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Results from a pragmatic prospective cohort study: Shared decision making improves outcomes for children with asthma

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ABSTRACT

Objective: Patient/provider shared decision making (SDM) improves asthma control in a pragmatic clinical trial setting. This study evaluated the impact of an evidence-based SDM toolkit on outcomes for patients with asthma implemented by providers in a real world setting. We hypothesized that these patients with asthma would demonstrate improved outcomes such as reduced emergency department (ED) visits, hospitalizations, and oral steroid use in the 12 months following a SDM visit compared to those who did not receive the intervention. **Methods:** Patients with asthma were identified within six primary care practices that serve vulnerable populations in Charlotte, NC (746 children; 718 adult patients). Propensity scores were used to match 200 children and 206 adults for analysis. The primary outcome variable was asthma exacerbation defined as an ED visit or hospitalization for asthma or outpatient prescription of an oral steroid. Patients were monitored at 3, 6, and 12 months after the intervention date. The outcome variables of ED visits, hospitalizations, and oral steroids were compared between intervention and matched control patients. **Results:** The proportion of pediatric patients with one or more exacerbations was significantly lower in the SDM intervention group compared to controls during 12 months after exposure to the intervention (33% vs. 47%, $p = 0.023$). For adults, there was not a strong association between use of the SDM intervention and outcomes improvement. **Conclusions:** The evidence-based SDM intervention implemented in this study was associated with improved asthma outcomes for pediatric patients but not adult patients in a real world clinical setting.

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Introduction

Asthma is a chronic lung disease that affects both children and adults and has significant morbidity and mortality. More than 23 million people in the United States are affected by asthma, including approximately 7 million children [1, 2]. The burden of asthma in the U.S. accounts annually for 13.6 million physician office visits, 2 million emergency department (ED) visits, 504,000 hospitalizations, and over 4,200 deaths while resulting in \$15 billion in direct medical costs [3–5].

Despite advances in medical knowledge, poor outcomes and disparities for patients with asthma persist and additional strategies to ameliorate the impact of asthma need to be developed, tested, and implemented in the primary care setting. The U.S. Institute of Medicine has recommended that primary care providers incorporate shared decision-making (SDM) approaches to care into outpatient clinical settings (6). SDM has produced notable positive changes in asthma outcomes and poses a promising strategy to improve both adult and pediatric

patients' clinical outcomes and satisfaction with their care [7, 8].

The process of SDM involves patients and their health-care providers actively engaging together to make joint decisions about medical tests and treatment for a specific disease or condition. Providers contribute knowledge and expertise about the medical condition and its treatment options, while patients bring expertise on their own personal values, lifestyles, and beliefs. Rivera-Spoljaric et al. emphasize the importance of providers jointly determining the treatment goals with patients and/or parents [9]. SDM approaches that incorporate teaching self-management may improve outcomes and reduce costs [10].

Personal health beliefs about asthma control can contribute to high rates of uncontrolled asthma in vulnerable populations if they undermine adherence to medication regimens [11]. Patient satisfaction plays an important role as well; parents with higher health literacy and satisfaction with the patient-physician interactions had

higher satisfaction with SDM and their children had better asthma control [7]. Previous studies have shown a correlation between the prevalence of obesity and asthma in the pediatric population and that using the SDM model leads to improved outcomes in both comorbidities [12, 13]. Despite the evidence of SDM on positive clinical outcomes and patient satisfaction, current adoption of SDM by healthcare professionals remains limited [10,14]. Further research is needed to evaluate SDM for asthma management after implementation into real world clinical practices [9].

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 as a part of a larger comparative study of the effectiveness of asthma care interventions in a large healthcare system from 2010 through 2013 [15–17]. The Better Outcomes for Asthma Treatment (BOAT) study, a randomized controlled trial by Kaiser Permanente, showed that use of the asthma SDM toolkit to involve patients in the negotiation process about treatment decisions significantly improved both clinical outcomes and patients' adherence to asthma control medication [8]. The theoretical model that served as the basis of the SDM intervention introduced choices, described options, and helped patients explore preferences and make decisions [18].

The MAPPR research team adapted and implemented the asthma SDM toolkit into routine clinical practice at six sites within a large healthcare system [15]. The toolkit followed the essential elements of SDM associated with the Elwyn four part SDM model. The toolkit was adapted to incorporate the 2007 NHLBI (National Heart, Lung, and Blood Institute) asthma guidelines and facilitate use in pediatric populations [8, 15] (Appendix 1).

