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ASTHMA IN THE PRIMARY CARE SETTING

Adapting community based participatory research (CBPR) methods to the implementation of an asthma shared decision making intervention in ambulatory practices

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Abstract

Objective: Translating research findings into clinical practice is a major challenge to improve the quality of healthcare delivery. Shared decision making (SDM) has been shown to be effective and has not yet been widely adopted by health providers. This paper describes the participatory approach used to adapt and implement an evidence-based asthma SDM intervention into primary care practices. Methods: A participatory research approach was initiated through partnership development between practice staff and researchers. The collaborative team worked together to adapt and implement a SDM toolkit. Using the RE-AIM framework and qualitative analysis, we evaluated both the implementation of the intervention into clinical practice, and the level of partnership that was established. Analysis included the number of adopting clinics and providers, the patients' perception of the SDM approach, and the number of clinics willing to sustain the intervention delivery after 1 year. Results: All six clinics and physician champions implemented the intervention using half-day dedicated asthma clinics while 16% of all providers within the practices have participated in the intervention. Themes from the focus groups included the importance of being part the development process, belief that the intervention would benefit patients, and concerns around sustainability and productivity. One year after initiation, 100% of clinics have sustained the intervention, and 90% of participating patients reported a shared decision experience. Conclusions: Use of a participatory research process was central to the successful implementation of a SDM intervention in multiple practices with diverse patient populations.

Introduction

The burden of asthma in the US is high, accounting annually for over 2 million emergency department visits, 504 000 hospitalizations, 13.6 million physician office visits, and 4200 deaths while resulting in \$50.1 billion in direct medical costs [1–5]. In addition, there are significant disparities in asthma prevalence and outcomes resulting in the disease having an even more significant impact in states with larger numbers of racial/ethnic minorities and low-income populations like North Carolina. Here, the overall prevalence of asthma in adults is over 12% and prevalence in children is near 18% [1,6]. Unfortunately, while asthma prevalence is increasing in the Carolinas, many patients with asthma lack adequate control of their symptoms, negatively impacting their overall quality of life. Subsequently, over a quarter of adults with

Keywords

Asthma interventions, implementation in outpatient clinics, participatory approach, shared decision making, vulnerable population

History

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asthma had an Emergency Department (ED) or urgent care visit every year and over one-third of adults had to miss one or more days of work because of asthma [7].

New approaches to care delivery that facilitate patient activation through involvement in their care are needed to improve medication adherence, patient outcomes, and reduce costs. Translating research findings into clinical practice, which requires altering clinician and staff behavior, is one of the biggest challenges in improving the quality of medical care. Existing guidelines are complex and poorly followed with few evaluation studies occurring within real-world settings. As the value of medical services replaces the volume of visits in new models of primary care delivery, new strategies are needed to address ongoing sustainability and productivity issues related to implementing evidence-based interventions. Recent findings have demonstrated the effectiveness of engaging patients as partners in their care [1-5]. Such findings supplement observational and other studies that suggest the need to provide information and decision aides to patients that enable them to participate in decisions about their care [6]. These findings increase the need for research on

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the effectiveness of different approaches to implementation of successful shared decision making (SDM) and decision support into routine practice [8–11]. In 2010, The Mecklenburg Area Partnership for Primary care Research (MAPPR), a practice-based research network (PBRN), was funded to develop and implement a SDM asthma intervention in the primary care setting [12]. Using elements from previously applied principles of community-based participatory research (CBPR) [13], with elements from the chronic care model [14], we implemented an evidence-based asthma SDM intervention in six ambulatory-care practices [7].

Shared decision making

SDM is a process where patients and their health-care providers are jointly engaged in making decisions about medical tests and treatment. This approach has given a promise as a new way to improve patient outcomes and satisfaction with their care, but SDM has not yet been widely adopted by health-care professionals [15–17]. Successful implementation of SDM is more likely when the provider's attitude is aligned with the goal of involving the patient in such decisions. Policy makers and health-care systems at risk for the costs of care may tend to view patient involvement in decisions about medical tests and treatment as a means of lowering health-care costs. Providers typically report that incorporating SDM into practice improves patient outcomes and health-care processes [18–20]. However, such a positive expectation alone does not necessarily alter provider-patient interactions that could lead to behavioral changes on the part of patients. Further, even motivated providers typically perceive barriers to involve patients in treatment decisions, including time constraints and concern that SDM may not be applicable to their patient population because of the patients' limited education or a preference that all medical decisions should be made by their physician [15,18,21].

