Shared Treatment Decision Making Improves Adherence and Outcomes in Poorly Controlled Asthma

Sandra R. Wilson[1], Peg Strub[2], A. Sonia Buist[3], Sarah B. Knowles[1], Philip W. Lavori[4], Jodi Lapidus[3], William M. Vollmer[5], and the Better Outcomes of Asthma Treatment (BOAT) Study Group*

[1]Palo Alto Medical Foundation Research Institute, Palo Alto, California; [2]The Permanente Medical Group, San Francisco, California; [3]Oregon Health and Science University, Portland, Oregon; [4]Stanford University School of Medicine, Stanford, California; and [5]The Kaiser Permanente Center for Health Research, Portland, Oregon

***Rationale*: Poor adherence to asthma controller medications results in poor treatment outcomes.**

***Objectives*: To compare controller medication adherence and clinical outcomes in 612 adults with poorly controlled asthma randomized to one of two different treatment decision-making models or to usual care.**

***Methods*: In shared decision making (SDM), nonphysician clinicians and patients negotiated a treatment regimen that accommodated patient goals and preferences. In clinician decision making, treatment was prescribed without specifically eliciting patient goals/preferences. The otherwise identical intervention protocols both provided asthma education and involved two in-person and three brief phone encounters.**

***Measurements and Main Results*: Refill adherence was measured using continuous medication acquisition (CMA) indices—the total days' supply acquired per year divided by 365 days. Cumulative controller medication dose was measured in beclomethasone canister equivalents. In follow-up Year 1, compared with usual care, SDM resulted in: significantly better controller adherence (CMA, 0.67 vs. 0.46; $P < 0.0001$) and long-acting β-agonist adherence (CMA, 0.51 vs. 0.40; $P = 0.0225$); higher cumulative controller medication dose (canister equivalent, 10.9 vs. 5.2; $P < 0.0001$); significantly better clinical outcomes (asthma-related quality of life, health care use, rescue medication use, asthma control, and lung function). In Year 2, compared with usual care, SDM resulted in significantly lower rescue medication use, the sole clinical outcome available for that year. Compared with clinician decision making, SDM resulted in: significantly better controller adherence (CMA, 0.67 vs. 0.59; $P = 0.03$) and long-acting β-agonist adherence (CMA, 0.51 vs. 0.41; $P = 0.0143$); higher cumulative controller dose (CMA, 10.9 vs. 9.1; $P = 0.005$); and quantitatively, but not significantly, better outcomes on all clinical measures.**

***Conclusions*: Negotiating patients' treatment decisions significantly improves adherence to asthma pharmacotherapy and clinical outcomes.**

Clinical trials registered with www.clinicaltrials.gov (NCT00217945 and NCT00149526).

Keywords: randomized controlled trial; asthma control; patient–clinician communication

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

The effects of shared patient–clinician decision making regarding asthma care on treatment decisions, treatment adherence, and asthma-related clinical outcomes have not been experimentally evaluated.

What This Study Adds to the Field

In a randomized controlled trial, patients with poorly controlled asthma who shared in making decisions about their treatment showed significantly better adherence to asthma controller medications and to long-acting β-agonists than patients who participated in either of two control conditions. As a result of both their medication choices and better adherence, patients with shared decision-making (SDM) received a higher cumulative dose of anti-inflammatory medication over a 1-year period. Compared to usual care, SDM was also associated with significantly 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.

Among patients with asthma, and others with chronic conditions that require pharmacotherapy, only about half take their medications at therapeutically effective doses (1, 2). Estimated nonadherence rates for asthma controller medications range from 30 to 70% (3–6), including in patients with so-called difficult asthma who might appear to require treatment with still more potent medications (7). Poor adherence exacerbates airway inflammation, and may result in suboptimal asthma control, functional limitations, decreased quality of life, excess health care use, and even death (8, 9).

A recent *Cochrane Review* (12) of adherence studies, including those that appeared to demonstrate improved adherence to some types of medications (e.g., antihypertensives) (10, 11), found serious methodologic problems, thereby limiting any conclusions regarding intervention efficacy. Furthermore, none of the included studies focused on asthma medication adherence. Consequently, there is a general lack of evidence of effective adherence interventions targeting adults with asthma, and specifically, poorly controlled asthma.

Observational studies suggest that failure to elicit and address patients' individual circumstances and goals/preferences regarding their regimen may contribute to treatment nonadherence (13). Asthma treatment guidelines recommend that clinicians consider patients' treatment goals, but little is known about clinician adherence to these recommendations or the effects of their doing so (8).

Charles and colleagues (14, 15) hypothesized that a shared treatment decision-making (SDM) process, in which the patient

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* A complete list of members may be found at the end of the article.

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Correspondence and requests for reprints should be addressed to Sandra R. Wilson, Ph.D., Palo Alto Medical Foundation Research Institute, 795 El Camino Real, Ames Building, Palo Alto, CA 94301. E-mail: wilsons@pamfri.org

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has actively participated, will result in a greater commitment and adherence to the selected regimen than to a regimen selected by the physician alone. The authors described four key defining features of the SDM model, namely, that both clinician and patient: (*1*) share relevant information; (*2*) express treatment preferences; (*3*) deliberate the options; and (*4*) agree on the treatment to implement.

There is a paucity of strong evidence from appropriately controlled trials that supports the inference from observational studies that SDM regarding treatment of a chronic disease (in which self-management is essential) actually results in patients accepting and adhering to the regimen and improves both treatment adherence and disease outcomes (16, 17). Although a recent review of SDM by Joosten and colleagues (18) identified 11 randomized controlled trials that met at least one of Charles and colleagues' criteria, none concerned asthma, and nearly half involved a one-time treatment decision, rather than decisions typical of chronic disease management. Furthermore, only one included medication adherence as an outcome, and none investigated clinical outcomes, other than a limited measure of patient well being. Although Joosten and colleagues noted the potential effectiveness of the SDM process, they recommended additional research that should include multiple clinical outcomes.

Better Outcomes of Asthma Treatment (BOAT) was a three-arm, multisite, randomized, controlled trial in 612 patients with poorly controlled asthma. The two experimental intervention arms were designed in the context of asthma care management, which refers to a period of targeted review of asthma treatment and control and asthma self-management education by a nonphysician health professional. The primary hypothesis was that patients with poorly controlled asthma who received care management using an SDM approach would exhibit greater adherence to controller medications, better asthma-related quality of life, and lower health care utilization for acute symptoms than patients who received usual care (no asthma care management). A contingent secondary hypothesis was that, given a demonstrated benefit over usual care, patients who participated in SDM would demonstrate better outcomes than patients who received the identical care management, except that treatment was determined by the care manager and physician alone (clinician decision making [CDM]). Secondary clinical outcomes included short-acting β-agonist (SABA) use, lung function, and asthma control.

Some results presented here have been previously reported in the form of abstracts based on preliminary results (19–23).

METHODS

The study has been approved annually by the institutional review boards of the Kaiser Foundation Research Institute in Oakland, California, and of the Kaiser Permanente (KP) Center for Health Research in Portland, Oregon, and Honolulu, Hawaii. Substantial additional information about the study methods and timeline are available in the online supplement.

Patient Recruitment and Eligibility Criteria

The target population was patients whose asthma was not well controlled, and whose adherence to their asthma regimen was likely to be inadequate. KP members, aged 18–70 years, with evidence suggestive of poorly controlled asthma, were identified at five clinical sites using computerized records of overuse of rescue medications (a controller/[controller + rescue medication] ratio $\leq$0.5 and at least three β-agonist dispensings in the past year) or a recent asthma-related emergency department (ED) visit or hospitalization. Exclusion criteria included intermittent asthma (brief exacerbations or symptoms less than once/wk), primary diagnosis of chronic obstructive pulmonary disease or emphysema, insufficient pulmonary function reversibility (for ex-/current smokers and those without regular controller use), regular use of oral corticosteroids, and current asthma care management.

Spirometry. Spirometry was performed at enrollment using standardized research methods (24) and equipment that met American Thoracic Society standards.

Randomization

A computer-based adaptive randomization algorithm (25) was used to ensure concealment from randomization staff and better-than-chance balance among the three groups on age (18–34, 35–50, and 51–70 yr), sex, race/ethnicity, hospitalization in the prior two years (yes/no), and frequency of asthma controller use in the past week (none, 1–3, $\geq$4 d).

Intervention Protocol

The SDM and CDM interventions were identical in format, content, and all patient education handouts and worksheets, except for the process by which treatment was decided.

