Agenda

- Welcome and Introductions
- COVID-19 Update
- Patient-Centered Outcomes Research and the PREPARE Study
- What is Patient-Centered Outcomes Research
- Hear about patient experiences with research and why they became patient advisors

Objectives:

- Describe the impact asthma has on the Hispanic/Latino community
- Discuss the role that patients can play in advancing the treatment of asthma
- Identify ways you can engage in research

Guest Speakers

- Elliot Israel, MD
  - Principal Investigator
  - PREPARE Study
- Margie Lorenzi
  - Asthma Patient Research Partner/Advisor
- Alex Colón Moya
  - Asthma Patient Research Partner/Advisor
- Courtney Clyatt, MA
  - FCAN Senior Program Officer
- Teeya Winders
  - CEO and President
  - Allergy & Asthma Network

Unidos hablemos de... United, Let’s talk about...

United, Let’s talk about...
Patient-Centered Asthma Studies

Thursday, November 4, 2021
4:30 PM Eastern Time
Patient Centered Outcomes Research (PCOR) and the PREPARE Study

Elliot Israel, MD
Asthma Specialist
Principal Investigator
PREPARE Study

Why are you interested in studying asthma in the Hispanic/Latinx population?

Polling Question #1
If you have asthma, how many times have you gone to an emergency room or urgent care for your asthma?
1) 0
2) 1
3) 2
4) 3
5) 4
6) 5 or more

Polling Question #2
If you have asthma, how many times have you been hospitalized for your asthma in the past year?
1) 0
2) 1
3) 2
4) 3
5) 4
6) 5 or more
Polling Question #3
Asthma Impact Question 1
Asthma happens in Hispanic/Latinx at what rate compared to Caucasians?
1) The same
2) 35% higher
3) 50% higher
4) 100% higher

Polling Question #4
Asthma Impact Question 2
Hispanic/Latinx are how many times more likely to go to the emergency room or be hospitalized for asthma than Caucasians?
1) The same
2) 2 times
3) 5 times

Polling Questions #5
Asthma Impact Question 3
The death rate of Puerto Rican's with asthma compared to Caucasians:
1) No difference, both the same
2) 25% higher
3) 50% higher
4) 75-200%

BACKGROUND
• Asthma prevalence is 100% higher in Hispanic/Latinx (H/L) and 35% higher in African American/Blacks (AA/B) than Caucasians
• Both H/Ls and AA/Bs have double the rates of asthma related emergency room visits and hospitalizations as Caucasians and 50% higher rates of re-hospitalization
• Puerto Rican’s experience 75% - 200% higher death rate due to asthma as Caucasians
• This has been difficult to improve
Why do we do medical research?
• To understand a particular concern about human health such as what can be done to minimize asthma deaths in Hispanic/Latinx by
• Developing a scientific plan to:
  • Collect data/information
  • Analyze and figure out what the data mean
  • Distribute the findings to those who are impacted:
    • Patients
    • Communities
    • Healthcare providers
    • Healthcare policy makers
    • Payers

Polling Question #6
How much do you trust researchers?
1) A lot
2) A little
3) Not very much
4) Not at all

Different types of clinical research
• Observational
  • Nothing is changed, the researchers observe the effect of something the people have in common such as taking Vitamin E to see if there is an effect on heart disease
• Experimental – Randomized Control Trial
  • People are assigned to one or more groups by chance (by the roll of the dice)
    • One group receives an intervention such as Vitamin E and the others get a placebo (looks like a Vitamin E pill, but is not)

Which research type is better?
• Observational studies have biases that may give you the wrong answers
Vitamin E
• Many observational studies suggest that people who took Vitamin E had lower rates of heart disease
 • BUT people who take Vitamin E might be different than those who don’t
  • Maybe they watch their diet more
  • Maybe they exercise more
  • Maybe they are more conscious about their health
  Maybe there are other differences we don’t understand as to why somebody may be a taker of Vitamin E

Randomized trial of Vitamin E
• Patients were assigned to Vitamin E or a fake pill by the flip of a coin
 • NO benefit on heart disease

Different ways to help asthma research
• Being a research subject enrolling into a study or,
• Becoming a patient partner if you have asthma or care for someone with asthma – advising the researchers, becoming part of the team

Polling Question #7
Would you be willing to be a research subject in an asthma study?
1) Yes
2) No
3) Not sure
4) Depends on whether my doctor thought it was a good idea or not
5) Depends on whether my family thought it was a good idea or not
PeRson EmPowered Asthma Relief
PREPARE study

Background
• Adherence to daily inhaled corticosteroid (ICS) use is generally poor
• In controlled studies, empowering patients to use their ICS each time they use their Albuterol, Patient Activated Releven-Trigged Inhaled CorticoSteroid (PARTICS) reduces exacerbations by almost fifty percent as compared to daily use of ICS
• Why? When a patient uses albuterol for an asthma attack she is opening airways in the lungs. We are asking to also use ICS which decreases inflammation in the lungs

PREPARE Research Question
• Does PARTICS work in a real life (uncontrolled) research study?
  In patient populations that bear an increased burden of asthma (Hispanic/Latinx (H/L) and African American/Black (AA/B) ) can instructing patients to use their ICS each time they use their rescue (Albuterol) improve outcomes of importance to patients, providers, and the health care system?