Recently, the better outcomes of asthma treatment (BOAT) trial, funded by VHLBI, used a randomized controlled study design to test the impact of an SDM intervention with adults with poorly controlled asthma. The BOAT study demonstrated that involving patients in a structured negotiation of treatment decisions significantly improved the patients' adherence to asthma control medication while also improving clinical outcomes [7]. As a part of a larger study of the comparative effectiveness of asthma-care interventions being implemented in a large health-care system in the Carolinas, we conducted a quantitative and qualitative process during the implementation of the BOAT SDM intervention. In this paper, we describe how a participatory research process was used to obtain practice engagement in the adaption of the SDM intervention across a variety of practice settings within the health-care system. 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 in other fields suggest 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, yet little has been published about real-world participatory approaches in clinical implementation settings. Here, we offer a pragmatic and structured approach to implementation and evaluation in process improvement.

Methods

The intervention: the asthma SDM approach

In both the BOAT and the present study, non-physician providers assessed patient's asthma control, provided basic asthma education, elicited the patient's goals for treatment and relative priorities regarding symptom control, regimen convenience, avoidance of side effects, and cost, and then negotiated a treatment regimen with the patient that accommodated the patient's goals and preferences. The patient is shown a list of the full range of regimen options for all levels of asthma severity, based on current national asthma guidelines, pharmacopeia, and formulary coverage. These options differ with respect to the number and type(s) of medications, dosing, and schedule, and the type of device used to deliver the medication, and are grouped according to guidelines recommendations for different levels of current asthma control or severity. Using a simple worksheet, the patient and clinician compare the pros and cons of all the options the patient wishes to consider, always including the option of continuing with the patient's current de facto treatment (i.e. the medications that patient is actually taking - often only a short-acting beta agonist) in order to arrive at a treatment that best accommodates the patient's goals and preferences. At the conclusion, an asthma action plan is prepared that incorporates the jointly agreed-upon treatment decisions.

Study locations

The SDM intervention was implemented between April 2011 and April 2012 in six practices: three primary care/family medicine, one internal medicine, and two pediatric community ambulatory clinics, one of which serves predominantly children of between 13 and 19 (Table 1). These clinics predominantly serve an urban, high-need patient population from underserved and/or disadvantaged backgrounds. The clinics share a unified electronic medical record (EMR) system and are members of MAPPR.

Development of an advisory team

Participants

This project emerged from the work of a community advisory board that uses CBPR methods to identify, develop, and oversee research projects [22,23]. Using an approach modeled on the CBPR framework, the PBRN investigators initiated an intervention development process through the formation of an advisory team. Initially, providers and staff members from five ambulatory practices were invited to a meeting to discuss partnership formation and possibilities around implementing an SDM intervention in their practice, with the idea of developing an intervention specifically tailored to the unique needs of each practice. The team identified a "champion" physician to represent each practice and agreed to meet monthly as an advisory team. To facilitate equivalent participation opportunities, meeting locations rotated to all practices. Table 1. Description of study practices.

	Total number of providers	Number of internally trained health coaches	Number of targeted asthma patients	Asthma patient demographics		
Clinic (in roll-out order)				Race	Insurance	
Clinic 1: Family Medicine 8		1 Pharmacist 2 Nurses	260	African American – 51% Caucasian – 12% Hispanic – 22%	Medicaid – 58% Medicare – 2% Insurance – 8% Self Pay – 30%	
Clinic 2: Pediatric Teen Specialty Health	4	1 Patient Educator 1 Pharmacist 1 Care coordinator (RN)	128	African American – 74% Caucasian – 16% Hispanic – 6%	Medicaid – 67% Other Insurance – 14% Self Pay – 19%	
Clinic 3: Family Medicine	8	2 Pharmacists	226	African American – 83% Caucasian – 11% Hispanic – 3%	Medicaid – 55% Medicare – 4% Other Insurance –11% Self Pay – 30%	
Clinic 4: Family Medicine	ne 40 ^a 1 Care coordinator (RN) 1 Pharmacist 1 Physician assistant		248	African American – 70% Caucasian – 22% Other – 8%	Medicaid – 56% Medicare – 10% Other Insurance –18% Self Pay –16%	
Clinic 5: Pediatrics	40 ^a	1 Pharmacist	643	African American – 60% Caucasian – 11% Hispanic – 26%	Medicaid – 87% Other Insurance – 5% Self Pay – 8%	
Clinic 6: Internal Medicine	48 ^a	1 Educator 1 Pharmacist 2 Nurses	561	African American – 75% Caucasian – 17% Hispanic – 3%	Medicaid – 21% Medicare – 33% Other Insurance – 10% Self Pay – 36%	

^aResidency training practices.

