

Inhaled corticosteroid beliefs, complementary and alternative medicine, and uncontrolled asthma in urban minority adults

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Background: Many factors contribute to uncontrolled asthma; negative inhaled corticosteroid (ICS) beliefs and complementary and alternative medicine (CAM) endorsement are 2 that are more prevalent in black compared with white adults.

Objectives: This mixed-methods study (1) developed and psychometrically tested a brief self-administered tool with low literacy demands to identify negative ICS beliefs and CAM endorsement and (2) evaluated the clinical utility of the tool as a communication prompt in primary care.

Methods: Comprehensive literature reviews and content experts identified candidate items for our instrument that were distributed to 304 subjects for psychometric testing. In the second phase content analysis of 33 audio-recorded primary care visits provided a preliminary evaluation of the instrument's clinical utility.

Results: Psychometric testing of the instrument identified 17 items representing ICS beliefs ($\alpha = .59$) and CAM endorsement ($\alpha = .68$). Test-retest analysis demonstrated a high level of reliability (intraclass correlation coefficient = 0.77 for CAM items and 0.79 for ICS items). We found high rates of CAM endorsement (93%), negative ICS beliefs (68%), and uncontrolled asthma (69%). CAM

endorsement was significantly associated with uncontrolled asthma ($P = .04$). Qualitative data analysis provided preliminary evidence for the instrument's clinical utility in that knowledge of ICS beliefs and CAM endorsement prompted providers to initiate discussions with patients.

Conclusion: Negative ICS beliefs and CAM endorsement were common and associated with uncontrolled asthma. A brief self-administered instrument that identifies beliefs and behaviors that likely undermine ICS adherence might be a leveraging tool to change the content of communications during clinic visits. (*J Allergy Clin Immunol* 2014;134:1252-9.)

Key words: Asthma, self-management, instrument development, beliefs, complementary and alternative medicine, inhaled corticosteroids, adherence, black, minority, urban, mixed methods, patient-provider communication

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Inhaled corticosteroids (ICSs) are the mainstay of asthma management for patients with persistent disease¹; with the correct use of ICSs, a significant number of asthma attacks and other complications are preventable.¹ However, ICS adherence is disappointingly low in all patient populations, in part because of patients' ambivalence about the need for ICSs during symptom-free periods, as well as concerns about effectiveness and safety.²⁻⁷ Recent studies suggest that personal beliefs about asthma and its pharmacologic treatment are among the most significant factors affecting adherence.^{4,8-11} Furthermore, different racial groups use ICSs at different rates, even when barriers to access have been removed.^{3,12,13} Le et al¹² offer a conceptual framework that describes the potential relationship between minority status, ICS beliefs, and adherence. In testing the model negative beliefs about ICS therapy were more prevalent in black than white subjects and partially mediated the relationship between minority status and adherence to ICS therapy. Negative ICS beliefs held by black adults with asthma include the fear of being overmedicated, developing tolerance or addiction to ICSs, or serious side effects and concerns that ICSs are a form of medical experimentation.^{3,4,6,7,12,14-16}

Previous research has shown lower rates of ICS adherence in subjects who endorse complementary and alternative medicine (CAM) modalities.^{7,14,17} CAM is defined as a group of diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine.¹⁸ When defined broadly, CAM encompasses mind-body interventions,

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Abbreviations used

CAM: Complementary and alternative medicine
CAM-A: Complementary and Alternative Management for Asthma
ICS: Inhaled corticosteroid
SABA: Short-acting β_2 -agonist

natural products, and approaches such as folk medicine, home remedies, and spirituality.¹⁸ These latter types of CAM are common and often include culturally specific health recommendations, such as the benefits of fresh air or avoiding cold weather or rain, which are perceived as causing enhanced susceptibility to colds and viruses.^{7,19,20} In our previous work we have found that as many as 88% of urban black adults with asthma prefer to use both conventional medical therapies and culturally relevant CAM together for asthma, an approach referred to as integrated therapies or integrated medicine.²⁰ A preference for CAM in black populations has been attributed to culture-bound traditions resulting from historical inequalities in access to and racism experienced in the health care system, greater distrust of health care providers, and a preference for less conventional care.^{21,22}

