

Using stakeholder engagement to develop a patient-centered pediatric asthma intervention



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Stakeholder engagement has the potential to develop research interventions that are responsive to patient and provider preferences. This approach contrasts with traditional models of clinical research in which researchers determine the study's design. This article describes the effect of stakeholder engagement on the design of a randomized trial of an

intervention designed to improve child asthma outcomes by reducing parental stress. The study team developed and implemented a stakeholder engagement process that provided iterative feedback regarding the study design, patient-centered outcomes, and intervention. Stakeholder engagement incorporated the perspectives of parents of children with asthma; local providers of community-based medical, legal, and social services; and national experts in asthma research methodology and implementation. Through a year-long process of multidimensional stakeholder engagement, the research team successfully refined and implemented a patient-centered study protocol. Key stakeholder contributions included selection of patient-centered outcome measures, refinement of intervention content and format, and language framing the study in a culturally appropriate manner. Stakeholder engagement was a useful framework for developing an intervention that was acceptable and relevant to our target population. This approach might have unique benefits in underserved populations, leading to sustainable improvement in health outcomes and reduced disparities. (J Allergy Clin Immunol 2016;138:1512-7.)

Key words: Asthma, stress, intervention, patient engagement, stakeholder engagement, protocol development

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Stakeholder engagement has emerged as a framework for developing research interventions that are responsive to the preferences of patients and other stakeholders and that are therefore more likely to improve care and outcomes.¹ This approach might be novel to most clinical researchers, who are generally more familiar with investigator-initiated study designs. The Patient-Centered Outcomes Research Institute defines engagement as the “meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process, with stakeholders reflecting the intended end users of research results.”^{2,3} Here we describe the novel use and effect of stakeholder engagement on the design of a behavioral intervention targeting parents of children with persistent asthma.

With funding provided by the Patient-Centered Outcomes Research Institute (AS-1307-05284), we sought to design and test an intervention aiming to improve child asthma outcomes through reducing parental stress. Psychosocial stress is well documented as a mediator of poor asthma outcomes,⁴⁻⁸ with growing evidence of a causal relationship between exposure to individual or community stressors and asthma morbidity through various mechanisms, including genetics, epigenetics, altered immune

Abbreviations used

NAC: National Advisory Core

SEC: Stakeholder Engagement Core

response, decreased response to treatment, and behaviors.^{7,9,10} Federal agencies have identified the link between stress and asthma as a high-priority research area.^{11,12}

Our study aims to address disparities by improving asthma outcomes among low-income African American children, who are at high risk for asthma morbidity.¹³⁻¹⁵ The goal of targeting psychosocial stress is particularly relevant in underresourced minority communities, which experience high rates of exposure to chronic stressors.^{10,16} We sought to develop an intervention relevant to community-specific perceptions of stress and intervention preferences.

This article describes the process and results of our stakeholder engagement and provides guidance to other study investigators seeking to engage patients in the collaborative development of patient-centered research protocols.

METHODS

Over a 12-month period (March 2014-February 2015), our study team engaged a broad range of community stakeholders from Washington, DC, and national collaborators in the first phase of a planned prospective randomized clinical trial: the design of a behavioral intervention addressing psychosocial stress among the parents of urban, low-income African American children aged 4 to 12 years with asthma.

Our engagement plan consisted of 3 integrated components, which operated in an iterative manner (Fig 1) to provide input to the team regarding the study design, patient-centered outcomes, and intervention structure and content:

1. *Stakeholder Engagement Core (SEC)*: Comprised of 4 parents of children with asthma, as well as 6 local providers of social, medical, legal, and educational services, the SEC met 6 times during the planning period. Activities of this component were overseen by a masters-prepared research team member (L.S.) who is also a well-established liaison between our hospital (Children's National Health System) and the broader Washington, DC, community. She had previously served as the Vice-Chair of the hospital's Parent and Patient Advisory Council.
2. *Qualitative research*: We conducted 2 focus groups and 10 one-on-one interviews with African American parents of children aged 4 to 12 years with asthma to understand key stressors, coping strategies, and intervention preferences.
3. *National Advisory Core (NAC)*: Comprised of 4 persons with expertise in asthma trials among at-risk youth, psychosocial stress, and medication adherence, the NAC met 3 times during the planning period.

