PATIENT ENGAGEMENT IN GOVERNANCE AND RESEARCH PRIORITIZATION FOR A PCORnet PATIENT-POWERED RESEARCH NETWORK

NIH COLLABORATORY GRAND ROUNDS
FRIDAY, SEPTEMBER 11, 2015
Speakers
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Patient partner, V-PPRN
Member, PCORI Patient Council
Agenda

- Introduce the Vasculitis Patient-Powered Research Network (V-PPRN)
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- Present the V-PPRN’s orientation and training program for patient-partners
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- Summarize the benefits and challenges of increased patient engagement in the V-PPRN
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- Present the V-PPRN’s orientation and training program for patient-partners
- Summarize the benefits and challenges of increased patient engagement in the V-PPRN
- Questions and Answers
Some Key Points about Vasculitis
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- Relapse of vasculitis is common leading to a chronic condition in many patients
INTRODUCTION TO THE V-PPRN
PCORI was created to fund comparative clinical effectiveness research (CER) that provides evidence to help patients and caregivers make better-informed decisions.

To facilitate more efficient CER, PCORI invested in the development of PCORnet: The National Patient-Centered Clinical Research Network.
PCORnet embodies a “community of research” by uniting systems, patients & clinicians

PCORnet:
A national infrastructure for patient-centered clinical research
V-PPRN Mission

Our **mission** is to improve the understanding, diagnosis, and treatment of vasculitis through the active engagement of patients with vasculitis, their caregivers, researchers, and healthcare providers in a Network that facilitates patient-centered research.
THE EVOLUTION OF THE V-PPRN

The Vasculitis Clinical Research Consortium (VCRC)
THE EVOLUTION OF THE V-PPRN

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The Rare Diseases Clinical Research Network (RDCRN)
The Evolution of the V-PPRN

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Patient-Centered Outcomes Research Institute Pilot Projects Program
Many additional VCRC partner sites in EU, Asia, Australia
Doctors & Investigators + Patients & Advocacy Groups
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Patient Engagement in Vasculitis Research: Evolution Over a Decade
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  - Support/promotion/recruitment → advice/review → co-investigators → co-governance on Steering Committee and research working groups
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  - Rapid growth of Network clearly due to patient engagement
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- Steadily increased trust, familiarity, and respect among leaders in the research and patient advocacy groups
V-PPRN GOVERNANCE

Onboarding patient-partners & governance decision-making process
Engaging Patients as Partners in Research Design
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**Step 1: Governance Structure**
- We designed a governance structure and decision-making process that is conducive for collaboration and participation.

**Step 2: Onboarding**
- We created a thorough vetting process for patient-partners and investigators.

**Step 3: Setting Expectations**
- Patient-partner orientation was a key component in setting expectations for all stakeholders involved.
V-PPRN Governance Structure

PCORnet

Task Forces and Policies
Coordinating Center
Executive Committee and Program Officers

V-PPRN Steering Committee

Principal Investigators

V-PPRN Members

Vasculitis Patient Advisory Council (V-PAC)

Working Groups

Patient Reported Outcome Data for Use in Clinical Trials (PRODUCT)
Recruitment, Engagement, & Communication (REC)
Research Innovation Planning Experiments (RIPE)
Recruiting and Selecting Patient-Partners
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Collaborated on process for selecting Patient-Partners

Established a rubric for evaluating candidates

Solicited interested candidates from the VF and VCRC

Resumes and letters of interest were reviewed by Patient-Partners

Qualified candidates interviewed by Patient-Partners and Network Manager

Steering Committee reviewed all applicants and made the final selections
Decision-Making Process within the V-PPRN

V-PPRN Decision Workflow

Workstreams Coordinated By Appropriate Manager [Project/Network/Data]

**Steering Committee**
- Assign Tasks to Working Groups

**Working Groups [RIPE, REC, PRODUCT]**
- Develop Program/Document Drafts
- Cross-Review with Other Working Groups

**Patient Advisory Council [V-PAC]**
- Draft
- Provides Feedback/Edits to Program/Draft

- Draft with Input from V-PAC
- Incorporates Final Edits and Implements

- Review
The V-PPRN is Research-Ready
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THE V-PPRN IS ABLE TO CONDUCT THE FOLLOWING:

- Comparative Effectiveness Research
- Cross-Sectional & Longitudinal Studies
- Randomized Clinical Trials
Partnering in Research Design

**Paradigm Shift**
Patient engagement in healthcare and clinical research is shifting the healthcare paradigm. To guarantee that collaboration is empowered and meaningful, all perspectives and input are respected and incorporated using innovative collaboration tools and decision-making models.

**Collaboration**
Working with multiple stakeholders is not intuitive, it takes some finessing. We approached this through open-communication and continual self-evaluation.

**Iterative Process**
We’ve found that multi-stakeholder research design is not one-dimensional. It is iterative and each component of our governance contributes to the research enterprise in different ways.
ORIENTATION FOR OUR PATIENT-PARTNERS

Setting expectations and empowering all governance members to feel comfortable engaging in the development of our research network.
OUR
PATIENT-PARTNER
PHILOSOPHY

Patient-partners are empowered with responsibility in Network development.

Patient-partners are equal stakeholders in decision-making.

Patient-partners are given the tools to maximally contribute to the groups’ goals.
Patient-Partner Orientation

1:1 Welcome Calls
- Each Patient-Partner was welcomed to the Network by the Network Manager, Kalen Young

Orientation Packet
- Working Group specific orientation packets were given to each new Patient-Partner

Certification Requirements
- All governance members were required to complete the on-line NIH Protecting Human Subject Research Participants training

Network Orientation
- An online Network orientation set expectations, answered questions, and welcomed all governance members to the V-PPRN
Patient-Partner Orientation

GOALS OF OUR ORIENTATION:
Patient-Partner Orientation

Goals of our orientation:

1. Introduce the V-PPRN and describe the Network’s purpose and goals
Patient-Partner Orientation

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Patient-Partner Orientation

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4. Answer questions about the V-PPRN and becoming a Patient-Partner
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4. Answer questions about the V-PPRN and becoming a Patient-Partner
5. Manage expectations
INVESTIGATOR PERSPECTIVE
Accepting and Celebrating Patient-Partners
Accepting and Celebrating Patient-Partners

**Shift Mindset**

- Embracing patient engagement in clinical research requires physician-investigators to give up some “control” and embrace change in how research is planned and conducted.
- This does *not* mean reducing the quality of work or veering from the scientific process.
- This is not an all or nothing structure: *shared* governance and oversight has worked extremely well for us.
Accepting and Celebrating Patient-Partners

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Allow Change to Develop

- Working with multiple stakeholders is different from usual practice
- It takes time to establish productive working rhythms, mutual goals, and good practices
Accepting and Celebrating Patient-Partners

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**Enjoy the Results**
- Partnering with patients in eye-opening and transformative for research.
- Our success has been based on trust, complementary skills and roles, and sharing common purposes and goals.
Grant/Funding Support for VCRC & V-PPRN

NIH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

pcori

FDA

Office of Rare Diseases Research
National Center for Advancing Translational Sciences – NIH

CTSA
Clinical & Translational Science Awards

NIH
National Heart, Lung, and Blood Institute

Genentech/Roche

Bristol-Myers Squibb

TerumoBCT

NHS
National Institute for Health Research

Arthritis Research UK

Penn

University of Pennsylvania

VASCULITIS FOUNDATION

VASCU CLINICAL RESEARCH CONSORTIUM
QUESTIONS?
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