Although the efficacy of most CAM therapies has not been established, the majority are thought to be innocuous, with a few exceptions.^{7,23-26} However, behaviors associated with CAM use might contribute to poor asthma outcomes when, for example, CAM therapies are substituted for ICSs and short-acting β_2 -agonists (SABAs), leading to delays in seeking health care.²⁷

Evidence suggests that patient-provider discussion of CAM endorsement and negative ICS beliefs might not occur routinely.^{28,29} Patients might not disclose, even if asked, fearing a disruption of the therapeutic alliance.^{14,29-31} Black subjects might be less likely to disclose CAM use than white subjects.^{32,33} Therefore the goal of this mixed-methods study was to develop and psychometrically test a brief questionnaire with low literacy demands, the Complementary and Alternative Management for Asthma (CAM-A) instrument, and evaluate its clinical utility in prompting conversations about CAM endorsement or negative ICS use during brief primary care visits with urban minority patients.

METHODS

Overview

The initial phase of instrument development began with the identification of the target concept, composition of the items, and construction of the item pool. This was accomplished by conducting a literature review and literacy assessment, as well as by convening content experts. This was followed by psychometric testing to determine the properties of the item bank and test the format of the instrument. The goal of the psychometric testing phase was to reduce the number of items to their most parsimonious form and to produce data that were valid (measures the construct of interest) and reliable (reproducible) and had clinical utility. In this study reliability was established through item reduction and stability testing. We focused on content (items were developed by experts in the field), construct (items represent the variables being investigated), and concurrent criterion validity (assessment tools effectively indicate the construct). We also explored the association between the instrument's score and the level of asthma control. Lastly, we evaluated the clinical utility of the instrument using qualitative content analysis of audio recordings of and debriefings after primary care clinic visits.

Instrument development phase

A comprehensive literature review and the results of the team's previous qualitative studies^{7,20} were used to identify potential items related to ICS

beliefs and CAM endorsement to develop the initial instrument. From 115 items, we excluded items reflected in case reports and phenomena of rare occurrence, thereby leaving 45 candidate items. Next, a group of 16 content experts (2 certified asthma educators, 8 primary care physicians, 2 allergists, and 4 adults living in a Philadelphia Zip code who self-identified as black with physician-diagnosed persistent asthma) assessed the content validity of the 45 items. No item was retained if 25% (>4) or more of the content experts believed it was "very unlikely" to be endorsed unless 1 asthmatic patient and 2 other content experts characterized it as "very likely" to be endorsed. By using this decision tool, 35 candidate items were retained, and 4 additional items were added. This first iteration of the CAM-A questionnaire included the 39 items identified by our content experts: 21 CAM items and 18 ICS items. The CAM-A was written at a 5.7 Flesch-Kincaid reading level with a calculated Flesch Reading Ease of 72.9 (ie, fairly easy).

Psychometric testing phase

Establishing properties of the item bank, formatting, and item reduction. The initial phase of psychometric testing was conducted in a convenience sample of 210 minority (most self-identified as black) adults (≥ 18 years of age) with persistent asthma living in a Philadelphia Zip code. Inclusion criteria included that participants be prescribed ICSs for provider-diagnosed persistent asthma. Exclusion criteria included inability to speak English or understand the informed consent process. This was a multicenter study with participants recruited from 1 federally qualified health clinic, 2 family medicine practices, and 2 internal medicine practices, representing 3 health systems. Participants were identified through review of electronic health records, referred by their primary care providers, or self-referred into the study in response to posted flyers. When medical records were not available for review, self-referred subjects were required to bring their prescription ICS medicines and photo identification to the study visit to confirm that they had been dispensed an ICS for persistent asthma.

Establishing initial validity. As a result of item reduction, the 39-item questionnaire was reduced to 17 items. Candidate items for removal were those with more than 5% missing data (no item met this criterion) and items for which more than 70% of the responders chose one end of the scale ("floor" or "ceiling" effects; 5 items met this criterion). An analysis of the interitem correlation matrix showed that 17 item pairs had correlations of greater than 0.4. The decision as to which of the highly correlated items to keep was based on their clinical relevance and clarity determined through cognitive interviewing, as described elsewhere.³⁴ These 17 items were then submitted to principle components analysis by using varimax rotation,³⁵ which confirmed 2 domains: CAM endorsement (9 items; Cronbach α coefficient = 0.68) and ICS beliefs (8 items; 6 reflecting negative beliefs and 2 indicating positive beliefs; Cronbach α coefficient = 0.59).

