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Asthma dissemination around patient-centered treatments in North Carolina (ADAPT-NC): a cluster randomized control trial evaluating dissemination of an evidence-based shared decision-making intervention for asthma management

Thomas Ludden, PhD^a, Lindsay Shade, MHS, PA-C^a, Kelly Reeves, BSN, RN, UXC^a , Madelyn Welch, BA^a, Yhenneko J. Taylor, PhD^b , Sveta Mohanan, MD^a, Andrew McWilliams, MD^b, Jacqueline Halladay, MD, MPH^{c,d}, Katrina Donahue, MD, MPH^{c,d}, Tamera Coyne-Beasley, MD, MPH^{c,d}, Rowena J. Dolor, MD, MHS^e, Paul Bray, MA, LMFT^f, and Hazel Tapp, PhD^a

^aDepartment of Family Medicine, Atrium Health, Charlotte, NC, USA; ^bCenter for Outcomes Research and Evaluation, Atrium Health, Charlotte, NC, USA; ^cUniversity of North Carolina Department of Family Medicine, Chapel Hill, NC, USA; ^dCecil G Sheps Center for Health Services Research, Chapel Hill, NC, USA; ^eDivision General Internal Medicine, Department of Medicine, Duke University School of Medicine, Durham, NC, USA; ^fVidant Medical Group, Greenville, NC, USA

ABSTRACT

Objective: To compare three dissemination approaches for implementing an asthma shared decision-making (SDM) intervention into primary care practices. **Methods:** We randomized thirty practices into three study arms: (1) a facilitator-led approach to implementing SDM; (2) a one-hour lunch-and-learn training on SDM; and (3) a control group with no active intervention. Patient perceptions of SDM were assessed in the active intervention arms using a one-question anonymous survey. Logistic regression models compared the frequency of asthma exacerbations (emergency department (ED) visits, hospitalizations, and oral steroid prescriptions) between the three arms. **Results:** We collected 705 surveys from facilitator-led sites and 523 from lunch-and-learn sites. Patients were more likely to report that they participated equally with the provider in making the treatment decision in the facilitator-led sites (75% vs. 66%, $p = 0.001$). Comparisons of outcomes for patients in the facilitator-led ($n = 1,658$) and lunch-and-learn ($n = 2,613$) arms respectively vs. control ($n = 2,273$) showed no significant differences for ED visits (Odds Ratio [OR] [95%CI] = 0.77[0.57–1.04]; 0.83[0.66–1.07]), hospitalizations (OR [95%CI] = 1.30[0.59–2.89]; 1.40 [0.68–3.06]), or oral steroids (OR [95%CI] = 0.95[0.79–1.15]; 1.03[0.81–1.06]). **Conclusion:** Facilitator-led dissemination was associated with a significantly higher proportion of patients sharing equally in decision-making with the provider compared to a traditional lunch-and-learn approach. While there was no significant difference in health outcomes between the three arms, the results were most likely confounded by a concurrent statewide asthma initiative and the pragmatic implementation of the intervention. These results offer support for the use of structured approaches such as facilitator-led dissemination of complex interventions into primary care practices.

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Introduction

An estimated 24 million people in the US, including 12% of children, have asthma [1,2]. Almost 50% of children who have asthma experience an asthma exacerbation annually [2]. Over 1.75 million patients with asthma visited an emergency department (ED) in 2011 [3]; patients with asthma also visited outpatient

offices over 10 million times in 2012 [4]. Given the high prevalence and associated morbidity of asthma, opportunities exist for interventions in the outpatient setting to improve outcomes.

In the ambulatory setting, newer approaches to treatment, such as shared decision making (SDM),

CONTACT Thomas Ludden, PhD  tom.ludden@atriumhealth.org  Department of Family Medicine, Atrium Health, Charlotte, NC, USA.
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have shown improved outcomes for patients with asthma [5,6]. However, the dissemination of such complex interventions has been slow or inconsistent [7]. Known barriers to widespread dissemination of complex interventions exist at ambulatory practices and include disparities in the patient population, limited support staff, lack of practice resources to absorb new care delivery approaches, competing pressures on practices to improve efficiency, and the complexity of electronic medical record (EMR) systems [8–10].

Common dissemination techniques include passive diffusion using presentations by subject matter experts, journal publications, and educational materials distributed in paper and online formats [11,12]. Because these methods have limited success, new dissemination approaches need to be tested for effectiveness [13]. Multifaceted, active knowledge translation methods, such as those involving face-to-face interactions in the clinical environment, are consistently more effective than passive dissemination strategies [14,15]. By comparing different dissemination methods, the most effective approach for successful dissemination can be identified.

Previous research suggests that implementation success is optimized when there are coordinated efforts to encourage participation, promote action, create supportive systems, and monitor and provide feedback on progress through practice facilitation [11,12,16]. Practice facilitation has been shown to improve evidence-based guideline adoption, prevention, smoking cessation, chronic illness care including diabetes, and cancer care [17–25]. In an earlier Asthma Comparative Effectiveness (ACE) Study, a facilitator-led approach using practice facilitation for dissemination of a complex evidenced-based SDM toolkit was implemented [6].

