

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

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