Establishing reliability. The 17-item questionnaire was then retested in a second convenience sample of 94 adults meeting the same inclusion/exclusion criteria as those recruited in the item reduction phase (Table 1). In this phase we recruited from the federally qualified health clinic and the 2 internal medicine practices used previously, again representing 3 health systems. Forty-one (19.5%) of the 210 subjects who participated in the initial psychometric testing phase more than 6 months earlier were allowed to re-enroll in this second phase of testing.

In this phase the instrument was administered twice; the second administration occurred 2 to 4 weeks after the initial administration. Test-retest analysis demonstrated that the median item difference score was 0, indicating consistency between responses in the test and retest phases. The intraclass correlation coefficient was 0.77 for the CAM items and 0.79 for the ICS beliefs items; these values indicate a high level of agreement between the responses in test-retest phases.³⁶

Examining the instrument's predictive ability. The predictive ability of the CAM-A to identify the level of asthma control (controlled/uncontrolled) was examined in exploratory regression modeling by using the 2 subscales separately. First, we dichotomized the CAM-A's 7-point Likert scale (1 = "strongly disagree" to 7 = "strongly agree") in the following manner. Responses 1 to 4 were characterized as not endorsing CAM or not holding negative ICS beliefs, and responses 5 to 7 were characterized as endorsing CAM or holding negative ICS beliefs. A cumulative score was

TABLE I. Patients' characteristics (n = 337)

| | |
|---|-------------|
| Age (y), mean (SD) | 47.2 (12.8) |
| Sex, no. (%) | |
| Male | 72 (21.4) |
| Female | 265 (78.6) |
| Race, no. (%) | |
| Black/African American | 270 (80.1) |
| White | 48 (14.2) |
| Other* | 19 (5.6) |
| Marital status, no. (%) | |
| Single | 150 (44.5) |
| Married | 90 (26.7) |
| Divorced/separated | 76 (22.6) |
| Widowed | 21 (6.2) |
| Occupation, no. (%) | |
| Unemployed | 140 (41.5) |
| Manual/service | 43 (12.8) |
| Skilled professional | 79 (23.4) |
| Student | 12 (3.6) |
| Retired | 38 (11.3) |
| Other (chef, EMS, on disability) | 24 (7.1) |
| Highest educational level, no. (%) | |
| Some high school | 62 (18.4) |
| Completed high school/obtained GED or vocational training | 129 (38.3) |
| Some college | 80 (23.7) |
| College graduate/postgraduate | 64 (19.0) |
| Insurance, no. (%) | |
| Medicaid | 129 (38.3) |
| Medicare/SSI | 71 (21.1) |
| Commercial | 111 (32.9) |
| Other | 25 (7.4) |
| Income, no. (%) | |
| \$0-\$9,999 | 131 (38.9) |
| \$10,000-\$19,999 | 62 (18.4) |
| \$20,000-\$29,999 | 38 (11.3) |
| \$30,000-\$39,999 | 30 (8.9) |
| \$40,000-\$49,999 | 30 (8.9) |
| ≥\$50,000 | 32 (9.5) |
| Refused to disclose | 18 (5.3) |
| Age when first given a diagnosis of asthma (y), mean (SD) | 23.6 (17.8) |
| Level of asthma control,† no. (%) | |
| Controlled asthma | 114 (30.9) |
| Uncontrolled asthma | 233 (69.1) |

EMS, Emergency medical services; SSI, Social Security Income.

*Including American Indian/Alaskan Native, Asian, and Native Hawaiian/Pacific Islander.

†Albuterol use more than 3 times in the last 7 days or nocturnal awakening more than 3 times in the last 30 days.

calculated by summing the individual items endorsed by each participant. For CAM endorsement, the cumulative score ranged from 0 to 9 (with higher scores representing more CAM endorsement), representing the 9 CAM items. For negative ICS beliefs, the range was 0 to 6 (with higher scores representing more negative ICS beliefs), representing the 6 negative ICS belief items (2 ICS items reflected positive endorsement and were not included).