The ACE Study facilitator-led method involved a participatory approach using 12-weeks of weekly engagement with each practice [26,27]. Each week a trained facilitator from the research team held hour-long meetings at the practice. Key personnel from the practice were invited to each meeting to form a core team with a goal to work through tailoring the adoption of the SDM intervention to the culture of the practice. Typically, the core team was comprised of a provider champion, practice manager, health coach, nursing and registration staff [27].

The asthma SDM intervention begins with non-physician providers, such as nurses or other clinical staff functioning as health coaches, to assess the patient's perception of asthma control. They provide basic asthma education, elicit the patient's goals for

treatment and relative priorities regarding symptom control, regimen convenience, avoidance of side effects, and cost, then work collaboratively with the patient to identify a treatment regimen that incorporates 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. The health coach narrows in on the treatment step that best matches the patient's actual severity or control level, then deliberates with the patient several regimen options based on the patient's medication preferences. An asthma action plan is prepared that incorporates the jointly agreed-upon treatment decisions. Improved outcomes for children with asthma were seen at six practices that previously adopted the SDM toolkit intervention using this facilitator-led approach [5].

In this current study, we evaluated the uptake of an asthma SDM intervention into primary care practices by comparing a structured facilitator-led dissemination, a traditional “lunch-and-learn” dissemination, and a usual care control (no dissemination). The facilitator-led approach is an evidence-based implementation method utilizing a 12-week rollout to fully support adoption of the SDM toolkit into practices and ongoing episodic needs-based contact including a refresher session after one year to support continued implementation [5], while the lunch-and-learn approach involves a traditional dissemination method in which a lunchtime presentation describing the SDM toolkit is given to practices once a year along with access to the toolkit materials and website (<https://asthma.carolinashealthcare.org>). The usual care control “no intervention” group did not receive any active dissemination intervention.

The primary outcome of the study was patients' perceptions of having shared in the treatment decision at an asthma visit in the active dissemination arms. Secondary outcomes were health outcomes for patients with asthma, including ED utilization, hospitalizations, oral steroid prescriptions, and one or more of these three “markers” of exacerbation for all three arms [5,8,26–28]. We hypothesized that practices receiving the facilitator-led dissemination approach would have a greater percentage of patients reporting having equally shared in the treatment decision about their asthma care with their provider than patients in the traditional lunch-and-learn practices. For our secondary outcome, patients with asthma in the facilitator-led or traditional lunch-and-learn practices were hypothesized to have a lower proportion of asthma exacerbations than patients in the usual care control practices.