Format. Session 1 of the intervention is outlined in Figure 1, highlighting the unique features of the SDM and CDM protocols. In session 2 ($\sim$1 mo after session 1), and in three brief phone calls 3, 6, and 9 months later, patient progress was assessed and medications were adjusted, as necessary, using the assigned care management approach. Except as noted subsequently here, both protocols used identical standardized interventionist scripts and materials.

The patient's asthma history was elicited using a standardized patient information form, the patient's level of asthma control was classified, and asthma education was provided. Once treatment was negotiated (SDM) or decided (CDM), patients were instructed in the correct use of the relevant inhaler medication devices using methods previously shown by this team to improve inhaler technique and eliminate common usage errors (26, 27). At the end of session 1, a written asthma management and action plan was created, and potential barriers to medication adherence were elicited and addressed using motivational interviewing techniques (28). Any subsequent changes made at session 2 or in a follow-up phone call were documented in the plan.

Treatment decision process. In the CDM model, the care manager prescribed an appropriate regimen based on the patient's level of asthma control, and explained that decision to the patient. The SDM model implemented the four key defining features described by Charles and colleagues (14, 15). The care manager elicited the patient's goals for treatment and relative priorities regarding symptom control, regimen convenience, avoidance of side effects, and cost. The patient was then shown a list of the full range of regimen options for all levels of asthma severity, based on the then-current national asthma guidelines (29) and KP pharmacopeia. These options differed with respect to the number and type(s) of medications, dosing, and schedule. Using a simple worksheet, the patient and clinician then compared the pros and cons of all of the options the patient wished to consider, which included the option of continuing the patient's current *de facto* regimen (i.e., how they were using their current asthma medications) to arrive at a treatment that best accommodated the patient's and care manager's goals.

For both groups, a SABA was always prescribed for rescue use as needed. If indicated, treatment of allergic rhinitis and/or gastroesophageal reflux disease was prescribed (CDM) or negotiated (SDM).

Care Manager Training and Intervention Quality Control

A total of 16 KP nurses, respiratory therapists, and pharmacists, as well as nurse practitioners and physician assistants, most of whom already served as asthma care managers, were recruited to serve as study care managers and assigned to the SDM or CDM program. SDM and CDM care managers were trained separately and worked independently.

For quality control purposes, audiotapes of both sessions of 10% of the patients were scored on a detailed performance checklist to determine whether the two protocols were delivered as intended. In addition, patients were given a stamped postcard to return to the research office after session 1 to report their perceived role in the treatment decision.

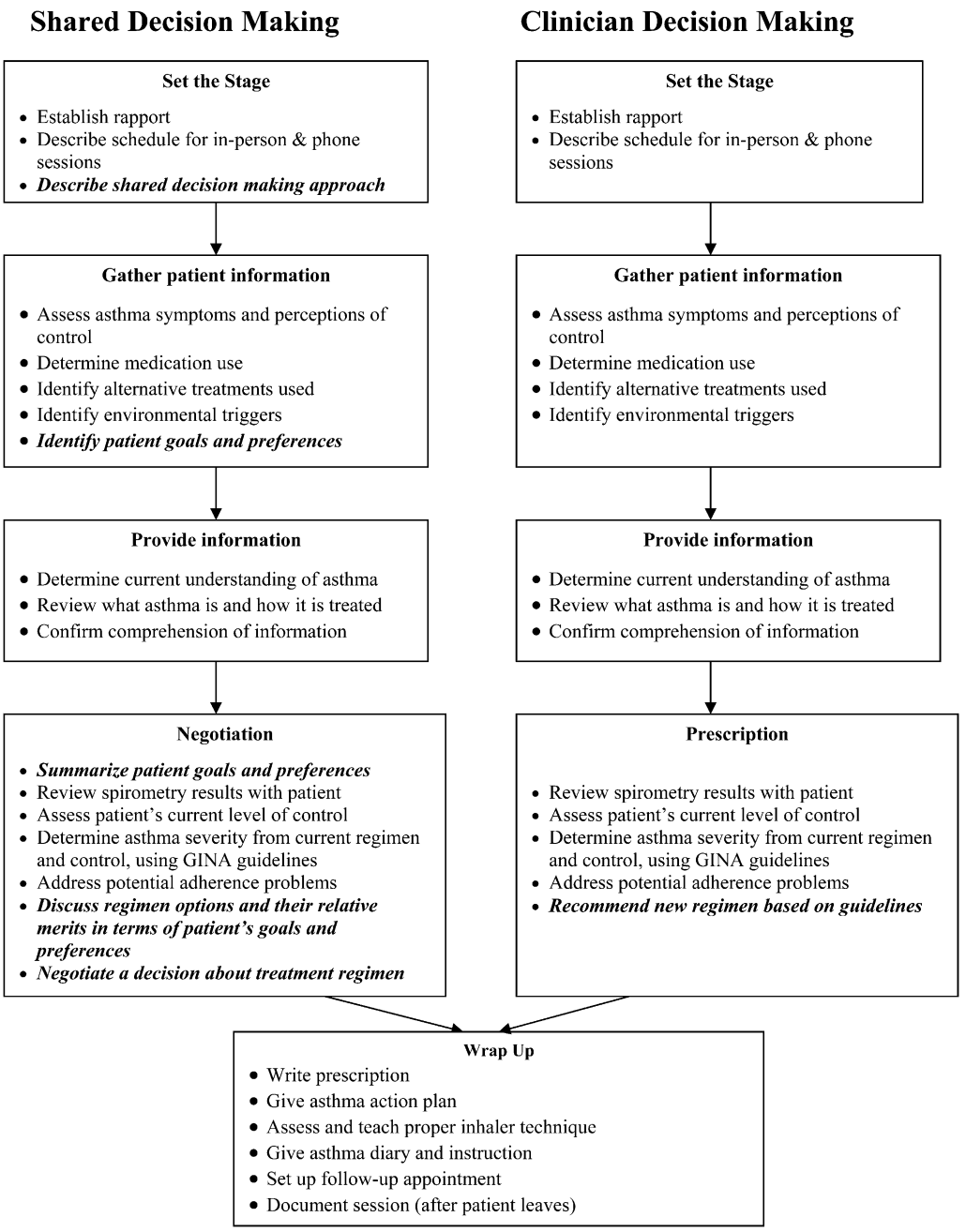

Figure 1. Outline of intervention protocols, with unique features of each highlighted.

Coordination with Patient's Physician

Care managers documented each encounter in the patient's chart, where it also was available to the patient's physician. The care managers discussed their recommendations with the physician if they or the physician had any questions about the new regimen. For care managers who were not licensed to prescribe, the physician reviewed and wrote the prescription.

Usual Care Control Condition

Usual asthma care at KP medical centers was based on a stepped-care approach to pharmacotherapy with the aim of long-term asthma control, as recommended by the National Asthma Education Prevention Program's *Expert Panel Report 2* (29). At some KP sites, physicians also had the option to refer patients to an asthma care management program, typically of less than 6 months' duration, in which a licensed health professional (nonphysician) provided asthma education and addressed adherence and other medication use and self-management issues in a manner similar to, but less structured than, the CDM intervention. However, asthma care management was neither a required aspect of usual care nor necessarily available at all BOAT sites, and current participation in that program was an exclusion criterion for the study. Once enrolled in BOAT, usual care and SDM or CDM patients (after the intervention phase) still had access to KP's existing care management services, if available, based on their physician's referral.

Outcome Data

Pharmacy data. Medication acquisition data were extracted from KP dispensing records for 1 year prerandomization and 2 years postrandomization. Fill/refill adherence was measured using a continuous medication acquisition (CMA) index for each year, calculated as the total days' supply acquired in a given year divided by 365 days (30–32). The index represents the proportion of the prescribed medication supply acquired by the patient during each 365-day period, and may potentially overestimate, but not underestimate, actual use.

Acquisition indices were calculated separately for: (*1*) all asthma controllers (inhaled corticosteroids [ICS], leukotriene modifiers, cro-

molyn sodium, and theophylline); (*2*) for ICS alone; and (*3*) for long-acting β-agonists (LABAs). Combination ICS-LABA medications (i.e., fluticasone-salmeterol) contributed to both the ICS and LABA index calculations.

A second pharmacy measure, beclomethasone diproprionate canister equivalents, was the estimated total number of canisters of beclomethasone to which the asthma controller medications dispensed in a given year were equivalent (i.e., equipotent in terms of their anti-inflammatory effectiveness). Per the method of Schatz and colleagues (33), each dispensing of a controller medication (excluding theophylline), in any form or quantity, was assigned a weight representing its equivalent in fractional or multiple canisters of beclomethasone 80 μg. The weighted values were summed for each patient for each 365-day period to obtain a cumulative measure of controller medication dose dispensed.