Initially, researchers described the basics of shared treatment decision making for asthma management using the BOAT trial SDM model, and introduced the participatory approach to implementation. At each meeting, names of additional key partners were suggested by the advisory team members. A sixth practice expressed interest in joining the rollout and began attending meetings. The advisory team eventually was made up of three patients, six physician champions, six nurses, six office managers, one health-care system administrator, four pharmacists, and four health educators.

Pre-implementation planning phase

The advisory team addressed the following challenges:

- (1) Productivity and sustainability: The team agreed that design of the intervention needed to (1) be sustainable beyond the life of the research project and (2) satisfy provider productivity expectations. The intervention was adapted so that the various components could be delivered by different types of staff members. For example, nurses performed spirometry and peak flow measurements; health coaches (typically a mid-level provider such as physician assistant, care-coordinator nurse, educator or clinical pharmacist) were trained in the use of the education and decision support tools, and physicians confirmed the shared treatment decision and correct use of medications and delivery devices.
- (2) Updating and adapting the decision support materials: The original intervention was based on 2003 asthma guidelines that needed to be updated to the 2007 NAEPP Expert Panel guidelines [24]. The six practices care for a

diverse population including English- and Spanishspeaking pediatric, adolescent, and adult patients as well as many disadvantaged low income and uninsured patients. Therefore, the original materials had to be translated into Spanish, had to be changed to accommodate patients with low health literacy, and had to be appropriate for pediatric and adult patients (Figure 1).

(3) Roll-out logistics:

- (a) *Recruitment*: Typically, patients were recruited for asthma clinic through a population report developed by the research team from the EMR. For inclusion in the study, patients had to meet the following criteria over the preceding 18 months: (1) two outpatient asthma visits; (2) one outpatient asthma visit and one ED asthma visit; or (3) one outpatient asthma visit and one asthma hospitalization. Priority was given to less controlled patients meeting criteria (2) or (3). Patients were also recruited by physician referral and flyers in the waiting and exam rooms. An estimate of the number of eligible and targeted patients is given in Table 2. Providers and other key stakeholder discussed barriers and solutions to engage patients during focus groups and monthly SDM lunch meetings.
 - (i) Roll out schedule: Based on each clinic's perceived readiness to change, the team decided on a gradual approach in which the implementation was rolled out to a given clinic over a 12-week timeframe, with 1-month overlap between rollouts to successive practices (Figure 2). Roll-out at the first clinic started approximately 6 months

FORM #2: HOW WELL CONTROLLED IS YOUR ASTHMA?



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



Quiero que mis medicamentos de asma ...

	Importante a mí	Importante a mis padres	Estamos de acuerdo que las metas más importantes son: Trabajen juntos para poner en orden de importancia (1-5)
<u>Controlen</u> la hinchazón/inflamación en mis pulmones y controlen mis síntomas			
No tengan <u>Efectos Secundarios</u>			
No <u>cuesten</u> tanto			
Sean <u>fáciles</u> de tomar y recordar			
Otro:			

*Pon un cheque para significar cual es importante a ti.

Figure 1. Examples of shared decision making materials adapted to accommodate Spanish-speaking and pediatric patients.

after the first meeting of the advisory team. The first site to roll out the intervention was chosen because of their experience in implementing a diabetes specialty clinic that was similar in nature to the asthma SDM intervention. Consequently, SDM implementation took the form of a monthly clinic that occurred on a fixed half-day and scheduled up to six asthma patients per clinic. (b) Individual site modification was based on the success of the initial roll-out. As subsequent sites implemented the SDM intervention, they all chose to use the same half-day model with minor modifications. For example, at one site, the physician added in same day work-in patients while also overseeing the asthma clinic. At another site, the monthly clinic time was reduced from 4 to 2 h. intervention

Table 2. RE-AIM analysis of roll-out of shared decision making intervention.

