Crowdsourcing: Using Social Media for CER-PCOR Data Capture

UMD CER-PCOR Summer Institute
August 10, 2016

Emil Chiauzzi, PhD
Research Director | PatientsLikeMe

Today’s Goals

1. Identify ways in which crowdsourced data can be used in research projects

and …

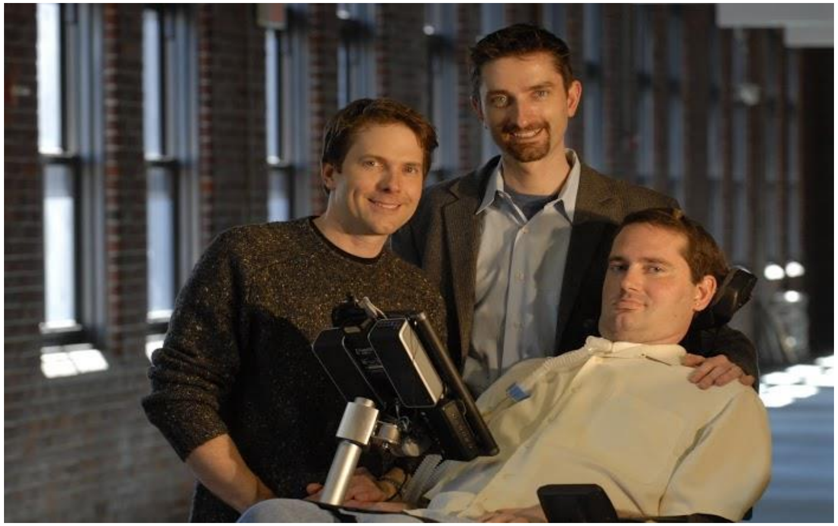
2. Understand the strengths and limitations of this data

What is PatientsLikeMe?

About PatientsLikeMe

Our mission is to improve the lives of patients through new knowledge derived from shared real-world experiences and outcomes

- Founded in 2004 as a direct response to their family's experience with chronic disease
- It is an online, open, patient-facing community for patients with life changing diseases
- Started in ALS in 2004 and expanded to all conditions in 2011. Deep patient data and experience in 30-40 chronic diseases
- Bringing together an ecosystem of forward thinking healthcare partners



PatientsLikeMe at a Glance

Patients

- 430,000+ patients
- 2,500+ conditions

Data

- 30+ million structured data points
- 3+ million free-text posts
- 15+ PROs

Insights

- 70+ publications, most peer reviewed
- Patient-generated taxonomy
- Safety monitoring platform
- Endpoints in clinical trials

Commercial & Partner Research

VALUE IN HEALTH 18 (2015) 1–4

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COMMENTARY

Can We Use Social Media to Support Content Validity of Patient-Reported Outcome Instruments in Medical Product Development?

CrossMark

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[1]Janssen Pharmaceutical Companies of Johnson & Johnson, Raritan, NJ, USA; [2]Novartis Pharmaceuticals Corporation; [3]PatientsLikeMe; [4]Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs, Study Endpoints and Labeling Development

ABSTRACT

We report a panel designed to open a dialog between pharmaceutical sponsors, regulatory reviewers, and other stakeholders regarding the use of social media to collect data to support the content validity of patient-reported outcome instruments in the context of medical product labeling. Multiple stakeholder perspectives were brought together to better understand the issues encountered in pursuing social media as a form of data collection to support content validity. Presenters represented a pharmaceutical sponsor of clinical trials, a regulatory reviewer from the Food and Drug Administration, and an online data platform provider. Each presenter shared its perspective on the advantages and disadvantages of using social media to collect this type of information. There was consensus that there is great potential for using social media for this purpose. There remain, however, unanswered questions that need to be addressed such as identifying which type of social media is most appropriate for data collection and ensuring that participants are representative of the target population while maintaining the advantages of anonymity provided by online platforms. The use of social media to collect evidence of content validity holds much promise. Clarification of issues that need to be addressed and accumulation of empirical evidence to address these questions are essential to moving forward.

Keywords: clinical trials, online communities, patient-reported outcomes, social media.