A third pharmacy measure—a clinical outcome—used a separate set of weights to standardize the amounts of all SABAs dispensed in terms of their bronchodilator effectiveness in canisters of albuterol, regardless of SABA type and delivery mode. The weights were summed to obtain the total number of albuterol canister equivalents acquired by the patient in each study year.

Other outcomes. The primary clinical outcomes were asthma-related quality of life and asthma health care utilization. Asthma-related quality of life for the prior 2 weeks was assessed by patient self-report at baseline and follow-up Year 1, using the five-item Symptom Subscale of the Juniper Mini Asthma Quality of Life Questionnaire (34).

Health care utilization data included the date, diagnoses, facility, and service (ED, hospital in-patient, urgent care, or out-patient department) of all visits to KP or contracted facility, including visits with *International Classification of Diseases, Ninth Revision* code prefix 493. These data were extracted from KP databases for 1 year prerandomization and 1 year postrandomization to calculate the annual asthma-related visit rate for each patient. BOAT intervention sessions were not included in these rates.

In addition to SABA use (*see above*), secondary clinical outcomes included self-reported asthma control and lung function measured at baseline and follow-up Year 1. Asthma control in the preceding 4 weeks was assessed using the four-item Asthma Therapy Assessment Questionnaire (ATAQ) (35). Lung function measures included FEV_1 expressed as percent of the predicted value based on age-, sex-, and race-specific norms (36), and the ratio of FEV_1 to FEV_6, expressed as a percentage.

Statistical Analysis

For each outcome, the primary hypothesis was that patients who participated in SDM would demonstrate a significant advantage relative to patients under usual care. The statistical significance of the secondary hypothesis, that SDM would demonstrate an advantage over CDM, was considered only if the primary null hypothesis was rejected. Given the conditional sequence of the hypotheses, no adjustment for multiple comparisons was needed to preserve the type 1 error rate of the secondary comparison (SDM vs. CDM) at the α level of 0.05. Because BOAT was designed to test an SDM model, there were no *a priori* hypotheses regarding differences between the CDM and usual care groups; however, results of these comparisons are informative and are presented for completeness.

Multivariable generalized linear regression analysis was used to estimate the intervention effect on each outcome (except ATAQ) at follow up, controlling for the baseline value of that outcome, site, and the randomization balancing variables. To estimate the odds ratios of having well-controlled asthma (ATAQ score = 0) at follow-up Year 1 relative to usual care, multivariable logistic regression analysis was used. Baseline estimates, overall and by group, are presented without adjustment for any other variable. Missing data were not imputed: baseline and follow-up analyses were restricted to those patients with complete data for the analytic model variables at both time points.

The ratings scores of the care managers, patients, and quality control evaluator regarding the treatment decision process were compared using the Wilcoxon test. Group differences in patient characteristics and asthma medication regimens were tested using either χ^2 tests or *t* tests. All group differences were tested using a two-sided α of 0.05, and all analyses used SAS software version 9.2 (37).

RESULTS

Recruitment

Initially, 5,414 patients were identified as being potentially eligible (Figure 2), of whom 2,534 were contactable and provided informed consent for preliminary eligibility screening (38). The final sample size was 612 (n = 204/group): Honolulu, n = 114; Oakland/Richmond, n = 180; Portland, n = 196; and San Francisco, n = 122. At the Year 1 follow-up clinic visit, 551 patients completed the patient assessment and lung function tests. Baseline and follow-up pharmacy and utilization data were extracted for all patients from existing clinical/administrative records.

Baseline Characteristics

As intended by the selection procedures and eligibility criteria, the sample consisted primarily of persons whose asthma, at baseline, was poorly or very poorly controlled (83.9%) (Table 1) when classified based on symptoms, rescue medication use, and lung function per guidelines of the Global Initiative for Asthma (39).

Intervention Process

Length and quality. Session 1 lasted an average of 77 (±17) minutes for the CDM group and 106 (±22) minutes for the SDM group. Session 2 averaged 31 (±18) minutes and 32 (±19) minutes, respectively. The follow-up phone contacts together averaged 30 (±25) minutes per patient for the CDM group and 35 (±25) minutes per patient for the SDM group. Intervention fidelity was high (*see* the online supplement).

Intervention cost estimate. Using KP salary guidelines, an average $54 per-hour rate for care manager salary and benefits (~$112,000/yr) was assumed and applied to the average length of the intervention sessions and follow-up telephone contacts, plus an average estimated 20 minutes additional time per patient for documentation and visit reminders. The estimated cost per patient treated was $174 using the SDM model (~3.2 h) and $142 using the CDM model (~2.6 h), a cost difference of $32.

Treatment decisions. At the conclusion of session 1, there were no differences in the proportions of the SDM and CDM groups whose regimen included an ICS or who were prescribed a LABA or allergic rhinitis medication (Table 2). However, for about 13% more SDM patients than CDM patients, the decision process resulted in selection of a higher dose fluticasone propionate preparation (220 μg) rather than the higher strength beclomethasone dipropionate (80 μg), KP's formulary-preferred ICS, or than the lower-dose fluticasone propionate preparation (110 μg).

Medication Acquisition

Controller use. During the prerandomization year, approximately 18% of patients did not acquire any controller medication, and overall adherence, per CMA values, was very poor. In follow-up Year 1, the adjusted mean acquisition index for all controller medications was significantly higher in the SDM group (CMA, 0.67) compared with both the usual care (CMA, 0.46; $P < 0.0001$) and CDM groups (CMA, 0.59; $P = 0.029$) (Figure 3A), and also significantly higher in the CDM than in the usual care group (0.59 vs. 0.46; $P = 0.0008$). Similarly, in follow-up Year 1, the adjusted mean index for ICS alone was significantly higher in the SDM group (CMA, 0.59) than in both the usual care (CMA, 0.37; $P < 0.0001$) and CDM groups (CMA, 0.52; $P = 0.017$), and significantly higher in the CDM than in the usual care group (0.52 vs. 0.37; $P < 0.0001$).

In follow-up Year 2, the SDM group's adjusted mean CMA indices for all controllers, and for ICS separately, remained