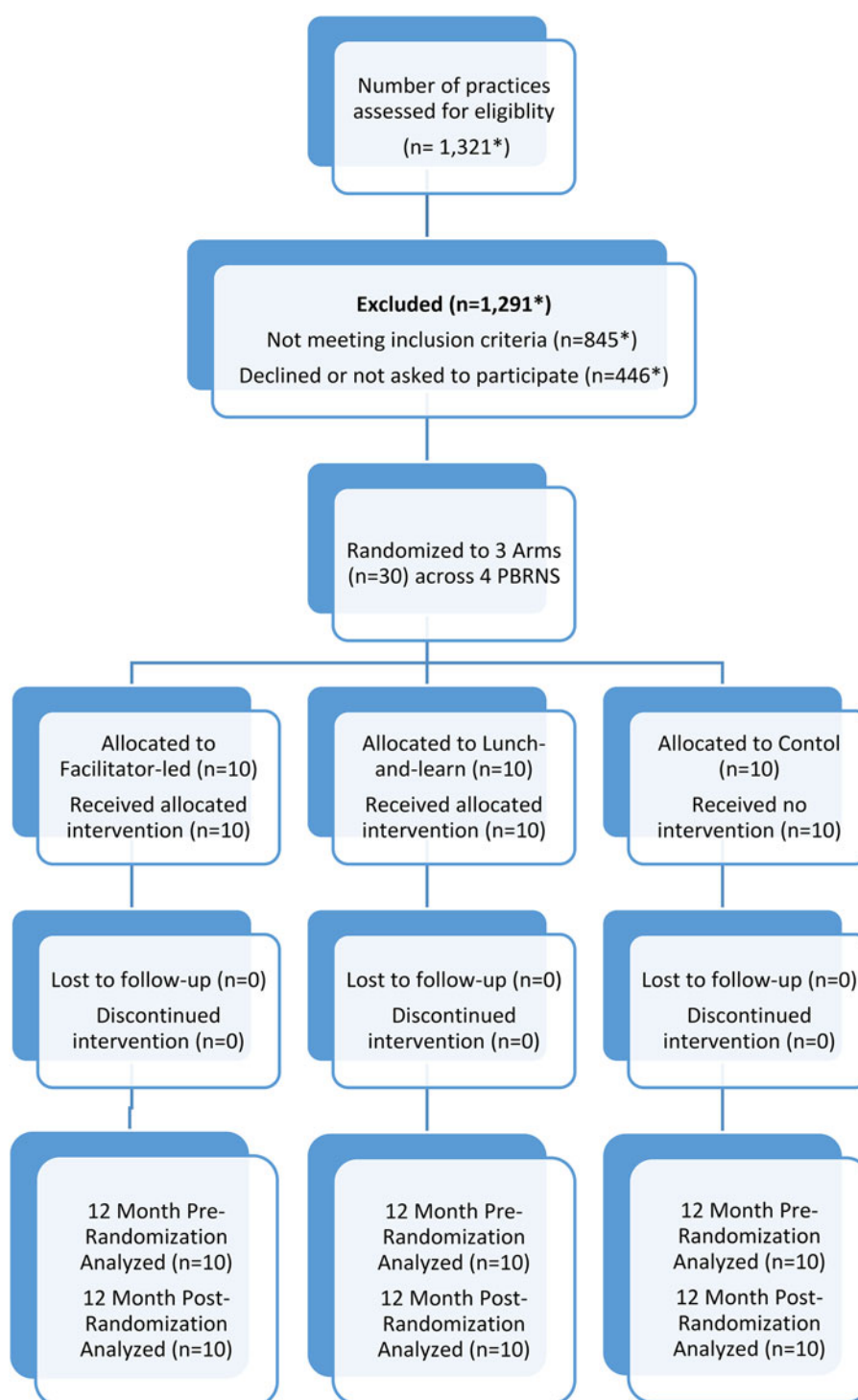


Figure 1. Consort diagram. n=number of practices; *Data received from CCNC already excluded those practices with less than 75 patients.

Methods

Trial design

The Asthma Dissemination Around Patient-centered Treatments in North Carolina (ADAPT-NC) Study utilized a cluster-randomized control design comparing the dissemination of an asthma SDM intervention

across three arms: a facilitator-led dissemination, a traditional lunch-and-learn dissemination, and no dissemination. Thirty primary care practices across the state of North Carolina were randomized into each arm of the trial (10 per arm). The practice randomization was clustered geographically across four Practice Based Research Networks (PBRN). Two PBRNs, North

Carolina networks (NCnet) with the University of North Carolina at Chapel Hill and Mecklenburg Area Partnership for Primary care Research (MAPPR) with Atrium Health, each recruited 9 practices (3 per arm), while the Duke Primary Care Research Consortium (PCRC) with Duke University and Eastern Carolina Association for Research and Education (E-CARE) with Vidant Medical Center each recruited 6 practices (2 per arm) [27]. The Consolidated Standards of Reporting Trials diagram summarizes the study design (Figure 1).

Participants

Primary care practices were eligible to participate if they had at least 75 Medicaid patients over the age of two diagnosed with Asthma (ICD-9: 493.XX; IDC-10: J45.9XX) and without Chronic Obstructive Pulmonary Disease (COPD). Eligible practices were identified from a list of all practices in North Carolina enrolled with Community Care of North Carolina (CCNC), an organization that manages Medicaid patients in North Carolina. Practices were recruited by the four PBRNs on a voluntary basis for participation in the study. Practices were sent a recruitment flyer by email and contacted by phone and/or in person during practice visits to establish their interest in the project. Patients included in the assessment of practice eligibility had to be enrolled in Medicaid for at least 11 months on a rolling 12-month basis. While practice eligibility was based on the Medicaid population, the intervention was designed to be practice-wide and included all payor types. Patient SDM surveys were collected for the two active intervention arms, facilitator-led and traditional lunch-and-learn dissemination.

Intervention

The trial consisted of three arms with two active dissemination intervention arms and one no dissemination intervention arm to evaluate the difference in patients' perceptions of shared decision making between the two dissemination arms and the health outcomes across all three arms. The facilitator-led method involved a participatory approach to the implementation of SDM to engage each practice. Each week over a period of 12 weeks, a trained facilitator from the research team held hour-long meetings at the practice. A core team, typically consisting of a provider champion, practice manager, health coach, nurse(s), and registration staff, was invited to each meeting with a goal to tailoring the adoption of the

12 Week Rollout Intervention at Facilitator-Led Practices	
Team	
Provider Champion, Practice Manager, Health Coach, Nursing, Registration staff	
Weeks 1-7	Asthma appropriate care and actions, Population management, Logistics of scheduling, Patient Recruitment, Shared Decision Making Toolkit
Week 8	First Shared Decision Making Visits
Weeks 9-12	Debriefing, Troubleshooting, Feedback

Figure 2. Description of roll-out of Facilitator-led intervention.

SDM intervention to the culture of the practice [26,27]. The research team practice facilitator led the core team at the practice through a new training topic each week including: asthma SDM toolkit training, asthma appropriate care and action plans, population management, logistics of scheduling, and patient recruitment. The facilitator assisted the practice in adapting the toolkit into a version that suited their specific needs. Generally, by the 8th week, the practice was encouraged to see their first asthma patients incorporating the SDM toolkit. The remaining weeks of the intervention involved debriefing, troubleshooting, and feedback to improve the process (Figure 2). To promote sustainability of the intervention, the practice facilitator revisited the practice for “refresher” training sessions the following year. The facilitator also made themselves available for extra training and consultation throughout the study period as needed.

