Overview

To initiate our accelerated effort to develop targeted funding announcements, PCORI staff reviewed existing research from multiple sources to identify gaps in comparative effectiveness research (CER), obtaining 488 topics and questions. We reviewed and ranked these topics, applying balancing criteria, and presented 11 topics to PCORI’s Program Development Committee for approval. In December 2012, PCORI’s Board of Governors approved the topic of treatment options for severe asthma in African-Americans and Hispanics/Latinos as one of five topics for potential development into a PCORI Funding Announcement.

On March 1, 2013, PCORI convened an ad hoc workgroup meeting in Washington, DC, to gain a multifaceted perspective on high-priority research topics, identify critical gaps in research, and distinguish research topics with the potential to produce long-lasting, high-impact results. The ad hoc workgroup included patients, researchers, stakeholders, and other webinar guests. Public comment was welcomed prior to, during, and after this meeting.

The workgroup discussed 12 themes and over 60 research gaps (see Table 1 at the end of this summary) that contribute to disparities in the treatment of asthma. Using a consensus-based process, the workgroup then identified the following five key research gap areas in treatment options for severe asthma in African-Americans and Hispanics/Latinos: (1) communication/behavior, (2) systems, (3) environment, (4) response to therapy, and (5) integration of care.

On May 6, 2013, these topics were presented to PCORI’s Board of Governors. The board approved the development of a funding announcement addressing treatment options for severe asthma in African-American and Hispanic/Latino individuals and communities.
Background

PCORI is interested in identifying research questions that evaluate important choices faced by patients and that have a good chance of providing evidence that can reduce uncertainty, support decision making, change practice, and improve patients’ health outcomes. PCORI views these gaps in the evidence base on treatment options for severe asthma in African-Americans and Hispanics/Latinos as an area where we can contribute to improving health outcomes.

Asthma is a long-lasting inflammatory disease of the airways that affects nearly 25 million Americans. Symptoms vary in strength and frequency and include coughing, shortness of breath, and tightening of the chest. Asthma disproportionately affects racial and ethnic minorities. African-Americans are one of the populations at highest risk, with almost 4.5 million people (~12%) reported to be affected in 2010. African-Americans suffer illness and death at rates significantly higher than people of other racial and ethnic groups. In 2010, 3.6 million Hispanics/Latinos (~7%) reported having asthma. Compared to the broader Hispanic/Latino population, Puerto Ricans have 2.6 times the rate of asthma. In addition, Hispanic/Latino children have a greater chance of dying from asthma compared to non-Hispanic/Latino Whites. For additional information, please see Opportunity Snapshot: Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos.¹

In December 2012, PCORI’s Board of Governors approved the topic of treatment options for severe asthma in African-Americans and Hispanics/Latinos as one of five topics for potential development into PCORI Funding Announcements. To learn more about the process followed to select these topics, see Summary of Accelerated Process to Generate Targeted PCORI Funding Announcements.²

PCORI convened an ad hoc workgroup to help identify research gaps and questions in this topic area. The workgroup participants represented diverse perspectives, including researchers, patients, other stakeholders, and PCORI Science and Engagement staff. See a list of participants³ and detailed biographies.⁴ For more on the workgroup selection process see Methodology for Selecting Workgroup Members for Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos.⁵ The workgroup met on March 1, 2013, in Washington, DC. Public comments were welcomed before, during, and after the meeting.

Meeting Summary

The workgroup meeting began with an opening, introduction of meeting participants, and overview of targeted PCORI funding announcements from Dr. Joe V. Selby, Executive Director of PCORI, and Romana Hasnain-Wynia, Director of PCORI’s Addressing Health Disparities Program. The moderator of the workgroup, Dr. James Kiley, Director of the Division of Lung Diseases at the National Heart, Lung, and Blood Institute presented an overview of disparities in asthma prevalence and outcomes among African-Americans and Hispanics/Latinos and the coordination of federal activities to reduce these disparities.