Reach

	Reach						
Clinic	Whether clinic adopted the intervention (yes/no)	Number (%) of asthma patients with SDM visit, N (%)	Half-day SDM clinics, N	Effectiveness ^a patient participation in treatment decision, N (%)	Adoption provider participation in intervention, N (%)	Implementation utilization of intervention components in SDM patient encounters, (%)	Maintenance continuation of delivery of SDM intervention, (%)
1	Yes	36/260 (13.85)	16	32/33 (97.0)	3/8 (37 5)	Office spirometry:	100% of practices
2	Yes	17/128 (13.28)	10	11/15 (73.3)	3/4 (75)	offered to 100% of	intend to continue
3	Yes	32/226 (14.16)	15	39/40 (98.0)	3/8 (37.5)	patients > 7 years	the intervention
4	Yes	17/248 (6.85)	11	23/24 (95.8)	9/40 ^b (22.5)	I	after the study
5	Yes	12/643 (1.87)	10	12/15 (80.0)	$4/40^{b}$ (10)	Medication planner	ends October 2013
6	Yes	11/561 (1.96)	5	10/13 (76.9)	2/48 ^b (4.2)	(decision support tool):	
Summar	y 6/6 (100%) of clinics who were offered the	125/2066 (6.05)	Average = 11.2 half-days	2 127/140 (90.7)	24/148 (16)	utilized in 100% of SDM visits	Evaluation of long-term maintenance is premature

^aProportion of patients surveyed who rated treatment choice as a shared decision between patient and health care provider. ^bResidency training practices.



Figure 2. Roll-out plan used to guide implementation of the shared decision making intervention.

All practices started the roll-out process with a practice-wide "kick off" meeting. This was followed by six to eight practice-focused discussions around logistics, and additional follow-up meetings after intervention implementation (Figure 2). Each site recommended a different composition of clinic team members for the site meetings. For example, during planning for the first clinic, the front desk staff, scheduling personnel, and the office manager all needed to be present along with a provider and the health coach.

(4) Training: Two types of training took place. First, an initial training session took place during a 1-day training session for providers and staff demonstrating the use of the original decision support materials from the BOAT study. A consultant (SRW) from the BOAT trial was present and led the participants through the use of the original materials. The second round of training took place at individual practices as a part of the roll-out and was led by the research team and participants from the first training session.

RE-AIM evaluation of the implementation

Success of the implementation was analyzed using the RE-AIM method that is the literature recommended approach to the analysis of implementation [25].

Reach

The reach of the implementation plan was assessed by the proportion of clinics that adopted the intervention among those that were offered the intervention and by the proportion of the targeted patients who participated in the SDM clinic sessions.

Effectiveness

Effectiveness was assessed by surveying patients who took part in the asthma SDM sessions on the degree of shared medical decision. Options were (1) I alone made the decision; (2) I mostly made the decision, and the provider played a small role in the decision making; (3) the provider and I participated equally in making the decision; (4) the provider mostly made the decision, and I played a small role in the decision-making; (5) the provider alone made the decision.

If the patient chose answer 2, 3, or 4, it was considered that a shared decision had been reached. Effectiveness was also qualitatively assessed through focus group sessions with patients who had attended the SDM clinics. Questions to these groups explored patients' perceptions of the length of the visit, the educational component, and if they had shared in making the treatment plan in partnership with their providers.

Adoption

Adoption was measured by the proportion of providers and physician champions in each practice who adopted the intervention.

Implementation

The components initially selected to evaluate extent of implementation were spirometry measurement at SDM visit,

determination of the level of control of the patient's asthma, patient goal setting, patient-centered prioritizing of criteria for establishing their medication regimen (control, side-effects, cost, ease of medication use, other), use of the Medication Planner tool, and creation of an asthma action plan during the SDM visit.

Maintenance

The sustainability or maintenance of the intervention was assessed by the proportion of practices and providers that continue the delivery of the intervention after 1 year.

Process evaluation using focus groups

As a part of the process evaluation, focus groups were held every 6 months with the advisory team in the absence of research members. Focus groups ran for 20–30 min and were recorded and transcribed with de-identification by an outside research team member not associated with the SDM implementation. A facilitator from outside the group led a discussion using questions from a previously developed participatory evaluative focus group guide. Focus group discussions assessed: (1) ongoing partnerships within the advisory team, and (2) implementation barriers and facilitators. Questions asked about positive and negative perceptions, and asked for suggested ways to improve. For example:

- Do you feel that meetings are productive?
- Is there something you would change?