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Introduction

Patient-reported outcomes (PROs) are increasingly recognized as important tools in adding value to the drug review and evaluation process [1] because they provide unique perspectives on medical conditions or their therapies that are known only to the patient [2]. "Content validity" describes the extent to which a

and response options through cognitive debriefing [5]. Best practices usually include either individual interviews or focus groups with participants who are experiencing the target condition or have recent experience with it. These traditional methods of collecting qualitative data to support the content validity of a new or existing PRO instrument, however, are labor intensive, time consuming, and relatively expensive. Although

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Patient (2014) 7:73–84
DOI 10.1007/s40271-013-0033-0

ORIGINAL RESEARCH ARTICLE

Quality of Life in Organ Transplant R
in an Online Transplant Community

Paul Wicks · Katherine A. Sulham ·
Ari Gnanasakthy

Published online: 6 November 2013
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Abstract

Background The PatientsLikeMe Organ Transplants online community allows patients to share detailed health information for research.

Objectives The objectives of our study were to describe and contrast data collected through an online community with the broader organ transplant population.

Methods Quantitative data were examined with respect to basic demographic characteristics and quantitative data including treatment, symptoms, side effects, and the PatientsLikeMe Quality of Life (PLMQOL) scale. Qualitative data including forum discussion posts and treatment evaluations were examined to support future development of standardized questions that could be added to the platform. Online data were compared with US national registry data from the United Network for Organ Sharing (UNOS).

Results Within 30 days of account creation, 1,924 single-organ transplant patients provided spontaneous, patient-reported data in the form of 915 reported symptoms, 938

with epilepsy, fibromyalgia, mood disorders, Parkinson's disease, multiple sclerosis, or ALS. Site users generated 2,169 posts to 346 unique topic threads in the transplants forum.

Conclusions Organ transplant patients are willing to report detailed health data through online communities across key domains—symptoms, treatment effects, and generic quality of life—that constitute the essential core of patient-reported outcomes. Patient-reported outcomes captured online have the potential to accelerate learning about patient experiences but suffer methodological challenges that must be overcome to maximize their utility.

Key Points for Decision Makers

- The Internet is no longer just where patients go to read leaflets or chat in forums, they are using the same tools used in clinical research studies to learn more about managing their disease and contribute to research.
- The number of patients online today is relatively small

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AstraZeneca
Takeda
MERCK
NOVARTIS
Biogen
genzyme
A SANOFI COMPANY
Genentech
A Member of the Roche Group
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https://www.patientslikeme.com/about/partners

Academic Research and Nonprofits

University of Michigan
Medical School

ALS untangled

Food and Drug Administration

BWH BRIGHAM AND WOMEN'S HOSPITAL
A Teaching Affiliate of Harvard Medical School

UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

National Kidney Foundation
Serving NEW ENGLAND

the schwartz center
FOR COMPASSIONATE HEALTHCARE

Robert Wood Johnson Foundation

USF HEALTH

NIH
National Institute
of Mental Health

KING'S College LONDON

Duke
ALS Clinic

ONE MIND

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BIONETWORKS

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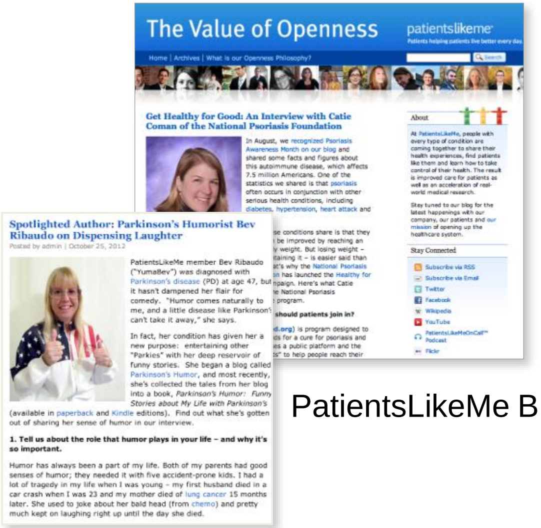
https://www.patientslikeme.com/about/partners

Who Joins PatientsLikeMe?

Patient Outreach

- Facebook, Twitter, banner ads
- Search engine optimization
- KOL outreach
- Partnerships with targeted non-profits
- Blogs and support groups



The Value of Openness

patientslikeme

Patients helping patients live better every day.

Home | Archives | What is our Openness Philosophy?