¹ Available at pcori.org/funding-opportunities/funding-announcements/treatment-options-for-severe-asthma-in-african-americansand-hispanicslatinos/#snapshot
² Available at pcori.org/assets/PCORI-Accelerated-Process-to-Generate-Targeted-Funding-Announcements.pdf
³ Available at pcori.org/assets/PCORI-Treatment-Options-Severe-Asthma-Workshop-Participants-030113.pdf
⁴ Available at pcori.org/assets/PCORI-Treatment-Options-Severe-Asthma-Biographies.pdf
⁵ Available at pcori.org/assets/PCORI-Accelerated-PFA-Methodology-Workgroup-Treatment-Options-Severe-Asthma.pdf
Dr. Kiley also provided an overview of mitigating factors thought to be associated with disparities in asthma severity and prevalence that included financial costs due to hospitalization and lost wages and the need for additional information within Hispanic/Latino groups and women, given their higher rates of asthma morbidity and mortality.

Research Presentations

During the meeting, topic experts presented current research and perspectives on research opportunities. These are summarized below and available here.6

- **“Multilevel Asthma Disparities Models”** Andrea Apter, MD, MSc, MA, Chief and Program Director, Section of Allergy and Immunology, University of Pennsylvania

  Despite demonstrated variations and disparities in asthma prevalence and severity, subpopulations that appear most affected (i.e., adults, women, African-Americans, and Hispanics/Latinos) have been inadequately studied. Despite the advancements in asthma therapies developed and disseminated in the 1980s and 1990s, these disparities remain. Rates of emergency room visits, hospitalization, and death due to uncontrolled asthma are consistently higher among African-Americans than among Whites. Factors associated with increased rates of asthma include culture and language barriers, poverty, health literacy, immigration, neighborhood locations, home environments, violence, and transportation. The most promising research advances in the reduction of asthma morbidity have been in studies that improve home environments, facilitate patient-provider communication during appointments, promote health literacy, and seek to improve the continuity of transitions in care.

- **“Pillars of Comprehensive Asthma Care”** Jean Ford, MD, Chair, Department of Medicine, The Brooklyn Hospital Center

  The paradigms for asthma have not changed significantly over the past few decades. Although some progress has been made in asthma management and decreased mortality of subpopulations, disparities remain. Efforts to reduce disparities by delivering culturally relevant interventions via tools that address literacy and language barriers show promise. There remains a need to focus on primary care practices that serve populations at risk for experiencing disparities. The development of guidelines tailored to subpopulations and improving adherence to evidence-based guidelines are important steps towards implementing sustainable interventions to improve outcomes and reduce disparities.

- **“Allergen Exposure”** Elliot Israel, MD, Director of Clinical Research, Pulmonary and Critical Care Division, Brigham and Women’s Hospitals

  Addressing delivery of and access to high-quality care are important considerations in eliminating asthma disparities. Data suggest that certain populations (e.g., minorities, low SES) may be at greater risk of certain exposures. To improve asthma outcomes, research focusing on how the healthcare system can play a role in identifying populations at risk for such environmental exposures may be important. Additionally, variability in medication responses suggests that a “one-size-fits-all approach” to asthma management may be inefficient. Customized treatment plans that take into account

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6 Available at http://www.pcori.org/assets/PCORI-Treatment-Options-Severe-Asthma-Workgroup-Presentations-030113.pptx.pdf
variability in treatment responsiveness, via clinical trials and observational studies, should be investigated further.

- “Incorporating Asthma Home Visits in Patient-Centered Medical Home” Susan Sommer, MSN, RNC, NP, AC-E, Nurse Case Manager, Children’s Hospital Boston Community Asthma Initiative

Incorporating asthma home visits, as one part of care delivery within the context of a patient-centered medical home, has demonstrated positive outcomes in quality of life for African-Americans and Hispanics/Latinos. Preliminary findings illustrate the need to continue to hone, advance, and explore the use of home visits for overcoming disparities in asthma morbidity and mortality. This would include developing tools and using technology (e.g., mobile devices, social media) to promote patient-provider communication, collecting information about the patient’s experience of care (e.g., health beliefs, attitudes, expectations, behaviors), and sharing health communication to inform treatment and management planning. Additionally, studies that focus on increasing medication adherence in the context of multiple barriers ranging from concerns about side effects to lack of employment and other competing demands faced by low-income families are needed.