Main outcome of interest
• Exacerbations: Asthma event with increased symptoms resulting in need for steroids (oral, shot or intravenous) or asthma related hospitalization.
• Can a patient empowered strategy (PARTICS) decrease the number of exacerbations per year?
PREPARE research patient population

- 19 US sites
  - Primary care and asthma specialty clinics
- 1200 patients, 600 AA/B and 600 H/L
  - Adults 18-75
  - Uncontrolled asthma
- 300 AA/B, 300 H/L – Assigned to PARTICS
- 300 AA/B, 300 H/L – Assigned to Usual Care

Research Patient follow up

- Patients are seen in person once, then followed for 15 months by monthly survey
- Last patient finished the study in April 2021 – analysis has begun to determine if PARTICS decreases the yearly number of exacerbations

PREPARE Study research team

- Typically research is conducted by trained researchers
- PREPARE is different: we include patient partners who work with the team

Why Involve Patients/Caregivers as advisors in Research

- Brings important views from people who will be impacted by the study results including what the research question should be
- Connects lived experience together with the research question
- Keeps research staff grounded
- Contributes to dissemination process & education of general public and/or relevant patient populations
PREPARE Patient Partner/advisor population

• H/L and AA/B Patient Partners/Advisors who are asthma patients or caregivers
  • 9 H/L – 3 Spanish speaking only
  • 7 AA/B
• Conference calls weekly at the beginning of the study – then at least once a month – continue 5 years later
  • Each month one in English and one in Spanish with the same information
• Involved in every aspect of our work
  • Study question, developing wording and education tools for patients

Changes made because of Patient Partner input

• Wording of instructions
• Shortened monthly survey (7-10 minutes)
• Giving patients a choice of how to answer the monthly survey: online, by phone interview or by mail
• Instructional videos depicting patients like them
• $20 payment for each survey completed
• Patients who fill out surveys within 6 days of receiving a reminder are entered into a raffle to win one of 3 monthly $150 prizes
• One click to answer the monthly survey

IMPACT

• Enrolled 598 H/L and 603 AA/B – sometimes difficult populations to enroll
• Consistent 90%+ survey return rate at 15 months – this is very unusual
• Low drop-out rate – 17/1201
• 84% of the patients assigned to using ICS with Albuterol (PARTICS) report adhering to using ICS with Albuterol all or most of the time over 15 months

Polling Question #8
Would you be willing to be a patient partner/advisor for an asthma study?

1) Yes
2) No
3) Not sure
4) Depends on whether my doctor thought it was a good idea or not
5) Depends on whether my family thought it was a good idea or not
Margie will share her story about her experience with asthma and research

What Is PCOR? And How Can You Get Involved?

Courtney Clyatt
Senior Program Officer
November 4, 2021

Who PCORI Is and What We Do

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns
- Helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information
How Is Our Work Different?

• We focus on answering questions most important to patients and those who care for them.
• We aim to produce evidence that can be easily applied in real-world settings.
• We engage patients, caregivers, clinicians, insurers, employers, and other stakeholders throughout the research process.
• This makes it more likely we’ll get the research questions right and the study results will be useful and taken up in practice.

What is different about PCOR

Focuses on research topics, questions, and outcomes most important to patients and those who care for them.

Works closely with a range of healthcare stakeholders— including patients, caregivers, scientists, clinicians, health systems, and insurers—to guide our research funding.

Requires that patients be engaged in the research we fund, not as subjects but as partners who help determine what to study and how.

Patient-Centered Outcomes Research (PCOR)

PCOR is a relatively new form of CER that...

• Considers patients’ needs and preferences, and the outcomes most important to them
• Investigates what works, for whom, under what circumstances
• Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options

Pays Particular Attention to

• Conditions that heavily burden patients, families, and/or the healthcare system
• Chronic or multiple conditions
• Rare and understudied conditions
• Conditions with varied outcomes across subpopulations
Engagement: Ensuring Patient/Stakeholder Partnership

- Patients and stakeholders from across the entire healthcare enterprise are actively and meaningfully involved in the entire research process—from the development of research priorities to the dissemination and uptake of research findings.
- Patients are treated as partners in research, not just subjects.
- To achieve critical goals:
  - To influence research to be patient-centered, relevant, and useful
  - To establish trust and a sense of legitimacy in research findings
  - To encourage successful uptake and use of research results.