Additionally, team members from the 10 facilitator-led practices were invited to participate in a monthly call with the practice facilitators and PBRN researchers which served as a time to provide project updates, share best practices and overcome barriers to implementation. Each call centered on a theme to guide the discussion.

Practices in the traditional lunch-and-learn arm received a one-hour presentation per year over 2 years that included a general overview of the SDM toolkit for asthma care with access to a website containing training materials and a paper copy of the toolkit. The first lunch-and-learn occurred immediately following randomization and the refresher training session occurred 1 year later.

The control practices did not receive any active intervention. Control practices were offered the option

of a lunch-and-learn intervention after the study was completed.

The objectives of the study were to compare the patients' perceptions of shared decision making in the active dissemination arms and health outcomes across all three arms.

Outcomes

For the primary outcome at facilitator-led and traditional lunch-and-learn practices, staff used convenience sampling to collect a post asthma visit one-question anonymous survey from asthma patients and caregivers to assess perceptions of shared decision making. The survey asked, "Who made the decision in your meeting with the care team (health coach and provider) about what your asthma treatment would be?" The respondents selected one of five choices: (1) I alone made the decision; (2) I mostly made the decision, and the care team played a small role in the decision-making; (3) The care team and I participated equally in making the decision; (4) The care team mostly made the decision, and I played a small role in the decision-making; or (5) The care team alone made the decision [5,8,26–28].

Practice staff approached and handed a paper survey to patients with asthma at the end of any asthma visit regardless of visit content. Not all asthma patients at all intervention practices filled out surveys as a convenience sample of asthma patients was collected. Practice facilitators collected surveys completed by asthma patients from the active intervention practices. To reduce the chances of contamination of the control arm with details of the SDM intervention, surveys were not collected from the control sites. We hypothesized that practices receiving the facilitator-led dissemination approach would have a greater percentage of patients reporting having equally shared in the treatment decision about their asthma care with their provider than patients in the traditional lunch-and-learn practices.

For the secondary outcomes, we collected asthma related ED visits, hospitalizations, and/or oral steroid prescription orders summarized by practice from the North Carolina Medicaid claims database as proxies for asthma exacerbations. Health outcomes included 12-month rolling counts of the number of patients in each practice covered by Medicaid and the number with ED visits and hospitalizations with a primary diagnosis of asthma (ICD-9 code of 493; ICD 10 code J45) or an outpatient oral steroid prescription. The oral steroid prescription had to be associated with a primary or secondary asthma diagnosis. Claims data were

aggregated at the practice level. Previous studies using insurance claims as indicators of outcomes in randomized control trials have provided important study data evaluating real-world large-scale interventions [29].

Data were collected for up to 18 months post-randomization. The Medicaid claims data used in this study allowed us to have a consistent source of outcomes data across the thirty study sites, which varied in the data systems used as well as their ability to extract that data for research purposes. Patients with asthma in the facilitator-led or traditional lunch-and-learn practices were hypothesized to have a lower proportion of asthma exacerbations than patients in the usual care control practices.

Practice characteristics collected included the distribution of race, ethnicity, gender, and age for patients at each practice.

Sample size

Sample sizes for each arm were calculated based on the number of practices and patients required to detect a difference between the groups for the health outcome measures. To achieve 80% power to detect a 7% decline in exacerbation rates, we needed 10 practices per arm with at least 50 Medicaid patients with asthma per practice between the dissemination intervention and no dissemination intervention arms. This number would ensure that a minimum of 50 patients per arm would be exposed to the intervention. Data from 30 practices with 1,500 patients was expected to have an intra-cluster coefficient of 0.1.

Randomization

After practices agreed to participate in the study and each PBRN had completed recruitment, the practices from each PBRN were randomly assigned to one of three study arms using SAS 9.4 (SAS Institute, Inc., Cary, NC) by a statistician who consulted on the project outside of the main research team. After randomization, each practice was told their assigned arm. The randomization date for each PBRN defined the start of the intervention for each practice and determined the data collection switch point from pre-implementation to post-implementation for each practice. For this practice level study, no patient-level consent was required.

Statistical methods

We used Chi-square tests to compare the proportion of patients at each practice who indicated that they

