, 2014

pcori | Patient-Centered Outcomes Research Institute

Table of Contents

Version 2.0 Amendments

Chapter 1

Introduction and Summary

Background

Asthma affects 25 million people in the United States, half of whom experience at least one asthma attack each year. Poor outcomes related to asthma result in part from the difficulty of implementing new ways of care delivery such as shared decision making (SDM) into clinical practice. Researchers from The Department of Family Medicine at Carolinas HealthCare System, led by Dr. Hazel Tapp, have been awarded a three-year, $2.1 million grant from the Patient-Centered Outcomes Research Institute (PCORI) to study the dissemination of shared decision making, designed to improve how caregivers interact with patients with chronic asthma to increase their understanding and management of their condition.

Despite rapid advances in medical knowledge, significant gaps remain in our ability to rapidly translate and disseminate new evidence into everyday practice. Indeed, the most common dissemination technique is passive diffusion which includes journal publications, didactic presentations at conferences, and educational material distribution. This process often fails to produce timely or sustainable practice level changes. The existing network of primary care practices across the state of North Carolina provides an ideal venue to examine the effectiveness of new, more effective methods of dissemination. For this study, we will leverage a partnership between the statewide Medicaid network and the statewide consortium of research networks to identify best practices for dissemination of an evidence-based shared decision making toolkit for asthma management. The asthma toolkit development was funding by the Agency for Healthcare Research and Quality (AHRQ) and tested across a regional network of pediatric, family medicine, and internal medicine ambulatory practices in Mecklenburg County, North Carolina. The initial results have showed marked improvement in patient outcomes (improved medication adherence and decreased asthma exacerbations) with increased patient involvement in the creation of the care plan. During this study, key principles of community based participatory research were used in engaging providers and patients to develop a facilitator-led participatory approach to dissemination. This ideal framework provided for rapid dissemination of the toolkit across six practices. This study will test this novel method for dissemination on a larger scale by randomizing 30 practices to 1 of 3 arms:

1. Facilitator-Led Participatory Approach to Dissemination
2. Traditional Dissemination with one didactic session and distribution of educational material
3. Control with no dissemination

The outcomes measured will be:

- Reduction in asthma exacerbations
- Beta agonist overuse
- Controller medication use
- Reported practice level use of the SDM toolkit
- Patients' perceptions of involvement in their asthma care decisions

This study will provide crucial data to support a novel method for dissemination of an evidence-based toolkit into primary care practices.

Chapter 2

Regulatory and Invoicing Information

Invoicing

The following information is needed in order to process invoices:

1) SSN/Federal Tax ID of the sub-site
2) Name (which will appear on the check, could be a department)
3) Person to whom the check should be sent to (Attn: Tonia Miller in Research Finance)
4) Address where check is to be mailed

Each sub-site should submit a monthly invoice for any approved study expenses (for example: personnel, travel, etc.) no later than the 5th of every month. For all items invoiced, please provide a detailed explanation of the expenses in a word document. Invoices and justifications can be emailed to **Tami Alkhazraji** at: thamara.alkhazraji@carolinashealthcare.org.

IRB Changes

Any IRB documents submitted at each sub-site should be submitted to the prime site (Carolinas HealthCare System, MAPPR) in order to place a copy on file with the prime's IRB. Please email all IRB documents to **Tami Alkhazraji** at: thamara.alkhazraji@carolinashealthcare.org.

Chapter 3

Recruitment and Randomization

Timeline

A list of all practices (including names, addresses and primary contacts) is due to MAPPR by ***3/10/14***.

This deadline will ensure each PBRN has sufficient time to complete the disseminations. For tracking purposes, please send a list of all practices you contact and include the following fields:

Practice Name	Practice Address	Primary Contact Name and Number	Agreed to participate in ADAPT-NC? Yes/No	Memorandum of Agreement signed? Yes/No, Date	If not participating, why?

	12/1/13	1/1/14	3/31/14*	4/4/14*	4/7/14*
Practice recruitment					
List of practices due to MAPPR					
Randomization results to PBRNs					
Inform practices of assignment					
Able to begin scheduling practices					

*Recruitment period may be extended but implementation should proceed as planned (see Chapter 4)

Recruitment Expectations by PBRN

Healthcare System – PBRN	Total # of Practices
CHS – MAPPR	9
UNC-CH – NC-FM-RN	9
Duke – PCRC	6
Vidant – E-CARE	6

Introduction

An important first step for the success of ADAPT-NC will hinge on successful practice recruitment. Recruitment presents a unique challenge because of the randomized nature of this trial. The practices must be sold on the potential benefits the study brings to the practice and ultimately agree to the possibility of participating in the Facilitator-

Led Participant Owned (FLOW) arm of the study (as this is the most time and effort intensive); yet at the same time, each practice must also accept the idea of participating in the Traditional dissemination or Control arms of the study. Because of the need to present information to the practices on the scope of the trial, there will inevitably be contamination of the Control practices. To minimize contamination and ensure that the dose is the same, we ask that during recruitment the PBRNs attempt to use only the content and script provided below. Of note, we would like to NOT provide the Control practices with the website asthma.carolinashealthcare.org that contains the Asthma SDM Toolkit. The provided Recruitment Flyer and Fact Sheet (below) convey the information we expect the practices may need to make the decision of whether or not to participate. They include the:

- Overview of the study and description of each study arm
- Concept of randomization into 1 of 3 arms
- Benefits of implementing the Asthma SDM Toolkit (improved care, quality measures/pay for performance, patient satisfaction, enhanced billing, etc.)
- Expected time commitment for each arm
- Timeline

If you encounter difficulties with recruitment or the practices have difficult questions with which you need help, we can arrange for a representative from MAPPR (including a physician champion) to speak with or visit the practice.

In addition to indirect benefits of participation, some PBRNs will have arrangements in place to pay practices. We recommend regardless of whether your PBRN is paying practices that you consider having a signed agreement in place that clearly outlines the expectations between the practice and PBRN. An example Memorandum of Agreement is included below for illustrative purposes only. Each sponsoring institution will likely have its own legal document.

Inclusion Criteria

- Primary care practice
- Approximately 100 Medicaid patients with asthma
- Existing staff member(s) available to be trained as a Health Coach
- Willing to participate for the duration of the study (approximately 2 years)
- Willing to incorporate *at a minimum* the 5 Essential Components of the Asthma SDM Toolkit – in addition to setting the stage and describing shared decision making, these include:

    1. Patient perception of control
    2. Medication adherence
    3. Treatment goals and medication preferences
    4. Asthma education
    5. Negotiation of several treatment options based on severity or control level

Target Population

In order to successfully power the trial and achieve changes in outcomes, at least 50 primary care Medicaid asthma patients will need to undergo shared decision making health coaching and complete a brief survey question (see Chapter 4 for complete details). Primary care practices are defined as family medicine, internal medicine, and pediatric practices. Specialty practices, including pulmonology and asthma, allergy and immunology practices are to be excluded from participation.

ADAPT–NC
Asthma Dissemination Around Patient-centered Treatments in North Carolina

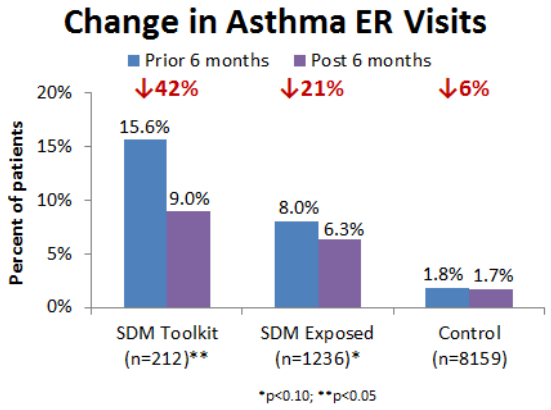
Recruitment Flyer

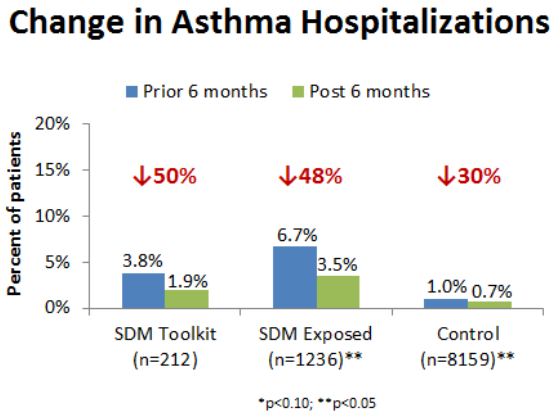
Congratulations! Your practice has met the pre-selection criteria for our project Asthma Dissemination Around Patient-centered Treatments in North Carolina (ADAPT-NC) to study implementing shared decision making (SDM) with asthma patients. The objective is to determine how best to incorporate shared decision making into practices. We are trying to determine the most effective way to bring successful patient engagement strategies to busy working practices such as yours.