Stakeholder engagement

Potential members of the SEC were identified in a process that began during proposal preparation. During this "pre-engagement" phase, the SEC liaison spoke with African American parents of children with asthma to learn about their experiences of stress and stress management. The principal investigator also contacted local medical, legal, and social service providers to discuss the planned study and to request their participation as stakeholders. Input from these conversations, as well as prior local qualitative research,¹⁷ informed the initially proposed study design.

Once funded, activities focused on preparing the parents of children with asthma to participate fully as stakeholders for this effort. The SEC liaison invited parents based on their level of expressed interest and commitment and

implemented an onboarding process that aimed to orient them to the research process and increase their confidence and comfort interacting with researchers and other professionals in this capacity.

In initial face-to-face meetings SEC members were introduced to the goals of the research project and oriented to the planning process. In the first meeting significant time was spent developing relationships and sharing perspectives. The research team shared our vision for the engagement process over the entire study period, with specific emphasis on the planned scope of involvement during the planning period before the launch of the trial. Stakeholders were informed that they would be compensated for their time. The investigators also provided background on asthma and stress management and explained the significance of our research question. In subsequent sessions the SEC were asked to review and refine the proposed questions for use in focus groups and interviews of parents of children with asthma and subsequently assisted the study team in interpreting results of this qualitative work. The feedback from the SEC was then used to revise study and intervention protocols. SEC meetings occurred primarily in a community location, with a telephone option for members who would otherwise be unable to participate. Some meetings included only the parent members, and others included both parents and local service providers.

Qualitative research

The study team gathered a broader range of parent perspectives through implementing a qualitative research study with African American parents of children aged 4 to 12 years. The Institutional Review Board at Children's National Health System approved this study. Participants were recruited from the IMPACT DC Asthma Clinic¹⁸ and the emergency department at Children's National Health System. This recruitment strategy targeted both parents who seek preventive asthma care services for their children and those who primarily receive episodic acute care.

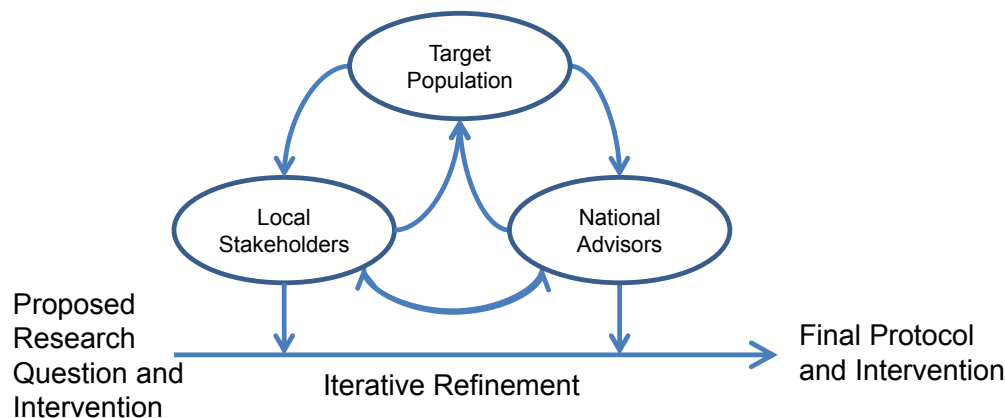
After providing informed consent, parents participated in either focus groups or one-on-one qualitative interviews to elucidate sources and experiences of stress, coping strategies, and intervention preferences. The focus groups and interviews were professionally transcribed and analyzed by using both *a priori* codes and emergent codes from parents' narratives. Preliminary analysis of the data was discussed in depth with the SEC and NAC, and the interpreted findings were used to adapt the draft intervention.

National advisors

The NAC convened every 3 to 4 months by telephone. It provided focused feedback on methodological questions and assisted the study team in contextualizing the input received from the SEC. Specifically, the NAC provided guidance on defining the study's intervention and control groups, refining the primary hypothesis, and selecting patient-centered outcome measures. The NAC assisted the study team in ultimately designing a study that was feasible and had potential to have an effect beyond our local community.