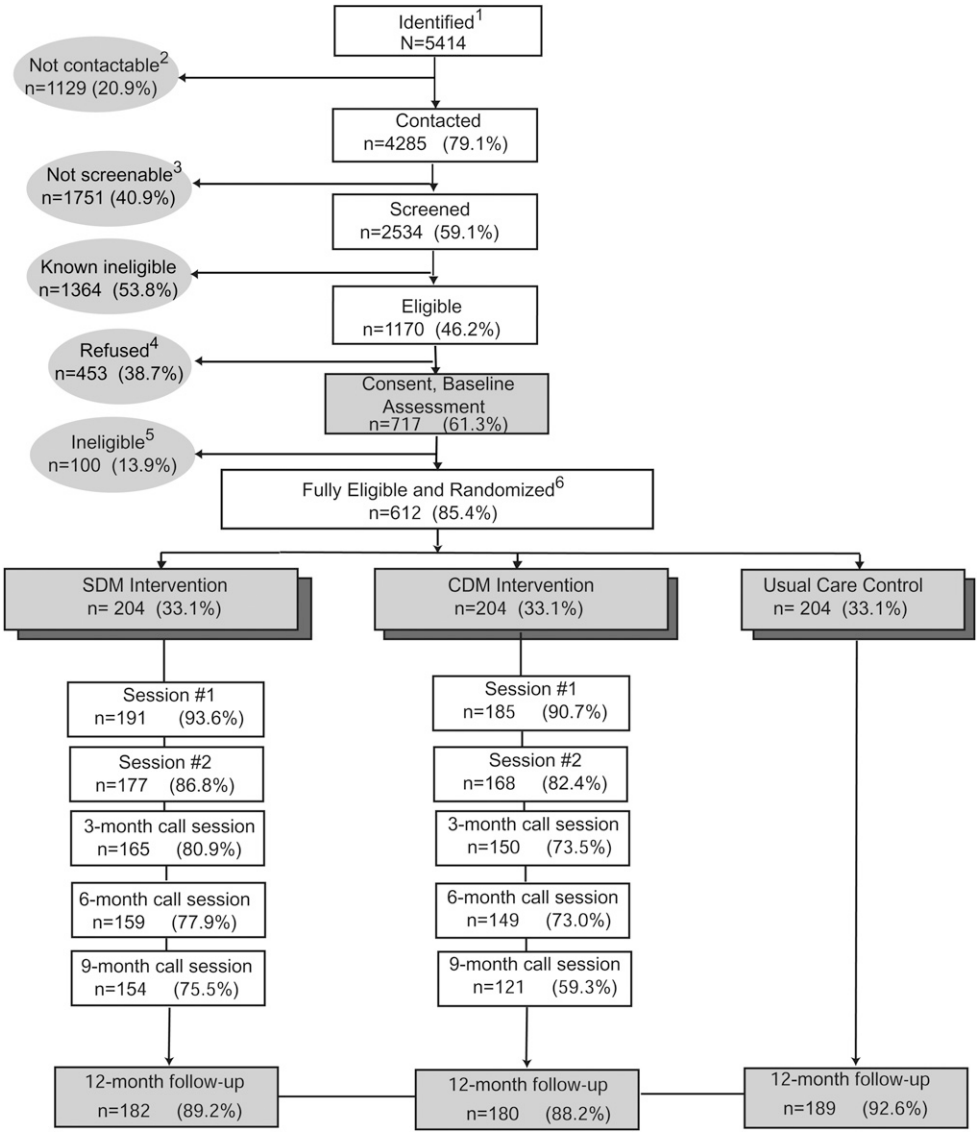

Figure 2. Case progress through the Better Outcomes of Asthma Treatment (BOAT) study: identification, eligibility determination, initial assessment, randomization, intervention, and follow up. [1]Patients were identified as potentially eligible based on their recent hospitalization or emergency department visit and a medication ratio of ± 0.50, indicating an overuse of rescue medication. [2]Not contactable includes patients whose primary care physicians (PCPs) were not notified, PCP did not respond, PCP did not assent, letters were not sent/received, or calls were not successfully completed. [3]Nonscreenable patients were not screened for multiple reasons, including disinterest in participating in the study. [4]Includes persons who passively refused by failing to keep two or more enrollment appointments. [5]Reasons for ineligibility include failure to meet spirometry criterion and other psychosocial and medical prerandomization exclusion criteria (e.g., drug rehabilitation or currently receiving asthma care management, etc.). [6]Excludes five postrandomization exclusions for previously undiscovered bahavioral/mental health problems: shared decision making (SDM), $n = 1$; clinician decision making (CDM), $n = 4$.

higher than at baseline, but were no longer significantly higher than the usual care or CDM groups' values (Figure 3A).

Controller regimen anti-inflammatory potency. In follow-up Year 1, the SDM group acquired more than twice as many beclomethasone canister equivalents than the usual care group (10.9 vs. 5.2; $P < 0.0001$), and also significantly more than the CDM group (10.9 vs. 9.1; $P = 0.005$; Figure 3B). The difference between CDM and usual care was also significant (9.1 vs. 5.2; $P < 0.0001$). In follow-up Year 2, the adjusted mean canister equivalents acquired by the SDM group remained greater than its baseline value (7.1 vs. 4.9), and continued to be significantly greater than those of the usual care (mean, 4.6; $P = 0.0002$) and CDM groups (mean, 5.8; $P = 0.04$; Figure 3B). There was no longer a significant difference between CDM and usual care.

LABA use. In the prerandomization year, 22.2% of the patients acquired a LABA at least once, and 11.0% of those prescribed a LABA acquired an ICS-LABA combination. In follow-up Year 1, significantly higher proportions of both SDM and CDM patients acquired a LABA compared with usual care patients (Table 3), and among those, patients in the SDM group were more likely than those in the CDM group to acquire a combination preparation (41.1% vs. 23.2%; $P = 0.005$). Among patients whose regimen included a LABA, the adjusted mean LABA acquisition index was significantly higher in the SDM group (CMA, 0.51) than either the usual care (CMA, 0.40; $P = 0.0225$) or CDM groups (CMA, 0.41; $P = 0.0143$; Figure 3C). There was no significant difference between the CDM and usual care groups.

For those on a LABA in follow-up Year 2, the adjusted mean LABA acquisition index remained significantly higher in the SDM group (CMA, 0.52) than in either the usual care (CMA, 0.42; $P = 0.0296$) or CDM group (CMA, 0.43; $P = 0.0346$) (Figure 3C), with no significant difference between the CDM and usual care groups. Patients in the SDM group also continued to be significantly more likely to acquire a LABA at least once than patients under usual care (Table 3), and significantly more likely to be using a combination ICS-LABA preparation than patients under CDM.

Clinical Outcomes

Asthma-related quality of life. At follow-up Year 1, both the SDM (mean, 5.5) and CDM groups (mean, 5.4) had significantly higher adjusted mean symptom subscale scores than the usual care group (mean, 5.1; respective $P = 0.0003$ and 0.009), but did not differ significantly from each other (Figure 4A). Furthermore, 70.3% of the SDM group had a score increase of greater

TABLE 1. BASELINE CHARACTERISTICS OF BETTER OUTCOMES OF ASTHMA TREATMENT PARTICIPANTS, BY GROUP

Characteristics	UC	CDM	SDM
Demographic characteristics			
Mean age, years*	45.1 ± 12.4	46.9 ± 12.1	45.7 ± 13.3
Sex*			
Female	117 (57.4)	114 (55.9)	115 (56.4)
Male	87 (42.6)	90 (44.1)	89 (43.6)
Ethnicity*			
Caucasian	127 (62.3)	124 (60.8)	128 (62.8)
African American	30 (14.7)	34 (16.7)	32 (15.7)
Asian	22 (10.8)	18 (8.8)	20 (9.8)
Hispanic	8 (3.9)	9 (4.4)	9 (4.4)
Pacific Islander	17 (8.3)	16 (7.8)	15 (7.4)
American Indian	0 (0.0)	3 (1.5)	0 (0.0)
Education			
Less than high school diploma	6 (2.9)	2 (1.0)	6 (2.9)
High school diploma/some college	116 (56.9)	132 (65.0)	114 (55.9)
4-yr college degree or higher education	82 (40.2)	69 (34.0)	84 (41.1)
Family income >$40,000/yr	134 (69.1)	139 (70.9)	133 (66.8)
Ever told by doctor they had COPD	11 (5.4)	14 (6.9)	4 (2.0)
Current smoker	33 (16.2)	33 (16.2)	31 (15.2)
Asthma characteristics			
Level of control			
Very poorly controlled	85 (42.1)	82 (40.2)	79 (38.7)
Poorly controlled	83 (41.1)	87 (42.7)	96 (47.1)
Moderately well controlled	29 (14.4)	24 (11.8)	17 (8.3)
Well controlled	5 (2.5)	11 (5.4)	12 (5.9)
Asthma controller medication use*			
None	50 (24.5)	43 (21.1)	42 (20.6)
1–3 d/wk	38 (18.6)	44 (21.6)	41 (20.1)
≥4 d/wk	116 (56.9)	117 (57.4)	121 (59.3)
Hospitalized for asthma in past 2 yr*	76 (37.3)	69 (33.8)	71 (34.8)
Daytime symptom frequency			
<1/wk	11 (5.4)	12 (5.9)	14 (6.9)
≥1/wk but <daily	111 (54.4)	114 (55.9)	101 (49.5)
Daily	82 (40.2)	78 (38.2)	89 (43.6)
Nocturnal symptoms			
≤2×/mo	113 (55.4)	116 (56.9)	114 (55.9)
>2×/mo but <5×/mo	22 (10.8)	24 (11.8)	29 (14.2)
≥5×/mo	69 (33.8)	64 (31.4)	61 (29.9)
FEV_1 % predicted			
>80%	76 (37.6)	79 (38.7)	70 (34.3)
60–80%	62 (30.7)	65 (31.9)	78 (38.2)
<60%	64 (31.7)	60 (29.4)	56 (27.5)

Definition of abbreviations: CDM = clinician decision making; COPD = chronic obstructive pulmonary disease; SDM = shared decision making; UC = usual care.
Values are expressed as *n* (%) or mean (±SD), *n* = 204 per group.
* Randomization balancing variable.