Get Healthy for Good: An Interview with Catie Coman of the National Psoriasis Foundation

In August, we recognized Psoriasis Awareness Month on our blog and shared some facts and figures about this autoimmune disease, which affects 7.5 million Americans. One of the statistics we shared is that psoriasis often occurs in conjunction with other serious health conditions, including diabetes, hypertension, heart attack and

se conditions share is that they
be improved by reaching an
y weight. But losing weight –
taining it – is easier said than
at's why the National Psoriasis
on has launched the Healthy for
npaign. Here's what Catie
e National Psoriasis
program.

should patients join in?

d.org) is program designed to
ds for a cure for psoriasis and
es a public platform and the
ts" to help people reach their

About

At PatientsLikeMe, people with every type of condition are coming together to share their health experiences, find patients like them and learn how to take control of their health. The result is improved care for patients as well as an acceleration of real-world medical research.

Stay tuned to our blog for the latest happenings with our company, our patients and our mission of opening up the healthcare system.

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PatientsLikeMeOnCall™ Podcast
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Spotlighted Author: Parkinson's Humorist Bev Ribaudo on Dispensing Laughter

Posted by admin | October 25, 2012

PatientsLikeMe member Bev Ribaudo ("YumaBev") was diagnosed with Parkinson's disease (PD) at age 47, but it hasn't dampened her flair for comedy. "Humor comes naturally to me, and a little disease like Parkinson's can't take it away," she says.

In fact, her condition has given her a new purpose: entertaining other "Parkies" with her deep reservoir of funny stories. She began a blog called Parkinson's Humor, and most recently, she's collected the tales from her blog into a book, *Parkinson's Humor: Funny Stories about My Life with Parkinson's* (available in paperback and Kindle editions). Find out what she's gotten out of sharing her sense of humor in our interview.

1. Tell us about the role that humor plays in your life – and why it's so important.

Humor has always been a part of my life. Both of my parents had good senses of humor; they needed it with five accident-prone kids. I had a lot of tragedy in my life when I was young – my first husband died in a car crash when I was 23 and my mother died of lung cancer 15 months later. She used to joke about her bald head (from chemo) and pretty much kept on laughing right up until the day she died.

PatientsLikeMe Blog

Non-Profit Pages

patientslikeme

National Kidney Foundation

Serving NEW ENGLAND

1 employee from National Kidney Fou
Serving New England has joined
PatientsLikeMe.

National Kidney Foundation Serving New Englan

Profile Activity
748

About National Kidney Foundation Serving Nev

patientslikeme

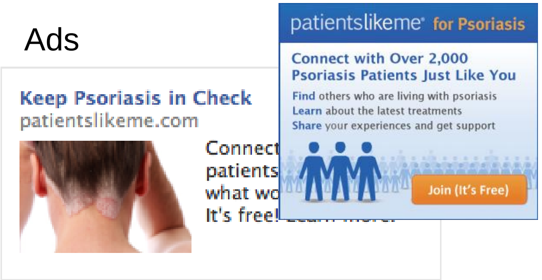
National Multiple Sclerosis Society

1 employee from National Multiple Sclerosis Society, Greater New England Chapter has joined PatientsLikeMe.

National Multiple Sclerosis Society, Greater New England C

Profile Activity
1069
15

Ads



Keep Psoriasis in Check

patientslikeme.com

Connect
patients
what wo
It's free!