- “Healthcare System Reorganization to Identify Individuals at Highest Risk for Asthma Morbidity and Mortality” Stanley J. Szeffler, MD, Director, Pediatric Clinical Trials Center; Head, Pediatric Clinical Pharmacology Training Program; Director, Allergy and Immunology–Pediatrics, National Jewish Health

Over the past 30 years, there have been significant reductions in overall mortality and hospitalization rates related to asthma. However, disparities in outcomes remain and need to be addressed to reduce the burden of asthma. Electronic health records (EHR) may provide an opportunity within the context of the healthcare system for prompting clinicians, patients, and caregivers to gather feedback and communicate about improved medication management (e.g., effectiveness, side effects, and adherence). Studies that focus on facilitating patients’, caregivers’, and clinicians’ ability to monitor care and medication management through communication and engagement tools are needed. The ability to monitor and adjust medications is as important as prescribing medication during the initial visit. Wellness with a focus on patient-centered outcomes is important. While researchers and physicians tend to focus on pulmonary functions measures, it is important to target outcomes that are important to patients and caregivers, such as quality of life, participation in work/school, and management of symptoms.
Patient and Stakeholder Perspectives on Information Gaps

After the researcher presentations, the patient and other stakeholder workgroup participants provided their perspectives on research and information gaps. These perspectives are provided below.

- Pharmacists and nurse case managers play an important role in communities, as they assist with education, medication, and care. Addressing comprehensive care management comprising patients, providers, nurses, and pharmacists is an area ripe for study.
- Biomarkers are an important area to study; however, given the time frame needed to see advances in this area, focusing on optimizing the healthcare system will be key to improving outcomes.
- Asthma specialists, including allergists and outpatient-based specialists, may help improve patient care because they provide education to and build relationships with patients.
- Physician communication approaches that are tailored to patient value systems may influence disease outcomes. More effective communication can affect how patients understand their disease and buy-in into physician recommendations, improving medication adherence and outcomes.
- Patients, parents, and teachers must be properly educated to recognize and address symptoms early. In addition, using the correct names for medications and specific terminology (e.g., “control inhaler” versus “rescue inhaler”) may have a huge effect on outcomes.
- Asthma treatment strategies that are tailored for specific patient populations need to be developed and used. Additionally, it is important to consider a local approach that takes into account variation in needs and personalizes an approach to asthma care.
- Researchers should study patients who are at greater risk for poorer outcomes, but have good asthma control despite being at greater risk. For example, there are patients living in a traditionally lower socioeconomic area of Washington, DC, with good control of asthma. Examining how and why these patients are doing well and identifying ways to implement the effective strategies to other patients at greater risk for disparate outcomes are necessary.
- Telehealth, smartphone applications, and social media may present opportunities for providers to review patient health records electronically and interact with patients from afar.
- Retrospective data from EHRs could be used to investigate factors that lead to asthma risk in children and/or factors that contribute to disparities, helping to prevent asthma before it begins.

Patients and Other Stakeholders

Patient Participants

Vernal Branch, Patient Advocate
Charryse Johnson, Patient Advocate
Perry W. Payne, Jr., MD, JD, MPP, Advisor, Asthma and Allergy Foundation of America
Nancy Sander, President and Founder, Allergy & Asthma Network/Mothers of Asthmatics

Other Stakeholder Participants

Michael Foggs, MD, President-Elect, American College of Allergy, Asthma, and Immunology
Sandra McKinney, MS, RN, CCM, Board Member, National Black Nurses Association
Lois Wessel, RN, CFNP, Associate Director, Programs, Association of Clinicians for the Underserved
Additionally, exploring the role of depression and stress on the onset of asthma attacks may also help to prevent asthma onset.