Next, using metrics recommended by the national guidelines,¹ asthma control was calculated by using standard patient-reported outcomes: the number of SABA doses in the prior 7 days, the number of nocturnal awakenings caused by asthma in the prior 30 days, or both. Participants were classified as having symptoms that were well controlled (SABAs ≤2 days per week and/or awakenings ≤2 times per month), not well controlled (SABAs >2 days per week and/or awakenings 1-3 times per week), or very poorly controlled (SABAs several times a day and/or awakenings ≥4 times per week). For the purpose of analysis and interpretation, we then collapsed the 2 categories of uncontrolled asthma (not well controlled and very poorly controlled) into 1 category (uncontrolled), which allowed us to characterize participants as having either controlled or uncontrolled asthma.

Statistical analysis

Statistical analysis was performed with the SPSS statistical analysis package (version 20; SPSS, Chicago, Ill).³⁷ Demographic categorical variables were summarized by frequencies, whereas continuous variables were summarized by means and 95% CIs, medians, SDs, and ranges. We also executed logistic regression models that included variables that were significant in bivariate comparisons.

Procedures for qualitative data collection at the primary care clinic visit (audio recordings and debriefings)

A convenience sample of 33 patients and 10 providers was recruited from 3 of the sites (representing 3 health systems) used for instrument development: the federally qualified health clinic and the 2 internal medicine practices. We chose these sites because they were busy practices with high rates of asthma and a largely minority patient panel. Providers were eligible for enrollment if they were either a medical doctor or a nurse practitioner responsible for the care of a panel of adults with persistent asthma. Providers received no training for this project. Informed consent simply stated that this was a study to learn more about how providers and patients talk about asthma. Patient participants were either identified by electronic medical records or their primary care providers or self-referred into the study in response to posted flyers; these patient participants met identical inclusion and exclusion criteria as used in the instrument development and psychometric testing phase. Five (15%) subjects who had previously participated in the initial phase of psychometric testing (establishing the item bank, formatting, and item reduction) were allowed to enroll in this qualitative data collection phase because they had completed the instrument more than 18 months earlier (range, 18-44 months; mean, 30 months) and were not likely to recall the content of the instrument. After qualitative data collection was complete, subjects were invited to return in 2 to 4 weeks to contribute data toward the test-retest stability (reliability) phase; all 33 did so.

Because we were interested in the influence of the CAM-A on clinic visits, we implemented a protocol to assign half of the visits to include CAM-A reports before the visit, with the other half not including CAM-A reports. Providers were allowed to participate up to 6 times (with different patients); patients participated only once. Each time a new provider was enrolled, the CAM-A was administered to the patient after the visit was complete, meaning neither the provider nor the patient could be influenced by having seen the CAM-A. However, if the provider participated more than once, then the CAM-A administration was alternated at each visit, either before or after. Using this pattern, providers did not see the CAM-A summary report the first, third, and fifth times they participated, but providers were given the CAM-A summary report with their second, fourth, and sixth patients. Three providers participated only once, 1 provider participated twice, 3 providers participated 4 times, 2 providers participated 5 times, and 1 provider participated 6 times. When providers participated more than once, we attempted to space the visits out over several weeks to reduce contamination from previous exposure to the CAM-A; an average of 23 days elapsed between visits when providers participated more than once.

Immediately after all 33 visits, both patients and providers were debriefed by the research assistant to determine what they perceived to be the key discussion points during the visit and what they had learned about asthma self-management at that visit. The debriefing was a 3-item, research assistant-administered paper-and-pencil tool. Patients and providers were asked to elaborate on any yes answers. The patient debriefing asked patients to recall whether the visit had included any discussions about nonpharmacologic management of asthma or personal ICS beliefs. Patients were also asked to evaluate the ability of the provider to advise them regarding CAM. The provider debriefing tool asked whether they had learned anything new about their patient's asthma management or ICS beliefs from the visit. In addition, providers were asked to comment on their confidence in responding to patients' questions about CAM. The accuracy of the debriefings was confirmed by review of transcripts.

Ethical considerations

The Institutional Review Boards of the University of Pennsylvania and Thomas Jefferson University approved the study. The University of

Pennsylvania served as the institutional review board of record for the federally qualified health center. Both patient and provider participants provided informed consent. Patient participants received a \$20 cash payment for their participation in the item development phase and \$50 for their involvement in the psychometric or clinical utility testing, as well as tokens or cash to cover their transportation and parking costs. Provider participants received a prepaid debit card (\$100) after debriefings.