RESULTS

The year-long engagement process produced a study protocol that began enrollment in May 2015 (ClinicalTrials.gov Identifier: NCT02374138). The study is a single-blind, prospective, randomized trial comparing our existing intervention (usual care: guideline-based asthma care in the IMPACT DC Asthma Clinic)¹⁸ with usual care plus parental stress management within a cohort of self-identified African American parent-child dyads in which the child meets the following enrollment criteria: age 4 to 12 years, persistent asthma, no relevant medical comorbidities, and public insurance. We selected the robust comparator of guideline-based asthma care to evaluate the independent contribution of the stress management intervention when provided in addition to the current standards of care. Consistent with the comparative effectiveness research goal of informing



Group	Description of Engagement
Local Stakeholders	Ongoing engagement of local providers of social, medical, legal and educational services, and parents of children with asthma.
Target Population	Focus groups and qualitative interviews with African American parents of children age 4-12y with asthma.
National Advisors	Consultation with experts in asthma interventions among at-risk youth, psychosocial stress, and medication adherence.

FIG 1. Iterative engagement process.

health care decisions by parents and clinicians, the study explores the effectiveness of a stress management intervention when provided in addition to guideline-based asthma care and not as an alternative to asthma care. All outcomes are assessed by trained research staff blinded to the participants' group assignment. Table I summarizes the changes made to the study as a result of our iterative process of stakeholder engagement.

Stakeholder contributions

The SEC's contributions ranged from suggesting alternatives for the primary outcome to helping refine the intervention content and structure. For example, the SEC felt strongly that our planned primary outcome (medication adherence) would mean far less to participants than the more patient-centered outcome of symptom-free days.¹⁹ SEC members also encouraged the inclusion of an intervention that addresses stress broadly, anticipating that some parents would identify the child's asthma as a primary stressor, whereas others would identify unrelated life challenges (eg, interpersonal and financial) that make managing their child's asthma more difficult and less of a priority. They emphasized the critical life demands associated with poverty, including poor housing conditions and underemployment, and the need for an intervention that was appropriate for challenges beyond the parents' control. The SEC also emphasized the need for a flexible, culturally relevant, and sensitive approach that is responsive to individual preferences.

In addition, the SEC provided key guidance on how best to frame the study for participants. The qualitative research showed that parents had mixed responses to the idea that their stress might negatively affect their child's health. Therefore SEC members helped the investigators to develop nonjudgmental language, acknowledging that all parents face stress and have a key role in modeling healthy responses to difficult situations. Both the recruitment script and intervention content emphasize coping

skills that are applicable in a broad range of settings and include specific wording suggested by stakeholders.

Qualitative research in the target population

Qualitative research was conducted at the midpoint of the intensive SEC engagement period. A total of 18 parents participated in focus groups and interviews, providing parent perspectives on experiences of stress, coping strategies, and intervention preferences. Parents described a broad range of stressful experiences, with the child's asthma sometimes seen as a key stressor but also as a factor making it difficult to cope with other issues. Importantly, parents had difficulty identifying coping strategies and indicated interest in learning new skills to deal with stress on an ongoing basis. Parents also emphasized the importance of relationship building, and they consistently endorsed a preference for face-to-face interactions. Although some parents expressed interest in technology-supported interventions (texting and video conferencing), many others rejected this approach. Finally, there was broad interest in in-person interactions with other parents in the study who they perceived would be facing similar challenges.

A key outcome of the engagement process was the decision to hire community wellness coaches to implement the stress management intervention. We had initially planned to hire masters-level psychologists or social workers with counseling backgrounds. As the intervention content evolved, we sought staff members who were both experts in the stress management modalities used in the intervention and relatable to participants (a key priority identified in the qualitative research). We developed the coach role, prioritizing individuals with experience teaching yoga, meditation, or other wellness activities in the District of Columbia's low-income African American community and active practice of the techniques in their own lives.