**Action**

The workgroup followed a two-step process to narrow broad research ideas into a concise list of well-defined high-priority research questions for potential PCORI funding:

**Step 1: Identify Priority Areas of Interest**

Workgroup participants and the public provided over 60 research and information gaps (see Table 1) across 12 main topic areas:

- Communication
- Integration of care
- Systems
- Standardization of guidelines and importance of local issues
- Quality of care
- Behavior
- Knowledge and health literacy
- Response to therapy
- Home environment/exposures
- Barriers
- Patient-centered outcomes
- Methodology

**Step 2: Narrow List of Research and Information Gaps and Tailor Questions**

From the broad list of identified research and information gaps, the workgroup narrowed down the list of research and information gaps and developed tailored questions that PCORI could address through comparative effective research. These included:

- **Communication/Behavior.** Patient-, provider-, and system-level barriers have been identified in providing optimum care for asthma, particularly in minority populations. The use of social media, telehealth, gaming technology, and other innovative applications coupled with advanced qualitative methods to delineate solutions are needed to overcome some of the barriers and to improve the management and treatment for the most severely affected populations. PCORI could fund comparative effectiveness research that:
  - Compares/evaluates tools that could improve provider and patient communication (e.g., tools that address language barriers, continuity of care, cultural differences, and social barriers).
  - Compares interventions to facilitate patient and provider engagement.
  - Compares the ability of innovative education methods (e.g., current technologies such as video storytelling or social media) to improve patient outcomes in patients with varying characteristics (e.g., health beliefs, literacy level, levels of self-efficacy).

- **Integration of Care.** Paradigms for asthma treatment have changed little since advancements made in the 1980s and 1990s. Though the medical industry has made some progress in certain areas, there have been failures in the development of comprehensive models of care for individuals with severe asthma. The decreasing number of asthma specialists coupled with the patient load of clinicians limits the amount of time available to engage in patient-centered discussions and to provide patients with the appropriate care. Preliminary studies demonstrate that home visits improve asthma management and medication adherence in African-Americans with severe asthma.
There is also a need to move to an asthma model with an objective of patient wellness, rather than a reactionary model (i.e., the control of asthma symptoms). A more comprehensive patient-centered model of care will also include the engagement of patients, providers, pharmacists, nurses, and community health workers. PCORI could fund comparative effectiveness research that:

- Compares models that integrate care (e.g., team-based care with various team members such as nurse case managers, community health workers, pharmacists, physicians, and linking clinical care with home visits) and determine effect on health outcomes and patient and provider experience.
- Evaluates models to improve transitions in care (e.g., transitions from ED to outpatient or from pediatrics to adult care).

**Systems.** EHR, administrative data, and other data sources can be used to overcome barriers for improving the management and treatment for the most severely affected populations. PCORI could fund comparative effectiveness research that:

- Evaluates models that use data integration (e.g., programs, interventions) to identify and target high-risk communities and conduct comprehensive interventions in those communities that link systems for health care, home, school, and workplace to support care.

**Environment.** Though the medical industry has made some progress in certain areas, studies reveal differences in the severity and chronicity of asthma in African-American and Hispanic/Latino populations. These differences have been attributed in part to environment, co-morbidities, genetic ancestry, neighborhood locations, exposures, violence, psychosocial factors, quality of life, and other major contributors. Factors that contribute significantly to the prevalence and exacerbation of asthma could be targeted to prevent the onset of asthma or reduce the severity of asthma symptoms. PCORI could fund comparative effectiveness research that:

- Compares mechanisms for mitigating the effects that stress, violence, and psychosocial dysfunction play in asthma, particularly in those who cannot get out of the environment.
- Identifies environmental interventions (e.g., home visits, school/work interventions, community-based) that are most effective and sustainable.
- Determines if the addition of novel environmental interventions affects patient outcomes among patients failing maximal medical therapy.