The research team analyzed de-identified transcripts for themes that were then reported back to the advisory team. The advisory team then used this information as a starting point to identify and address problems with the research and implementation process. Ongoing issues without immediate solution were placed as agenda items for discussion at every meeting.

Results

RE-AIM evaluation of the implementation

Reach

Success of the approach has been measured using the RE-AIM measures around sustainability of the intervention. As such all six sites implemented fully functioning dedicated asthma clinics. For the asthma half-day session, all the sites agreed that the patients they were particularly trying to reach were those with poorly controlled asthma, especially those using ED and inpatient facilities, and newly diagnosed patients. By the end of the first year of the SDM implementation, the proportion of patients reached varied between 2% and 18% of the total eligible asthma population at the six sites (Table 2) with a total of 125 patients enrolled. The engagement rate has continued to increase as more patients come in to the clinics.

Physicians were able to schedule other asthma patients they felt would benefit from involvement in the intervention. In addition, through the recruitment posters, patients were able to ask to attend the clinic if interested. Therefore, the numbers for reach provided in Table 2 slightly underestimate the numbers of patients impacted by the intervention.

Effectiveness

One year after the start of the implementation 90.7% of the 125 patients who received the intervention reported that their visit involved a *shared* decision about asthma treatment, while 9.3% reported that the provider alone or the patient alone made the decision. About 79.3% reported that their influence on the treatment decision was equal to that of the provider. One issue that arose was patients who failed to keep a scheduled appointment in the asthma SDM intervention clinic with rates ranging from 55% up to 82%. These no-show rates are consistent with typical rates across these practices that serve a large number of patients with limited resources and dependence on public transportation.

The following excerpts are implementation themes collected through qualitative analysis:

Education: "You freely can ask questions and they answer them and they show you things and they tell you about the breathing and the mucus building up in your lungs and you know it helped me..."

"I had a spacer for my asthma, but I never used it before but they taught me how to use it so [the medication] can help me more...to prevent having the asthma attacks .. so, it was a good visit for me."

When I went there they told me that I was not using the right medication at the right time... because I was using it the wrong way. But then when I went there and they taught me how to use it, I started to feel much better later on."

The SDM process:

"I feel great... I'm doing a lot better than I was before....all the medicine that wasn't helping me...it was just a waste of time. I feel good being a part of my decision of my medication."

"When I moved here, I was on a lot of asthma medicines [list of medications]. We came to a lot of decisions over my medication."

Adoption

All six physician champions implemented the intervention (6/6) and 16% of all providers at the six practices participated in the intervention. The goal of the project was to eventually have all providers from the clinics adopt and take part in the intervention. As of the end of 1 year, 24/148 providers have taken part in the intervention. Notably, this denominator (148) includes 84 family, pediatric and internal medicine residents. Three of the clinics also have multiple part-time providers who are teaching faculty or serve in other roles making exposure to the intervention more difficult. Gradually, the number of providers at each site who adopted the intervention has expanded. At each monthly SDM meeting sites discussed individual plans for expanding the number of providers. Almost all permanent providers were already familiar with the materials from the "kick off" meeting and had functioning staff able to run the sessions. Typically, patients attending the asthma SDM clinics were not seen by their continuity provider. At one site, residents were assigned to the

intervention and were provided with supervision from physicians that had already been trained in the SDM intervention and were able to guide the residents through the provider role.

Implementation

Spirometry was provided to all patients of 7 years of age and older at 100% of the SDM encounters. We were able to evaluate SDM through (1) completion of a decision support tool – 100% of the patients completed the tool, (2) a SDM survey – 90% of patients that completed the survey agreed that the decision was shared, and (3) the quality assurance checklist – random audits of the health coaches using this tool found 100% compliance for all five required elements of SDM. Providers issued electronic or paper generated asthma action plans as a part of the SDM toolkit (https:// asthma.carolinashealthcare.org). During the first year, the number of patients who received a provider-issued asthma action plan could not be evaluated from within the EMR.

Maintenance

All six (100%) of the practices and all participating providers intend to continue the delivery of the intervention. Due to the limited time span between the structured roll-out of the intervention and the present study's data analysis, it is too early to determine actual long-term maintenance past 1 year. Three factors are likely to have positively impacted the SDM intervention's sustainability. First, this project was designed from inception to have sustainability as an outcome. With this in mind, a participatory research approach was used and the intervention was tailored to the needs and culture of each practice. Second, the use of the process evaluation and feedback was used to quickly identify and address barriers to sustainability. Finally, the patient education materials, decision support tools, and the asthma action plan are all being built into the EMR, making them easier to access and incorporate into ongoing care processes.