TABLE 2. PRESCRIBED MEDICATIONS AT THE END OF SESSION 1, BY GROUP

Medication	CDM* *n* (%)	SDM* *n* (%)	*P* Value
Any controller†	181 (97.8)	186 (97.4)	1.0‡
Any ICS	178 (96.2)	181 (94.8)	0.50§
Beclomethasone 80	108 (60.7)	90 (49.7)	
Fluticasone 220‖	53 (29.8)	78 (43.1)	0.032§
Other ICS¶	17 (9.6)	13 (7.2)	
LABA**	91 (49.2)	92 (48.2)	0.84§
SABA	185 (100.0)	191 (100.0)	N/A
Allergic rhinitis medication	48 (26.0)	39 (20.4)	0.20§
GERD medication	5 (2.7)	0 (0.0)	0.028‡

Definition of abbreviations: CDM = clinician decision making; ICS = inhaled corticosteroid; GERD = gastroesophageal reflux disease; LABA = long-acting β-agonist; N/A = not applicable; SABA = short-acting β-agonist; SDM = shared decision making.
* SDM group, *n* = 191; CDM group, *n* = 185.
† Controllers include ICSs, leukotriene modifiers, and theophylline, but not LABAs. No patients in this sample were prescribed oral prednisone for daily/alternate day use.
‡ Fisher's exact test for cell sizes ≤5.
§ *P* values estimated from Pearson's χ^2.
‖ Includes flovent 220 preparations in combination with a LABA.
¶ Includes ICS-LABA combination, budesonide, aerobid, beclomethasone 40, fluticasone 110, and beclomethasone with strength unspecified (*n* = 2).
** Includes single preparations (salmeterol and folmoterol) and ICS-LABA combination preparations (fluticasone-salmeterol 100, fluticasone-salmeterol 250, and fluticasone-salmeterol 500).

than 0.50 points, compared with 55.6% of the UC group and 61.1% of the CDM group.

Health care use. During the prerandomization year, approximately 35% of patients had no asthma-related visits. In follow-up Year 1, both the SDM and CDM groups had significantly lower visit rates (1.0/yr and 1.1/yr) than the usual care group (1.4/yr; $P = 0.0161$ and 0.0147, respectively) (Figure 4B).

SABA use. In follow-up Year 1, the SDM group acquired significantly fewer albuterol canister equivalents (adjusted mean, 6.5) than the usual care group (adjusted mean, 8.1; $P = 0.002$), but not the CDM group (adjusted mean, 7.1; $P = 0.09$) (Figure 3D). The CDM group also used significantly less SABA than usual care (7.1 vs. 8.1; $P = 0.038$). In follow-up Year 2, SABA use continued to decrease for all three groups as KP instituted policies limiting the number of SABA refills that physicians could authorize per prescription. The SDM group continued to use significantly less SABA than the usual care group (4.7 vs. 6.3; $P = 0.0141$) and less than the CDM group (4.7 vs. 6.0; borderline $P = 0.06$), but with no significant difference remaining between CDM and usual care.

Asthma control. At follow-up Year 1, ATAQ scores decreased in each group (SDM $\Delta = -0.80$, CDM $\Delta = -0.54$, UC $\Delta = -0.46$), but the SDM group had nearly twice the odds of reporting no asthma control problems (ATAQ = 0) than the usual care group (odds ratio, 1.9; 95% confidence intervals [CIs], 1.3–2.9; $P = 0.002$) (Figure 4C), but not significantly greater odds than the CDM group. The CDM group also had greater odds of no control problems than the usual care group (odds ratio, 1.6; 95% CI, 1.1–2.4; $P = 0.0239$).

Lung function. At follow-up Year 1, the adjusted mean percent predicted FEV_1 for the SDM group was significantly greater than the usual care group (76.5% vs. 73.1%; $P = 0.0068$), but not the CDM group (76.5% vs. 75.8%; $P = 0.47$) (Figure 5A). The adjusted mean FEV_1:FEV_6 ratio was also significantly greater for the SDM group compared with the usual care group (72.8% vs. 70.0%; $P = 0.0005$), but not the CDM group (72.8% vs. 71.8%; $P = 0.09$) (Figure 5B). However, there was no significant difference between the CDM and usual care groups (71.8% vs. 70.0%; $P = 0.07$).

Patient-Perceived Roles in Treatment Decision Making

On the postcards mailed back after session 1, patients in the SDM group anonymously rated their influence on the treatment selection as being approximately the same as the care manager's influence (mean rating, 3.1 ± 0.6 on the five-point scale), but with neither being more influential than the other. The ratings of patients in the SDM group were significantly different from those in the CDM group, with the latter feeling that their care managers had a greater influence (mean, 2.5 ± 0.9; $P < 0.0001$) than they themselves did.

DISCUSSION

Patients who shared in decisions regarding their asthma treatment were significantly more likely to adhere to ICS and other controller therapy, and also to LABA medications, than patients