This prospective cohort study evaluated asthma outcomes after practices adopted the SDM intervention. The goal of this study was to evaluate outcomes for patients with asthma in this real world setting where implementation of the toolkit had taken place into routine clinical practice. We hypothesized that patients with asthma would demonstrate improved patient-oriented clinical outcomes that had not been previously evaluated, such as number of ED visits, oral steroid use, and hospitalizations in the 12 months following a shared decision making visit. Through evaluation of these clinical outcomes, this study sought to demonstrate the success of this real world implementation of the asthma SDM intervention that focused on sustainability, scalability, clinical productivity, and adaptability to the culture and needs of each practice [15].

The research question asked whether the use of a structured shared decision making toolkit improves clinical outcomes for pediatric and adult patients with asthma in a real world setting.

Methods

Setting

This prospective cohort study received approval from the Carolinas HealthCare System's Institutional Review Board, an independent research ethics committee. The evaluated intervention was implemented practice-wide, therefore patients were not consented for participation, nor did patients receive payment or incentive. Intervention participants were consented for an anonymous survey. The study took place at six primary care practices within a large healthcare system that serve a vulnerable, predominantly Medicaid, Medicare, and self-pay population in Charlotte, NC. Practice demographics and the implementation of the study are previously described [15]. Three of the six practices specialized in Family Medicine, two in Pediatrics, and one in Internal Medicine.

SDM training and implementation of the SDM toolkit intervention at the six participating practices was staggered over 12 months, with the "rollout" at each practice taking approximately 12 weeks to complete. A family medicine provider, who was also a research team member, facilitated and tailored the implementation of the SDM toolkit to the individual needs of each practice. The rollout typically consisted of 12 one-hour-long weekly sessions with clinic providers and staff. Topics included asthma health maintenance, population management, explanation of SDM and motivational interviewing, scheduling logistics for the asthma visits, patient recruitment, and toolkit training.

Clinic staff varied across the six practices but typically included a provider champion, practice manager, nurse manager, registration supervisor, interpreter if applicable, and health coaches. Health coaches included pharmacists, nurses, or patient educators who were interested in taking a more active role in asthma care at their clinic. Each site had 1–3 health coaches. The toolkit contained SDM materials, forms, and decision aids used by the health coach to guide a patient through the SDM process culminating in negotiation of evidence-based treatment options [8, 15] (Appendix 1). In order to ensure fidelity of the intervention, the practice facilitator periodically observed the health coaches during a SDM visit and provided them with quality assurance feedback. Once the intervention

was adopted at each practice, the recruitment period for the study lasted 12 months.