Table 3. Overview of process evaluation focus group themes.

Process evaluation of monthly planning meetings

Process improvement through focus groups

Process evaluation began with a focus group consisting of advisory team members that was held 6 months after the first planning meeting, when the first roll-out was beginning, and a second such focus group took place 6 months later. The focus groups sought to evaluate both the success of the adoption and the implementation of the intervention, and to evaluate the participatory process used to engage the team.

Implementation related themes

The following primary themes emerged in these focus groups and are summarized in Table 3.

(1) Intervention sustainability: Discussions on this theme included the ability of the practices to continue the intervention after the research project ended and to support implementation-trained personnel. Concerns over project sustainability were voiced in focus group discussions. One participant commented, "I think sustainability might be difficult after the research part is done because of the no-show rates and the staffing, and the amount of patients that you see during the half day".

Despite these concerns, providers felt that the intervention would be successful and were comfortable incorporating the intervention into their practice. They remained committed to figuring out "a realistic way to make it work".

(2) Productivity: This is defined as the ability of the practice to continue to maintain a predefined clinical volume over time. One provider noted that while the SDM intervention may lead to better patient outcomes for a few patients, it may take time away from treating a greater volume of patients

A decline in productivity would also affect revenues for the practice. "To have our providers who are productivity-based only see four to six patients in a half-day, it is not something

Major themes	Sub themes
Intervention implementation	 Intervention sustainability – ability of the intervention to continue after the research project finished, given clinic resources, and the retention of implementation-trained personnel Productivity – need for providers to maintain practice productivity targets. Providers were concerned that, while the SDM intervention may lead to better outcomes for a few patients, it may take time away from treating a greater volume of patients Tailoring – the need for the intervention to adapt to the culture and patient population of each individual clinic Stakeholder identification – focused on recognition that each clinic operates and utilizes its personnel differently and that the needs and perspectives of different groups and individuals needed to be accommodated Intervention training – an issue that emerged as practices rolled out the intervention and as new staff were recruited. Improvements in the training process were developed based on focus group comments
Participatory process	 Inclusion – participants were intentionally included in the roll-out and participatory process. A research-team-initiated feedback process consisting of individual practice updates at each meeting, coupled with an informal and open atmosphere, allowed for an honest and on-going discussion of the implementation process Knowledge exchange –members were able to freely discuss and brainstorm solutions to problems as well as anticipate potential and perceived barriers. Facilitators allowed those involved in implementation to exchange knowledge on what worked while pre-implementation practices still had time to proactively address potential issues Open communication – members not only felt that they were able to voice their opinions and reflect upon their experiences but also felt that the intervention would help their patients. In particular, they mentioned the patients would benefit from shared decision making and the availability of better resources for asthma care Productivity – meeting structure, frequency, and rotating location allowed action items and productivity targets to be met in a timely manner

we can sustain... we can do it once, maybe twice, but we are not able to cut our revenue to accommodate that over the long term".

It is important to note that the team eventually expects that as quality outcomes gradually replace quantity of visits in models of financing primary care, measures of productivity targets are likely to change.

(3) *Intervention tailoring*: The practices have diverse patient populations including a majority of non-English speakers, patients with low health literacy, children, and patients with variable public and private insurance or who lack insurance. The tailoring of the protocol to each individual clinic helped with *provider buy-in, satisfaction*, and belief that the initiative would be *sustainable* in the long-term.

"I think the team has been very good about realizing that [Clinic X] does not function the same as [Clinic Y] and that's okay. We don't all have to fit into this neat little box; we can do things a little bit differently and still get the same outcomes".

(4) Stakeholder identification: Recognition that each clinic operates and utilizes its personnel differently. Participants desired a more structured plan for who should attend each meeting in order to ensure efficiency and the clear dissemination of information.

"Identify your key players and who's going to be doing what, for future roll-outs. I think it's really important to identify [things such as] 'these are the folks that will be doing these tasks,' 'these are the folks that need to be at these meetings'...'

(5) *Intervention training needs*: Needs were a desire for more roll play; a mock clinic as part of roll-out process; a training video for the intervention.