TABLE I. Changes to study design resulting from stakeholder input

Initial protocol*	Final protocol	Rationale
Primary outcome measure: adherence to ICSs	Primary outcome measure: symptom-free days	Medication adherence is not a primary goal of many parents/patients. Being healthy and able to participate fully in activities is a more patient-centered asthma outcome.
Intervention to be staffed by social workers or psychologists	The intervention is staffed by “community wellness coaches,” who are individuals with experience teaching yoga, meditation, or other wellness activities in the low-income African American community in Washington, DC.	Parents indicated a preference for staff who were relatable and had a high level of expertise.
Intervention to be supplemented by one-on-one or group support from peers	Addition of peer support groups facilitated by community wellness coaches	Parents strongly emphasized the desire for social support from other parents of children with asthma and expressed interest in group support.
Consideration of multiple technologies, including bidirectional monitoring and communication, as well as virtual support groups	Texting technology was used only to reinforce content and provide reminders.	Parents provided very mixed feedback regarding use of social media and other technologies.
All content focused on parental stress.	Addition of tools to adapt stress management techniques for participants to use with their own children	Although the intervention targets parental stress, parents and other stakeholders indicated their desire to help their children manage stress.
Initial draft intervention focused on problem solving, cognitive reframing, and parenting skills, as well as breathing, positive thinking, and self-care.	Final intervention includes mindfulness, deep breathing, positive thinking and self-care, gratitude, and how to use these tools with their children.	Content was developed to be applicable to a wide range of life stressors, with an emphasis on maintaining wellness despite challenging situations that might be beyond a parent’s control.

ICS, Inhaled corticosteroid.

*As part of initial applications, the Patient-Centered Outcomes Research Institute required a draft study design and intervention, acknowledging that it would be adapted during a period of stakeholder engagement.

National perspectives

The NAC interpreted and reinforced many of the SEC’s contributions. For example, the NAC confirmed the nonpatient centeredness of medication adherence as a primary outcome and instead suggested symptom-free days as the patient-centered primary measure. In addition, the NAC assisted us in making decisions about how to maintain a feasible intervention given the range of input we received. For example, the qualitative research indicated a strong preference for a support group, and SEC members recommended providing intervention content in a group setting. The NAC advised us to add group sessions to our planned intervention but to retain our emphasis on highly flexible individualized sessions to maximize participation.

The ultimate product of the stakeholder engagement process was the development of our protocol, titled *Breathe with Ease: A Unique Approach to Managing Stress*. Table II includes the principal components of the final intervention. All study participants receive comprehensive asthma care and care coordination through the IMPACT DC Asthma Clinic before randomization into the *Breathe with Ease: A Unique Approach to Managing Stress* study. Participants in the intervention group receive a multidimensional intervention led by community wellness coaches, with content focused on breathing exercises, mindfulness, and positive thinking. Core content is provided in 4 one-on-one sessions, with reinforcement through group sessions and text messages.

Enrollment in this study ended in May 2016. The experience with recruitment indicated a high level of acceptability of the study within our target population. For example, of the 290

eligible participants, 248 (86%) agreed to participate. Of those who refused, the majority indicated that the time commitment was their primary reason for refusal.

DISCUSSION

Through an iterative process of multidimensional stakeholder engagement, our study team developed a flexible and patient-centered study protocol with relevance to a broad range of partners, including parents of children with asthma, local program leaders and decision makers, and researchers interested in understanding how psychosocial stress affects asthma outcomes of low-income minority youth. Although this process was new and challenging for us, we ultimately succeeded in developing a study protocol that was responsive to community stakeholder feedback and substantively different from our initial proposal. As more investigators use stakeholder engagement to develop research priorities and to refine their proposed studies, the experience from us and others might provide both evidence for the benefits of engagement and useful logistical frameworks.²⁰⁻²³

Key to our local community engagement was including the input of low-income African American parents of children with asthma. Through both the SEC and our qualitative research, parents were generous in sharing their experiences and in helping us to understand how different approaches to recruiting participants and implementing our intervention might be received. This is particularly critical in underserved communities, which face complex barriers to achieving optimal health outcomes that might be poorly understood by researchers.^{23,24}

TABLE II. Stress management intervention**Component 1: One-on-one stress management sessions**

Four sessions are delivered by a trained community wellness coach. The coaches aim to conduct the first 2 sessions in person and to offer subsequent sessions by telephone.

Session	Content
1	Challenges of asthma in children and families; role of stress and introduction of tools for stress management; breathing exercise
2	Introduction to mindfulness
3	Positive thinking, self-nurturing, and gratitude exercises
4	Working together with your child in deep breathing, mindfulness, positive thinking, and gratitude <i>Wrap up:</i> Encourage continuing peer support

Component 2: Peer support

Participants are invited to take part in support groups conducted on a rolling basis for up to 6 months after enrollment. Sessions are facilitated by the community wellness coaches. Sessions include content related to stress management and/or asthma management, with the majority of time used for facilitated discussion and support. In addition, content from the intervention sessions are reinforced by periodic text messages and calls from the coaches, who will also encourage ongoing participation in the support groups.