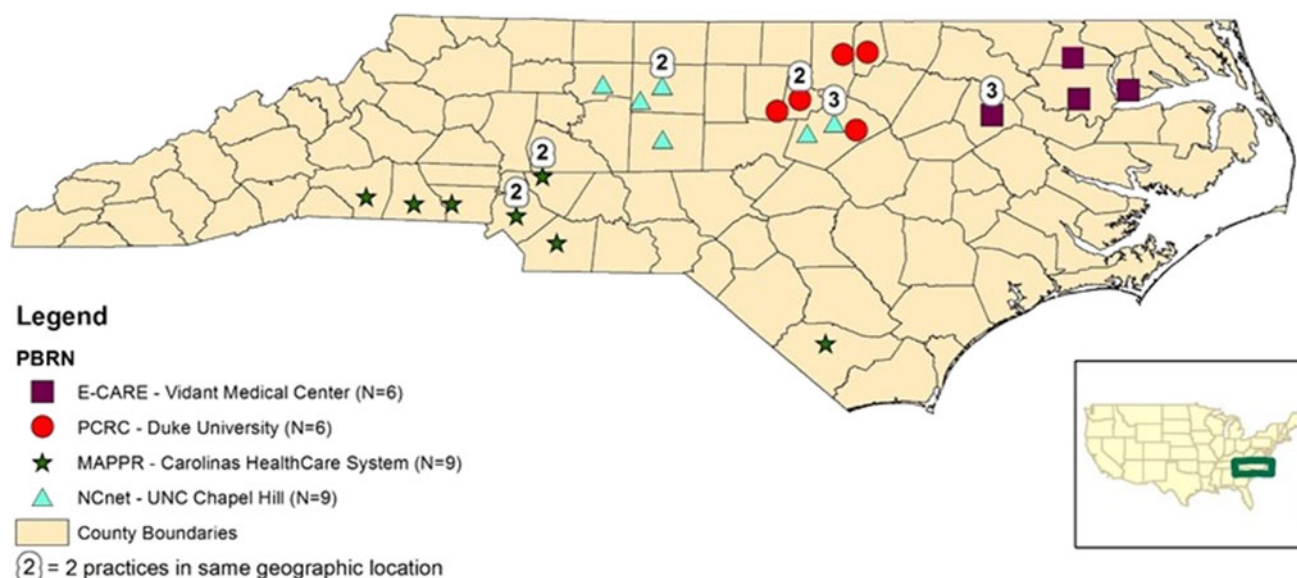


Figure 3. Practice recruited in North Carolina by Practice Based Research Networks (PBRNS) for the ADAPT-NC Study.

shared equally in making the decision between the facilitator-led practices and the traditional lunch-and-learn practices. We counted each one of the five answers separately and compared them between the two arms. We analyzed the data at the practice level.

For asthma exacerbation measures defined as ED visits, hospitalizations, and/or oral steroid prescriptions for asthma, we summarized the proportion of patients at each practice with ED visits, hospitalizations, oral steroid prescriptions with a primary diagnosis of asthma (ICD-9 code of 493; ICD 10 code J45) or an oral steroid in the outpatient setting. We also examined the proportion of patients at each practice with one or more of these exacerbation measures. We compared the facilitator-led arm to the control arm and the traditional lunch-and-learn to the control arm using adjusted logistic regression. We calculated the odds of exacerbation post randomization using adjusted odds ratios to compare the proportion of patients for each practice with an exacerbation marker across the three groups. To understand changes in exacerbation rates within each study arm, we compared the 12-month baseline rates of ED visits, hospitalizations, and oral steroid prescriptions for asthma to the 12 months post-randomization values for each arm using Chi-Square tests.

Results

Participant flow

From all 30 practices recruited by the 4 PBRNS, each arm was randomly assigned with 10 practices in each

arm where each practice represented a cluster and were included in the final analysis (Figure 1).

Practice recruitment

We screened 1,321 NC Medicaid practices for eligibility. Of these, 845 did not meet the inclusion criteria of a minimum of 75 asthma patients and 6 were excluded for participation in the pilot study that informed ADAPT-NC. PBRN leaders invited eligible practices from this group by recruitment flyers, emails, and phone calls until a total of 30 practices representing 7% of the eligible practices agreed to participate. 440 practices declined or were not asked to participate. Practice recruitment took eight months (January 2014 to August 2014) for all four PBRNS to recruit the required number of practices prior to randomization (Figure 3).

Baseline data

The number of patients with asthma covered by Medicaid for each arm's practice location varied from 25 to 831 (Table 1). The average number of patients was the highest in the lunch-and-learn arm ($n = 252$), while the control arm's mean was ($n = 225$) and the facilitator-led arm's mean was ($n = 150$). The proportion of patients who were under the age of 21 was the greatest in the facilitator-led arm at 82.8% with the lunch-and-learn arm being significantly different at 74.6%. The facilitator-led arm also had the lowest proportion of African-American patients at 46.5%

Table 1. Baseline data for the 30 practices recruited for the study.

