Enrolling African-American and Latino patients with asthma in comparative effectiveness research: Lessons learned from 8 patient-centered studies


Background: African-American and Latino patients are often difficult to recruit for asthma studies. This challenge is a barrier to improving asthma care and outcomes for these populations. Objectives: We sought to examine the recruitment experiences of 8 asthma comparative effectiveness studies that specifically targeted African-American and Latino patients, and identify the solutions they developed to improve recruitment. Methods: Case report methodology was used to gather and evaluate information on study design, recruitment procedures and outcomes from study protocols and annual reports, and in-depth interviews with each research team. Data were analyzed for themes, commonalities, and differences. Results: There were 4 domains of recruitment challenges: individual participant, institutional, research team, and study intervention. Participants had competing demands for time and some did not believe they had asthma. Institutional challenges included organizational policies governing monetary incentives and staff hiring. Research team challenges included ongoing training needs of recruitment staff, and intervention designs often were unappealing to participants because of inconveniences. Teams identified a host of strategies to address these challenges, most importantly engagement of patients and other stakeholders in study design and troubleshooting, and flexibility in data collection and intervention application to meet the varied needs of patients.

Conclusions: Asthma researchers may have greater success with recruitment by addressing uncertainty among patients about asthma diagnosis, engaging stakeholders in all aspects of study design and implementation, and maximizing flexibility of study and intervention protocols. However, even with such efforts, engagement of African-American and Latino patients in asthma research may remain low. Greater investment in research on engaging these populations in asthma research may ultimately be needed to improve their asthma care and outcomes. (J Allergy Clin Immunol 2016;138:1600-7.)

Key words: Comparative effectiveness research, patient-centered outcomes research, asthma, study recruitment, vulnerable populations

Underrepresentation of minorities in asthma research limits progress toward improved health and health care for people with the disease and for members of minority populations.1,4 The problem persists despite evidence that African-Americans and Latinos are as interested in participating in research as Caucasians.1 A new opportunity to identify better strategies for engaging minority patients in asthma research occurred with the funding of 8 comparative effectiveness studies in 2013 by the Patient-Centered Outcomes Research Institute’s Asthma Disparities Program.2 All 8 studies involved patients and other stakeholders represent the views of PCORI, its Board of Governors, or the Methodology Committee.

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as research partners in every element of study design, including recruitment, as recommended by Patient-Centered Outcomes Research Institute’s methodology standards and a patient engagement rubric. The objective of this report was to describe the context for recruitment activities of the 8 studies, and to summarize the challenges to recruitment they faced and the solutions they developed to improve recruitment of African-American and Latino patients for comparative effectiveness studies of asthma care.

METHODS

We used case study methodology to examine the recruitment methods and their effects among the 8 addressing disparities. Using qualitative data collection methods, case studies are well-suited for describing methods used in programs and the perspectives of key informants on their effectiveness, as well as retrospectively gauging their impact, with the intent of understanding how and why events occur, in this case in the context of clinical research. Conclusions from case studies provide a unique contribution to the development or modification of theories and to a deeper understanding of the underlying processes, themes, and components of the topic under investigation.

Data sources

Information on study design, recruitment procedures, and recruitment outcomes was summarized from the 8 study proposals and subsequent progress reports. Each of the principal investigators (or a designee) was asked to review this information for accuracy and completeness, providing updates and revisions as necessary (see the sample interview in this article’s Online Repository at www.jacionline.org).

Telephone interviews were then conducted with the principal investigators, either solely or with other team members (eg, project manager), for a range of 1 to 5 team members at each interview. A structured guide was used to ask open-ended questions about challenges and solutions to recruitment, followed by questions about specific barriers identified from previous discussions with investigators and from a review of literature on recruiting hard-to-reach populations. Interviewees were asked for their perceptions of the most and least successful approaches to recruitment. Interviews were conducted by 2 of the investigators (S.D. and L.L.) and an assistant documented responses verbatim.

Analysis

Iterative cycles of data collection and analysis were conducted to identify the information most relevant to the case study’s research questions and to classify patterns and themes. The following case facts and context were documented for all teams: (1) the planned and final study population; (2) recruitment techniques, incentives, and percent enrollment at study midpoint; and (3) recruitment challenges that teams faced and methods used to surmount them.