Background

At Carolinas HealthCare System, we previously tested a shared decision making toolkit that was developed by Kaiser Permanente. We partnered with 6 pediatric, family medicine, and internal medicine ambulatory practices in Charlotte and worked together to tailor the intervention to the practice environment. Asthma prevalence is increasing in the Carolinas; many patients with asthma lack adequate control of their symptoms, negatively impacting their overall quality of life. Shared decision making engages the patient and provider to tailor the treatment plan to meet their combined goals for care.

Previous Results





What our Clinic Providers Say about Shared Decision Making

“Shared decision making allows for a surprising dialogue to occur between patient and provider - I learned more about where the gaps were in my patient’s chronic disease

education than I ever had before, and they weren't always in areas that I thought were most relevant. My ED visits have dropped for exacerbations, and most importantly, patients seem to feel more empowered, and more participatory in their visits. It has helped me be better attuned to patient priorities in asthma - whether it is frequency of med administration, or having meds that can be put in a purse, or preferring pills over inhalers."

"I have started implementing SDM, or shades of this into my other visits, to form a partnership where the patient and I are on more equal footing. I have also noticed adherence is better when you focus on the conversations- we all love self-determination!"

What this Means for Your Practice

Each practice will be trained to use all or part of an Asthma SDM Toolkit that guides patients and providers to reach a shared decision for their asthma management. This Toolkit will not be a one size fits all.

Considerations for you may be the time this will take, whether you have staff and resources for this, how to schedule this, etc. Depending on the project arm assigned to you, our project is designed to test different ways of working with you to implement, including working closely using a multidisciplinary approach to address individual clinic needs and concerns, enhance the experience, and also make the project sustainable and productive.

Using this Asthma SDM Toolkit provides an added benefit of satisfying Medicaid/Medicare appropriate care measures such as symptoms assessment (history), asthma action plan (AAP), trigger assessment, and use of controller medications.

The Toolkit will not cost anything, and we will work with you to make this cost neutral or even beneficial through coding improvements. A practice incentive may also apply.

We have three 2 year approaches or "study arms" (see definition on next page) that will test the most effective way to help your practice use the shared decision making Toolkit:

- Arm 1 – A Practice Facilitator from the research team will come in over several weeks, train your practice in the intervention and work through issues from within your setting to adapt the intervention to your clinic's needs and culture.

- Arm 2 – A "lunch-and-learn" where a Practice Facilitator comes in to your practice once per year to demonstrate how the Toolkit works.

- Arm 3 – Usual care. No involvement of the practice for the first 18 months then the opportunity for the "lunch-and-learn."

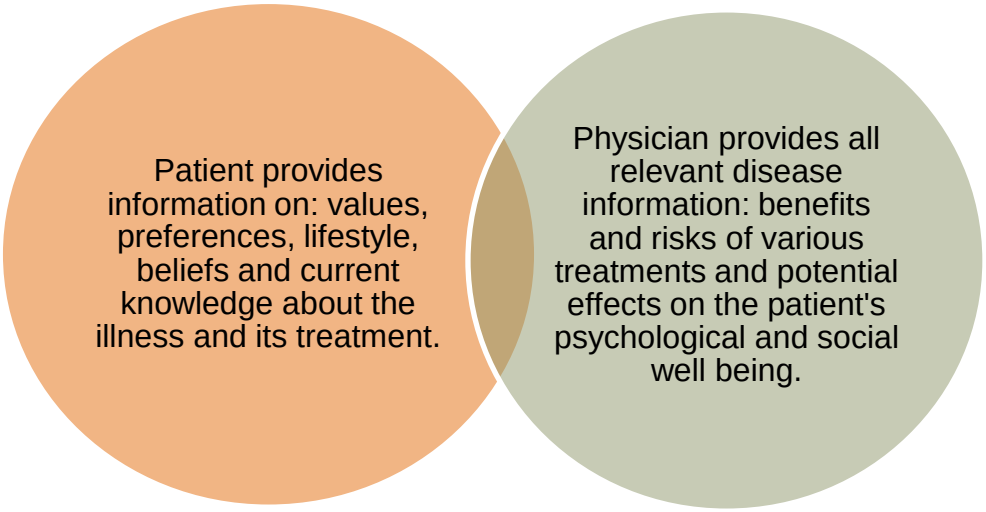
Fact Sheet

What is a Randomized Trial?

We will take a group of practices from within each region of North Carolina (either 6 or 9 sites) that have agreed to be randomized. We assign a number to each practice and have a computer randomize the numbers into three groups of 2 or 3. These are the assignments for the 3 “arms” of the trial.

What is Shared Decision Making?

We think of shared decision making as a meeting of 2 experts. The patient is the expert on what matters to them; the provider / health coach is expert on the clinical knowledge.



How Long Does the Study Last?

Implementation is for 2 years.

Will this Cost us Anything?

No, there is no cost associated with participating in this project. The research team will work with you to tailor the intervention to your clinic.

For Further Information Please Contact:
Kelly Reeves, BSN, RN - Practice Facilitator/Nurse Consultant
kelly.reeves@carolinashealthcare.org, Work: 704-304-7175, Cell: 704-512-1701, or
Lindsay Kuhn, PA-C: lindsay.kuhn@carolinashealthcare.org
Andy McWilliams, MD, MPH: andrew.mcwilliams@carolinashealthcare.org
Hazel Tapp PhD: hazel.tapp@carolinashealthcare.org

ADAPT–NC
Asthma Dissemination Around Patient-centered Treatments in North Carolina

EXCELLENT ASTHMA TOOLS FOR PRIMARY CARE PRACTICE

Hello and Happy Winter!

Medical practices throughout North Carolina are participating in a project where they can receive onsite guidance on using effective asthma tools with their patients. The use of these tools by primary care practices within Carolinas HealthCare System has resulted in significantly **reduced Emergency Room visits and hospitalizations** for patients with asthma.

Due to this success, there are now funds* to support personnel from CHS to visit your office and share these tools with you and your staff.

This is a great resource for practices with dedicated asthma clinics, those interested in enhancing their management of asthma patients (pediatric and adult patients), or are thinking of setting up a new system for enhanced asthma care in their practices.

The study is called ADAPT-NC. Since this is a research project, interested practices will be randomized in to 1 of 3 different "arms" of the study. Each arm provides a different "dose" of practice instruction on how to use the asthma tools. The main requirement for practices is that you have approximately 100 Medicaid patients with asthma and that you are open to learning about these evidence-based tools.

We would like to speak with you about this to give you more details and can do this via **phone or via a 30 minute office visit in December, January or the 1st week of February 2014.**

This study will not require access to your patient's records or use of an electronic health records. Practice compensation ranges from **$500 to $2,000** depending on which arm of the study you are in. All study arms will learn about the tools and how to efficiently use them.

For Further Information Please Contact:
Kelly Reeves, BSN, RN - Practice Facilitator/Nurse Consultant
kelly.reeves@carolinashealthcare.org, Work: 704-304-7175, Cell: 704-512-1701, or
Lindsay Kuhn, PA-C: lindsay.kuhn@carolinashealthcare.org
Andy McWilliams, MD, MPH: andrew.mcwilliams@carolinashealthcare.org
Hazel Tapp PhD: hazel.tapp@carolinashealthcare.org

* Funding from the Patient Centered Outcomes Research Institute (PCORI)

Example
Memorandum of Agreement

This Memorandum of Agreement outlines the agreement between [Health System/PBRN] and [Primary Care Practice] to conduct the project titled "Asthma Dissemination Around Patient-centered Treatments in North Carolina" (ADAPT-NC).