Participatory process-related themes

(1) *Inclusion*: Participants reported feeling included and part of the implementation process. A team-initiated feedback process of individual practice updates at each meeting, coupled with an informal and open atmosphere, allowed for an honest and on-going discussion of the implementation process.

According to one participant: "It gives everybody an opportunity to speak – to say what's going on. So, you feel included."

Members present at the meetings also commented on the "team" attitude apparent at these meetings: "I've heard people specifically say that it seems like its good teamwork, we are working well together, and things are moving seamlessly."

(2) *Knowledge exchange*: Members were able to freely discuss and brainstorm solutions to problems as well as anticipate potential and perceived barriers.

Facilitators allowed those involved in implementation to exchange knowledge on what worked while pre-implementation practices could proactively address potential issues. Participants commented on the usefulness of the practice updates and the benefits of having a diverse group of participants present at each monthly meeting:

"Those [practice updates] have been the ones that I have been most interested in and found the most informative – to hear everybody else's struggles and successes and quirks and problems and fixes".

"The sharing of information has been tremendous. So, the collaboration – just, like learning what we just learned, talking about what works in your clinic situation versus another,... [and] bringing unique perspectives to the table".

(3) Open communication: Members not only felt that they were able to voice their opinions and reflect upon their experiences but also that their opinions were respected during the process. Feedback was not only acknowledged but also put into action and adopted:

"They've taken a lot of our opinion into account in as to how to tailor some of the meetings and when we meet, and where [we] meet. We've had to move locations a couple of times. Our Pharm.D. had a tremendous input in some of the materials,...they immediately changed it when they realized he had a really good idea."

(4) Investment: Team members felt that the intervention would help their patients. In particular, they mentioned the patients would benefit from SDM and the availability of better resources for asthma care. Examples of such comments include:

"[By talking with the patients in the SDM sessions] We are identifying a lot of issues that you might not otherwise tease out. So that's been really beneficial for our patients" "[The intervention is] hugely beneficial from a provider standpoint as well. You are now gaining the knowledge about your patient that you didn't know before so that you could hopefully impact them and treat their condition better".

"I do like the concept of the whole shared decision and feel the patient will benefit greatly because they will be more compliant as I understand so, hopefully, overall,... [if] we get a better show rate and we can somehow see more patients, it is very beneficial for patients and the practice"

Engagement, the formation of relationships based on trust (between providers and research staff, and other providers), and collectively working towards a greater goal all ensured a high provider buy-in and retention.

The team members also cited the investment of the research staff as a strength of the participatory process. Research staff members were present and available throughout the roll-out process, supplied providers with a detailed overview of the project and with project materials, and oversaw all phases of the implementation.

Maintaining regular, ongoing communication with the providers, and soliciting their feedback reassured the providers that the staff were invested and committed to the project and helping each provider succeed. One strategy the research team implemented was to provide asthma population reports for each clinic site. These reports help to identify patients that have had hospitalizations and/or have not been seen by a primary-care provider within the last 6 and 12 months so that they may be scheduled for asthma clinic.

(5) *Productivity*: Meeting structure and frequency allowed action items and productivity targets to be met in a timely manner. The use of a meeting agenda and a consistent schedule of established meeting times ensured efficiency in meetings and member retention. According to one participant, the meetings were "always very well organized, timely, they start on time, they end on time. They stay... on the agenda."

Discussion

The participatory approach used in this implementation appears to have been critical to overcoming many of the perceived and actual barriers to implementation of SDM. Satisfaction among the participants, as reported in the focus groups, was high. Team members appreciated the opportunity to give feedback and for the team to address the concerns they expressed. For example A training video was made and can be found at https://asthma.carolinashealthcare.org/

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 SDM 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 were de-identified and presented back to the research team to help to improve the research process. Provider "buy-in" was a success as evidenced by the full adoption of the program into all potential practices. CBPR can employ a wide range of methodologies, but its key principles as utilized in the present clinical implementation were (1) building trusting relationships with partners from the outset in order to promote co-learning and capacity building, (2) using cyclic and iterative processes to build the process, (3) disseminating results to all partners, (4) involving key stakeholders in all aspects of the research process, and (5) ongoing assessment and improvement of the partnership [26–30].

Previously, we used CBPR to build partnerships among researchers, health providers, and community members [13,22,27,31–36]. Mendel et al. [37] have emphasized the value of using such a community-based, participatory approach to support implementation of new clinical interventions [38].