patientslikeme for Psoriasis

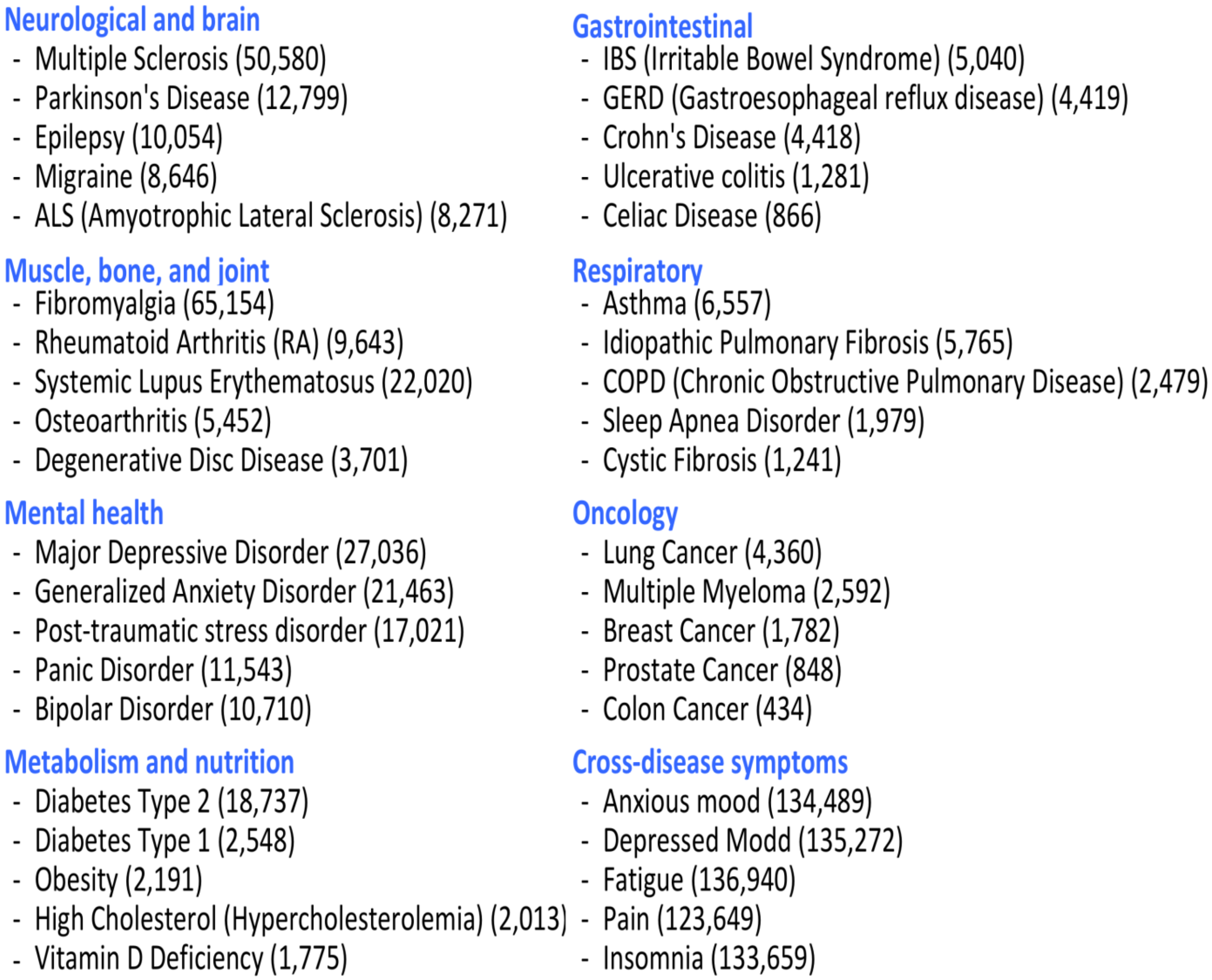
Connect with Over 2,000 Psoriasis Patients Just Like You

Find others who are living with psoriasis
Learn about the latest treatments
Share your experiences and get support

PatientsLikeMe Members

- 70% Female
- 16% non-Caucasian
- 40s-50s
- Chronic diseases (“PLM-able”)
- Multiple comorbidities
- English-speaking
- 60% US

Conditions on PLM



Neurological and brain
- Multiple Sclerosis (50,580)
- Parkinson's Disease (12,799)
- Epilepsy (10,054)
- Migraine (8,646)
- ALS (Amyotrophic Lateral Sclerosis) (8,271)

Muscle, bone, and joint
- Fibromyalgia (65,154)
- Rheumatoid Arthritis (RA) (9,643)
- Systemic Lupus Erythematosus (22,020)
- Osteoarthritis (5,452)
- Degenerative Disc Disease (3,701)

Mental health
- Major Depressive Disorder (27,036)
- Generalized Anxiety Disorder (21,463)
- Post-traumatic stress disorder (17,021)
- Panic Disorder (11,543)
- Bipolar Disorder (10,710)

Metabolism and nutrition
- Diabetes Type 2 (18,737)
- Diabetes Type 1 (2,548)
- Obesity (2,191)
- High Cholesterol (Hypercholesterolemia) (2,013)
- Vitamin D Deficiency (1,775)