This agreement will be in effect from [start date, for example: February 17, 2014] and shall end on [end date, for example: October 1, 2016], and may be terminated prior to the effective end date upon the full written approval of all the undersigned.

The roles and expectations of [Primary Care Practice] are outlined below:

- Participate as a randomized practice site for ADAPT-NC for the full project period (approximately 2 years).

- If assigned to the Facilitator-Led Participant Owned (FLOW) Dissemination Arm:
    - A practice provider champion, health coach(es) and staff will participate in 3 months of Practice Facilitator-led Rollout sessions AND one 1 hour Refresher session to be held approximately 12 months after the initial Rollout.
    - Attempt to incorporate, at a minimum, the 5 Essential Components of the Asthma Shared Decision Making Toolkit into the practice's asthma specific visits. In addition to setting the stage and describing shared decision making, these include:
        1. Patient perception of control
        2. Medication adherence
        3. Treatment goals and medication preferences
        4. Asthma education
        5. Negotiation of several treatment options based on severity or control level
    - Participate in up to 4 focus groups (each 1 hour in duration) to be held at [Primary Care Practice].

- If assigned to the Traditional Dissemination arm:
    - Practice providers and staff will attend a 1 hour "lunch-and-learn" presentation to be held annually (total of 2) at the [Primary Care Practice].
    - Participate in 1 focus group (1 hour duration) to be held at [Primary Care Practice] before January 15, 2016.

- If assigned to the Control / Usual Care arm:
    - Participate in 1 focus group (1 hour duration) to be held at [Primary Care Practice] before January 15, 2016.

- [Primary Care Practice] personnel will be responsible for distribution and collection of patient survey cards.

- [Primary Care Practice] will allow ADAPT-NC staff to observe or discuss asthma visits in the practice 1 to 2 times per year to evaluate quality assurance.

- [Primary Care Practice] personnel will be responsible for delivery of all patient care.

[Health System/PBRN] will pay [Primary Care Practice] the following amounts on [dates]. The payment schedule is dependent on which study arm [Primary Care Practice] is assigned (table below) to AND payment is contingent on fulfillment of expectations as outlined above:

Study Arm	**Practice Reimbursement per 12 Month Period**
Facilitator-Led Participant Owned (FLOW) Dissemination Arm	$ [Amount]
Traditional Dissemination Arm	$ [Amount]
Control / Usual Care Arm	$ [Amount]

Signatures

_____ _____
Date

_____ _____
Date

Chapter 4

Practice Facilitators

Introduction

Each practice based research network (PBRN) will have at least one trained Practice Facilitator. This individual(s) will lead their PBRN's practices through the dissemination approach to which each practice is randomized. The 3 dissemination methods (also referred to as study arms) are:

- Facilitator-Lead Participant OWned (FLOW) Approach to Dissemination
- Traditional Dissemination (Active Diffusion) with Facilitator Exposure
- Control / No Active Dissemination

Practice Facilitator-related questions and/or concerns should be directed to the lead Practice Facilitator at the prime site, MAPPR:

Lindsay Kuhn, MHS, PA-C
704-304-7150 or lindsay.kuhn@carolinashealthcare.org

Planning

Strategically planning one's time early on in the project will ease scheduling challenges and assure completion of milestones in a timely manner. After successful recruitment and randomization, Practice Facilitators will ultimately coordinate the following:

- FLOW practices will receive a 12 Week Practice Facilitator-led Rollout in Year 1 (2014) followed by a "Refresher" session in Year 2 (2015).
- Traditional practices will receive a Lunch-and-Learn in Year 1 followed by a "Refresher" session in Year 2.
- Control practices will have the opportunity to receive a Lunch-and-Learn similar to the Traditional practices' 18 months after their PBRN's first FLOW practice has kicked off. These practices will not receive a "Refresher" session.

Beginning after the Practice Facilitator Training Day, WebEx conference calls with all Practice Facilitators across the 4 PBRNs will serve as an opportunity for sharing best practices and troubleshooting. These calls will begin bi-weekly then move to monthly once they are needed less frequently.

Below are a few examples of how to consider structuring deployment into the 3 arms at the 6 or 9 practices. There are countless possibilities. Be mindful that participation from each practice is an important underlying theme of the project; therefore flexibility on the Practice Facilitator's part is highly recommended.

Initiation of Rollouts to FLOW practices and completion of the Traditional practices' Lunch-and-Learns should occur before the ***6/15/14*** milestone during Year 1. Completion of Rollouts to FLOW practices should occur before the ***9/15/14*** milestone.

Example Planning Calendars for 6 Practices (Duke, Vidant)

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Rollout										
F 2				Rollout								
T 1			Lunch									
T 2					Lunch							
C 1												
C 2												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Refresh										
F 2				Refresh								
T 1			Refresh		Refresh							
T 2												
C 1								Lunch				
C 2								Lunch				

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Rollout										
F 2					Rollout							
T 1		Lunch										
T 2					Lunch							
C 1												
C 2												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Refresh										
F 2					Refresh							
T 1		Refresh										
T 2					Refresh							
C 1								Lunch				
C 2								Lunch				

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1			Rollout									
F 2			Rollout									
T 1		Lunch										
T 2		Lunch										
C 1												
C 2												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1			Refresh									
F 2			Refresh									
T 1		Refresh										
T 2		Refresh										
C 1									Lunch			
C 2									Lunch			

F = FLOW practice, T = Traditional practice, C = Control practice
Rollout = 12 Week Rollout, Lunch = Lunch-and-Learn, Refresh = Refresher session

Example Planning Calendars for 9 Practices (CHS, UNC-CH)

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Rollout										
F 2			Rollout									
F 3					Rollout							
T 1	Lunch											
T 2	Lunch											
T 3	Lunch											
C 1												
C 2												
C 3												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Refresh										
F 2			Refresh									
F 3												
T 1	Refresh				Refresh							
T 2	Refresh											
T 3	Refresh											
C 1								Lunch				
C 2								Lunch				
C 3								Lunch				

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Rollout										
F 2				Rollout								
F 3						Rollout						
T 1			Lunch									
T 2					Lunch							
T 3							Lunch					
C 1												
C 2												
C 3												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Refresh										
F 2				Refresh								
F 3						Refresh						
T 1			Refresh									
T 2					Refresh							
T 3							Refresh					
C 1								Lunch				
C 2								Lunch				
C 3								Lunch				

2014												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Rollout										
F 2				Rollout								
F 3						Rollout						
T 1	Lunch											
T 2	Lunch											
T 3	Lunch											
C 1												
C 2												
C 3												
2015												
Practice	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**JUL**	**AUG**	**SEPT**	**OCT**	**NOV**	**DEC**
F 1		Refresh										
F 2				Refresh								
F 3						Refresh						
T 1	Refresh											
T 2	Refresh											
T 3	Refresh											
C 1								Lunch				
C 2								Lunch				
C 3								Lunch				

F = FLOW practice, T = Traditional practice, C = Control practice

Rollout = 12 Week Rollout, Lunch = Lunch-and-Learn, Refresh = Refresher session

Facilitator-Led Participant OWned (FLOW) Approach to Dissemination

Background

This approach to dissemination allows practices some freedom to tailor the asthma 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.

The success of the Asthma Comparative Effectiveness (ACE) Study, which the ADAPT-NC Study is based upon, was in part due to continued emphasis on participatory methods of adaptation. Each PBRN and all practices randomized to receive the FLOW approach to dissemination are unique. Reinforcing this concept is central to implementation and sustainability. While integrating half-day asthma SDM clinics utilizing the Toolkit in its entirety is optimal, it is not required.

Practice Facilitators will work with their 2 or 3 FLOW sites to incorporate *at a minimum* the 5 Essential Components of the Asthma SDM Toolkit into their practices. In addition to setting the stage and describing shared decision making, these include:

1. Patient perception of control
2. Medication adherence
3. Treatment goals and medication preferences
4. Asthma education
5. Negotiation of several treatment options based on severity or control level

This will be accomplished through a 12 Week Rollout in Year 1 of the project, to be initiated before the ***6/15/14*** milestone and completed before the ***9/15/14*** milestone.