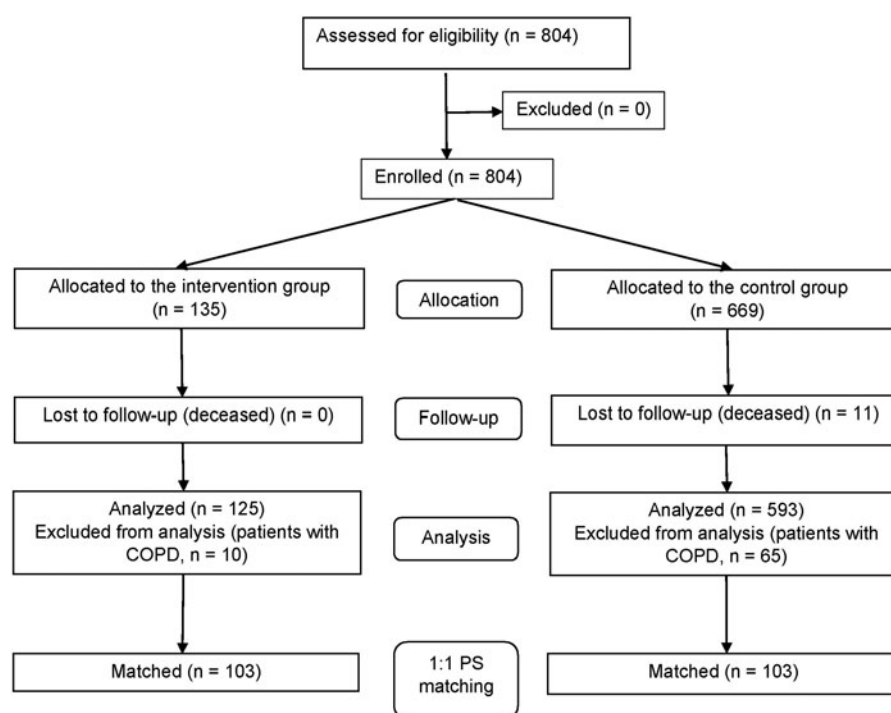
Participants

Provider referrals augmented by asthma population reports were the main patient recruitment method for intervention participants. Adult and pediatric patients were recruited for the intervention based on provider knowledge of their need for additional asthma education as indicated by frequent ED visits, hospitalizations, oral steroid use (a marker of exacerbation), or general lack of asthma control. Examples of indicators of poor control include frequent daytime or nighttime symptoms such as coughing, wheezing, shortness of breath, or chest tightness; increased rescue inhaler use; or interference with normal activity. When seen during an exacerbation or in follow-up from a recent one, providers would refer their patients to a future SDM intervention visit. To aid in this recruitment effort outside of scheduled visits, the research team developed population reports by querying the electronic medical record (EMR) to identify a provider's asthma patients [15] using an International Classification of Disease, Ninth Revision (ICD-9) code of 493.xx (x range: 0–9). The resulting population reports were designed to call attention to asthma patients with at least one of the following inclusion 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. Providers utilized these population reports to select high priority patients for shared decision making, then asked the clinical staff to schedule the patients for an upcoming SDM intervention visit.

Patients from the six primary care practices who met the inclusion criteria for the asthma population reports created by the research staff but did not receive the shared decision making intervention were assigned to the control group. These patients received usual care at these same practices and had at least one standard outpatient visit over the study period related to their asthma care.

A total of 804 adults (135 in the intervention group and 669 in the control group) and 746 children (121 in the intervention group and 625 in the control group) satisfied the inclusion criteria. Eleven adults (all in the control group) deceased during follow-up and were excluded from the analysis. Seventy-five adults (10 in the intervention group and 65 in the control group) were found to have chronic obstructive pulmonary disease (COPD) and were excluded from the analysis. The final study population consisted of 718 adults (125 in the intervention group and 593 in the control group) and 746 children (121 in the intervention group and 625 in the control group) (Figures 1 and 2).



COPD = chronic obstructive pulmonary disease; PS = propensity score

Figure 1. Adult inclusion criteria for propensity scoring.

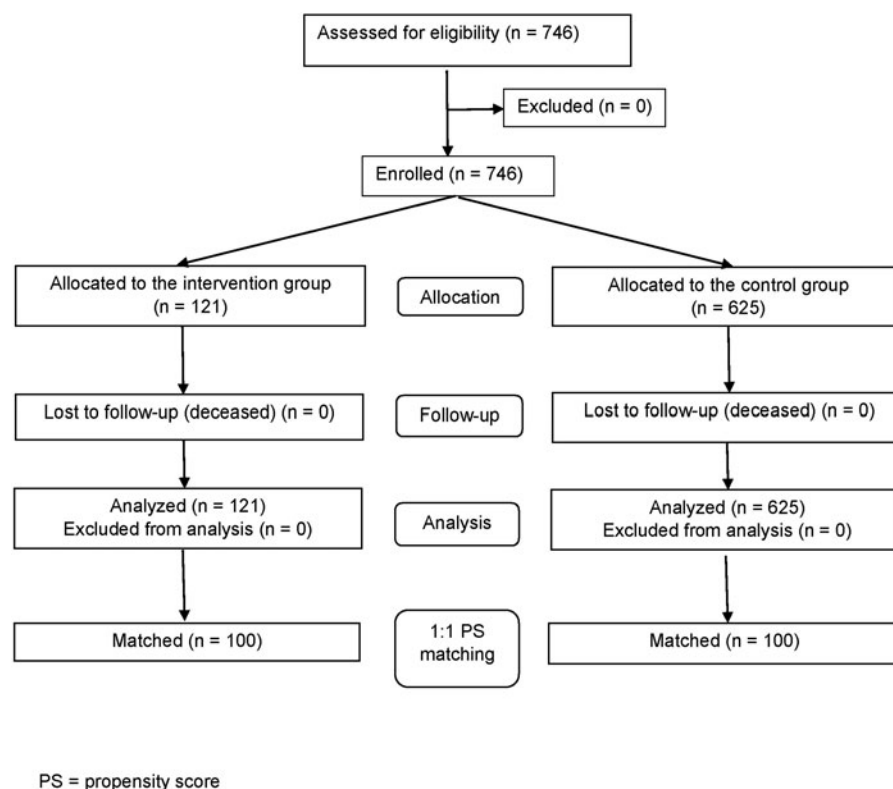


Figure 2. Pediatric inclusion criteria for propensity scoring.