The content of the study proposals, progress reports, and interview notes was analyzed manually to categorize the information and identify commonalities across studies. Data for each variable or domain (eg, recruitment techniques, involvement of patient advisors) were arrayed by the 8 teams. Frequencies for quantitative variables were calculated. Findings were also summarized by documenting patterns and themes on the basis of context, activities, and phenomena that characterized the recruitment experiences. Data tables were reviewed, interpreted, and further summarized by the authors during 3 group teleconferences. Data were organized into 4 levels of recruitment challenges: (1) participant (individual with asthma or caregiver), (2) institutional (ie, organizational policies governing study procedures), (3) research team (resources, experiences), and (4) study intervention (features, constraints).

RESULTS

Participants’ characteristics

All 8 studies targeted minority populations (Table I): African-Americans alone (3), Latinos alone (1), or both African-American and Latino populations (4). Studies focused on children (4) or adults alone (3), including 1 targeting adults older than 60 years, and 1 study included both children and adults. Most enrolled individuals from urban environments. Eligibility for each study was based, in part, on asthma severity or control at baseline although different criteria were applied. Severity was defined by physician classification documented in the electronic health record. Control was defined by patient-reported control level based on standardized questionnaires measuring symptom days, use of emergency department and hospital visits related to asthma, and medication use.

Study design and recruitment

A unique feature of the Patient-Centered Outcomes Research Institute funding was the requirement for in-depth stakeholder participation. Determining who is a stakeholder was at the discretion of the individual research teams, but they always included patients or their representatives such as caregivers and family members. Other stakeholders were advocacy organizations, community-based service providers, health care providers, and insurers. Stakeholders were actively and extensively involved in intervention and recruitment procedures for all 8 studies. This included contributions to development of the recruitment strategies and materials, and troubleshooting recruitment when problems arose.

The interventions consisted primarily of asthma self-management support or implementation of an alternative treatment strategy of 6- to 15-month duration administered by care coaches or community health workers (CHWs) in patients’ homes, other community settings, and clinical practices (Table II). Although all the study interventions addressed asthma in vulnerable populations, the interventions themselves required different time commitments for patients, ranging from 7.5 to 19 hours through multiple encounters.

Recruitment procedures varied as well. Most studies initiated patient contact by recruitment letter, which was followed by a telephone call or in-person encounter, or both. To optimize recruitment at study implementation, the teams used various strategies, including low-literacy communication techniques to clearly explain study procedures, culturally concordant individuals for recruitment (eg, CHWs), and financial incentives. Total compensation for study participation ranged from $50 to $345. In addition, several teams used nonmonetary incentives, typically asthma supplies such as mattress covers, spacers, and air filters. Travel costs were supported through vouchers or reimbursement.

The 8 studies had planned enrollment periods of 10 to 12 months, with enrollment targets ranging from 200 to 640 participants. By study midpoint, 6 studies had recruited fewer than half of patients originally targeted for that time period and 5

Abbreviations used

CHW: Community health worker
IRB: Institutional review board
had recruited less than 25% of their midpoint goals, despite the patient-centered approaches to recruitment originally designed for these studies and the intensive involvement of patients and other caregivers in recruitment design. Accrual ranged from 3% to 67% of goal at study midpoint. The 5 with the lowest percentage recruitment also offered the lowest monetary incentives.

**Recruitment challenges and solutions**

**Participant challenges.** Barriers to recruitment at the individual participant level fell into 6 categories, and 2 of the 6 were specific to recruitment of people with asthma (Table III). Five of the 8 research teams reported that patients initially refused to participate in the study because they (or their caregivers) did not think they had asthma even though clinical records indicated they did and they were prescribed inhaled corticosteroids. To accommodate these self-perceptions, some research teams adjusted their recruitment language to substitute “breathing problems” and similar terms for the word “asthma.” Another strategy was to have the patients’ physicians speak with the patients to clarify their asthma diagnoses.

Other patients appeared uninterested in participating in the studies because although they acknowledged their asthma diagnosis, they did not consider it a serious health problem or they placed a higher priority on another chronic health problem,
such as diabetes or cancer. One approach to addressing the reluctance of such patients was to emphasize the collateral (nonasthma focused) benefits of participating in the study. For example, some interventions addressed issues that might be of greater concern to patients, such as assistance with remediation of mold or cockroach problems, other housing issues, or assistance with navigating the health care system.

The other 4 recruitment barriers presented by patients were not asthma-specific. They included aversion to participating in research in general, competing priorities such as childcare or work, inability to be contacted, and “no shows” at baseline encounters. All 8 studies reported that large proportions of the patients/caregivers they approached were simply uninterested in participating in any type of research. Although teams typically sought to understand why patients did not want to participate, they were not always forthcoming. A common strategy used to stimulate the patients’ interest was to point out that their physician recommended them for the study. Recruitment staff also spent extra time with reluctant patients to explain the study and its benefits.