A goal of at least 50 patients will undergo asthma SDM health coaching and complete a brief survey question in this arm of the study.

Scheduling

After randomization, the Practice Facilitators will engage and coordinate with each FLOW site's practice manager and/or provider champion to set up their 12 Week Rollout schedule for implementing asthma SDM into their practice. The ideal time for these meetings is during the lunch hour, however practices may choose before or after patient care hours. For simplicity, the day of the week and time usually remains constant (for example: every Wednesday from 12:30-1:30pm beginning 2/5/14 for 12 weeks). Practices may be encouraged to provide lunch and/or pay staff for their time during these sessions.

On occasion, scheduling conflicts may arise during the Rollout timeframe (for example: the practice can only meet 3 out of 4 Wednesdays a month due to another regularly scheduled meeting). It is the Practice Facilitator's responsibility to assure integrity of the Rollout while fostering participation and brainstorming creative solutions to cover all proposed topics outlined below (for example: covering the topics of Weeks 3 and 4 together during an extended meeting from 12:30-2:00pm). Any concerns can be discussed during the regularly scheduled Practice Facilitator WebEx conference calls.

Core Team Members

Encourage early identification of core members for the practice's team. This typically includes a:

- Provider champion to lead the team
- Additional providers particularly interested in asthma care
- Practice manager
- Nurse manager
- Registration supervisor or scheduling staff
- Health Coaches: may include pharmacists, nurses, patient educators, care managers, etc.
- Medicaid case manager (where applicable)
- Interpreter (where applicable)

Rollout Binders

Plan to prepare a Year 1 Rollout Binder for each member of the core team (typically 6-10 people) at each practice. Attach the Practice Facilitator's contact information or business card. The Binder should include all materials for the 12 Weeks as outlined below. These materials will be included on a flash drive given at the Practice Facilitator Training Day and can also be found on the asthma.carolinasheathcare.org website.

Meeting Planners

Meeting planners for the 12 Week Rollout meetings should be sent to all team members, either by the practice manager or Practice Facilitator. These serve as good reminders, keeping the meetings visible and making them a priority.

Pre-Planning

It would be helpful if the practices would take the opportunity to watch the Asthma Shared Decision Making - Health Coach Training Video on the

asthma.carolinashealthcare.org website prior to their Kick-Off. Ask them to be thinking about ahead of time if they would like to:

- Incorporate the entire Asthma SDM Toolkit into their practice (the ideal), or focus on the 5 Essential Components?
- Schedule asthma SDM half-day clinics (the ideal), or work the health coaching into their regular clinic flow?

Identifying these different directions early on in the process will help the Practice Facilitator to be better prepared for the upcoming Rollout.

Patient Surveys

Collecting surveys around the patients' perception of shared decision making provides important outcomes data for the ADAPT-NC Study. Ultimately, the practices will ask their asthma patients to complete a brief survey question after each asthma SDM visit:

Tell Us About Your Asthma Visit

Practice Name: _____ Today's Date: _____

Who made the decision in your meeting with the care team (health coach and provider) about what your asthma treatment would be?

- ☐ I alone made the decision
- ☐ I mostly made the decision, and the care team played a small role in the decision making
- ☐ The care team and I participated equally in the decision making
- ☐ The care team mostly made the decision, and I played a small role in the decision making
- ☐ The care team alone made the decision

A goal of at least 50 patients will complete this brief survey question at each FLOW practice. It will be up to the practice to decide how they would like to survey their patients (for example: the nurse could give the patient the survey at the end of their asthma SDM visit; survey boxes could be placed in exam rooms or at checkout).

The Practice Facilitator should prepare plenty of survey cards and collection boxes for each practice and work with the site to determine the best way to obtain the surveys and how often they should be transferred to the PBRN for analysis.

In order to analyze the results, the Practice Facilitator will need to enter the survey data into a web form (for example Survey Monkey or Red Cap) for transmission to the coordinating center, MAPPR. This will be shared with the PBRNs at a later date.

Ideally, every SDM asthma patient should be given a survey and these surveys should be collected by the Practice Facilitator monthly.

Survey collection should begin before the ***8/15/14*** milestone, or when the first asthma SDM patients are seen.

Proposed FLOW Practice 12 Week Rollout Schedule – Year 1

Week	Topic	Suggested Team Members
1	Kick-Off and Introduction to Asthma SDM	Entire practice
2	Asthma Appropriate Care and Action Plans	Providers, Practice manager, Nurse manager, Health coaches, Medicaid case manager
3	Population Management	Providers, Practice manager, Nurse manager, Health coaches, Medicaid case manager
4	Logistics of Scheduling	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling
5	Patient Recruitment	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling, Medicaid case manager
6	Asthma SDM Toolkit Training	Providers, Practice manager, Nurse manager, Health coaches
7	Health Coach Role Playing	Providers, Practice manager, Nurse manager, Health coaches
8	Final Preparation and Dress Rehearsal	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling
9	1st Asthma SDM Clinic or Toolkit Visit	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling
10	Debriefing from 1st Asthma Clinic/Visit	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling
11	Feedback and Troubleshooting	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling
12	Feedback and Troubleshooting	Providers, Practice manager, Nurse manager, Health coaches, Registration/scheduling

Week 1: Kick-Off and Introduction to Asthma SDM

This is the Practice Facilitator's chance to introduce his- or herself to the entire practice and promote the study. The Practice Facilitator will be spending a good amount of time at the site and will want to come across as friendly and helpful so everyone can eventually assimilate them with asthma SDM. They will guide the practice through transformation which for some can be difficult. Having an optimistic attitude will engage the practice and prove to them that they can incorporate asthma SDM into their culture.

Ideally, lunch is provided during the Kick-Off to improve participation. This can either be by the PBRN or coordinated by the practice manager.

Present the core team members with their 12 Week Rollout Binders at the Kick-Off.

This first meeting is intended to be a time to set the stage for what will occur over the next 3 months. Explain what SDM is with regards to asthma. It may be helpful to present an overview of the ACE Study including the favorable results seen. A summary PowerPoint is included in the Year 1 Rollout Binder along with a copy of the results poster presented at the 2013 North American Primary Care Research Group (NAPCRG) Conference. Briefly:

- The ADAPT-NC Study, funded by PCORI, is studying the best way to disseminate the promising results of the Carolinas HealthCare System Department of Family Medicine Research Division's Asthma Comparative Effectiveness (ACE) Study.
- Six primary care "safety-net" practices in Charlotte, NC participated in the intervention from April 2011 through September 2013.
- Providers, staff and Health Coaches were trained in SDM using an evidence-based decision support Toolkit and half-day asthma clinics were implemented.
- Among SDM half-day participants, asthma-related ER visits dropped 42% (compared with 6% in the control group) and hospitalizations were reduced by 50% (compared with 30% in the control group). Oral steroid prescription orders for acute exacerbations were significantly decreased by 46% within 3 months of the intervention and 24% within 3 months (compared with 26% and 10% respectively in the control groups).

Introduce the asthma.carolinashealthcare.org website. This website will serve as their one stop for all materials needed to successfully implement asthma SDM at their practice. It contains links to the:

- Asthma Action Plan Generator
    - A tool that provides rapid determination of peak flow expectations, assessment of asthma severity or control, guideline-based decision support for medication management, and generation of an individualized asthma action plan patient handout to support self-management.
- Shared Decision Making Toolkit

    - Videos
        - Asthma Shared Decision Making - Health Coach Training video
        - Voices of Asthma Shared Decision Making promotional video
    - Toolkits
        - 2-4 years old, 5-11 years old, 12 years and older
        - English and Spanish (if needed)
- Implementation Resources
    - Asthma Educational Resources
    - Asthma SDM Clinic Resources

If everyone on the core team has not had the opportunity to view the Asthma Shared Decision Making - Health Coach Training Video on the asthma.carolinashealthcare.org website, remind them to do so. It will engage them in the upcoming process and give them a better frame of reference for the future Rollout. Again, ask them to start narrowing down if they would like to:

- Incorporate the entire Asthma SDM Toolkit into their practice (the ideal), or focus on the 5 Essential Components?
- Schedule asthma SDM half-day clinics (the ideal), or work the health coaching into their regular clinic flow?