ID	Pre #Patients	Post #Patients	Female	African American	Caucasian	Hispanic	Under 21
Facilitator-led practices							
P1	153	186	35.4%	78.2%	14.4%	7.0%	98.3%
P2	131	160	41.8%	9.8%	86.4%	3.3%	92.9%
P3	272	292	41.2%	26.4%	71.4%	15.1%	97.3%
P4	25	30	60.0%	17.8%	80.0%	2.2%	57.8%
P5	89	98	55.3%	52.7%	42.7%	5.3%	66.7%
P6	221	208	46.6%	53.0%	36.2%	11.4%	95.0%
P7	101	91	64.0%	74.0%	16.8%	6.4%	59.2%
P8	175	186	36.6%	63.4%	34.8%	6.3%	97.3%
P9	220	274	38.8%	35.7%	59.1%	5.5%	96.5%
P10	116	133	58.0%	53.7%	41.4%	3.1%	67.3%
Average	150	166	47.8%	46.5%	48.3%	6.6%	82.8%
Total	1503	1658					
Lunch-And-Learn							
P11	716	707	41.8%	40.0%	58.5%	2.6%	97.0%
P12	329	371	43.6%	67.3%	22.0%	16.0%	95.9%
P13	75	81	55.2%	23.8%	75.2%	2.9%	53.3%
P14	61	60	55.2%	44.8%	51.7%	11.5%	59.8%
P15	78	93	67.2%	56.6%	37.7%	11.5%	34.4%
P16	298	326	52.4%	67.8%	26.8%	3.6%	71.1%
P17	106	63	37.4%	64.5%	15.9%	17.8%	93.5%
P18	52	61	72.0%	82.9%	14.6%	1.2%	45.1%
P19	47	55	40.3%	52.2%	40.3%	1.5%	100.0%
P20	761	796	39.3%	62.6%	24.1%	18.2%	95.6%
Average	252	261	50.4%	56.2%	36.7%	8.7%	74.6%
Total	2523	2613					
Control							
P21	163	169	44.1%	61.6%	29.9%	11.8%	94.8%
P22	361	369	42.8%	63.8%	26.1%	17.4%	93.6%
P23	98	101	36.1%	50.8%	40.2%	4.1%	95.1%
P24	144	138	39.9%	34.4%	60.1%	12.6%	98.4%
P25	831	810	39.2%	68.4%	20.7%	14.9%	95.3%
P26	80	104	69.0%	71.0%	26.9%	0.7%	0.0%
P27	373	348	41.7%	72.4%	12.2%	14.1%	100.0%
P28	54	59	51.9%	84.4%	15.6%	0.0%	48.1%
P29	57	68	48.3%	55.1%	36.0%	5.6%	93.3%
P30	87	107	43.8%	32.1%	54.7%	29.2%	99.3%
Average	225	227	45.7%	59.4%	32.2%	11.0%	81.8%
Total	2248	2273					

Table 2. Final Survey results for the facilitator-led and “lunch and learn” dissemination arms. The survey asked “Who made the decision in your meeting with the care team (health coach and provider) about what your asthma treatment would be?”

	Facilitator-led N = 705	Lunch-and-Learn N = 523	p-value
Question Answer: 1–5	Percent of Surveys (95% CI)		
The provider alone made the decision	4.8 (3.2–6.4)	7.6 (5.6–9.6)	0.08
The provider mostly made the decision, and I played a small role in the decision-making	12.2 (9.8–14.6)	15.1 (12.5–17.7)	0.15
The provider and I participated equally in making the decision	74.9 (71.7–78.1)	66.3 (62.8–69.8)	0.001
I mostly made the decision, and the provider played a small role in the decision-making	4.3 (2.8–5.8)	5.0 (3.4–6.6)	0.56
I alone made the decision	3.8 (2.4–5.2)	5.9 (4.2–7.6)	0.10

whereas the other two arms were majority African-American.

Outcomes

For the primary outcome, survey collection commenced three months after the first presentation for the lunch-and-learn and after the facilitator-led practices completed their 12-week rollout. Practices were requested to collect a minimum of 50 surveys from

patients regardless of whether they had Medicaid insurance coverage. More than one survey could have been completed by the same asthma patient during the period of study. Therefore, the number of surveys could exceed the number of Medicaid patients with asthma. For pediatric patients, a caregiver would have mostly likely have filled out the survey. A total of 1,228 anonymous surveys were collected; 705 surveys were collected from the facilitator-led practices and 523 surveys were collected from the lunch-and-learn

Table 3. Within arm comparison of exacerbation outcomes for patients with asthma.

Study Arm (N = Patients)	Baseline – 12 months %(Patients)	Post-Randomization – 12 months ^a %(Patients)	Absolute	Relative	p-value
Patients with ED visits					
Facilitator-led (N = 1658)	9.6%	8.3%	–1.3%	–13.76%	0.21
Lunch-and-Learn (N = 2613)	14.1%	12.4%	–1.6%	–11.60%	0.09
Control (N = 2273)	12.8%	13.9%	1.1%	8.86%	0.28
Patients with Hospitalizations					
Facilitator-led (N = 1658)	1.5%	1.6%	0.1%	6.42%	0.93
Lunch-and-Learn (N = 2613)	1.1%	1.0%	–0.2%	–13.43%	0.68
Control (N = 2273)	1.7%	1.1%	–0.6%	–34.93%	0.12
Patients with Oral Steroid Prescriptions					
Facilitator-led (N = 1658)	36.6%	30.8%	–5.8%	–15.94%**	<0.001
Lunch-and-Learn (N = 2613)	38.7%	33.6%	–5.1%	–13.23%**	<0.001
Control (N = 2273)	34.0%	30.4%	–3.6%	–10.55%**	<0.001
Patients with one or more exacerbations					
Facilitator-led (N = 1658)	39.9%	32.6%	–7.3%	–18.20%**	<0.001
Lunch-and-Learn (N = 2613)	40.9%	37.0%	–3.9%	–9.53%*	<0.01
Control (N = 2273)	36.0%	32.2%	–3.8%	–10.50%*	<0.01

* $p < 0.01$, ** $p < 0.001$.