Gastrointestinal
- IBS (Irritable Bowel Syndrome) (5,040)
- GERD (Gastroesophageal reflux disease) (4,419)
- Crohn's Disease (4,418)
- Ulcerative colitis (1,281)
- Celiac Disease (866)

Respiratory
- Asthma (6,557)
- Idiopathic Pulmonary Fibrosis (5,765)
- COPD (Chronic Obstructive Pulmonary Disease) (2,479)
- Sleep Apnea Disorder (1,979)
- Cystic Fibrosis (1,241)

Oncology
- Lung Cancer (4,360)
- Multiple Myeloma (2,592)
- Breast Cancer (1,782)
- Prostate Cancer (848)
- Colon Cancer (434)

Cross-disease symptoms
- Anxious mood (134,489)
- Depressed Modd (135,272)
- Fatigue (136,940)
- Pain (123,649)
- Insomnia (133,659)

What is the Member Experience?

https://vimeo.com/168201921/0290849187

Data Domains

Basic Information
(age, sex, etc.)

Diseases
(early signs, diagnosis status, etc.)

General & Specific Symptoms
(onset, severity status, etc.)

Treatments & Side Effects
(Rx, OTC, Supp., non-drug, etc.)

Quality of Life & Behavior Status
(all patients, some disease specific)

Outcome Measures of Disease
(disease dependent)

Patient-generated narrative text,
wearable and sensor data

Engagement

Data Integrity

Standards *

Evidence

Knowledge

Empowerment

patientslikeme®

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* Patient data mapped to ICD-10, ICF, SNOMED, MedDRA, RxNorm

Why Would I Use This Data?