Ask the provider champion if they would like to begin collecting baseline survey data now, or wait until later in the Rollout. The Practice Facilitator should provide the practice with plenty of survey cards and collection boxes if the site is ready to get started. Survey collection should begin before the ***8/15/14*** milestone, or when the first asthma SDM patient is seen.

Also included in the Week 1 section of the Year 1 Rollout Binder is a copy of Dr. Sandra Wilson's publication "Shared Treatment Decision Making Improved Adherence and Outcomes in Poorly Controlled Asthma." FLOW practices may be interested to read this article describing results of the Better Outcomes of Asthma Treatment (BOAT) Study, which the ACE Study is based upon.

Before the meeting ends, remind the core team what the next week's topic will be.

Week 2: Asthma Appropriate Care and Action Plans

To best care for asthma patients, providers should strive to achieve documentation of appropriate care measures. Each PBRN, healthcare system or practice may have slightly different performance metrics to promote quality improvement for asthma. Community Care of North Carolina's (CCNC) includes:

1. Assessment of symptoms
2. Asthma action plan
3. Environmental trigger assessment

4. Controller medication therapy for persistent or poorly controlled asthma

Additional asthma-related measures may include:

- Annual flu vaccination
- Spirometry

During this week of the Rollout, the Practice Facilitator can work with the site to identify any challenges in documenting their necessary metrics, as reimbursement for services is often tied to the ability to achieve compliance here. If available, the practice's Medicaid case manager can assist with this too.

The Practice Facilitator should also demonstrate the ease of using the Asthma Action Plan Generator from the asthma.carolinashealthcare.org website. A step-by-step guide is included in Week 2 of the Year 1 Rollout Binder.

Before the meeting ends, remind the core team what the next week's topic will be.

Week 3: Population Management

Asthma SDM is particularly useful for patients who are moderate-to-severe persistent or not well controlled. This includes patients who are seen for multiple office visits for asthma, have frequent emergency room (ER) visits or have been hospitalized.

Some electronic medical record (EMR) systems are able to generate reports detailing this information. The Medicaid network also captures these high-risk patients and prioritizes them for case management. Leveraging the practice's relationship with their Medicaid case manager can assist with future recruitment for asthma SDM half-day clinics or Toolkit visits.

During this week of the Rollout, Practice Facilitators should lead a discussion with the team around what resources are available to improve the health of their asthma population and identify prime candidates for future SDM clinics or Toolkit visits.

Before the meeting ends, remind the core team what the next week's topic will be. At this point, they should have a general idea of how they would like to proceed with incorporating the entire Asthma SDM Toolkit or *at a minimum* the 5 Essential Components and whether they would like to set up half-day asthma SDM clinics or work the health coaching into their regular flow (Toolkit visits).

Week 4: Logistics of Scheduling

Half-day asthma SDM specialty clinics were deployed throughout the 6 practices involved in the ACE Study. Briefly, a nurse would room the asthma patient as usual and

perform peak flow and/or spirometry tests if available and applicable. Then the Health Coach would go through the SDM Toolkit with the patient and huddle with the provider to relay important information afterwards. The provider would then examine the patient and confirm the plan, reinforcing the patient's understanding through teach-back. Below is the complete list of responsibilities:

- **Registration**
  - Check patient in at front desk and collect co-pay if applicable
- **Nurse**
  - Bring patient back to exam room
  - Enter chief complaint as "asthma shared decision making visit"
  - Update pharmacy information
  - Obtain and document vital signs
    - Weight, height, blood pressure, heart rate, respiratory rate, temperature, pulse ox (if having difficulty breathing)
  - Update tobacco use and exposure
  - Measure peak flow (if applicable)
    - Chart best of 3, instruct patient how to test at home, give patient peak flow meter
  - Perform spirometry (if applicable)
    - Test 3 times (more if necessary), print results for Health Coach and provider to review
- **Health Coach**
  - Describe shared decision making approach
  - Complete Patient Information Sheet (thorough history)
  - Determine current understanding of asthma
  - Review what asthma is and how it is treated
  - Confirm comprehension of information
  - Identify treatment goals
  - Review spirometry results (if applicable)
  - Determine current asthma severity or control level
  - Work with patient to define medication preferences
  - Discuss regimen options
  - Negotiate a decision about treatment
  - Complete documentation of coaching session for provider
- **Provider**
  - Perform physical examination
  - Teach back to confirm patient understands new treatment plan
  - Update asthma appropriate care measures in medical record
  - Write/e-prescribe prescriptions
  - Review proper inhaler technique
  - Complete and give asthma action plan
  - Give asthma diary
  - Type up and give discharge instructions
- **Check Out**
  - Set up follow-up appointment in 2-6 weeks

Depending on the complexity of the patient, the length of each portion of the SDM visit performed in its entirety averages:

- Nurse: 5-20 minutes (20 minutes if performing spirometry)
- Health Coach: 20-60 minutes (60 minutes if coaching both a child and parent, or if in Spanish)
- Provider: 10-15 minutes

Ideally, the ADAPT-NC practices randomized to receive the FLOW dissemination method would also adopt these half-day clinics. However, since practice participation is crucial to the success of this project, and they know best what will work in their setting, it is imperative to ask for their input as to how they would like to proceed.

The Year 1 Rollout Binder includes the ACE Study half-day clinic flow example and sample questions to guide scheduling decisions with the practice. Feel free to amend the questions to suit the practice's setting. Example and blank scheduling templates are also supplied. By the end of this week's meeting, the core team should have a firm understanding of what their half-day SDM clinics or Toolkit visits will look like and when their first one will occur during Week 8 of the Rollout. If planning half-day clinics, it's advisable to start off with a smaller number of patients scheduled for the first one or two clinics.

It's also a good time this week of the Rollout to narrow down how and when the asthma SDM surveys of "who made the treatment decision" will be collected. Questions to be answered include:

- How frequently will the collection boxes be checked? Who will check them?
- Will the Practice Facilitator pick the surveys up in person? Or will the practice mail them to the Practice Facilitator? In this case the Practice Facilitator will need to provide the practice with self-addressed stamped envelopes for convenience.

Ideally, every patient with a visit for asthma should be given a survey. These surveys should be collected from the practice by the Practice Facilitator monthly. Finalize the plan for this data collection along with the clinic or visit logistics.

Summarizing action items prior to concluding the meeting is helpful, as is circulating minutes of the decisions made back to the core team. Be sure to include who is responsible for each action item (for example: Sandra, the registration supervisor, will create new asthma clinic templates in the scheduling software).

Before the meeting ends, remind the core team what the next week's topic will be.

Week 5: Patient Recruitment

This week's topic is vital to successfully implementing and sustaining asthma SDM clinics or Toolkit visits. The Practice Facilitator should leverage the core team's experience with previous efforts to coordinate care for their patients (for example: find out how they pulled their diabetes clinic together, or informed patients to come in for annual flu shots last fall).

Historically, provider self-referral has been the most effective means of recruitment for the ACE Study. Providers can identify their persistent and/or poorly controlled asthmatics when they see them in their regular clinic, inform them of the opportunity to receive specialized care, and then ask them to schedule an asthma SDM visit at checkout.

Remember, each FLOW practice should have at least 50 Medicaid asthma patients receive asthma SDM health coaching.

Letters can be mailed or calls can be made to asthma patients from population reports. The Year 1 Rollout Binder includes a call script for staff to utilize. The Medicaid case manager may be particularly helpful in this area.

Recruitment flyers can be placed in exam rooms and other high volume places around the practice like the waiting room or laboratory. English and Spanish versions are available on the asthma.carolinashealthcare.org website.

The asthma SDM clinics or Toolkit visits can be promoted by the core team and provider champion at practice meetings and/or provider meetings.

Remind the team that they now have 3 weeks until their first asthma SDM clinic or Toolkit visit.

Once patients are scheduled for asthma SDM clinics or Toolkit visits, reminder calls can be helpful to support high show rates. Encourage the practice staff to call patients 1-2 days before their scheduled visits to remind them of their upcoming appointment and ask them to bring their inhalers with them. Identify who will be responsible for this important job during this week's meeting.