Competing priorities such as childcare or work kept potential participants from attending baseline visits and reduced phone access. Recruitment staff members were trained to respond flexibly to such constraints, for example, by offering visits and phone calls during nonwork hours and weekends and evenings. If participants needed to bring their children with them, staff made sure the children had toys and coloring materials to occupy them. Research and clinical visits were scheduled in tandem to reduce rescheduling appointments.

Study teams used various strategies, often time intensive, to address the common challenge of reaching potential participants/caregivers for recruitment, especially by telephone. Aside from checking the accuracy of or updating contact information, study teams varied the time and days at which they made recruitment calls, including early morning, evenings, and weekends. They also used text messaging with patients to determine best times for calls, left written messages on patients’ home doors, and sent flyers home to parents through the schools.

Screening for study eligibility was typically followed by an in-person meeting, in a home, office, or emergency department, to review the study protocol, obtain signed consent, and conduct the baseline interview. “No shows” were problematic for 6 teams, arising from work schedule conflicts, childcare responsibilities, lack of transportation, inclement weather, and health problems, among others. Again the strategies to overcome these challenges were varied and resource intensive, but most often involved having the flexibility to adapt to patients’ schedules. The most intensive strategy involved home visits (used by 4 of the studies).

### TABLE III. Participant challenges to study recruitment and solutions

<table>
<thead>
<tr>
<th>Specific challenges</th>
<th>No. of awardees affected</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients/caregivers (or caregivers) do not believe they (or their child) have asthma</td>
<td>5</td>
<td>• Asked the treating physician to explain asthma diagnosis to patients/caregivers</td>
</tr>
<tr>
<td>Asthma considered to be less important than other chronic conditions (eg, diabetes and cancer)</td>
<td>3</td>
<td>• Engaged patients/caregivers in a conversation about their symptoms and medications so that they would prioritize their asthma diagnosis</td>
</tr>
<tr>
<td>Patients/caregivers were averse to participating in research</td>
<td>8</td>
<td>• Emphasized connection with known and trusted health care provider (eg, sent recruitment letters on community health center letterhead)</td>
</tr>
<tr>
<td>Unable to reach patients/caregivers by telephone</td>
<td>8</td>
<td>• Offered early morning, evening, and weekend appointments, and flexibility in rescheduling appointments</td>
</tr>
<tr>
<td>Competing priorities</td>
<td>8</td>
<td>• Offered early morning, evening, and weekend appointments</td>
</tr>
<tr>
<td>Work</td>
<td></td>
<td>• Offered in-home or phone appointments</td>
</tr>
<tr>
<td>Child care</td>
<td></td>
<td>• Scheduled research-related visits in tandem with clinical appointments</td>
</tr>
<tr>
<td>Missed baseline meeting</td>
<td>8</td>
<td>• Improved the experience for children who attend visits by providing materials such as crayons and coloring sheets</td>
</tr>
<tr>
<td>Unable to recruit adolescents aged 12-15 y</td>
<td>1</td>
<td>• Although parental consent was needed for children younger than 18 y, study team also met individually with teens aged 12-15 y who wanted to be treated as individuals and make their own decisions about participation</td>
</tr>
</tbody>
</table>
Incentives: How and when incentives were disbursed differed by institution (cash, check, gift certificate, debit card)

- Staff were encouraged to communicate with patients/caregivers as often as possible to confirm appointments through the approved channels
- Staff explained to patients/caregivers why they could not accommodate their preferences for text and email reminders
- Staff communicated with partner organizations to motivate them to recruit to the study

Incentives: Insufficient funding for incentives and/or limitations on incentives

- Used nonmonetary incentives, eg, asthma supplies, which could be obtained by the study team at no or low cost, or did not violate rules on limits for financial incentives

Institutional regulations

- Hired CHWs as independent contractors, enabling more flexibility in hiring and compensation across multiple sites
- Used different position titles to achieve equity in compensation for institutional and contracted employees

Technical language (required) of consent forms difficult for target population to understand

- Revised standard consent template and assent forms to improve readability
- Recruitment staff trained to use low-literacy communication techniques
- Recruitment staff readdressed key elements of the consent letter at baseline interviews
- Teams created companion materials using concise, plain language