RESULTS

We enrolled 304 adults with persistent asthma (77% female; 78% black/African American; 81% with a high school education or less; mean age, 49.7 years) into the psychometric testing phases of the study. We evaluated the clinical utility of the CAM-A in an additional 33 adults with persistent asthma (97% female; 100% black/African American; 83% with a high school education or less; mean age, 48.1 years) and their 10 primary care providers (5 physicians; 5 nurse practitioners; 80% female; 80% white; mean of 18.3 years in practice; [Table I](#)).

Prevalence of CAM endorsement

Endorsement of the CAM for asthma self-management was high, with 93% of participants endorsing at least 1 CAM behavior for asthma self-management. The importance of fresh air/air movement was the most popular (67%), followed by water (42%), steam or prayer (38%), and coffee (20%). An item about the importance of finding natural ways to manage asthma was endorsed by 82% ([Table II](#)).

Prevalence of ICS beliefs

There was high endorsement for the need for daily ICSs (75%) and a belief that ICS use controlled asthma (82%). However, negative ICS beliefs were also common, with 68% of participants identifying at least 1 negative belief. Forty-two percent of participants believed they were the best judge of whether an ICS was needed. Twenty-three percent expressed fears of tolerance from regular use, and 12% believed that ICSs could cause cancer or organ failure ([Table II](#)).

Predictive ability of the CAM-A to identify level of asthma control

Most participants (69%) were characterized as having uncontrolled asthma. We explored whether CAM endorsement or negative ICS beliefs were associated with asthma control. To conduct the analysis, we first examined the bivariate differences in clinical/sociodemographic variables and prevalence of CAM/ICS beliefs in patients with controlled and uncontrolled asthma.

We found that race, educational level, insurance status, CAM, and ICS beliefs differed significantly between the participants with controlled and uncontrolled asthma. Specifically, black race, lower educational attainment, higher CAM endorsement, and more negative ICS beliefs were all associated with uncontrolled asthma. Logistic regression models found that CAM endorsement ($P = .04$) and lower levels of education ($P = .011$) were significantly associated with uncontrolled asthma. A 1-unit increase in the cumulative CAM endorsement score (described above) increased the odds of uncontrolled asthma by 1.41. Furthermore, participants with less than a high school degree were almost 10

times more likely to experience uncontrolled asthma than participants with college or postgraduate degrees ([Table III](#)).

Preliminary evaluation of clinical utility

Lastly, we evaluated the clinical utility of the CAM-A at 33 primary care visits. At 15 (45%) of the 33 visits, providers were given their patients' CAM-A summary report before the audio-recorded visit; at 18 visits, the CAM-A was administered after the audio-recorded visit, and the providers did not receive CAM-A results. The length of the primary care visits ranged from 9 to 50 minutes, with a median time of 22 minutes (which included 6 minutes of silence) in both groups ([Table IV](#)).

Of the providers given patients' CAM-A summary reports before the visit, during 80% of the visits, providers reported that they learned something new about their patients' asthma self-management. This included new knowledge about negative ICS beliefs (eg, fears about developing tolerance or addiction) and culturally relevant CAM behaviors (eg, use of fans, black coffee, tea, and prayer for asthma self-management). These data provide support for the CAM-A's construct validity.

If the providers did not receive CAM-A data, 39% reported that they learned something new. However, debriefings indicated that providers were confident in their ability to address negative ICS beliefs or advise their patients on CAM in only 15 (45%) of 33 visits.

When providers knew their patients' CAM-A summary report, 73% of patients reported that their provider initiated a dialogue on the correct use of ICSs, their negative ICS beliefs, or non-pharmacologic management of asthma (eg, diet and weight loss, adequate hydration, exercise, breathing techniques, and herbal preparations). Importantly, 85% characterized their provider as "able to advise and answer questions" about CAM, despite the provider's low self-rating.

The accuracy of the patient and provider debriefings was verified by review of the audiotaped clinic visit (concurrent criterion validity). Audio recordings also revealed that providers did not initiate any discussion about negative ICS beliefs at visits during which they did not see the CAM-A summary report, despite having seen the CAM-A previously. This was also true for CAM discussions, with the exception of 1 provider who participated multiple times; this provider initiated a discussion about CAM use at a visit in which the CAM-A had not yet been administered. These data suggest that the washout period was generally adequate.