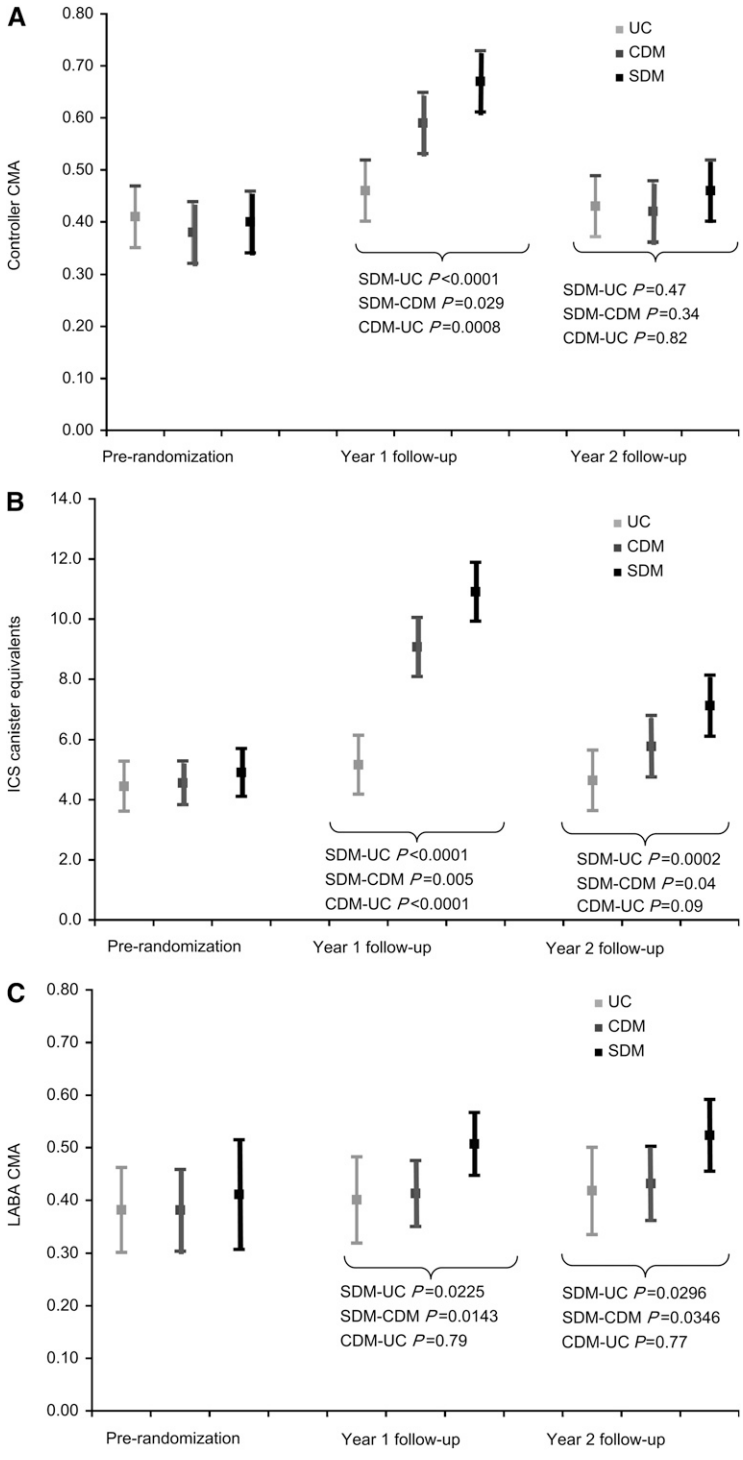

Figure 3. Group differences in pharmacy outcomes. (*A*) Group differences in controller medication acquisition for each study period. Controller medications include inhaled corticosteroids (ICS), leukotriene modifiers, and theophylline, and exclude long-acting β-agonists (LABAs) and oral prednisone. Prerandomization values are unadjusted, and follow-up values are adjusted for baseline CMA and the balancing variables. The 95% confidence intervals (CIs) are shown. Group differences and 95% CIs for controller CMA values at follow-up Year 1: shared decision making (SDM)-usual care (UC) = 0.21 (95% CI, 0.13–0.28); SDM–clinician decision making (CDM) = 0.08 (95% CI, 0.01–0.15); CDM-UC = 0.13 (95% CI, 0.05–0.20). At follow-up Year 2: SDM-UC = 0.03 (95% CI, −0.05–0.11); SDM-CDM = 0.04 (95% CI, −0.04–0.12); CDM-UC = −0.01 (95% CI, −0.09–0.07). The number of patients per group at each time point: SDM, *n* = 204; CDM, *n* = 204; UC, *n* = 204. (*B*) Group differences in ICS canister equivalents for each study period. Controller medications include inhaled corticosteroids and leukotriene modifiers, and exclude theophylline, LABAs and oral prednisone. Prerandomization values are unadjusted, and follow-up values are adjusted for baseline ICS canister equivalents and the balancing variables. The 95% CIs are shown. Group differences and 95% CIs for ICS canister equivalents at follow-up Year 1: SDM-UC = 5.8 (95% CI, 4.5–7.0); SDM-CDM = 1.8 (95% CI, 0.57–3.1); CDM-UC = 3.9 (95% CI, 2.6–5.2). At follow-up Year 2: SDM-UC = 2.5 (95% CI, 1.2–3.8); SDM-CDM = 1.4 (95% CI, 0.04–2.7); CDM-UC = 1.1 (95% CI, −0.18–2.4). The number of patients per group at prerandomization and follow-up Year 2 is: SDM, *n* = 204; CDM, *n* = 202; UC, *n* = 204; and at follow-up Year 1 is: SDM, *n* = 204; CDM, *n* = 202; UC, *n* = 203. (*C*) Group differences in LABA acquisition, among those on a LABA, for each study period. LABA medications include fluticasone-salmeterol 100, fluticasone-salmeterol 250, fluticasone-salmeterol 500, and formeterol. Prerandomization values are unadjusted and follow-up values are adjusted for baseline CMA and the balancing variables. The 95% CIs are shown. Group differences and 95% CIs for LABA CMA at follow-up Year 1: SDM-UC = 0.11 (95% CI, 0.02–0.20); SDM-CDM = 0.09 (95% CI, 0.02–0.17); CDM-UC = 0.01 (95% CI, −0.08–0.10). At follow-up Year 2: SDM-UC = 0.11 (95% CI, 0.01–0.20); SDM-CDM = 0.09 (95% CI, 0.01–0.18); CDM-UC = 0.01 (95% CI, −0.08–0.11). The number of patients per group at each time point is: prerandomization, SDM, *n* = 40; CDM, *n* = 44; UC, *n* = 52; follow-up Year 1: SDM, *n* = 112; CDM, *n* = 108; UC, *n* = 59. (*D*) Group differences in short-acting β-agonist (SABA) use for each study period. For each patient, the number of canister-equivalents is the mean of the sum of all SABAs dispensed to that patient, each weighted relative to one canister of a standard albuterol canister. Prerandomization values are unadjusted, and follow-up values are adjusted for baseline albuterol canister equivalents and the balancing variables. The 95% CIs are shown. Group differences and 95% CIs for SABA use at follow-up Year 1: SDM-UC = −1.6 (95% CI, −2.5 to −0.78); SDM-CDM = −0.73 (95% CI, −1.6 to 0.12); CDM-UC = −0.89 (95% CI, −1.7 to −0.05). At follow-up Year 2: SDM-UC = −1.2 (95% CI, −2.1 to −0.24); SDM-CDM = −0.91 (95% CI, −1.9–0.04); CDM-UC = −0.28 (95% CI, −1.2–0.67). The number of patients per group at each time point is: SDM, *n* = 204; CDM, *n* = 204; UC, *n* = 204.

who experienced either usual care or who received care management in which the clinician played the primary role in choosing the treatment regimen. By virtue of both (*1*) their greater fill/refill adherence and (*2*) the pattern of their regimen choices, patients in the SDM group also acquired a significantly higher average daily dose of asthma controller medication (a larger number of beclomethasone canister equivalents) than either patients under usual care or active control patients. Additionally, patients who shared in making treatment decisions had significantly better clinical outcomes on all six measures—asthma-related quality of life, asthma health care utilization, use of rescue medication, lung function, and the likelihood of well-controlled asthma—compared with those receiving usual care. Although the SDM approach, and the behavioral and regimen changes it induced, were not associated with significantly better clinical outcomes compared with the CDM approach, the differences were consistently in a direction favoring SDM on both objectively measured and patient-reported outcomes. Furthermore, the clinician decision model only resulted in significantly better clinical outcomes compared with usual

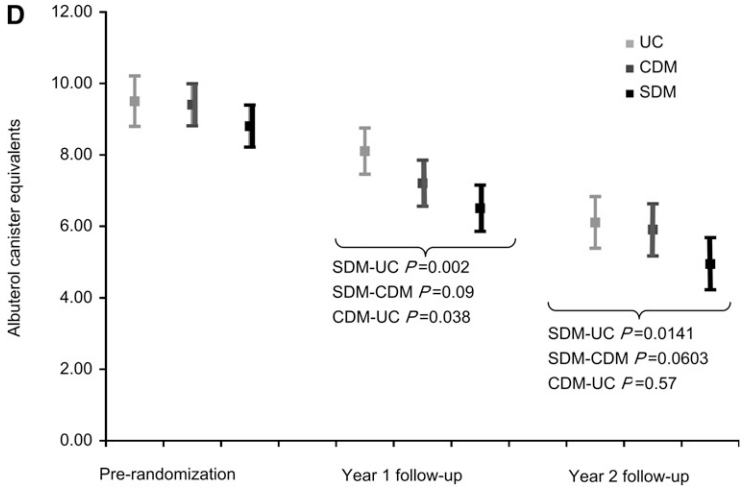

Figure 3. (*Continued*).

care on four of the six clinical outcomes, and not in significantly less SABA use or a higher FEV_1:FEV_6 ratio. Only among patients in the SDM group was SABA use (the only clinical outcome available for the second follow-up year) significantly lower than that of usual care in follow-up Year 2.

The greater advantage of the SDM than the CDM model over usual care, as well as the greater persistence of its effectiveness in reducing SABA use, support a treatment preference for the SDM approach. However, a rigorous, long-term cost-benefit analysis is required to determine whether these clinical benefits are accompanied by cost savings that offset the cost of the CDM or the additional cost of the SDM intervention.

There was no evidence that the SDM approach resulted in a significant proportion of patients avoiding corticosteroids or electing inadequate doses. In fact, patient involvement resulted in higher proportions receiving the highest-dose fluticasone (220 μg) over the highest-dose beclomethasone (80 μg), and the combination ICS-LABA over separate preparations. Both tendencies appeared to be due to the greater convenience of the regimen (i.e., the need for fewer puffs of fluticasone [220 μg/d] than beclomethasone [80 μg/d] to achieve an equipotent dose), and the convenience of a single inhaler in the case of the combination preparation. Without the patient's active involvement, the CDM care managers tended to choose the formulary-recommended ICS and separate ICS and LABA preparations.

Significance of Findings

An SDM approach is consistent with the concept of patient-centered care, and this study demonstrates that it is an important component with significant potential to not only change patient behavior through increased adherence, but also to improve clinical outcomes. The present findings have significant implications for asthma treatment and research, and potentially for the treatment of a wide range of other chronic conditions.

The findings also provide previously unavailable information on the average degree of clinical improvement, on a range of outcome measures, that is associated with a specific average increase in the cumulative annual ICS dose. This finding may help in evaluating the clinical importance of other interventions directed at improving medication adherence that may lack some or all of the clinical outcome measures obtained in the present trial.

The observation of a mean improvement in the quality of life score of 0.40 points, attributable to the SDM model, is less than the putative 0.50 minimal clinically important difference on that measure (40). However, questions exist regarding the methodology used to establish that minimal clinically important difference value (41, 42). The fact that the SDM group reported significantly higher quality of life at follow up, and that more than 70% of the group experienced a score improvement of greater than 0.50 points, is additional evidence that the clinical benefits of the intervention were evident to the patients.

Methodological significance. Concern with the quality of clinician–patient communication dates back at least 4 decades (43). Until now, observational studies have been the norm. Few controlled experimental studies have been conducted of modifications in communication around the treatment decision process, as distinct from other aspects of clinician–patient communication, and none of those that have been conducted concerned asthma. Most have emphasized one-time or acute treatment decisions, rather than the ongoing decisions associated with chronic conditions. Previous research also has generally focused on patient satisfaction, and has shown little evidence of significantly changing patient behavior or improving clinical outcomes. Furthermore, lack of assessment of the quality of the interventions, as delivered, has severely limited the interpretability of the largely negative trials (16).