Our engagement process also benefited greatly from incorporating a broad range of other local and national perspectives. Community-based providers of medical, legal, and social services helped us understand how local leaders could use the results of the study in their own work. National experts provided additional perspectives based on their depth of experience in what approaches would be most valuable to the broader field of asthma research.

Throughout the engagement process, we learned the importance of building trust and providing stakeholders with the resources and support needed to contribute meaningfully. The study team gave great thought to community-based meeting locations and initially conducted some smaller group meetings with parents alone to build relationships, develop trust, and enable these stakeholders to provide input in a more focused way. We benefited from the leadership of a community-based advocate, who helped frame the parent/stakeholder role, provided training and ongoing support regarding the research process, and helped the research team remain sensitive to the perceptions of medical research within the African American community.

Typically, we found that stakeholders were able to contribute most significantly when presented with very specific questions and draft materials. Although the broad feedback we received in initial meetings was helpful in developing a shared language and understanding viewpoints, open-ended discussions frequently led to confusion about the goals and purpose of our project. For example, our parents and community stakeholders frequently discussed the need for interventions beyond the scope of the project, proposing diverse approaches ranging from home remediation to school nurse training. It was at times challenging to reorient the group to the goal of creating a behavioral intervention targeting psychosocial stress.

In fact, the most consistent challenge through the engagement experience was preserving the feasibility and generalizability of our intervention while incorporating input from a broad range of partners. Managing the transparent process of decision making was complex and nuanced, and deadlines necessitated a rapid process.

We were also concerned about potential damage to our community relationships if our ultimate design was not responsive to the feedback we received. We made great efforts to explain to our partners why we selected certain approaches and were

unable to incorporate all of the feedback received. Specifically, we acknowledged their perspectives, reoriented to the scope of the current study, and recorded the other ideas as a potential future direction for our research. We have continued to be engaged with our partners and have recently identified opportunities to continue working with many of these stakeholders on new initiatives, some of which aim to address proposed intervention components that were not incorporated into the current study.

Other recent studies report meaningful benefits from engagement, including more culturally relevant and sensitive study designs and materials, despite challenges, such as establishing relationships and trust, lack of time and resources, deficits in stakeholder training, difficulty identifying appropriate stakeholders, and lack of training within research teams.^{21,25} Our multifaceted approach to engagement, involving diverse groups of stakeholders over the course of a year, enabled us to develop strong relationships and incorporate feedback to make the study both more appealing to parents and valuable to community providers. At the end of this process, we collaboratively developed a framework for subsequent study activities, including the involvement of stakeholders in training and troubleshooting during study implementation, interpreting and framing results for dissemination to different audiences, and planning for sustainability and future studies.

For other projects considering engaging stakeholders in research protocol development, we recommend the key strategies below:

1. Define stakeholders broadly, so that research findings can be useful and feasibly implemented across diverse settings and populations, including parents and/or patients, other health care and service providers, and researchers.
2. Incorporate key engagement principles of reciprocal relationships, colearning, partnerships, transparency, honesty, and trust.²⁶
3. Develop infrastructure to facilitate meaningful engagement. In our case a trusted community-based partner was essential in helping the study team understand what information, resources, and approaches would help stakeholders feel valued and heard. Funds are needed to support the commitment of time and effort by both researchers and stakeholders.

As we aim to reduce the stark disparities in asthma care and outcomes, it is essential to understand the needs, preferences, and goals of parents and children with asthma. Engagement can have practical benefits to research, such as enhancing recruitment and retention efforts. However, the biggest benefit might be in the development of generalizable and acceptable patient- and family-centered interventions that honor stakeholder priorities and preferences, making them more likely to produce sustainable improvement in health outcomes.

We thank all of our stakeholders, especially the parents of children with asthma, for their contributions to this effort.

Key concepts

A broad group of stakeholders was engaged in refining an intervention targeting psychosocial stress of parents of children with asthma. This iterative process produced a protocol that is responsive to our community's identified needs. Recommendations for researchers considering engagement include the following: (1) define stakeholders broadly, such that research findings can be useful across domains of end users (parents and/or patients, other health care and service providers, and researchers); (2) incorporate key engagement principles of reciprocal relationships, colearning, partnerships, transparency, honesty, and trust; and (3) develop infrastructure to facilitate meaningful engagement.

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