Patients never initiated discussions about negative ICS beliefs or CAM use when the CAM-A summary report was shared with their providers. Only once did a patient initiate a discussion of CAM with his or her provider, and this was at a visit in which the CAM-A had not yet been administered. Blinded transcriptionists characterized 88% of the clinic visits as having a friendly tone, even when negative ICS beliefs or CAM endorsement were discussed. Together, these data provide preliminary evidence for the clinical utility of the CAM-A.

DISCUSSION

We developed a robust measure of negative ICS beliefs and CAM endorsement and have preliminary evidence of its clinical utility as a communication prompt in a multicenter primary care study. This study documents high prevalence of CAM use and

TABLE II. CAM-A* instrument items (n = 304)

| Item | Item domain | Positive response, no. (%) |
|---|---------------------|----------------------------|
| (Insert BRAND NAME ICS) controls my asthma | Positive ICS belief | 250 (82) |
| Having air movement from a fan, air conditioner or open window helps my asthma | CAM endorsement | 202 (66) |
| I need my (insert BRAND NAME ICS) every day | Positive ICS belief | 227 (75) |
| It is important to me that I find a natural way to treat my asthma | CAM endorsement | 128 (42) |
| Drinking water helps my asthma | CAM endorsement | 128 (42) |
| I am the best judge of whether I need to take my (Insert BRAND NAME ICS) | Negative ICS belief | 127 (42) |
| Steam or warm things on my chest helps my asthma | CAM endorsement | 116 (38) |
| Praying, or having someone pray for me, helps my asthma | CAM endorsement | 114 (37) |
| My asthma can get worse if I go out with a wet head | CAM endorsement | 109 (36) |
| I make decisions about whether I need my (Insert BRAND NAME ICS) on a day-by-day dose-by-dose basis | Negative ICS belief | 106 (35) |
| Drinking tea (herbal or regular) helps my asthma | CAM endorsement | 99 (32) |
| I am afraid that I will build up a tolerance to (Insert BRAND NAME ICS) | Negative ICS belief | 71 (23) |
| Drinking coffee helps my asthma | CAM endorsement | 61 (20) |
| Using Vicks VapoRub helps my asthma | CAM endorsement | 53 (17) |
| Doctors compensated for writing ICS prescriptions | Negative ICS belief | 39 (13) |
| ICS causes cancer or organ damage | Negative ICS belief | 35 (11) |
| ICS causes side effects | Negative ICS belief | 33 (11) |

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negative ICS beliefs in urban minority adults with asthma. To our knowledge, this is the largest study of these beliefs and behaviors in black adults and is the only study in minority adults to associate negative ICS beliefs and a broad range of culturally relevant CAM behaviors with poor disease control.

In bivariate comparisons we observed that black race, lower educational attainment, higher CAM endorsement, and more negative ICS beliefs were associated with poorer asthma control. However, in the logistic regression model only lower educational attainment and higher CAM endorsement predicted uncontrolled asthma. The logistic regression model also identified a trend ($P = .099$) toward more negative ICS beliefs and greater likelihood of having uncontrolled asthma, supporting a link between disease control and nonadherence because of negative ICS beliefs^{3,12} and CAM use^{38,39} reported by others. This has important research implications because both CAM endorsement and negative ICS beliefs are potentially modifiable barriers to adherence. Greater concordance in patients' and providers' treatment preferences has been shown to improve medication adherence in patients with other chronic diseases, such as acute coronary syndrome,⁴⁰ diabetes,⁴¹ and hypertension.⁴²

Providers do not routinely ask patients about their CAM use or negative ICS beliefs, perhaps because of the limited time with patients, which forces providers to focus on traditional medications to the exclusion of other important topics. Also, providers might not appreciate the clinical relevance of these beliefs and behaviors on medication adherence. Patients do not volunteer this information. A reluctance to disclose CAM use might be rooted in patients' fears that their provider will not respond approvingly or will become angry, ridicule them, or be unable to engage in a knowledgeable discussion of CAM. Although these types of responses have been reported,⁴³ they are not typical of current patient-centered management styles. In addition, there are many reasons why disclosures are necessary, particularly when patients are using dangerous types of CAM or when CAM use contributes to unnecessary delays in seeking medical attention.^{6,20,26}

Negative ICS beliefs are not likely to be modified by educational interventions alone. These beliefs might reflect trepidation about ICS side effects (eg, osteoporosis, blood sugar

and blood pressure increase, weight gain, and bruising) that might be legitimately concerning patients and causing them to decline ICS use, as well as deep-rooted distrust of the medical establishment that often has a historical basis. Minority patients' fears of being exploited or experimented on will require long-term engagement by the provider if patients' treatment beliefs are to be more closely aligned with the medical model. Motivational and cognitive-behavioral interventions might be more effective strategies for both engaging and changing patients' ICS beliefs than educational strategies alone. Therefore openly discussing these beliefs and negotiating for a mutually acceptable disease management plan are necessary first steps to optimizing patient outcomes.