Multiple IRB approvals for multisite studies

- Developed collaborative/cooperative agreements between site IRBs
- Received IRB approval at primary site; then used IRB-approved materials for submission to other IRBs
- Go to the same IRB group for any amendments to prevent delays in review/approval
- Made language generalizable to limit what needs to be approved (eg, rather than list a specific number of calls that will be made, phrase as “make additional calls as appropriate”)

IRB-related issues

- Staff explained to patients/caregivers why they could not accommodate their preferences for text and email reminders
- Staff communicated with partner organizations to motivate them to recruit to the study

Institutional challenges. Institutional review board (IRB) policies created several challenges for recruitment. Four studies were subject to approval from multiple IRBs, which created both complicated logistical procedures and recruitment delays (Table IV). To reduce the impact of complex IRB coordination and reduce subsequent delays, some teams first submitted all study materials and protocols to a single IRB and when approved, used them as the templates for submission to the other IRBs. A cooperative or reciprocal agreement between IRBs further streamlined this process but was not permitted in 1 study. A strategy that helped reduce the number of IRB modifications was to use language that was as general as possible, for example, “make additional calls as necessary” rather than specifying the number of follow-up calls. Teams working in organizations with multiple IRBs arranged submissions to ensure review by the same IRB.

Stakeholders on 4 study teams found that the standard consent language required by their IRBs was overly complex, resulting in difficult-to-understand language that was inadequate for communicating risks and benefits to study participation. The research teams worked around these communication barriers by creating companion materials to explain the studies in accessible and succinct ways, by training staff in low-literacy communication techniques, and working with research staff to anticipate questions they might receive from patients or caregivers about the study and consent and develop appropriate responses. One team wanted its patient partners to listen to recruitment calls and provide feedback to the staff to improve their recruitment communication skills, but institutional policies required them to undergo lengthy research ethics training, which proved too onerous for most.

Other institutional policies governed how study staff could be hired and paid. Budgetary and equity problems arose when study teams were composed of individuals from multiple organizations. For example, teams that sought to use CHWs from different organizations faced concerns of equitable compensation when employees with comparable skill sets and job descriptions had different salaries owing to their institutional affiliation. One way of working around this particular problem was to create new job titles to allow greater flexibility in compensating study team members.

Policies regarding the amount and type of incentives that could be offered to participants were set by some governing institutions.

This approach was especially helpful for recruitment of adults too impaired by illness to make clinic visits. However, it was not universally accepted by patients, many of whom were reluctant to have study staff in their homes.

Flexibility to meet the needs of patients was also achieved by allowing appointments to be rescheduled, multiple times if needed. Additional flexibility was applied to the study protocol; an example was to substitute in-person interviews with phone interviews. Transportation challenges were addressed by providing vouchers for public transportation or car/cab services, and for parking. Frequent appointment reminders also helped: through mailings, text messaging, and multiple telephone calls.
Research teams worked around limited financial incentives by offering asthma supplies such as spacers, vacuums, and air filters.

**Research team challenges**

Recruitment challenges inherent to the teams themselves mainly arose from the need for continuous training, staff retention, and limited support from partner physicians and organizations for recruitment (Table V). Although these challenges affect many clinical studies, they may require extra preparation for studies of patients from minority and low-income communities owing to language, literacy, other sociocultural concerns, greater suspicion of researchers, and logistical challenges (eg, transportation and child care).

Ongoing training of staff was needed to continually refine recruitment procedures, problem-solve, and develop new processes. Training on how to best reach subjects, introduce and describe the study in lay language and in culturally appropriate ways, and how to engage participants were all topics that needed ongoing attention and discussion as the studies progressed. Staff turnover was another serious problem that contributed to slow recruitment and newly hired staff required extensive trainings. Several studies relied on recruitment through physician offices that were isolated from the study staff and motivating partners to recruit for the study required ongoing communication and building of trust.

**Study intervention challenges.** There were also challenges inherent to the nature of the interventions themselves (Table VI). Some patients were interested in participating only in a specific arm of the study and wanted to choose the study arm for themselves. Some were unwilling to make the number of office visits required by the intervention, or to allow study staff in their homes. Many did not want to spend the time it would take to participate. Finally, the studies enrolled patients for a year or longer and during the seasons when asthma is less active for some, recruitment was slower. These issues were addressed through flexibility with how the interventions were delivered, for example, allowing fewer visits than those originally planned for the intervention. Improvements in communication about the study, including its processes and benefits, during the consent process sometimes also overcame barriers of this type.