Intervention implementation

During an asthma SDM visit, health coaches assessed patients' perception of asthma control, provided basic asthma education, and elicited patients' goals for treatment [8,15,16]. Providers helped each patient determine relative priorities for medication options regarding symptom control, regimen convenience, avoidance of side effects, and medication cost. Each patient's actual level of severity or control was reviewed, which was often found to be worse than the patient originally thought. Ultimately, the provider and patient/parent negotiated a treatment regimen that accommodated the patient's goals and preferences. The patient/parent was shown a list of the full range of age-appropriate treatment options for all levels of asthma severity and control, based on current national asthma guidelines [19], pharmacopeia, and formulary coverage, narrowing in on a treatment plan that achieved optimal control in the light of patient preferences [20].

These options differed with respect to the number and type(s) of medications, dosing, schedule, and the type of device used to deliver the medication. Medications were grouped according to established recommendations from the NHLBI for different steps of severity or control levels with regards to preferred, alternative, additional, and less preferred regimens [19]. Using a simple worksheet, the patient and clinician compared the pros and cons of all

of the options the patient wished to consider, taking into account their attitudes and beliefs regarding medications. The option of continuing with the patient's current *de facto* treatment (i.e. the medications that patient was actually taking, often only a short-acting beta agonist) was always included to arrive at a treatment that best accommodated the patient's goals and preferences. After the discussion of medication options and negotiation of treatment plan, an asthma action plan was completed with the jointly agreed-upon treatment decisions. After completion of the initial SDM visit, a follow-up visit was scheduled 4–6 weeks later based on provider preferences. All patients in the intervention group had at least one SDM visit.

Measures

The primary outcome variable, exacerbations of asthma, was defined as any hospitalization or ED visit with a primary asthma diagnosis (493.xx) or an oral steroid prescription order for asthma in the outpatient setting. In addition to a comparison of individual exacerbations, a composite outcome of "any exacerbation," a variable indicating whether a patient had one or more of the three individual outcomes, was also compared. The proportions of patients who had exacerbations were compared at 3, 6, and 12 months after the intervention date (for the intervention group) or date of first provider's visit for

usual care after clinics began offering the intervention (for the control group). These clinical relevant time periods were selected based on the typical asthma follow-up time points for uncontrolled asthma and to address any seasonal patterns of exacerbations.

The intervention group patients' perceptions of their participation in treatment decision making using surveys was examined. After each SDM visit, patients were invited to complete a short one question, anonymous survey asking: "Who made the treatment decision today?" with five possible answer options. The 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 selected answer 2, 3, or 4, it was considered that a shared decision had been reached. These anonymous surveys were collected quarterly from each practice.

Statistical analysis

We used propensity scores to match patients in the SDM intervention group to similar patients in the control group. Propensity scoring is a method to achieve balance between groups for comparison in observational studies when assignment to groups is nonrandom [21]. Use of propensity scores reduces confounding by mimicking randomization based on observed covariates [22]. We calculated propensity scores as the probability of being in the SDM intervention group based on the following covariates: age, race/ethnicity, gender, insurance, comorbidities (growth delay, developmental delay in children, upper respiratory infection, rhinitis, diabetes, hypertension, and congestive heart failure), baseline exacerbations (asthma-related inpatient and ED visits and oral steroid prescription orders during 12 months prior to intervention date), and neighborhood characteristics (poverty and education level). Propensity scores were generated using generalized estimating equations (GEE) to adjust for clustering among individuals residing in the same geographic area. Separate analyses were performed for children and adults. Propensity score matching was performed using an established macro [23], which uses a nearest neighbor matching algorithm. Each patient in the SDM intervention group was matched to one patient from the control group. Matching was without replacement and used a caliper distance of 0.05. Propensity matching resulted in 103 matched pairs of adults and 100 matched pairs of children (Figures 1 and 2).

We reported means and standard deviations for continuous variables and frequencies and percentages for

categorical variables. Bivariate analyses were conducted for comparison of baseline characteristics between intervention and control groups. For unmatched samples, chi-square/Fisher's exact test (for categorical variables), Student's *t*-test (for normally distributed continuous variables), and Wilcoxon rank sum test (for continuous variables with skewed distribution) were used. GEE models were used for comparison of matched groups on demographic characteristics and outcomes measures. All analyses were performed using SAS Enterprise Guide v5.1 (SAS Institute Inc., Cary, NC).

