Patient-participant perspective: Applying a decision aid to future RWE studies

W. Benjamin Nowell, Ph.D.
Director, Patient-Centered Research
Global Healthy Living Foundation
Patient-Powered Research Network: Research registry of more than 16,000 “activated” patient participants with rheumatic and musculoskeletal disease

- Created in 2015 with support from PCORI, one of 20 PPRNs and 33 networks within PCORnet
- Capacity to designate study cohorts and create customized user flows for each new study
- Novel data collection techniques (passive data)
- Individual health tracking so patients can view symptom data over time and share with their

Smartphone App for mobile collection of patient data

- Patient-Reported Outcome Measurement Information System (PROMIS®) developed by the NIH
- Other PRO measures in library that can be quickly updated with new instruments as needed
- Custom surveys (via HIPAA-compliant SurveyMonkey API)
ArthritisPower Features

- **Tracking** - symptoms; active/past medications; complementary treatments*; add other measures (flares*, depression, disease impact on social satisfaction); personal symptom note entries for context*; import VectraDA® lab results*; future biosensor innovation

- **Analytics** - longitudinal results graphing; overlay medication usage to see how symptoms change with new medications*

- **Share** - electronic reports can be sent to doctors, caregivers and others

- **Research Opportunities** - browse available studies for participation

- **Connect** - invite other patients or caregivers to connect through in-app messaging with option to share notes, analytics*

- **Education** - CreakyJoints social media feed, including patient blogs / Twitter; disease specific content on treatments, coping and support*

*New features developed for v2
ArthritisPower Features

Approx time to complete
8~9min

Physical Function
In the past 7 days How tired did you feel on average?

- Not at all
- A little bit
- Somewhat
- Quite a bit
- Very much

Pain Interference

Your average score is 64
Your current score is 64
ArthritisPower Features

It looks like you have some homework to do!
Having medications on file is an integral part of the application. The benefits are more accurate and detailed reports, ...

Let's start

You have 3 Active Medications

- Etanercept
- Methotrexate
- Meloxicam

Start Date: 11/13/15
Dosage: 2 weeks

Pain Interference

Your average score is 64
Your current score is 64

Physical Function

Your average score is 40
Your current score is 40

Anxiety

Your average score is 60
Your current score is 60
Engagement

• What information do patients need to make a decision?
  Research → Information → Health care decision

• Which data and study design will permit us to answer the research question?

• Which partners are appropriate?
  Shared values, Access to data

• Which data and study design will permit us to answer the research question AND engage our partners?
  Participant experience (UI/UX), Consent, Incentive
The Comparative Health Outcomes in Immune-mediated diseases CollaborativeE (CHOICE) Study
Aims of CHOICE Study

1. Evaluate the comparative risks for infection, heart attack and stroke
2. Evaluate the comparative clinical effectiveness of various medications using Patient Reported Outcomes (PROs)
Aims of CHOICE Study

1. Evaluate the comparative risks for infection, heart attack and stroke

2. Evaluate the comparative clinical effectiveness of various medications using Patient Reported Outcomes (PROs)
What is the need?

Patients and doctors want to know which treatment works best, for whom, and under what circumstances.
What is the need?

What we know:
Physicians and patients need to make challenging decisions among a variety of treatment options. This can be difficult given widely variable safety profiles and limited data on medication effectiveness from a patient’s perspective. Most of our approved medications work reasonably well, for most patients, most of the time.

What we don’t know:
• How well do these medications work?
• How quickly do they work?
Which data?

Diagnosis & Treatment:
• Self-reported data (condition, physician name, treatment
• Additional screening questions
• Linked EMR or claims data

Patient experience:
• Symptoms, patient-reported outcomes (PRO)
• Reasons for changing or stopping treatment
Effectiveness:
Important to have PRO data contributed regularly

FROM THIS (data erratically entered)

TO THIS

Interval between data totally unpredictable, not protocolized

Treatment Change Event

~ 6 months

PRO Data Entered
Which partner?

What does this have to do with me as a patient?

You are the **only one** who can tell us how well or not well a treatment works for you.

When you tell us how well a medication is working (or not working) for you, your **Patient Reported Outcome (PRO)** describes your experience with this medication. Your voice is heard and this benefits other people like you.

Data like this from you and thousands of other patients is turned into information that physicians and other patients can use to make decisions about treatments.
How can I help?

As a member of ArthritisPower, *when you contribute regular data*, you are helping to make comparative effectiveness information available.

There are three easy steps:

1. Fill out your medication data and keep it current
2. Complete your ArthritisPower PROs regularly
3. Be sure to include WHY changes were made
Considerations...

• Harmonizing data collection with other partners
  — What are others’ collecting, how and with what frequency?
• Additional data required for validation
• Adjustments to informed consent
• Incentive
• Patients’ visualization of their own data, comparisons with others
• Participant experience on digital platform, UX
• Dissemination of findings to patient participants
• Integration with clinical care
Thank you