Attributing the observed adherence, regimen potency, and clinical benefits to the patients' active participation in their treatment decisions is justified because the SDM and CDM interventions were identical in all respects, except the treatment

TABLE 3. PRE- AND POSTRANDOMIZATION PERCENTAGE OF PATIENTS DISPENSED A LONG-ACTING β-AGONIST, BY GROUP

Dispensed a LABA*	UC *n* (%)	CDM *n* (%)	SDM *n* (%)	*P* Value†
Prerandomization‡				SDM-UC: $P = 0.16$
Yes	52 (25.5)	44 (21.6)	40 (19.6)	SDM-CDM: $P = 0.62$
No	152 (74.5)	160 (78.4)	164 (80.4)	CDM-UC: $P = 0.35$
Follow-up Year 1†				SDM-UC: $P < 0.0001$
Yes	59 (28.9)	108 (52.9)	112 (54.9)	SDM-CDM: $P = 0.69$
No	145 (71.1)	96 (47.1)	92 (45.1)	CDM-UC: $P < 0.0001$
Follow-up Year 2				SDM-UC: $P = 0.002$
Yes	63 (30.9)	90 (44.1)	93 (45.6)	SDM-CDM: $P = 0.77$
No	141 (69.1)	114 (55.9)	111 (54.4)	CDM-UC: $P = 0.006$

Definition of abbreviations: CDM = clinician decision making; LABA = long-acting β-agonist; SDM = shared decision making; UC = usual care.

* Includes fluticasone-salmeterol 100, fluticasone-salmeterol 250, fluticasone-salmeterol 500, salmeterol, and formoterol.

† *P* values estimated from Pearson's χ^2.

‡ UC = 204; CDM = 204; SDM = 204.

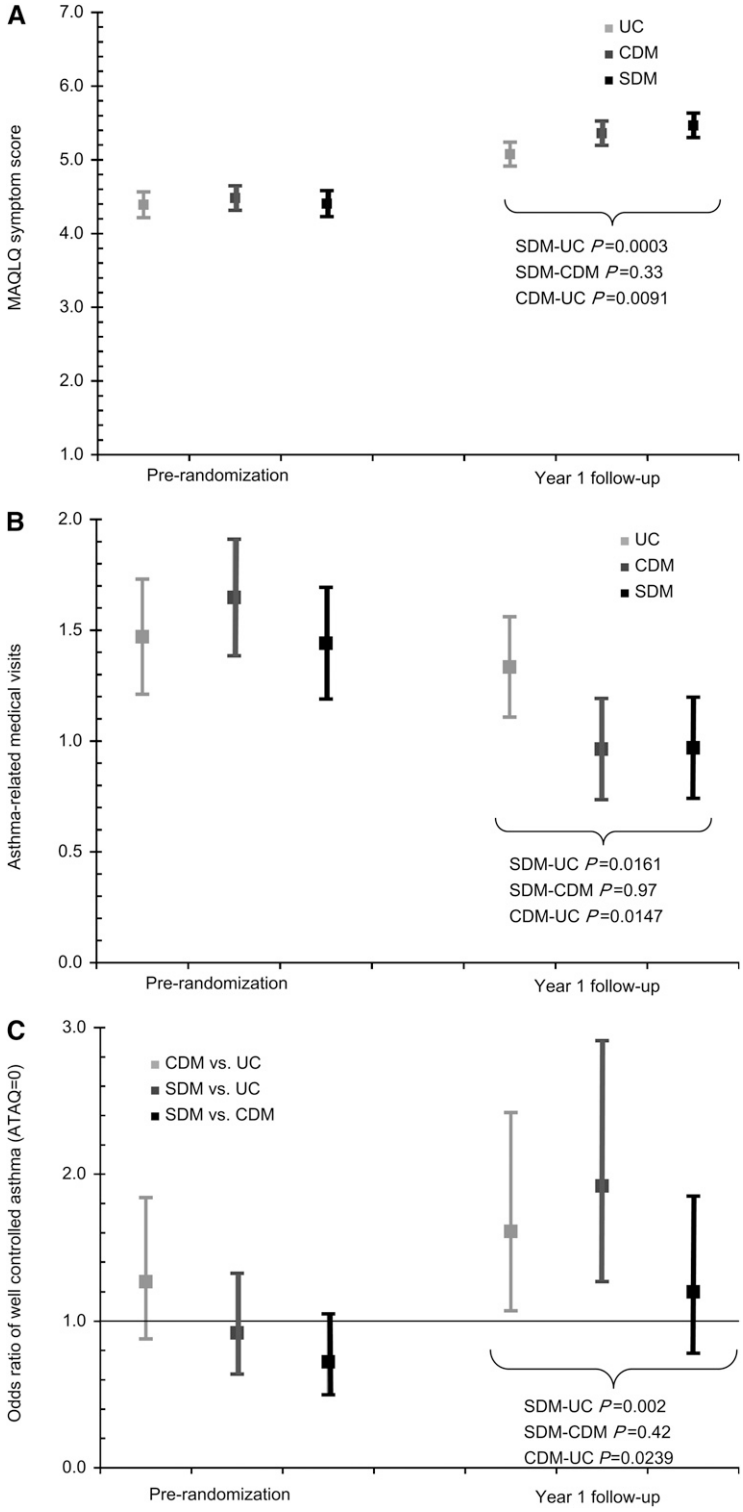

Figure 4. Group differences in asthma-related quality of life, asthma-related health care utilization, and asthma control. (*A*) Group differences in asthma-related quality of life. The five-item Mini Asthma Quality of Life Questionnaire (MAQLQ) subscale is scored on a symptom scale of 0 (All of the time) to 7 (None of the time). Subscale items include: shortness of breath, bothered by coughing, chest tightness or heaviness, difficulty sleeping, and chest wheeze. Pre randomization values are unadjusted and follow-up values are adjusted for the baseline score and the balancing variables. 95% confidence intervals (CIs) are shown. Group differences and 95% CIs for MAQLQ score at follow-up Year 1 are: shared decision making (SDM)-usual care (UC) = 0.39 (95% CI, 0.18–0.60); SDM–clinician decision making (CDM) = 0.11 (95% CI, −0.11–0.32); CDM-UC = 0.28 (95% CI, 0.07–0.50). The number of patients per group with no missing values at either time point is SDM $n = 182$, CDM $n = 180$, UC $n = 189$. (*B*) Group differences in the annual rate of asthma-related health care utilization (visits/yr). Prerandomization values are unadjusted, and follow-up values are adjusted for baseline asthma-related health care utilization and the balancing variables. The 95% CIs are shown. Group differences and 95% CIs for medical visits at follow-up Year 1 are: SDM-UC = −0.36 (95% CI, −0.66 to −0.07); SDM-CDM = 0.01 (95% CI, −0.29–0.30); CDM-UC = −0.37 (95% CI, −0.67 to −0.07). The number of patients per group at each time point is: SDM, $n = 204$; CDM, $n = 204$; UC, $n = 204$. (*C*) Odds ratios of well controlled asthma at each time period. The usual care group was the referent value when estimating the odds for the SDM and CDM groups. The CDM group also served as the referent value for the SDM group. The Asthma Therapy Assessment Questionnaire (ATAQ) scale is from 0 (no control problems; ''well controlled'') to 4 (four control problems). Well controlled asthma is based on an ATAQ score = 0. Pre-randomization odds ratios are unadjusted and follow-up odds ratios are adjusted for the baseline ATAQ score and the balancing variables. 95% CIs are shown. The number of patients per group with no missing values at either time point is: SDM, $n = 182$; CDM, $n = 180$; UC, $n = 189$.

decision process. This experimental difference was also reflected in the perception of those in the SDM group that they had a greater role in the treatment decisions than did the patients in the CDM group. Previous controlled trials of SDM have given insufficient attention to the choice of the control condition. Joosten and colleagues' review (18) did not consider the appropriateness of the control condition as a design criterion; most studies reviewed simply compared their intervention to the current standard of care. Without an active control for features of the intervention other than the treatment decision process (e.g., providing patient education), it is difficult to know the extent to which any positive results are attributable specifically to the patient's involvement in the treatment choice. The contribution of the BOAT study is enhanced by the existence of such a control, which allowed the elucidation of the unique contribution of the shared decision process itself.