Advantages

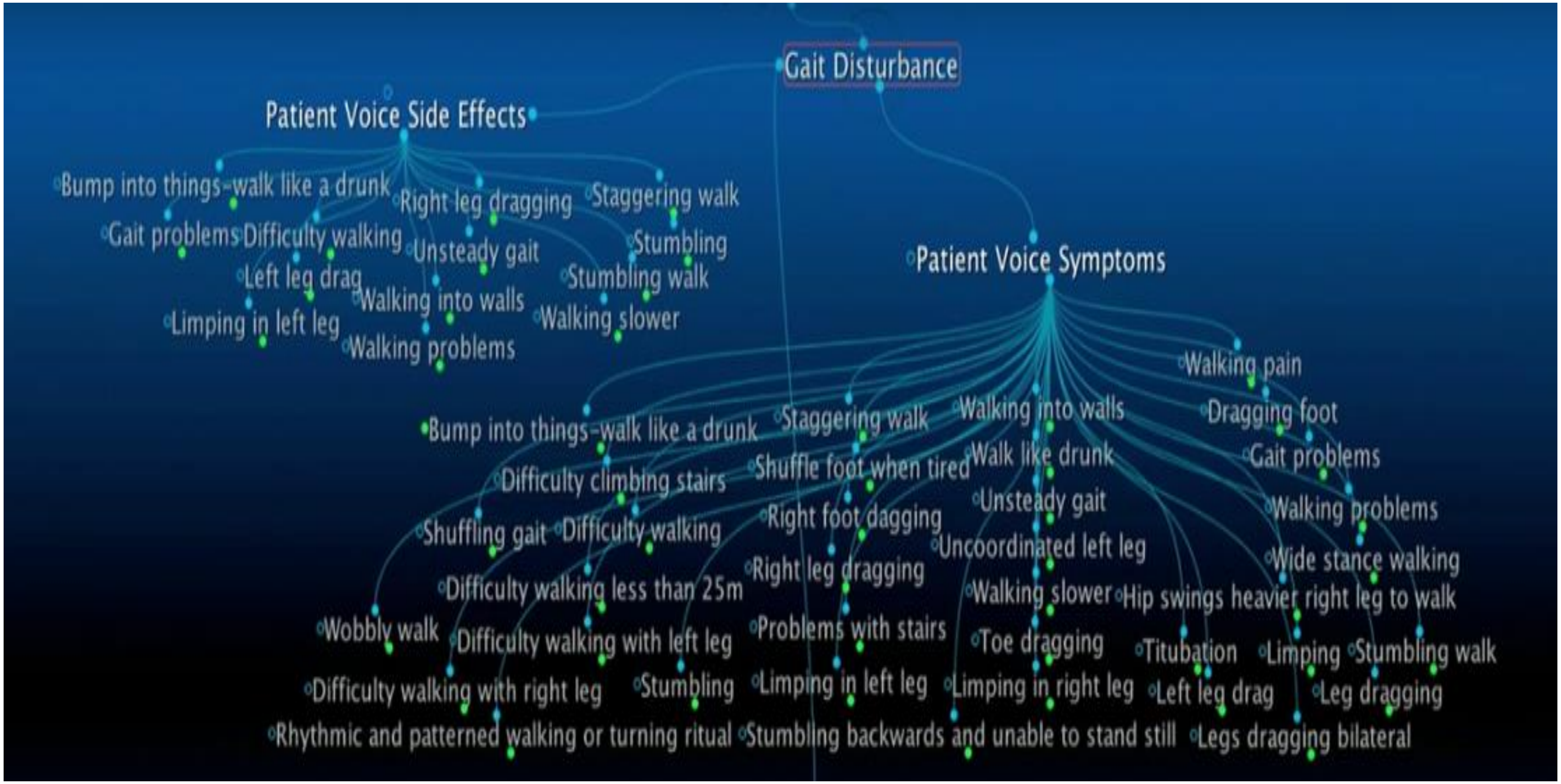
Patient Voice

- Need to understand the patient journey or experience
- Avoid helicopter research
- Folksonomy
- Need patient partner(s) in research
- Patient conceptual models valued
- Patients as research partners and not “subjects”
- Patient defined outcomes
- Patient led studies