Our study also found an association between low educational attainment and asthma control, which suggests an important clinical role for CAM-A use. Although it is unclear what role health literacy played in this association, low health literacy has been linked to negative medication beliefs,⁴⁴ as well as other measures of low socioeconomic status implicated in a wide range of poor clinical outcomes.⁴⁵ The CAM-A questionnaire might be useful in clinical practice because it is brief, can be self-administered, has low literacy demands, and can quickly identify areas around medication beliefs for discussion. In this study knowing patients' beliefs or behaviors prompted providers to initiate a conversation with their patients. These discussions, although not lengthening the time of the office visit, appeared to change the content of the clinical conversation. Patients never initiated these discussions.

High rates of CAM endorsement and negative medication beliefs are a compelling area for future research and support the need for clinical models of care to enhance patient-provider communication and shared decision making. When providers have knowledge of patients' "hidden" beliefs and behaviors, a discussion of the risks and merits associated with treatment options can help reconcile differences. These conversations might lead to higher-quality decisions that best match patients' needs with evidence-based recommendations.^{46,47} This model has been applied to asthmatic patients, and ICS adherence, asthma quality of life, pulmonary function, and disease control improved in those

TABLE III. Bivariate comparisons and multivariate logistic regression of factors associated with asthma control

| Characteristics | Bivariate comparison | | | Logistic regression † |
|---|----------------------------|-------------------------------|-------------|-------------------------------|
| | Controlled asthma (n = 97) | Uncontrolled asthma (n = 207) | P value | OR (95% CI), P value |
| Level of CAM endorsement, mean (SD) | 2.9 (2.1) | 3.5 (0.15) | .032 | 1.41 (1.1-2.31), .04 |
| Level of ICS negative belief endorsement, mean (SD) | 1.12 (1.19) | 1.5 (1.33) | .035 | 1.4 (0.94-2.1), .099 |
| Age (y), mean (SD) | 48.1 (1.53) | 50.5 (0.87) | .15 | |
| Sex | | | .29 | |
| Male | 26 (27%) | 44 (21%) | | |
| Female | 71 (73%) | 163 (79%) | | |
| Race | | | .001 | .56 |
| White | 28 (29%) | 20 (10%) | | Referent |
| Black/African American | 63 (65%) | 174 (84%) | | 1.6 (0.55-4.63), .39 |
| Other* | 6 (6%) | 13 (6%) | | 2.37 (0.43-12.9), .32 |
| Marital status | | | .33 | |
| Single | 36 (37%) | 99 (49%) | | |
| Married | 32 (34%) | 50 (25%) | | |
| Divorced/separated | 19 (21%) | 43 (21%) | | |
| Widowed | 8 (8%) | 11 (5%) | | |
| Occupation | | | .06 | |
| Unemployed | 30 (31%) | 99 (49%) | | |
| Manual/service | 11 (11%) | 27 (13%) | | |
| Skilled professional | 35 (36%) | 36 (18%) | | |
| Student | 4 (4%) | 6 (3%) | | |
| Retired | 12 (13%) | 22 (11%) | | |
| Other (chef, EMS, on disability) | 5 (5%) | 11 (6%) | | |
| Highest educational level | | | .001 | .011 |
| Some high school | 7 (7%) | 46 (22%) | | Referent |
| Completed high school/obtained GED/vocational training | 31 (32%) | 87 (42%) | | 0.44 (0.15-1.34), .17 |
| Some college | 23 (24%) | 52 (25%) | | 0.32 (0.1-1.1), .07 |
| College graduate/postgraduate | 36 (37%) | 22 (11%) | | 0.09 (0.02-0.38), .048 |
| Insurance | | | .002 | .77 |
| Medicaid | 27 (27%) | 91 (45%) | | Referent |
| Medicare/SSI | 15 (16%) | 46 (22%) | | 1.57 (0.61-4.03), .35 |
| Commercial | 48 (50%) | 53 (26%) | | 1.11 (0.46-2.7), .81 |
| Other | 7 (7%) | 15 (7%) | | 0.83 (0.22-3.04), .78 |
| Income | | | .08 | |
| \$0-\$9,999 | 23 (24%) | 91 (44%) | | |
| \$10,000-\$19,999 | 16 (17%) | 40 (20%) | | |
| \$20,000-\$29,999 | 12 (12%) | 24 (12%) | | |
| \$30,000-\$39,999 | 12 (12%) | 14 (7%) | | |
| \$40,000-\$49,999 | 10 (10%) | 11 (5%) | | |
| ≥\$50,000 | 17 (18%) | 11 (5%) | | |
| Refused to disclose | 7 (7%) | 14 (7%) | | |
| Age when first given a diagnosis of asthma (y), mean (SD) | 22.4 (18.1) | 23.6 (18.6) | .588 | |