Asthma care management. The target population of patients with poorly controlled asthma was a specific subset of patients with asthma within a very large managed health care system that had a long-standing commitment to high-quality asthma

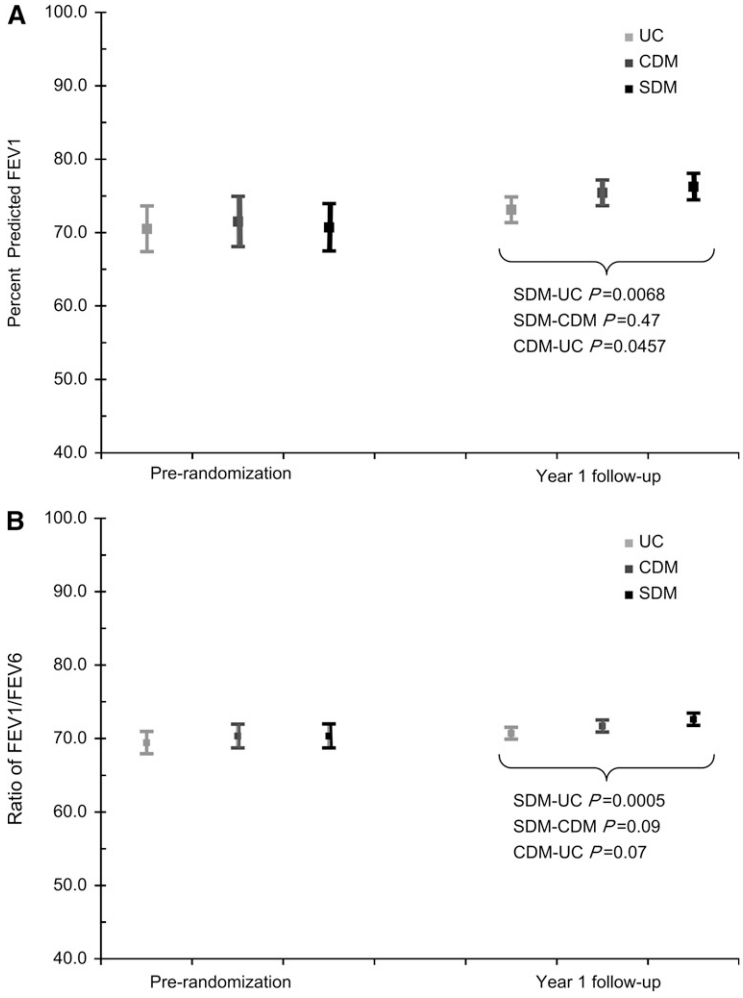

Figure 5. Group differences in lung function. (*A*) Group differences in percent predicted FEV_1 for each study period. Prerandomization values are unadjusted, and follow-up values are adjusted for baseline percent predicted FEV_1 and the balancing variables. The 95% confidence intervals (CIs) are shown. Group differences and 95% CIs for percent predicted FEV_1 at follow-up Year 1 are: shared decision making (SDM)–usual care (UC) = 3.2 (95% CI, 0.87–5.4); SDM–clinician decision making (CDM) = 0.85 (95% CI, −1.4–3.1); CDM-UC = 2.3 (95% CI, 0.04–4.6). The number of patients per group with no missing values at either time point is: SDM, $n = 165$; CDM, $n = 170$; UC, $n = 172$. (*B*) Group differences in the ratio of FEV_1:FEV_6 for each study period. The ratio is expressed as a percentage. Prerandomization values are unadjusted, and follow-up values are adjusted for the baseline FEV_1:FEV_6 ratio and the balancing variables. The 95% CIs are shown. Group differences and 95% CIs for the ratio of FEV_1:FEV_6 at follow-up Year 1: SDM-UC = 1.9 (95% CI, 0.84–3.0); SDM-CDM = 0.92 (95% CI, −0.14–2.0); CDM-UC = 0.98 (95% CI, −0.07–2.0). The number of patients per group with no missing values at either time point is: SDM, $n = 165$; CDM, $n = 170$; UC, $n = 172$.

care, education of patients with asthma, and physician adherence to asthma treatment guidelines, and that, at some sites, offered asthma care management as an optional part of usual medical care. Virtually all of these patients had medication benefits with modest copayments that varied with the provisions of their insurance plans. Nevertheless, in the baseline year, these patients had acquired only about one-third of the days' supply of medication that had been prescribed for them, and were experiencing frequent symptoms and activity limitations. Nearly one-fifth were not using an asthma controller at all. Our findings reveal that care management using a clinician decision model was clearly beneficial in terms of medication adherence and many clinical outcomes, and suggest that the likelihood of achieving the hoped-for benefits, and their magnitude, is increased by specifically involving the patient in the choice of treatment.

Need for ongoing reinforcement. The fall-off in asthma controller adherence/acquisition that was observed during follow-up Year 2 in both care management conditions is not surprising, and suggests that further follow up and reinforcement may be important to sustain the benefits of a shared decision process and of care management in general. For both models, the interventions typically occurred very early in follow-up Year 1, with no external reinforcement of the intervention processes after the patients' 9-month follow-up intervention phone calls.

Primary care providers and other clinicians at KP who may have seen patients subsequently had no access to the intervention materials, and hence were very unlikely to have used a comparable shared treatment decision approach. Patients in both care management conditions were also less likely than patients under usual care to have asthma-related medical visits during follow-up Year 1, which would also reduce the opportunity for reinforcement.

The fall-off in adherence may also suggest that, having experienced a clinical benefit in Year 1, patients began to "step down" therapy on their own. There is a need for further investigation into the pattern and causes of the decline in medication adherence over time, and whether periodic review by a care manager or physician can sustain both adherence and clinical benefits.

Intervention cost versus benefits. Compared with usual care, in follow-up Year 1 the SDM care management intervention increased the total days' supply of controller medication acquired by the patient by an average of 77 days and by 9.6 beclomethasone canister equivalents, increased the quality of life score by 0.4 points, decreased asthma-related physician visits per year by 0.4 visits, reduced albuterol acquisition by 1.6 canister equivalents, increased the FEV_1:FEV_6 ratio by an average of 2.8 percentage points, and doubled the likelihood of having well controlled asthma. Although the SDM intervention required a per-patient investment of $174 for care manager time, and resulted in some increase in cost to the patient and health care system for medications, it also resulted in decreased costs for asthma-related provider visits. The study was not

powered to detect specific differences in the more costly ED visits and hospitalizations; hence, any cost savings in this regard are unknown, and should be the focus of future research.

Strengths

The SDM intervention included all four defining features of the SDM model (mutual information sharing, expressing treatment preferences, discussing the options, and agreeing on treatment). The study design tested the hypothesized benefits of this model in a randomized, controlled trial with a very strong active, as well as a passive, control group. Care managers' adherence to their respective intervention protocols was objectively assessed, and confirmed the fidelity of intervention delivery, and it was documented that the interventions resulted in differing perceptions of patients' own influence on the treatment decisions.

Other strengths include the use of objective measures of medication acquisition and refill adherence and health care utilization, available for all patients during follow up, high-quality spirometry, and multiple validated patient-centered measures.

Limitations

As an initial efficacy trial, this study was not powered to detect differences in ED visits or hospitalization rates—the most costly types of utilization; hence, a true cost–benefit analysis was not performed. The results of this study are also limited to adult patients; it remains to be determined whether the effects of a shared decision process can be generalized to pediatric patients (i.e., to treatment decisions made by parents on their child's behalf). Finally, in settings in which different treatment options have more pronounced differential cost implications for patients (e.g., non–managed care organizations), or in which asthma management guidelines support different patterns of medication usage (e.g., greater use of combination products), the priorities of adult patients may be more or less consonant with clinician recommendations than was observed here.

Although pharmacy dispensing data were obtained for both follow-up years, the inability to continue active follow-up and to extract health care utilization data through follow-up Year 2 is a modest limitation. However, even a 1-year follow up of multiple behavioral, clinical, and health care utilization outcomes greatly exceeds the duration of most previous studies.

Conclusions

An SDM approach to the selection of asthma pharmacotherapy, in the context of asthma care management, is efficacious in improving both medication adherence and clinical outcomes. An appropriately powered study to determine the cost-effectiveness of this approach is warranted, as are further studies of the effectiveness of this approach in patients with other poorly controlled chronic diseases and in both younger and older patients.

Conflict of Interest Statement: S.R.W. received up to $1,000 from Asthmatx, Inc., for consulting related to assessment of patient-centered outcomes of bronchial thermoplasty; P.S. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript; A.S.B. received $1,001–$5,000 from GlaxoSmithKline, $1,001–$5,000 from AstraZeneca, $1,001–$5,000 from Merck, $1,001–$5,000 from Sepracor, and $1,001–$5,000 from Schering Plough in advisory board fees; S.B.K. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript; P.W.L. received $5,001–$10,000 from Pfizer, Inc., in consultancy fees, and $5,001–$10,000 from the Palo Alto Medical Foundation Research Institute in consultancy fees; J.L. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript; W.M.V. received up to $1,000 from Merck in advisory board fees, more than $100,001 from GlaxoSmithKline, more than $100,001 from Pfizer, more than $100,001 from Novartis, $50,001–$100,001 from Sepracor, and $50,001–$100,000 from Boheringer Ingelheim in unrestricted educational grants, holds more than $100,001 in stock ownership or options in Vanguard Health Care, a mutual fund, and is employed by Kaiser Permanente, a managed care organization that has contracts with entities who are interested in the American Thoracic Society.

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