Results

Baseline characteristics were collected for both groups of children (Table 1) and adults (Table 2). Analysis of the study population revealed significant differences in the groups. Compared to the control group of children, the pediatric intervention group had a smaller proportion of Caucasians, a smaller proportion with commercial insurance, a larger proportion of children were obese, and a higher mean number of baseline ED visits. Propensity score matching yielded 100 intervention-control matched pairs of children ($n = 200$) and statistically non-significant differences were observed between the matched groups for all the characteristics in the study sample. Propensity scoring controlled for all common confounders, such as ED visits, oral steroid orders, and insurance type (Tables 1 and 2). Compared to the unmatched control group of adults, the unmatched adult intervention group had a larger proportion of commercial insurance, a greater number of ED visits at baseline, and a higher mean baseline of oral steroid orders (increased orders are associated with decreased control of asthma). These differences were eliminated after propensity score matching, which yielded 103 matched pairs of adults in the study sample ($n = 206$).

Pediatric group

The proportion of patients with asthma exacerbations (defined as asthma-related hospitalizations and ED visits and/or oral steroid prescription orders) were analyzed separately for the children (Table 3) and adults (Table 4). Significantly, children in the SDM intervention group experienced fewer exacerbations at 12 months compared to children receiving usual care (33% vs. 47%, $p = 0.023$). Differences in the percent of children receiving oral steroids at 12 months was marginally significant (SDM: 21%; control: 33%, $p = 0.075$). No outcomes were significantly different between the two groups at 3 and 6 months.

Table 1. Baseline characteristics of the study sample (children).

Variable, N (%)	Unmatched sample			Matched sample		
	Control (n = 625)	Intervention (n = 121)	P value*	Control (n = 100)	Intervention (n = 100)	P value [#]
Age, Mean (SD)	8.5 ± 4.1	8.7 ± 4.5	0.5962	9.0 ± 4.2	8.9 ± 4.7	0.8145
Race/ethnicity						
Caucasian	55 (8.8)	3 (2.5)	< 0.0001	3 (3.0)	3 (3.0)	0.4941
African American	328 (54.1)	66 (54.6)		62 (62.0)	56 (56.0)	
Hispanic	113 (18.1)	45 (37.2)		27 (27.0)	35 (35.0)	
Other [^]	119 (19.0)	7 (5.8)		8 (8.0)	6 (6.0)	
Insurance			0.0222			0.8071
Commercial	88 (14.1)	10 (8.3)		7 (7.0)	9 (9.0)	
Medicare	1 (0.2)	0 (0)		0 (0)	0 (0)	
Medicaid	519 (83.0)	102 (84.3)		90 (90.0)	87 (87.0)	
Other	17 (2.7)	9 (7.4)		3 (3.0)	4 (4.0)	
Gender			0.2954			0.7728
Male	383 (61.3)	68 (56.2)		57 (57.0)	55 (55.0)	
Female	242 (38.7)	53 (43.8)		43 (43.0)	45 (45.0)	
Obesity			0.0347			0.4328
Yes	55 (8.8)	16 (13.2)		18 (18.0)	14 (14.0)	
No	550 (88.0)	105 (86.8)		82 (82.0)	86 (86.0)	
Missing	20 (3.2)	0 (0)		0 (0)	0 (0)	
Growth delay	3 (0.5)	0 (0)	0.9999	0 (0)	0 (0)	—
Developmental delay	8 (1.3)	1 (0.8)	0.9999	1 (1.0)	0 (0)	—
Upper respiratory tract infection	17 (2.7)	6 (5.0)	0.2434	3 (3.0)	4 (4.0)	0.7055
Rhinitis	24 (3.8)	3 (2.5)	0.6011	2 (2.0)	3 (3.0)	0.6547
Gastroesophageal reflux disease	6 (1.0)	0 (0.0)	0.5966	1 (0)	0 (0)	—
Hypertension	1 (0.2)	0 (0)	0.9999	0 (0)	0 (0)	—
Cancer	1 (0.2)	0 (0)	0.9999	0 (0)	0 (0)	—
Diabetes	1 (0.2)	0 (0)	0.9999	0 (0)	0 (0)	—
Baseline ED visits, Mean (SD)	0.2 ± 0.6	0.4 ± 0.7	0.0001	0.4 ± 0.8	0.4 ± 0.6	0.9104
Baseline inpatient visits, Mean (SD)	0.1 ± 0.5	0.1 ± 0.4	0.9255	0.1 ± 0.3	0.1 ± 0.4	0.6547
Baseline oral steroid use, Mean (SD)	0.4 ± 0.9	0.5 ± 0.9	0.1396	0.5 ± 1.1	0.5 ± 0.9	0.8448

*Based on Student's *t*-test, Wilcoxon rank sum test, and Chi-square/Fisher's exact test.[#]Based on generalized estimating equations.[^]The category "Other" includes Asian and those with multiple races.

Adult group

The proportion of adults with exacerbations was compared between the intervention and control groups (Table 4). All comparisons were statistically non-significant at all time points.