**Response to Therapy.** Inhaled corticosteroids and long-acting beta agonists are often prescribed as the first line of therapy for individuals with persistent and severe asthma. Compared to their White counterparts, African-Americans and Hispanics/Latinos with severe asthma appear less responsive to these therapies when prescribed as part of the general asthma guidelines. The lack of treatment efficacy in these groups may be due to a variety of factors including race/ethnicity, genetics, culture, and environment. PCORI could fund comparative effectiveness research that:

- Evaluates the effect of adapting evidence-based guidelines to subpopulations on health outcomes.
- Compares modifiable mechanisms that underlie differential responses to therapy (e.g., mechanisms specific to African-American and Hispanic/Latino populations that respond differently to pharmacologic therapy).
- Compares modifiable factors, including environmental and genetic markers, that could contribute to the high risk for greater morbidity and mortality in these two populations and...
compare factors that could be used to identify patients who would benefit from aggressive intervention.

On May 6, 2013, these topics were presented to PCORI’s Board of Governors and approved for PCORI to develop funding announcements in one or more of the research gap areas. PCORI’s target release date for a funding announcement is June 2013, with awards slated for December 2013.

Meeting summary prepared by Romana Hasnain-Wynia, Ayodola Anise, and Amy Grossman. Posted June 6, 2013, and available on PCORI’s website. 7

7 Available at pcori.org/events/targeted-pfa-workgroup-webinar-treatment-options-for-severe-asthma-in-african-americans-and-hispanicslatinos-2/?type=past
### Table 1: Compiled Research Questions/Gap Areas