Eugene Washington PCORI Engagement Award Program

- Support projects to build a community of patients and other stakeholders equipped to participate as partners in PCOR/CER, as well as serve as channels to disseminate PCORI-funded study results
- Funding to support engagement in, and with, research, not to conduct research

Engagement in Research

PATIENTS AND OTHER STAKEHOLDERS ARE INVOLVED IN...

- Research Priorities
- Methodology and study design
- Outreach and recruitment
- Data collection
- Ongoing and final dissemination
- Patient input
- Data quality assurance
- Research impact

Our Growing Research Portfolio
Snapshot of Funded Projects

Number of funded awards:
Nearly 1,800

Amount awarded:
• More than $2.9 billion

Number of states where we are funding projects:
49 (plus the District of Columbia and Puerto Rico)

About Our Research Portfolio

Most Studied Conditions:
• Mental Health
• Cancer
• Diarrheal Diseases
• Neurological Disorders
• N日至al and Metabolic Disorders

Most Studied Populations of Interest:
• Racial/Ethnic Minority
• Low Socioeconomic Status
• Seniors
• Older Adults
• Individuals with Multiple Chronic Conditions

Questions that matter

Research Addressing Questions That Matter

PATIENT
My asthma is really bad. I’m always using my meter every day, but I’m still having a lot of problems. What are the signs that I’m having an asthma attack?

HEALTH SYSTEM ADMINISTRATOR
Our medical center treats an exceptional number of patients who have asthma. What are the most effective strategies or combinations of strategies we can use to improve the lives of our patients?

$52 MILLION TO FUND 15

BY THE NUMBERS

BY THE NUMBERS

Number of funded research projects:
15

Number of states funding projects:
49

Number of patients with asthma:
7,142,000
How We Engage Stakeholders

Advisory Panels
Research Fundamentals Training
Webinars and Workshops
Ambassadors

Opportunities to Get Involved

PCORI Ambassador Center

About the PCORI Ambassador Program

Get Involved

Learning Need Navigation Tool

Research Fundamentals Structure

Five Interactive Learning Modules
1. **Provide foundational knowledge in PCOR/CER to non-scientist participants on research and other projects, and to patient and stakeholder merit reviewers, peer reviewers, and PCORI Ambassadors.**

2. **Provide training and resources to support multi-stakeholder teams in both the engagement of patient and stakeholder partners and effectively working together (i.e., team science).**

Self-paced and focused on just-in-time needs throughout the PCOR process.

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**Find Out About Other Ways to Get Involved**

- PCORI Peer Review Process: [https://www.pcori.org/research-results/peer-review/peer-review-process](https://www.pcori.org/research-results/peer-review/peer-review-process)
- Health Disparities and Delivery Research
- Patient Engagement
- Clinical Trials
- Axon Damage
- Clinical/Behavioral and Decision Science
- PCORI Peer Review Process: [https://www.pcori.org/research-results/peer-review/peer-review-process](https://www.pcori.org/research-results/peer-review/peer-review-process)
- PCORI Engagement Tools and Resources Repository: [https://www.pcori.org/engagement/engagement-resources/engagement-tool-resource-repository](https://www.pcori.org/engagement/engagement-resources/engagement-tool-resource-repository)
- Subscribe to PCORI’s Newsletter: [https://www.pcori.org/webform/subscribe](https://www.pcori.org/webform/subscribe)

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**Contact Information**

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**Unidos hablamos de...**

**United, Let’s talk about...**

Alex has asthma and will share his experience as a research patient. Hear how and why he became a research patient advisor/partner.

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Alex Colón Moya
Asthma Patient Research Patient Advisor/Partner
Question & Answer time with our panel

Elliot Israel, MD  
Asthma Specialist  
Principal Investigator  
PREPARE Study

Courtney Clyatt, MA  
PCORI  
Senior Program Officer

Margie Lorenzi  
Asthma Patient  
Research Patient  
Advisor/Partner

Thank you for attending!

• Join us next month, Dec. 2, 2021 – Let's keep the conversation going!
• Sign-up to receive our free AAN Research Newsletter
• Join our Asthma Registry – help make a difference in asthma research
• Get involved with AAN patient focus groups, ad boards, research studies
• Learn how you can become an AAN Patient Advisor
• Free Access AAN asthma and COVID-19 education materials
• Participate in one of our asthma studies!

contact
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