Survey results

Patient surveys asking, "Who made the treatment decision today?" were collected from 319 of the SDM toolkit visits with both adult and pediatric patients/parents. Of the respondents, 87% reported a shared decision was made between patient and provider (options 2, 3, and 4) with 6% indicating the patient mostly made the decision (option 2), 74% indicating it was shared equally (option 3) and 7% indicating the provider mostly made the decision (option 4).

Discussion

Based on statistical analysis of the exacerbation results in the study sample, the use of a SDM toolkit intervention was associated with fewer exacerbations for pediatric, but not adult, patients with asthma. To our knowledge, this

is the first study of shared decision making with asthma patients to show significantly improved outcomes for a pediatric population in a real world clinical setting. This study contrasts with previous results of the SDM intervention showing significantly better controller adherence and higher controller use with adults in a randomized trial, the BOAT study [8]. The BOAT study recruited patients from within the Kaiser Permanente insured patient population. Recruitment of patients within this private insurance population was conducted using researchers in a clinical trial setting, whereas our study was conducted in a real world clinical setting using providers, health coaches, and clinic staff to recruit patients and to administer the SDM toolkit. This study was designed to evaluate differences in ED visits, oral steroid use, and hospitalization rates – the costliest and least desirable disease outcomes for both patients and healthcare systems.

The lack of change in exacerbation rate outcomes within the adult population may be due to the lower rate of treatment adherence found in adult versus pediatric populations [24], undiagnosed COPD [25], and/or other comorbid conditions such as undiagnosed congestive heart failure, gastroesophageal reflux disease, or allergic rhinitis. Patients with COPD and these other comorbid conditions may exhibit indicators of poor

Table 2. Baseline characteristics of the study sample (adults).

Variable, N (%)	Unmatched sample			Matched sample		
	Control group (n = 593)	Intervention group (n = 125)	P value*	Control group (n = 103)	Intervention group (n = 103)	P value#
Age, Mean $\pm$ SD	49.2 $\pm$ 15.7	48.5 $\pm$ 14.6	0.6516	47.9 $\pm$ 15.1	47.8 $\pm$ 15.0	0.9928
Race/ethnicity			0.6147			0.5867
Caucasian	71(12.0)	20(16.0)		20(19.4)	17(16.5)	
African American	444(74.9)	91(72.8)		70(68.0)	73(70.9)	
Hispanic	43(7.3)	7(5.6)		9(8.7)	6(5.8)	
Other [^]	35(5.9)	7(5.6)		4(3.9)	7(6.8)	
Insurance			0.0007			0.7165
Commercial	201(33.9)	52(41.6)		37(35.9)	45(43.7)	
Medicare	187(31.5)	27(21.6)		28(27.2)	23(22.3)	
Medicaid	185(31.2)	33(26.4)		29(28.2)	28(27.2)	
Other	20(3.4)	13(10.4)		9(8.7)	7(6.8)	
Gender			0.9604			
Male	115(19.4)	24(19.2)		20(19.4)	18(17.5)	
Female	478(80.6)	101(80.8)		83(80.6)	85(82.5)	
Obesity			0.2483			0.8886
Yes	381(64.2)	89(71.2)		75(72.8)	74(71.8)	
No	196(33.1)	35(28.0)		28(27.2)	29(28.2)	
Missing	16(2.7)	1(0.8)		0 (0)	0 (0)	
Upper respiratory tract infection	17(2.9)	1(0.8)	0.3393	2(1.9)	1(1.0)	0.5637
Rhinitis	108(18.2)	15(12.0)	0.0939	8(7.8)	15(14.6)	0.1266
Gastroesophageal reflux disease	107(18.0)	16(12.8)	0.1573	13(12.6)	14(13.6)	0.8273
Hypertension	227(38.3)	46(36.8)	0.7567	34(33.0)	37(35.9)	0.6617
Cancer	28(4.7)	4(3.2)	0.6336	5(4.9)	3(2.9)	0.4142
Diabetes	127(21.4)	22(17.6)	0.3390	21(20.4)	19(18.4)	0.7389
Congestive heart failure	23(3.9)	3(2.4)	0.5995	4(3.9)	3(2.9)	0.7055
Baseline ED visits, Mean $\pm$ SD	0.2 $\pm$ 0.7	0.4 $\pm$ 1.1	0.0226	0.3 $\pm$ 1.2	0.3 $\pm$ 0.7	0.5245
Baseline inpatient visits, Mean $\pm$ SD	0.1 $\pm$ 0.3	0.0 $\pm$ 0.2	0.2938	0.0 $\pm$ 0.1	0.0 $\pm$ 0.2	0.1025
Baseline oral steroid use, Mean $\pm$ SD	0.5 $\pm$ 1.0	0.9 $\pm$ 1.6	0.0014	0.8 $\pm$ 1.3	0.8 $\pm$ 1.3	0.8613

*Based on Student's *t*-test, Wilcoxon rank sum test, and Chi-square/Fisher's exact test.