^aThis 12-month data collection period begins 6 months after the randomization date which coincides with the end of data collection time period 18 months post randomization.

^bPatients have either one or multiple Hospitalizations, ED Visit, or Oral Steroid Prescription with in the time period.

practices. In 74.9% (95% CI 71.7–78.1) of patient visits at facilitator-led practices, patients indicated they participated equally with the provider in making the treatment decision compared to 66.3% (95% CI 62.8–69.8) of patient visits from the lunch-and-learn practices ($p = 0.001$) (Table 2).

For the secondary outcomes, data were collected from 30 practices pre-randomization and post-randomization (Table 3). Comparisons of outcomes for patients in the facilitator-led ($n = 1,658$) and lunch-and-learn ($n = 2,613$) arms respectively vs. control ($n = 2,273$) showed no significant differences for ED visits (Odds Ratio [OR] [95%CI] = 0.77[0.57–1.04]; 0.83[0.66–1.07]), hospitalizations (OR [95%CI] = 1.30 [0.59–2.89]; 1.40 [0.68–3.06]), oral steroid prescription orders (OR [95%CI] = 0.95[0.79–1.15]; 1.03[0.81–1.06]), or one or more of these exacerbation measures (OR [95%CI] = 0.91[0.75–1.10]; 0.98[0.92–1.17]; (Table 4).

Discussion

This comparative effectiveness study is the first cluster randomized design to evaluate different dissemination strategies to guide the implementation of an evidence-based asthma SDM intervention in real-world practice settings. Patient level survey results indicate that the facilitator-led intervention showed a statistically significant higher proportion of patients who shared in the treatment decision than the traditional lunch-and-learn dissemination arm, suggesting a greater level of intervention adoption at facilitator-led practices. Comparisons of health outcomes showed no significant differences between the three arms. One possible

explanation for the lack of a significant difference between arms is that concurrent to this intervention, CCNC led a state-wide asthma intervention in all practices with Medicaid patients. Overlap between interventions occurred as the CCNC workgroup incorporated some asthma education materials from the SDM toolkit. CCNC practices also had access to a facilitator to help improve management of asthma.

These asthma outcome results can be compared with previous asthma studies using the SDM toolkit. The degree to which patients perceived having shared in the decision about their treatment plan for the facilitator-led practices in this study (75%) was like the ACE Study, in which 70% of patients reported having shared equally in the treatment decision. Also in the ACE Study, children with asthma showed improvement in outcomes, but not adults [5]. The original Better Outcomes to Asthma Treatment (BOAT) Study which provided the framework for the ACE Study indicated that adult patients with poorly controlled asthma that underwent the SDM intervention showed significantly better adherence to asthma medications than patients with no intervention and had better asthma-related quality of life, fewer asthma-related medical visits, lower use of rescue medication, higher likelihood of well controlled asthma, and better lung function. This patient-level study was conducted with Kaiser Permanente under a strict clinical trial regimen [6].

A systematic review and meta-analysis of practice facilitation in primary care has shown success with using a facilitator-led approach [21]. However, other pragmatic approaches to disseminate complex interventions through different levels of practice facilitation

Table 4. Odds of exacerbation between study arms post randomization for all three arms of the study.

Study Arm (N = Patients)	Practices	Patients (%)	Adjusted Odds Ratio ^a (95% CI)	p-value
Patients with ED visits				
Facilitator-Led (N = 1658)	10	137(8.3)	0.77(0.60 to 1.01)	0.09
Lunch-and-Learn (N = 2613)	10	325(12.4)	0.83(0.66 to 1.07)	0.15
Control (N = 2273)	10	317(13.9)	1.0	
Patients with Hospitalizations				
Facilitator-Led (N = 1658)	10	27(1.6)	1.3(0.59 to 2.89)	0.74
Lunch-and-Learn (N = 2613)	10	26(1.0)	1.4(0.68 to 3.06)	0.33
Control (N = 2273)	10	25(1.1)	1.0	
Patients with Oral Steroid Prescriptions				
Facilitator-Led (N = 1658)	10	510(30.8)	0.95(0.79 to 1.15)	0.60
Lunch-and-Learn (N = 2613)	10	996(33.6)	1.03(0.81 to 1.06)	0.75
Control (N = 2273)	10	629(30.4)	1.0	
Patients with One or More exacerbations				
Facilitator-Led (N = 1658)	10	540(32.9)	0.91(0.75 to 1.10)	0.34
Lunch-and-Learn (N = 2613)	10	966(39.1)	0.98(0.92 to 1.17)	0.85
Control (N = 2273)	10	733(32.0)	1.0	

* $p < 0.01$, ** $p < 0.001$.