In addition to adapting CBPR into our approach to the implementation of SDM, we also incorporated elements from two practice guideline implementation frameworks [14,37,39]. These frameworks suggest 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.

These frameworks draw on relevant concepts from the social and behavioral sciences [38,40-46]. For example, the key barriers to facilitators of implementation and sustainability involve provider beliefs, attitudes, motivation, and norms. Innovation characteristics interact not only with provider/ staff-level attributes but also with clinic-level attributes such as culture (norms and practices of the system) and climate (worker's perceptions of, and reaction to, the characteristics of the work environment) [47]. We began with an intervention that had been documented to improve patient medication adherence and disease outcomes in a research clinical setting, and then utilized a participatory approach to implementation in order to allow adaptations to be made by the participants themselves. We did this by (1) allowing the favorable and unfavorable predisposing characteristics of the providers who were to implement the intervention (beliefs, attitudes, productivity concerns, etc.) to be voiced; and (2) addressing the perceived issues with local solutions and ways to make the intervention less complex.

One of the inherent challenges was that of implementing the intervention in multiple practices with very diverse, complex urban underserved patient populations and with patients of diverse ethnic/racial backgrounds. One anticipated limitation of SDM in these settings was provider perception that an SDM is a good idea but would not work with the provider's patient population. By involving providers in the adaption of the intervention to each practice's patient population and culture, we were able to improve provider buy-in and positive feelings around sustainability. The majority of the patients enrolled also felt positive about being involved in the decisions about their/their child's asthma treatment. Anecdotal report from the providers also suggests that the response of the patients who participated in the SDM clinics was very positive, further reinforcing provider buy-in and positive feelings.

Study strengths and limitations

A major strength of this project is the purposeful use of qualitative process evaluation. By undertaking this evaluation, the research team was able to gather data that helped them to plan for a future large-scale intervention implementation with the goal of reducing the time between discovery of a new evidence-based practice and its subsequent widespread adoption into primary care. Additionally, the process evaluation results were rapidly fed back all members of the team allowing for rapid identification and resolution of problems. This process allowed the team to understand and increase the effectiveness of their role in the implementation process. Our experience implementing a complex SDM intervention that required significant changes in the care delivery process contributes to the accumulating findings on team-based collaborative interventions. However, this implementation process still needs to be tested in future large-scale studies in order to be generalizable. To date, this process for SDM implementation has been tested in only a small number of clinics that primarily serve underserved, albeit diverse, clinical populations. In addition, the number of patients with whom the approach has been applied is modest. In contrast, this study demonstrated that an SDM intervention

could successfully be implemented in teaching clinics that serve disadvantaged patients. This counters the perception that such an approach is more suitable and more acceptable to more affluent or highly educated patients that were enrolled in the BOAT study.

The adoption of any research-based intervention in a "real-world" clinical setting carries significant pros and cons. This is especially true when the implementation process engages clinical personnel in adapting the methods and materials. The positive aspects of using the participatory research approach to implementation include improved provider acceptance and commitment to sustaining the program. A potential negative is that the adaptations may alter key elements of the intervention such that it loses some or all its effectiveness. An obvious, and important, limitation of the present report is that we have covered only the process evaluation. The overall plan for the present study is to use health-care utilization data as well as patient outcomes before and after implementation of the SDM intervention as well as against matched controls to examine the impact of this work. Preliminary results of this SDM intervention show a reduction in ED use, hospitalizations and oral steroidal use (marker of exacerbation) in patient's engaged in SDM as compared to usual care. Preliminary results are not included in this paper to avoid confusion with fully validated results to be published separately after the completion of the study.

Implications and future directions

The CBPR implementation process that was described above will be evaluated in an additional 90 practices within our health-care system and a further 30 practices across North Carolina.

Conclusions/key findings

This study demonstrated the successful use of a participatory research approach to adaptation and implementation of a SDM intervention. Success of the approach was measured using the RE-AIM measures around sustainability of the intervention. As such all six sites implemented fully functioning half-day dedicated asthma clinics and the participatory approach, as demonstrated qualitatively, allowed for full clinic and champion provider engagement in the process. This intervention significantly changes the care delivery models from clinic scheduling to patient–clinician interactions. Future research will determine the sustainability of the practice changes required along with the clinical effectiveness of the intervention on patient outcomes.

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Declaration of interest

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