#Based on Generalized Estimating Equations.

[^]The category "Other" includes Asian and those with multiple races.**Table 3.** Percentage of exacerbations among children with asthma in the intervention and control groups before and after an asthma shared decision making intervention (*n* = 200).

	Percentage											
	Baseline		3 months post			6 months post			12 months post			p*
	C	SDM	C	SDM	p*	C	SDM	p*	C	SDM	p*	
ED visits	24.0	28.0	4.0	2.0	0.311	8.0	10.0	0.666	18.0	12.0	0.110	
Hospitalizations	8.0	7.0	1.0	0.0	n.e.	2.0	3.0	0.566	6.0	6.0	>0.999	
Oral steroid use	31.0	32.0	10.0	10.0	0.989	18.0	15.0	0.567	33.0	21.0	0.075	
One or more exacerbations (ED visit, hospitalization, oral steroid use)	47.0	50.0	14.0	11.0	0.461	23.0	23.0	0.874	47.0	33.0	0.023	

**p*-value comparing intervention and control patients from generalized estimating equations, adjusted for baseline values.

C, Control; SDM, SDM intervention; n.e., not estimable.

Table 4. Percentage of exacerbations among adults with asthma in the intervention and control groups before and after an asthma shared decision making intervention (*n* = 206).

	Percentage											
	Baseline		3 months post			6 months post			12 months post			p*
	C	SDM	C	SDM	p*	C	SDM	p*	C	SDM	p*	
ED visits	17.5	18.4	4.9	5.8	0.785	9.7	8.7	0.758	15.5	13.6	0.621	
Hospitalizations	1.0	4.9	1.9	0.0	n.e.	3.9	1.0	0.213	3.9	3.9	>0.999	
Oral steroid use	38.8	38.8	10.7	13.6	0.516	18.4	26.2	0.168	32.0	39.8	0.189	
One or more exacerbations (ED visit, hospitalization, oral steroid use)	52.4	46.6	16.5	18.4	0.628	25.2	32.0	0.200	40.8	47.6	0.178	

**p*-value comparing intervention and control patients from generalized estimating equations, adjusted for baseline values.

C, Control; SDM, SDM intervention; n.e., not estimable.

control of asthma such as frequent coughing or shortness of breath making causality difficult to determine.

The implementation of this project involved principles of participatory research to maximize implementation success through coordinated efforts to encourage participation, promote action, create supportive systems, and monitor and provide feedback on progress [15]. The key barriers and facilitators of implementation and sustainability involve provider beliefs, attitudes, motivation, and norms. Key barriers for the providers in this study were the beliefs that that intervention would take up too much time, affect productivity, and not be sustainable. Key facilitators were to incorporate process improvement methods to address provider concerns and to facilitate communication across all the practices to trouble shoot and offer tips for each other during the implementation process [15]. The participatory approach involved allowing adaptations of the intervention by clinics and providers based on their specific needs and productivity concerns. 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 demonstrating that a SDM intervention could successfully be implemented in real world ambulatory practices that serve disadvantaged patients.

Current asthma guidelines offer categories of asthma severity levels such as mild intermittent, mild persistent, moderate persistent, and severe persistent. These severity levels may have been considered by referring physicians for the SDM intervention; however, they were not available for the control group. Although asthma severity was evaluated for individual patients as part of the toolkit, these evaluations were conducted by providers and not collected for analysis by the research team. Although members of the control group were matched based on hospitalization and ED visits, no matching was performed based on degree of clinical severity, which could vary between intervention and control patients.

This pragmatic study sought to both implement and evaluate best practices while directing limited resources to patients who were most in need. Therefore, patients thought to have very high severity and/or difficult to treat asthma based on provider perception and ED services and hospitalization were enrolled in the SDM intervention. This approach had the potential to influence the outcomes of the study as patients with complex and difficult to control asthma may respond differently to the SDM approach than patients with moderate or mild asthma. For example, the study was unable to show an impact of SDM for adult patients. As discussed, adult participants had additional comorbidities (including undiagnosed COPD) that may have driven their hospitalizations and ED visits despite an improving control of their asthma. Adult patients may

well have focused more intently on their asthma control in lieu of maintaining control of the comorbid conditions resulting in the lack of change in rates of acute care services.