^aModels adjusted for proportion of patients for a 12-month data collection period beginning 6 months after the randomization date which coincides with the end of data collection time period 18 months post randomization.

have shown mixed results. In one study of chronic care model implementation, continuous quality improvement and reflective adaption resulted in improved outcomes for all arms [30], while another stepped wedge study disseminating a chronic care model for diabetes and COPD indicated mixed results that were difficult to distinguish from concurrent initiatives [31]. A consistent result across many of these studies, including the ADAPT-NC Study, showed that patient perceptions of improved decision-making outcomes associated with the intervention were statistically significant however, significant improvements in disease outcomes between arms were harder to detect. These findings indicate that further research is needed to assess the effects of SDM on disease outcomes.

Since the facilitator-led dissemination occurred in real-world practice settings, the research team could assess which aspects of the intervention worked better than others. The participatory approach used in the study allowed the team to tailor the intervention to each practice depending on the number of providers and staff who were interested in working with the research team. While practice facilitation interventions may increase time and intensity, they add value by building relationships, improving communication, fostering change, and sharing resources [32]. Practice facilitators partner with their practices to help them introduce and sustain organizational change, thereby addressing the challenges associated with implementing evidence-based guidelines into practice, a skill many practices struggle to achieve independently [31].

Common obstacles to implementation included practice staff turnover and lengthy distances for practice facilitators to travel to some of their practices. Since the facilitator-led intervention resulted in working with practices over an 18-month period, providers

and staffing changes were expected. As part of the study, it was necessary to keep in constant contact with the practices involved in the study to make sure there was continuity of the overall study. Some practices were better able to maintain broad sustainability of the project. In general, sustainability of the intervention during the study depended on the level of engagement and overall size of the practice. Larger practices had more flexibility to include the intervention into their overall practice flow, whereas smaller practices were challenged with lack of practice staff and only one or two providers. Other challenges included communication. Reaching busy providers by phone and email was not easy, nor was finding common meeting times for key personnel and their practice facilitator.

Limitations

This was a pragmatic, real-world implementation study at the practice level that did not allow for individual patient results to be evaluated. Outcome measures summarized at the practice level were only collected from Medicaid patients who were attributed to each practice, so the results do not represent the care of non-Medicaid asthma patients in the practice. Due to practice and patient changes during the study, some practices were included in the analysis despite the number of patients dropping to less than 75 during the reporting periods.

Since severity of exacerbations and existing medications prescribed could not be verified by clinical chart review, we do not know the severity of the exacerbations except that the ED or inpatient visit was associated with an asthma diagnosis. While the oral steroid prescription was also associated with an asthma

diagnosis, it is still possible that asthma was not the primary reason for the visit or prescription.

While summarized outcomes data were only available for Medicaid patients in the practice, the surveys were given to patients regardless of insurance status who attended the practices for asthma related visits. Since the total number of asthma patients and visits at each practice are unknown, the proportion of asthma patients completing surveys and assessed for asthma exacerbations could not be calculated. Because the survey responses were anonymous, and we used convenience sampling at each practice, the survey response rate could not be calculated. To reduce unintended intervention exposure to control (no intervention) practices, surveys were only collected from facilitator-led and lunch-and-learn practices. Recruitment and selection bias may exist since patients who completed the survey may not have been a representative sample of all the patients in the practice as they were selected by practice staff as candidates for the SDM intervention. The patient reported outcomes may suffer from selection and detection bias due to non-blinded convenience sampling; however, the clinical outcomes were determined using routinely collected data and should be free of such bias due to randomization.

Because of a billing code change from ICD-9 to ICD-10 midway through the study, the number of asthma patients counted before and after the code change could have resulted in different patient counts that were not consistent across all three arms due to differing code change uptake and interpretations across practices.

We did not plan to control for practice size as part of the analysis [27], but the average practice size for the lunch-and-learn and control were significantly larger than the facilitator-led. The small sample size of the study did not allow sufficient power to include additional confounding variables. Stratifying by practice size before randomization would have allowed us to normalize for practice size.

Generalizability is likely limited to Medicaid populations and practices serving large Medicaid populations. The ADAPT-NC study compared outcomes at the practice level; therefore, patient level outcomes could not be analyzed. Additionally, in contrast to a previous study where we had patient-level data [5], this study could not distinguish outcomes based on age (pediatric or adults).

Conclusion

The facilitator-led dissemination was associated with a significantly higher proportion of patients sharing

equally in the decision-making with the provider during an asthma visit when compared to a traditional lunch-and-learn approach. While there was no significant difference in exacerbation outcomes between the three arms, the results were most likely confounded by a concurrent statewide asthma initiative by the state Medicaid network and the pragmatic implementation of the intervention. These results offer support for the use of structured approaches such as facilitator-led dissemination of complex interventions into primary care practices.

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Conflicts of interest

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

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ORCID

Kelly Reeves  <http://orcid.org/0000-0003-0729-2192>
Yhenneko J. Taylor  <http://orcid.org/0000-0002-5336-5666>

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