Before the meeting ends, remind the core team what the next week's topic will be. If team members, particularly the future Health Coaches, have not had a chance to view the Asthma Shared Decision Making – Health Coach Training Video, remind them to visit the asthma.carolinashealthcare.org website before next week's meeting. It is also advised to read through the SDM Script in preparation (included in Week 6 of the Year 1 Rollout Binder).

Week 6: SDM Toolkit Training

The Year 1 Rollout Binder includes a copy of the asthma SDM initial visit Script for reference as well as a PowerPoint containing screen shots of the health coaching forms. The Practice Facilitator should walk the team through the Toolkit in its entirety, briefly explaining the purpose of each form. Using the PowerPoint or flipping through a demonstration binder will be helpful.

By the end of this week's meeting the team should decide which portions of the SDM Toolkit they'd like to incorporate into their clinics or visits. This should include *at a minimum* the 5 Essential Components of the Asthma SDM Toolkit. In addition to setting the stage and describing shared decision making, these include:

1. Patient perception of control – asking the patient how well controlled they think their asthma is using the dial
2. Medication adherence – asking the patient how they have been told to take their medications compared with how they actually have been taking them, assessing their inhaler technique
3. Treatment goals (often times activity-related) and medication preferences (ranking control, cost, convenience, side effects, etc.)
4. Asthma education – what is asthma, controller vs. rescue medications, correct inhaler technique, trigger avoidance
5. Negotiation of several treatment options – based on actual severity or control level according to the dial and insurance type

Reviewing proper inhaler technique with the core team this week would be helpful.

The Practice Facilitator should customize Asthma SDM Toolkit Binders matching the practice's preferences with regards to their selected elements. In general each site should receive 1-3 Toolkits for each age and language that they manage.

Week 7: Health Coach Role Playing

During this week of the role out, Health Coaches have the opportunity to practice using the SDM Toolkit. Pair the Health Coaches with a pretend patient played by a provider, nurse or other staff member. Observe the interactions, giving constructive feedback when needed. The team should be able to go through the coaching session at least once during this time period. If additional practice is needed, they can set up extra time with a colleague outside of the Rollout meetings.

Week 8: Final Preparation and Dress Rehearsal

The Practice Facilitator this week should take the opportunity to troubleshoot any last minute questions or logistic concerns that have arisen to date. Encourage the team to

perform a “dress rehearsal” where each member can practice their portion of the upcoming visit to gain confidence.

The asthma SDM survey collection should be finalized at this point, ready to deploy next week if not already in use.

Week 9: 1st Asthma SDM Clinic or Toolkit Visit

The long awaited first asthma SDM half-day clinic or Toolkit visit has finally arrived! Whether 1 patient has been scheduled for a Toolkit visit or an entire half-day clinic set up, the Practice Facilitator should make every effort to be present and provide support during this big day. Observe the process and make notes of areas for improvement to discuss during the debriefing session.

Depending on when in the week the asthma SDM half-day clinic or Toolkit visit occurs in relation to the weekly Rollout meeting, the team may have extra time for Toolkit practice or get the opportunity to debrief early (for example: if the clinic/visit occurs on a Monday and the weekly Rollout meetings are on Wednesdays, the debriefing could occur the same week; if the clinic/visit is scheduled for Friday and the Rollout meetings occur on Wednesdays, an extra practice session could occur this week).

Week 10: Debriefing from 1st Asthma SDM Clinic or Toolkit Visit

Time is set aside this week to summarize what went well during the first asthma SDM half-day clinic or Toolkit visit and where there are opportunities for improvement. Congratulate the team for all their hard work over the previous 2 months. Let each member share their experience.

The Practice Facilitator can also share what has been working well at their other sites and at other PBRN’s sites per the regularly scheduled Practice Facilitator WebEx conference calls.

Members from the practice’s team should be encouraged to join the FLOW team WebEx conference calls for additional support after Rollout completion which will begin before the ***8/30/14*** milestone.

Weeks 11 and 12: Feedback and Troubleshooting

The last 2 weeks of the 12 week rollout are reserved for additional feedback and troubleshooting to set the practices up for long-term success. The Practice Facilitator should share what has gone well at other sites and offer assistance in improving their SDM experience.

After the Year 1 Rollout

Members from the practice's team should be encouraged to join the FLOW team WebEx conference calls for additional support after Rollout completion.

Practice Facilitators should set up regularly scheduled times to return to the practice for survey collection and additional support if able (for example: if the practice has their asthma SDM half-day clinics the 3rd Friday morning of each month, the Practice Facilitator could plan to work remotely from there and be available if questions arise).

Quality Improvement

Returning to the practices will also provide the Practice Facilitators time to assess for quality improvement and assure validity of the SDM process. This can be accomplished through direct observation of Health Coaches or post-visit through key informant interviews using the Quality Control Checklist available on the asthma.carolinashealthcare.org website under the Implementation Resources section or other means to be established at a later date.

Year 2 "Refresher" Session

Approximately 12 months after each FLOW practice's Kick-Off (before the ***6/15/15*** milestone), the Practice Facilitator should plan to return for a "Refresher" session with the original core team. The purpose of this meeting, or series of meetings if preferred by the practice, is to promote sustainability with the goal of improving outcomes for their asthma patients.

The practice may want to discuss expansion to additional providers, adding more Health Coaches, or productivity concerns. If data is available by this time it can serve as a useful tool to reinvigorate the practice.

Traditional Dissemination (Active Diffusion) with Facilitator Exposure

Background

The Traditional method of dissemination, otherwise known as "active diffusion," typically involves one of more of the following to spread information:

1. Didactic presentations
2. Academic detailing
3. Exposure to journal publications and subject matter experts
4. Education material distribution

Practices randomized into this arm of the project will receive one lunchtime presentation by the Practice Facilitator on shared decision making in Year 1 *(*before the ***6/15/14*** milestone*).* The presentation will give:

1. An overview of the Asthma SDM Toolkit
2. Access to the internet link (asthma.carolinashealthcare.org) with additional information
3. Copies of all printed materials associated with the Toolkit

Subsequently, the Practice Facilitator will provide each practice with a "Refresher" during Year 2 (before the ***6/15/15*** milestone) of the project.

A goal of at least 50 patients will undergo asthma SDM health coaching and complete a brief survey question in this arm of the study.

Scheduling

Once it is known which practices will receive the Traditional dissemination after randomization, the Practice Facilitator will contact their 2 or 3 practices' managers and/or provider champions to schedule the Lunch-and-Learn session (before the ***6/15/14*** milestone). Be sure to stress the following to each practice when coordinating their meeting:

1. The entire practice is encouraged to attend
2. If applicable, meeting planners serve as helpful reminders (ask the practice manager to send one out to everyone)
3. Ideally lunch is provided to improve participation (this can either be by the PBRN or coordinated by the practice manager)
4. Viewing the Asthma Shared Decision Making – Health Coach Training Video prior to the luncheon will set the stage

Year 1 Lunch-and-Learn

In most cases the practices will have approximately 1 hour in between their morning and afternoon clinic sessions. Some providers may arrive late or have to leave early so concentrating the bulk of information into the middle 30 minutes is advised. This should include:

1. Introductions
2. Brief overview of shared decision making
3. ACE Study results
4. SDM Toolkits
5. Asthma website
6. Survey collection

1. Introductions
    - Welcome everyone to the ADAPT-NC Study, funded by PCORI. Introduce yourself as the Practice Facilitator and describe your role, including how you can help them. Make sure they have your contact information. Have everyone go around and state their name and role at the practice.

2. Brief overview of shared decision making
    - SDM is a process based on the principles of motivational interviewing that takes into account patients' individual treatment goals and medication preferences, aiming to promote adherence and improve outcomes. The patient provides information on their values, preferences, lifestyle, beliefs and current knowledge about the illness and its treatment. The Health Coach and/or provider provides all relevant disease information including benefits and risks of various treatments and potential effects on the patient's psychological and social well-being.