**DISCUSSION**

This case study of 8 concurrently implemented but separate comparative effectiveness studies to reduce asthma disparities identified 4 levels of barriers to recruitment: participants (patients and their caregivers), institutional, research team, and study design. Maintaining recruitment milestones was difficult despite the use of patient-centered designs and extensive stakeholder engagement before implementation.

**Participant level**

Particularly notable among the recruitment barriers arising from patients themselves was the belief that they did not have asthma and therefore should not participate in an asthma study. This observation is consistent with the well-described belief among many people with asthma that when asthma symptoms are not present, neither is the disease. This “no symptoms-no asthma” belief appears more commonly among adults who are at risk for poorer asthma outcomes in general, such as those with low levels of health literacy, indicating that this is a barrier that may result in the exclusion of patients who may be among those most likely to benefit from novel interventions to improve asthma outcomes. Most commonly, the studies described here addressed the belief barrier by including recruitment language that emphasized symptoms over the diagnostic label of asthma, for example, by discussing difficulty breathing. Some engaged clinicians to help explain to patients that they did indeed have asthma. Importantly, although the no symptoms-no asthma belief is common in some populations, many patients who denied having asthma were correct and were mislabeled with the diagnosis. Others may have had asthma but believe that it was well controlled and therefore participation in a study on asthma may not have seemed like a worthwhile use of their time.

Most other barriers arising from patients were typical of those recruiting individuals from low-income or minority populations. The strategies used by the 8 teams to address such barriers were similar to those described in a recent review of the literature on recruitment. These demonstrate that successful recruitment of people from minority communities, whether with asthma or not, must be preceded by understanding the social context of the participants and identification of barriers and facilitators.

Patient-centered approaches can lead to more culturally competent recruitment methods. The researchers recommended early and regular inclusion of patient-stakeholder feedback to monitor recruitment progress. It is important to note that recruitment of hard-to-reach populations takes a considerable investment of time and other resources. Funders may want to acknowledge this in their funding announcements and consider that additional resources spent on recruitment have an opportunity cost that may be detrimental to other aspects of the study. Notably, the 4 studies with lowest recruitment at midpoint also had the lowest monetary incentives. A careful examination of the burden versus incentive trade-off that people make when considering research participation is warranted to ensure that we are neither coercive nor underestimating the value of time and money to vulnerable populations. Future studies that involve recruitment of hard-to-reach patients should consider using stakeholder advisory groups to provide more insight into how best to compensate patients for their participation.

**Institutional level**

Barriers to recruitment arising from other sources, such as unclear or confusing language in consent forms or the lack of age or race concordant recruiters, were also similar to those described elsewhere, as were the solutions. Although IRB’s aim is to protect human subjects, patients and stakeholders found the required consent language confusing and therefore counter to IRB goals. Similarly, institutions disallowed contact by text and email when those were preferred modes of contact for participants. Each contact modality carries distinct Health Insurance Portability and Accountability Act (HIPAA) risks, requiring institutions to develop new policies, which is time-intensive or resisted.

Another important barrier observed among the studies was the challenge that some groups faced with onboarding CHWs from outside institutions. Academic-community collaboration is increasingly recognized as a powerful method for delivering improved health care for patients at high risk for poor health outcomes, yet interinstitutional collaboration often faces various barriers to smooth functioning, including human resources.
Safety concerns about home-based interviews. Patients/caregivers concerned about the reach and impact of clinical research. Researchers from the target communities is critical for maximizing the traditional academic silo of research to involvement of nonrole-play. These observations demonstrate that moving beyond stakeholder partners, and using them in staff development through studies.

Table V. Research team and study intervention challenges to study recruitment and solutions

<table>
<thead>
<tr>
<th>Research team-level challenges</th>
<th>No. of awardees affected</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited resources and staff time for patient/caregiver recruitment</td>
<td>4</td>
<td>● Multiple contacts by study staff to explain benefits</td>
</tr>
<tr>
<td>Safety concerns about home-based interviews</td>
<td>3</td>
<td>● In ED, initiated recruitment before discharge of patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● Move from ED to another location to complete recruitment and open the ED bed</td>
</tr>
</tbody>
</table>

Table VI. Suggested practices for recruiting African-American and Latino patients in asthma comparative effectiveness research studies

- Include patient-stakeholders early in study design and implementation
- Include patient-stakeholders in training of research staff (eg, role playing) and engage them in recruitment monitoring and troubleshooting
- Employ CHWs or patient/caregiver-peers as recruiters
- Consider engaging potential study participants through discussion of their pulmonary symptoms rather than centering the recruitment effort on their asthma diagnosis
- Have flexibility in data collection efforts and intervention delivery protocols to accommodate participant preferences (eg, location of visits)
- Use low-literacy communication strategies with verbal communication and print materials
- Budget finances and time generously for the recruitment effort: lengthy training for staff and prolonged recruitment periods, extra recruitment staff, and large stipends

Concerns. No easy solutions to overcoming this barrier were identified by the study teams, indicating that more work is needed to facilitate this level of collaboration between the academic and community-based organizations, enabling projects to benefit from the strengths of each.