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<tr>
<th>Treatment Options for Severe Asthma in African-Americans and Hispanics/Latinos</th>
<th>Prioritized Research Questions/Gap Areas</th>
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<td><strong>Medical Factors</strong></td>
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| **Communication** | ▪ What are the best ways to overcome language barriers between patients and clinicians?  
▪ Is there time for meaningful communication?  
▪ What is the best communication technique? SDM, MI, situation?  
▪ How can the EHR help patients and providers communicate?  
▪ Social tailoring: delivering culturally appropriate interventions using knowledge we have |
| **Integration of Care** | ▪ Among asthma patients with frequent emergency department visits, compared to an educational intervention in the context of usual care, does the addition of a team-based, patient-centered, and culturally and socially tailored care management intervention improve asthma outcomes?  
▪ Compare models for team-based care with different team members (nurse case manager, community health works, pharmacist, physicians) and linking clinical care with home visits  
▪ How does integration of tailored case management and home visit model in patient-centered medical home change patient and provider experience?  
▪ Integrate services in clinic versus home settings  
▪ What is the best use of home visit?  
▪ How is the home visit and clinic information communicated/coordinated?  
▪ Importance of nurse in medication reviews and co-morbidities  
▪ Transitions in care; care coordination  
  ▪ Organize care for continuity  
  ▪ Better serve patients who need urgent care  
  ▪ Transition from teenage to adult care  
  ▪ Shortage of PCPs and overwhelmed EDs |
| **Systems** | ▪ Need for interface between healthcare system and individuals/community  
▪ How do we reorganize healthcare system to identify populations at high risk for asthma burden and mortality?  
▪ Can healthcare redesign address the need to involve community and home environments?  
▪ Do we have systems to address disparities?  
▪ What has worked locally and how can it be applied/ disseminated?  
▪ How can we evaluate the use and benefits of community participatory interventions?  
▪ What is sustainable?  
▪ Are group visits useful?  
▪ How can we identify “hot spots” of disparities? Especially using EHR |
| **Standardization (Guidelines) and** | ▪ Is what “works” local?  
▪ Cost of services such as home visits; how are most costly interventions |
| Importance of Local Issues | integrated into treatment algorithm?  
|---------------------------|-------------------------------|
| ▪ Should the algorithms be the same in all ethnic groups? How should guidelines be modified?  
| ▪ Are ICS better in AA?  
| ▪ Under-dosing in specific populations  
| ▪ Are one-size-fits-all guidelines possible?  
| Quality of Care | Differences in quality of care based on race/ethnicity?  
|-----------------|---------------------------------------------|
| ▪ Are there evidence-based approaches to improve asthma outcomes in all populations?  
| ▪ What are the differences between providers?  
| Behavior | How can we change the behaviors of care providers to improve use of guidelines/evidence-based care?  
|-----------------|---------------------------------------------------------------|
| ▪ How do PCPs get updated on latest in asthma research?  
| ▪ How do we change organizational behaviors?  
| ▪ Do patient experience, self-efficacy, and asthma control improve among patients/caregivers who engage with current technologies, such as video storytelling or social media, for communication around their asthma, compared to usual care?  
| ▪ How do we consistently induce behavior modification in minority populations with asthma and change their locus of control from external to internal?  
| ▪ How do low self-efficacy, unemployment, beliefs about lack of medication efficacy, expectations for control, powerlessness affect outcomes? Could patient-centered approaches improve this?  
| Knowledge, Health Literacy | Patient understanding of asthma as a chronic disease, knowledge of asthma diagnosis  
|-----------------|-----------------------------------------------------------------|
| ▪ How do we help families or support those who are willing to do anything to help but do not know what to do?  
| Response to Therapy | Are current asthma guidelines for initiation and escalation of medications appropriate for African-Americans/Hispanics/Latinos at all levels of severity?  
|-----------------|---------------------------------------------------------------|
| ▪ Why has there been negligible improvement in asthma morbidity in African-Americans over the past few decades?  
| ▪ What makes the African-American and Hispanic/Latino populations different in regards to response to conventional therapy? What factors contribute to the high risk for greater morbidity and mortality in these two populations?  
| ▪ Potential factors that account for steroid resistance?  
| ▪ Why are asthma prevalence, morbidity, and mortality so high in African-American women and in Puerto Ricans and what are the most important variables that negatively impact their poor asthma outcomes (e.g., obesity, stress, vitamin D deficiency, etc.)?  
| ▪ Can genetics/ancestry informative markers identify patients who would benefit from aggressive intervention?  
| ▪ How important is admixture?  
| ▪ Are there unique pathophysiologic mechanisms that drive the disease and alter the response to conventional therapies in this population? Do we need to alter current treatment strategies to more effectively achieve asthma control in this high-risk population?  
| ▪ Why are Puerto Rican individuals more affected than Mexicans?
What are the gender interactions with ethnicity?
- Lack of data on Hispanic/Latina groups
- Safety and efficacy of drugs; need for new drugs

### Environment: Home Environment/Exposures
- What can be done for the home environment that would reduce asthma morbidity?
- Are there remediable allergenic exposures that will improve outcomes? For example, school-based and workplace remediation
- In socially disadvantaged neighborhoods, compared to a standard asthma education program, does a participatory intervention design improve population-level asthma control?
- How does the patient let the provider know if medication is not working?
- Are exposures different and does this identify remediable exposures?
- Is reaction to environmental exposures different?
- Significant differences in home versus school environment (e.g., mice in schools) and asthma outcomes; greater opportunity in schools to impact many children?
- Is pollution a cause of greater morbidity in minority populations?
- What roles do stress, violence, and psychosocial dysfunction play in the expression of asthma and what can be done to neutralize their effects while they are still operative?

### Community

#### Barriers
- Poverty
- How can we reduce social burdens (family burden, work, neighborhood)?
- What are we doing about barriers (transportation)?
- Do we understand all of the barriers (only education)?

#### Patient-Centered Outcomes
- What do patients think is important?

### Methodology
- Is RCT needed to find factors we have not conserved?
- EHR or real world
- Need clinician agreement
- Guidelines must evolve
- Patient-centered outcome to direct future care
- Challenges to inform consent
- Immigration status
- Are there patient-centered approaches (e.g., for choice of medications)?
- Develop questionnaire to capture patient experience in asthma care?