3. ACE Study Results
    - The ADAPT-NC Study, is studying the best way to disseminate the promising results of the Carolinas HealthCare System Department of Family Medicine Research Division's Asthma Comparative Effectiveness (ACE) Study. Six primary care "safety-net" practices in Charlotte, NC participated in the intervention from April 2011 through September 2013. Providers, staff and health coaches were trained in SDM using an evidence-based decision support toolkit and half-day asthma clinics were implemented. Among SDM half-day participants, asthma-related ER visits dropped 42% (compared with 6% in the control group) and hospitalizations were reduced by 50% (compared with 30% in the control group). Oral steroid prescription orders for acute exacerbations were significantly decreased by 46% within 3 months of the intervention and 24% within 3 months (compared with 26% and 10% respectively in the control groups).

4. SDM Toolkits
    - Prepare and bring at least 1 age- and language-specific binder for the practices' targeted demographic for demonstration (for example: an internal medicine practice will only need the 12 years and older Toolkit). Binders should include 10 or more copies of each form. Flip through the Toolkit Binder, briefly describing each form in sequence.

5. Asthma website – asthma.carolinashealthcare.org
    - This website will serve as their one stop for all materials needed to successfully implement asthma SDM at their practice. It contains links to:
        - Asthma Action Plan Generator
            - A tool that provides rapid determination of peak flow expectations, assessment of asthma severity or control, guideline-based decision support for medication management, and generation of an individualized asthma action plan patient handout to support self-management.
        - Shared Decision Making Toolkit
            - Videos
                - Asthma Shared Decision Making - Health Coach Training
                - Voices of Asthma Shared Decision Making promotional video
            - Toolkits
                - 2-4 years old, 5-11 years old, 12 years and older
                - English and Spanish if needed
        - Implementation Resources
            - Asthma Educational Resources
            - Asthma SDM Clinic Resources

6. Survey collection
    - Collecting surveys around the patients' perception of shared decision making provides important outcomes data for the ADAPT-NC Study. Ultimately the practices will ask their asthma patients to complete a brief survey question after each asthma SDM visit:

Tell Us About Your Asthma Visit

Practice Name: _____ Today's Date: _____

Who made the decision in your meeting with the care team (health coach and provider) about what your asthma treatment would be?

- ☐ I alone made the decision
- ☐ I mostly made the decision, and the care team played a small role in the decision making
- ☐ The care team and I participated equally in the decision making
- ☐ The care team mostly made the decision, and I played a small role in the decision making
- ☐ The care team alone made the decision

- A goal of at least 50 patients will complete this brief survey question at each Traditional practice. It will be up to the practice to decide how they would like to survey their patients (for example: the nurse could give the patient the survey at the end of their asthma SDM visit; survey boxes can be placed in exam rooms or at checkout). The Practice Facilitator should prepare plenty of survey cards and collection boxes for each practice and work with the site to determine the best way to obtain the surveys and how often they should be transferred to the PBRN for analysis. Survey collection should begin before the ***8/15/14*** milestone, or when the first asthma SDM patient is seen.

Year 2 "Refresher" Session

Approximately 12 months after each FLOW practice's Kick-Off (before the ***6/15/15*** milestone), the Practice Facilitator should plan to return for a "Refresher" session with the original core team. The purpose of this meeting, or series of meetings if preferred by the practice, is to promote sustainability with the goal of improving outcomes for their asthma patients.

The practice may want to discuss expansion to additional providers, adding more Health Coaches, or productivity concerns. If data is available by this time it can serve as a useful tool to reinvigorate the practice.

Control / No Active Dissemination

Background

Control practices, also referred to as “usual care,” receive no active or formal dissemination. Instead, they may have passive exposure to the concepts of SDM though:

- Media
- Conferences
- Social networks

Scheduling

Eighteen months after the first FLOW practice from the PBRN kicks off, the Practice Facilitator will offer each Control practice a Lunch-and-Learn similar to the Traditional dissemination arm (see section above). For example, if the first FLOW practice kicked off on 3/10/14, the Control practices can receive their lunchtime presentation after 9/10/15. See Example Planning Calendars on pages 14 and 15 for more details.

Chapter 5

Focus Groups

1. Create a consent appropriate for your IRB and be sure to consent patients before beginning the focus group. An example of a CHS consent can be found on the next page.

2. Get IRB approval for the focus group guide.

3. Plan ahead!!
    - Focus groups take time to schedule. Sometimes they can take up to 2 months. Start planning them before your 6 month mark approaches.
    - Focus groups can be completed between 4 and 7 months after the previous round of focus groups.
    - It is best for analysis to not wait longer than 7 months after the previous round.

4. Recruitment
    - Give yourself 1 to 2 months to plan and schedule ALL focus groups.
    - Many times providers and/or practice managers will be wary about you coming in to their clinic to do focus groups because often they don't understand the purpose.
        - Be prepared to be patient and explain the focus groups.
        - We often describe them as "discussion groups."
        - We found that emailing the fact sheet out answered a lot of the questions ahead of time that providers and practice managers might have around hosting a focus group at their clinic (see fact sheet below).
    - Speak directly to physicians and/or practice managers to set up focus groups.
        - Email is usually the best with a follow-up phone call.
        - Remind them it will only be 1 hour of their time (see attached materials).
        - Recruit patients by phone (get a list of asthma patients from the clinic). You will need to recruit approximately 12 patients per focus group in order to get 6-8 in attendance. Depending on the clinic, show rates can be pretty low on average they are about 50%.
        - Recruit 2-3 providers (physicians, PAs, NPs, nurses, health coaches, etc.) which may mean you need to recruit 4 providers just to get 1-2 to show.

5. Decide if you will offer lunch and/or gift cards. The CHS team pays for lunch and a $25 gift card for ALL participants. Lunch and gift cards of any amount are encouraged to compensate the participants for their time.

6. The guides do not have to be followed exactly, they are there to help you move conversation along.

7. Record all focus groups and once recording is finished please mail or email the audio to **Lauren Mowrer** for transcription and analysis of themes.

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EXAMPLE ADAPT-NC – Patient and Provider Focus Group Consent

INTRODUCTION

Thank you for agreeing to take part in our asthma health discussion group. We will begin by reading the following statement so that you are aware of the purpose, risks/benefits, etc. of participating in this focus group.

Dr. Michael Dulin is asking if you want to take part in a research study with Carolinas HealthCare System (CHS) because we are trying to learn more about asthma. You are being asked to participate because you have been diagnosed with asthma by your physician. This research is being done to learn more about your illness and how to treat it. You will be one of approximately 50 people involved in this research project at CHS, and your participation will last for one hour.

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 asthma shared decision making visit. The focus group meeting will be audio-taped and later transcribed. The focus group will last approximately one hour.

RISKS

There are no foreseen physical or psychological risks associated with this study.

BENEFITS

Taking part in this research study may or may not benefit you personally, but researchers may learn new things that will help others with their asthma care.

ADDITIONAL COST

There is no financial cost to you to participate in this study.

COMPENSATION

If you qualify and volunteer to participate in this study you will receive a $25 gift card upon completion of the focus group.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

CONFIDENTIALITY:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Any references to your identity will be removed or disguised prior to the preparation of research reports and/or publications. Audio-tapes will be destroyed or erased at the completion of the study. Your last name will not be used in the transcripts of the recordings. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

FINANCIAL INTEREST OF INVESTIGATOR

None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

EXAMPLE Call Script for Patient Recruitment

RT = Research Team Member
P = Patient

RT*: Good afternoon, Mr. or Mrs. X, This Lauren Mowrer from Carolinas HealthCare System. I am working with [clinic name] and [physician name] conducting focus groups with patients and providers about asthma. This focus group is a one hour discussion group giving us feedback on asthma and asthma care. Is this something that you would be interested in?*
P: *Yes.*
RT: *Great, we will be meeting next Wednesday from 12-1PM at [clinic name]. I will give you a reminder call the on Tuesday afternoon to make sure you can still come. If you have any questions between now and then you can call me back at 704-355-xxxx.*
P: *Good. See you then.*
RT: *See you then*.

EXAMPLE Email to Practice Managers for Recruitment

Dear Mr./Mrs. X:

My name is Lauren and I am working on an asthma comparative effectiveness study with Drs. X, Y and Z *(I try to mention people they know here)* and we were wondering if you would be interested in participating in an asthma focus group. I've attached some information *(see Fact Sheet below)* for your review, but in short, the focus group will be one hour at lunch time (or whatever time works best for your practice), we will need 1 or 2 providers to participate as well as asthma patients. I, personally, will call and recruit patients and set up the lunch. If you are interested, I just need to know from you a day and time that will work and if you have a conference room available that we can use.