Research team level

Study teams must consider strategies to promote greater stability among research staff to reduce turnover and build depth in communication and recruitment skills with patients from minority communities. Employing CHWs was identified as one solution toward this objective. Another was the engagement of stakeholder partners, and using them in staff development through role-play. These observations demonstrate that moving beyond the traditional academic silo of research to involvement of non-researchers from the target communities is critical for maximizing the reach and impact of clinical research.

Study intervention level

Considerable flexibility was required of study teams to enable patients to participate in the activities of the study interventions. To cope with the various barriers to research participation faced by members of minority communities, whether with asthma or not, more and more studies will need to adopt pragmatic trial designs. In contrast to efficacy trials, pragmatic trials focus on the effectiveness of interventions in settings with minimal constraints imposed by the research design. Although such an approach to research may sacrifice gaining knowledge about the maximum potential impact of the intervention on outcomes, the benefit may be greater participation in research by difficult-to-engage patients and a real-world understanding of an intervention’s likely impact on those patients.

Study strengths and limitations

This article has a number of strengths. First, it examines the experience of 8 geographically unique studies that covered the lifespan of individuals with asthma, and thus it provides a uniquely broad view of experience with recruitment of people with asthma from African-American and Latino communities. Second, although recruiting African-Americans and Latinos may pose similar challenges for studies addressing other chronic illnesses, this article identified a barrier to study participation not previously described in the research literature that is specific to asthma—the commonly held belief among patients with asthma that they do not have asthma. Third, this article highlights that
Despite the intensive, patient-centered, and stakeholder-engaged efforts undertaken to recruit minority patients for asthma research, recruitment was an enormous challenge for most of the 8 studies. This finding should alert agencies such as the National Heart, Lung, and Blood Institute to the urgent need to promote research into engaging improvement of patients with asthma in asthma research. Without a significant commitment of funding for such research, participation in asthma research by members of minority communities will remain low and racial and ethnic disparities in asthma care and outcomes will persist.

Despite these strengths, this article has some notable limitations. We conducted a case study, which provides narrative rather than quantitative data, so conclusions about the prevalence of barriers to engagement in research studies and their impact cannot be determined with high levels of precision. Second, recruitment strategies used by the study teams were not formally evaluated within each study, so the real impact of the strategies also cannot be determined. Finally, this report focused on recruitment, which may or may not also generalize to retention of minorities with asthma in clinical trials.

In conclusion, asthma is a common and serious health problem in minority communities. Our data indicate that asthma researchers must address a broad range of asthma-specific and non–asthma-specific barriers to recruiting patients for their studies to improve the health and health care of minority patients with asthma. Serious involvement of patients with asthma, other stakeholders, and members of these very communities in research design and implementation is critically important to overcoming barriers to research participation. Broader use of pragmatic trial designs, which provide flexibility in interventions and data collection to make research participation attractive and feasible for patients whose participation in research has been historically low, is another strategy that may improve study participation. But as demonstrated in this evaluation, many of the 8 patient-centered comparative effectiveness asthma studies that involved extensive stakeholder engagement and use pragmatic trial designs struggled or failed to reach their recruitment goals. Such a finding should be a wakeup call to agencies that fund asthma research and reviewers of asthma research proposals alike to recognize that recruiting low-income patients from minority communities for asthma studies is often slow, labor intensive, and costly, and that greater investments in determining how best to engage patients with asthma in clinical research is warranted.

We thank Ayodola Anise, MHS, for her support throughout the studies. We express our deep gratitude to the colleagues and Patient and Stakeholder advisors on our teams who contributed to recruitment activities as well as many other aspects of the studies.

Key messages

- Recruitment of African-American and Latino patients for asthma studies may be enhanced by clarifying diagnoses, including stakeholder advisors, removing impediments, and maximizing study flexibility.
- Recruitment from minority populations requires extra time and resources.
- These conclusions can apply to the practice setting.

REFERENCES