Values shown in boldface are statistically significant.

EMS, Emergency medical services; SSI, Social Security Income.

*Including American Indian/Alaskan Native, Asian, and Native Hawaiian/Pacific Islander.

†For the logistic regression, 0 indicated controlled asthma and 1 indicated uncontrolled asthma.

in the shared decision-making condition.⁴⁸ Improved ICS adherence has also been reported in a randomized controlled trial of treatment negotiation delivered at home visits in inner-city children with asthma⁴⁹ and in a quasiexperimental study of office-based treatment negotiation in rural children with asthma.⁵⁰ Approaches such as these should be evaluated for their usefulness in urban minority adult populations.

There are several important limitations of this study. There is a potential for selection bias when participants are either referred or are recruited as part of a convenience sample. Enrolled participants are likely different from those who declined participation. The generalizability of these findings is limited by the use of a sample from 1 geographic location. The CAM-A might require validation in other populations. There is also the risk that

participants overreported CAM use or negative ICS beliefs (Hawthorne effect) and that self-reported asthma control might be inaccurate because of recall bias. It should also be noted that the reliability of the ICS items ($\alpha = .59$) was lower than desired. In future studies, we plan to validate the CAM-A with an outcome measuring ICS adherence and to comprehensively assess control using validated questionnaires, objective measures of lung function, and additional patient-reported outcomes.

In conclusion, we have developed a robust self-administered questionnaire that captures CAM endorsement and negative ICS beliefs in urban minority adults with persistent asthma. We also offer preliminary evidence of its clinical utility in prompting providers to initiate conversations about beliefs and behaviors not typically discussed but that likely undermine adherence to

TABLE IV. Description of clinic visits (n = 32*)

| | Saw CAM-A results | | Did not see CAM-A results | | P value (t test) |
|---------------------------------------|-------------------|-------------|---------------------------|------------|------------------|
| | Mean (SD) | Range | Mean (SD) | Range | |
| Length of visit | 23.05 (9.14) | 12.53-50.04 | 23.36 (9.04) | 9.23-38.23 | .93 |
| Time when provider is talking | 9.29 (3.57) | 4.03-12.3 | 9.33 (3.57) | 3.21-16.56 | .97 |
| Time when patient is talking | 7.63 (3.94) | 3.08-17.47 | 7.69 (3.9) | 1.45-14.18 | .96 |
| Time of silence | 6.87 (8.26) | 1.3-29.08 | 5.14 (3.19) | 0.25-12.04 | .43 |
| No. of interruptions made by provider | 8.21 (8.15) | 0-30 | 7.72 (5.89) | 1-23 | .84 |
| No. of interruptions made by patient | 7.71 (7.48) | 0-23 | 7.89 (6.82) | 0-24 | .95 |

*The recording of 1 primary care visit was corrupted and not included in the interview analysis.

medical advice. It is the provider who must take responsibility for eliciting this information and for responding in a manner that strengthens the partnership with the patient. Further research is needed to fully understand the clinical value that such patient-provider communication might have on enhanced disease control.

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Clinical implications: Patient-provider discussions about CAM endorsement and negative ICS beliefs might not routinely occur. This study demonstrates that both are associated with uncontrolled asthma and likely undermine ICS adherence.

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