In contrast, asthma is by far the most prevalent chronic condition with only a small fraction of the children participants having any other comorbid conditions. Therefore, we speculate that without the contamination of these comorbidity conditions, the participants under the age of 18 had fewer confounders, allowing the study to demonstrate clear effectiveness between the intervention and ED visits and/or hospitalizations. Alternately, the differences in outcomes in children and adults might be related to their perceived ability to self-manage the disease or perhaps with long periods of experimentation with their disease, adults become less likely to receive additional benefits related to the negotiation process inherent within the SDM intervention.

Limitations

This prospective cohort study had limitations. One limitation was the potential for adult patients diagnosed with asthma to have undiagnosed COPD. The potential mixing of these two distinct populations within the adult cohort is a confounding factor and may have contributed to the difficulty in showing significant improvement for adults. An indicator that asthma alone is well controlled is a diminishing need for rescue treatment (such as using an albuterol or other steroid inhaler), absence of exacerbations, and normal pulmonary function. Patients with both asthma and uncontrolled COPD may not have normal pulmonary function and they often remain symptomatic with activity limitations and exacerbations, despite treatment [26].

An additional confounder with asthma in adults may be contingent upon various behavioral factors. Successful control is achieved by minimizing exposure to triggers, avoiding smoking, and medication regimen adherence [27,28]. Poor adherence to medication regimens in adults may in part be due to difficulties with inhaler devices, complicated regimens, side effects, and cost [28,29].

Children as young as two years diagnosed with wheezing associated with respiratory illness may have been misclassified as asthma patients due to similar symptoms and enrolled in the study, despite the recruitment focus on patients with severe, prolonged symptoms.

Although the intervention and control patients were treated at the same practices, providers performed the SDM visit as a discrete asthma-orientated visit that incorporated the use of the toolkit in a binder. Feedback from practices suggested any potential spillover between intervention and control groups was limited. It is likely that

selection bias was introduced in who was referred to the intervention and who was motivated to accept the intervention. Risk of bias existed due to observational design and lack of blinding.

Although we considered the sample size reasonable, larger sample sizes would have offered opportunities for enhanced power to detect significance. However, data collection takes longer and involves more expense. The sample size in this prospective cohort study gave us the power to distinguish the difference in outcomes between patients who were in the intervention group and control group for the pediatric population.

Finally, a limitation of the propensity score methodology used for matching intervention and control patients is that it cannot account for unobserved differences between groups. We were able to achieve good balance on observed covariates. Patients in our matched sample may still differ on unobserved factors.

Conclusions

The evidence-based SDM intervention implemented in this study showed improved asthma outcomes for pediatric patients, with the proportion of pediatric patients with one or more exacerbations significantly lower in the SDM intervention group compared to controls after exposure to the intervention. For adults, there was not a strong association between use of the SDM intervention and outcomes improvement. Shared decision making is a valuable tool in chronic disease self-management that is associated with improved asthma-related outcomes through decreased exacerbations.

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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Appendix 1. Shared Decision Making Toolkit Contents

1. **Patient Information Sheet:** form for obtaining a detailed history including symptoms, triggers, previous medications and alternative treatments; uses motivational interviewing to elicit comprehensive information
2. **Blank Control Dial:** color-coded form for patients/parents to indicate their current level of asthma control
3. **Treatment Goals and Medication Preferences:** form to notate goals for treatment (often activity related) and rank medication preferences including control, side effects, cost and convenience
4. **Facts About Asthma:** handout depicting what happens in the lungs with asthma and the differences between controller and rescue medications
5. **Allergy Information:** educational handout explaining common allergic triggers and how to avoid them
6. **Smoking Cessation Information:** handout with tips to quit smoking
7. **Severity and Control Dials:** color coded forms outlining the components of asthma severity and control, used to determine actual level and compare with the perceived level from #2 above and guide treatment step selection
8. **Medication Options:** step-wise approach to treatment with age and insurance specific evidence-

- based medications separated into preferred, alternative, additional and less preferred options
9. **Medication Planner:** form used to negotiate 2–4 medication options based on patient/parent preference from #3 above
 10. **General Types of Asthma Medications:** handouts with detailed information on classes of asthma medications
 11. **How to Use Your Inhaler Handouts:** handouts with step-by-step instructions and pictures to promote proper inhaler technique
 12. **Asthma Diary:** form for patients/parents to record their asthma symptoms, medications, triggers and peak flows for self-monitoring
- Contents can be accessed at asthma.carolinashealthcare.org.