Everyone that participates will receive lunch and a $25 gift card. We will be doing these focus groups in rounds and would like to have yours scheduled before the end of June 2014. This will be a one time, one hour commitment, but if you find it beneficial we can certainly come back and do more.

Please don't hesitate to call or email me with questions about the overall study and/or focus groups.

Looking forward to working together!

Sincerely,

Lauren

EXAMPLE Fact Sheet for Providers and Practice Managers

The overall goal of this asthma study is to improve health outcomes for patients with asthma using comparative effectiveness research and evaluate shared decision making interventions and their effects on asthma outcomes.

Focus Group Goals

To use an informal conversation between 6 – 8 patients and 1-2 providers (together or separate) that helps us to better understand the **current** state of asthma care at Carolinas HealthCare System.

How does the focus group work?

Informal questions are used to guide the conversation. Examples include:

- What are the barriers that stop you from keeping asthma under control?
- Are there goals you may have regarding your asthma care?
- How do your values, traditions, and culture affect your asthma care?

How is it analyzed?

We look for themes around asthma care delivery. Typically, we prioritize themes according to how often they are mentioned.

What are the benefits of participation?

- Enhance engagement between providers, administration, and patients
- The information collected may be used to implement change and improve our delivery of care
- The process will help in the preparation for future group visits that will be designed to help manage patients with chronic diseases like asthma.
- A small remuneration is made to compensate all participants for their time

What decisions need to be made by the practice?

1. Are you interested in participating?
2. Are you willing to participate with patients or would you rather just interact with other providers?
3. Do you want to oversee the recruitment of patients for participation and/or select a specific subset of patients for the project?

If you have any further questions feel free to contact:

Name
xxx-xxx-xxxx
First.last@emailaddress.com

ADAPT-NC Focus Group Plan

Each PBRN is responsible for recruiting, scheduling and conducting the following groups. **Lauren Mowrer** is your point of contact and available to help facilitate your first group or walk you through the process. You can contact her at: lauren.mowrer@carolinashealthcare.org or 704-355-7310.

Focus Group Type	Ideal Timeline	Must Complete By:	# of Practices Needed	Recurrence	Who?	Total # of Focus Groups
SDM Evaluation with FLOW practices	After Week 8 of Rollout	09/15/2014	1	Every 6 months	Patients and Providers	4
Evaluation with Traditional practices	Within12 months of Lunch-and-Learn and concurrent with 1 of the 6 month intervals	01/15/2016	1	1 time	Patients and Providers	1
Evaluation with Control practices	At the same time as the Traditional practices	01/15/2016	1	1 time	Patients and Providers	1
					Grand Total	6

Possible FLOW focus group scenarios

- The 4 focus groups completed every 6 months with the same practice
- Start focus groups in 1 practice and then alternate between the other FLOW site(s)
- Start with 1 practice and complete the other 3 focus groups with a different site

ADAPT-NC – SDM Patient and Provider Focus Group Guide

Hello, thank you all for being here. I would like you to think about your shared decision making visits around asthma. These are the longer visits that you have had with your provider and a health coach. I am referring to the visit that you had where you went over many different types of materials explaining asthma (i.e. dials on your asthma control, a medication planner, red, yellow and green medication options and goals sheets). We will refer to these visits as "SDM" or "Shared Decision Making" visits.

Patients = Green **Providers = Blue** **Both = Black**

- **For patients:** *When you were at your visit with your provider what was discussed as far as a plan to improve your asthma?*
  - **For providers:** *How do you design and communicate plans for managing your patients' asthma?*

- **For patients:** *When meeting with your provider, what sorts of things did you discuss? Who initiated these discussions?*
  - **For providers:** *What topics do you talk about or bring up when helping patients' manage their asthma?*

- **For patients:** *What sort* of goals around your asthma care did you and your healthcare provider talk about?
  - **For providers:** *What sorts of goals do you discuss with your patients? Who sets those goals?*

- **For patients:** *What choices were you given to decide on for your asthma treatment?*
  - **For providers:** *Are you able to give your patients any choices around their asthma care?*

- **For patients:** *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?*
  - **For providers:** *Are you able to start discussions around planning ahead? If so, how do you plan for that? Who initiates these discussions?*

- **For patients:** *So, considering this SDM visit, how did you feel about the overall experience?*
  - **For providers:** *What is your overall experience? Does it fit well into your clinic day?*

- **For patients:** *Do you feel like you helped to make the decisions about your asthma care?*
  - **For providers:** *Are you able to share the decision with your patient?*

        - *How is this visit different from what you normally do with your patients?*

- **For patients:** What did you think about the length of the visit? How was the pace of the visit and waiting times?
    - **For providers:** *How was the length of the visit and the pace in comparison to your normal visits?*
        - *Do you feel comfortable incorporating this into your everyday schedule?*

- **For patients:** *Did you complete a health questionnaire like this (show SDM questionnaire)?*

- **For patients:** *How useful did you feel the health questionnaire was? Did you like all the questions? Did they help you to think about things differently?*

- **For patients:** *Did the SDM visit help you to think differently about your asthma? If so, in what ways?*
    - **For providers:** *After doing SDM, do you think differently about how you treat your asthma patients? If so, in what ways?*

- **For patients:** *In comparison with previous visits with your doctor around your asthma, what do you think about this last visit?*

- **For patients:** *Is there anything that you would change about this visit?*
    - **For providers:** *How do you think the SDM visits could be improved?*
        - *What would you change?*
        - *Can they be more efficient? If so, how?*

- **For patients:** *Do you think this visit affected how you take your medication OR how often you take your medications?*
        - **For providers:** *Do you think this visit affected how your patients' take their medication?*

- **For patients:** *Do you believe that the visit affected your asthma? If so, in what way?*
        - **For providers:** *Do you think this visit affected your patients' asthma? If so, in what way?*

- **For patients:** *What would you tell your friends and family with asthma about your last visit?*

- ***For both:*** *What did you like least about this visit?*

- ***For both:*** *What did you like most about this visit?*

Those are all of the questions that we have for today. Do you have any other comments or anything else to say about what we have been talking about?

Thank you so much for your time, we greatly appreciate your input!

ADAPT-NC – Non-SDM Patient and Provider Focus Group Guide

Hello, thank you all for being here. 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 for your asthma and respond to the following questions.

Patients = Green **Providers = Blue** **Both = Black**

- **For patients:** *When you were at your appointment with your provider what was discussed as far as a plan to improve your asthma?*
  - **For providers:** *How do you design and communicate plans for managing your patients' asthma?*

- **For patients:** *When meeting with your provider, what sorts of things did you discuss? Who initiated these discussions?*
  - **For providers:** *What topics do you talk about or bring up when helping patients' manage their asthma?*

- **For patients:** *What sort* of goals around your asthma care did you and your healthcare provider talk about?
  - **For providers:** *What sorts of goals do you discuss with your patients? Who sets those goals?*

- **For patients:** *What choices were you given to decide on for your asthma treatment?*
  - **For providers:** *Are you able to give your patients any choices around their asthma care?*

- **For patients:** *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?*
  - **For providers:** *Are you able to start discussions around planning ahead? If so, how do you plan for that? Who initiates these discussions?*

- **For patients:** *Do you feel like you helped to make the decisions about your asthma care?*
  - **For providers:** *Are you able to share the decision with your patient?*

- **For patients:** *Did your asthma visit help you to think differently about your asthma? If so, in what ways?*
  - **For providers:** *How do you encourage patients to think differently about their asthma?*

- **For patients:** *Is there anything that you would change about your asthma visit?*
  - **For providers:** *How do you think asthma visits could be improved?*

- **For patients:** *Do you think your asthma visit affected how you take your medication OR how often you take your medications?*
  - **For providers:** *Do you think talking about asthma with your patients affects how your patients' take their medication? If so, how?*

- ***For both:*** *What did you like least about your last asthma visit?*

- ***For both:*** *What did you like most about your last asthma visit?*

Those are all of the questions that we have for today. Do you have any other comments or anything else to say about what we have been talking about?

Thank you so much for your time, we greatly appreciate your input!