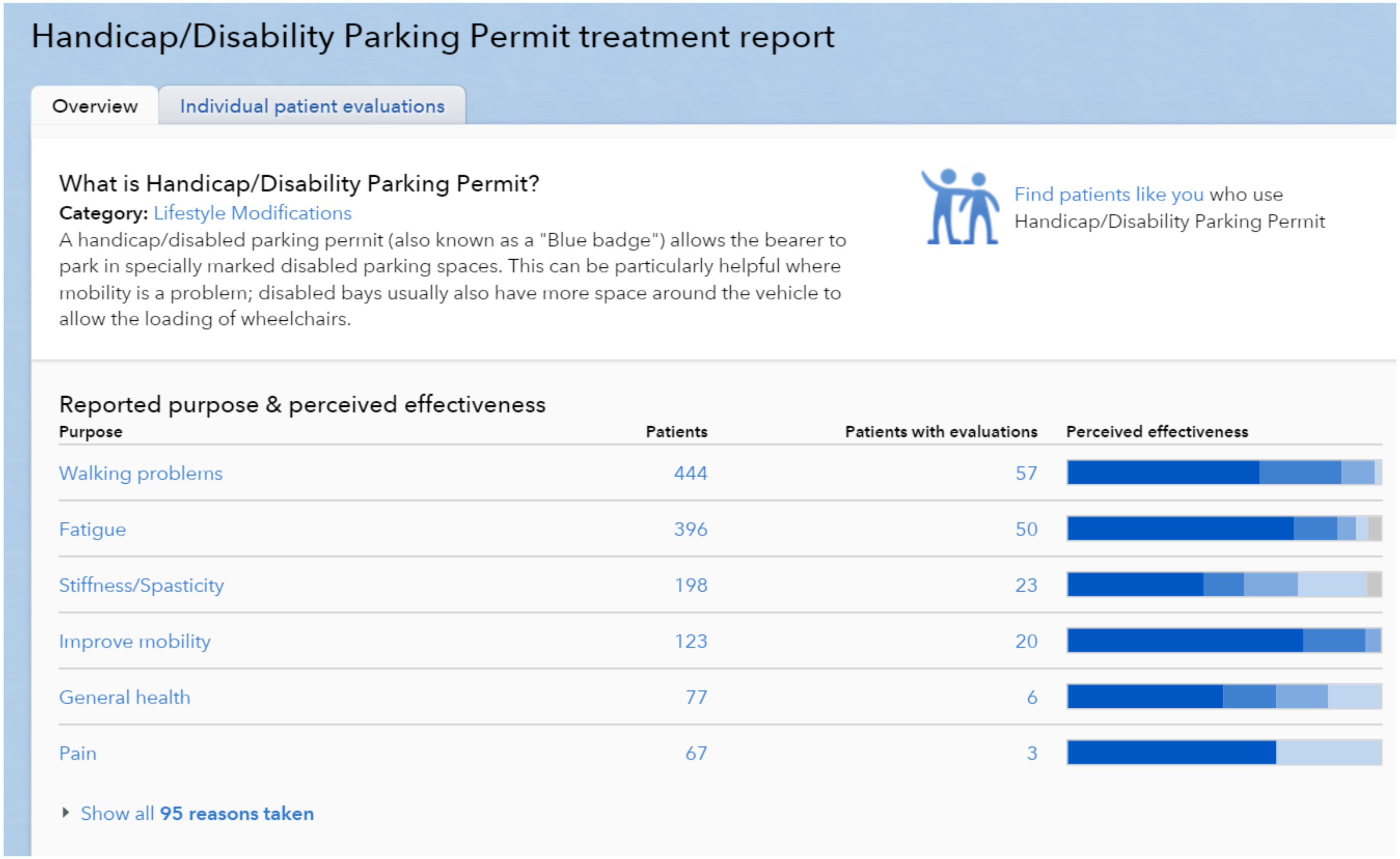
Data Enhancement

- Data is not locked up in research databases – patients have access
- Multiple comorbidities – often these people do not qualify for other studies
- Ability to consider symptoms across conditions (break out of diagnostic categories)
- Rare conditions
- Stigmatized conditions – fibromyalgia
- Rapid recruitment and sampling
- Longitudinal picture
- Engage patients beyond funding limits

Folksonomy


Gait Disturbance
Patient Voice Side Effects
Bump into things-walk like a drunk
Right leg dragging
Staggering walk
Gait problems
Difficulty walking
Unsteady gait
Stumbling
Left leg drag
Walking into walls
Stumbling walk
Limping in left leg
Walking slower
Walking problems
Patient Voice Symptoms
Walking pain
Dragging foot
Bump into things-walk like a drunk
Staggering walk
Walking into walls
Gait problems
Shuffle foot when tired
Walk like drunk
Difficulty climbing stairs
Unsteady gait
Walking problems
Shuffling gait
Difficulty walking
Right foot dagging
Uncoordinated left leg
Wide stance walking
Difficulty walking less than 25m
Right leg dragging
Walking slower
Hip swings heavier right leg to walk
Wobbly walk
Difficulty walking with left leg
Problems with stairs
Toe dragging
Titubation
Limping
Stumbling walk
Difficulty walking with right leg
Stumbling
Limping in left leg
Limping in right leg
Left leg drag
Leg dragging
Rhythmic and patterned walking or turning ritual
Stumbling backwards and unable to stand still
Legs dragging bilateral

A Broader View of “Treatments”



Handicap/Disability Parking Permit treatment report

What is Handicap/Disability Parking Permit?

Category: Lifestyle Modifications

A handicap/disabled parking permit (also known as a "Blue badge") allows the bearer to park in specially marked disabled parking spaces. This can be particularly helpful where mobility is a problem; disabled bays usually also have more space around the vehicle to allow the loading of wheelchairs.

Find patients like you who use Handicap/Disability Parking Permit

Reported purpose & perceived effectiveness

Purpose	Patients	Patients with evaluations	Perceived effectiveness
Walking problems	444	57	
Fatigue	396	50	
Stiffness/Spasticity	198	23	
Improve mobility	123	20	
General health	77	6	
Pain	67	3	

▸ Show all **95 reasons taken**

Why Would I Not Use This Data?

Challenges

Engagement Burden

- Patient reported data is hard to get/need sustained effort
- Engagement infrastructure should you pay participants
- Forced data entry vs. engagement

Measurement

- Self-report driven
- Measure validity vs. patient friendliness
- Length of measures
- Longitudinal assessment
- Temporality
- Missing data

Sampling Issues

- Representativeness (but … many of these people are not often represented!)
- Likely attracting a more health conscious and knowledgeable population
- Diagnostic validation - lack of provider documentation
- Inaccuracies in primary condition designation

How Do You Involve Patients?

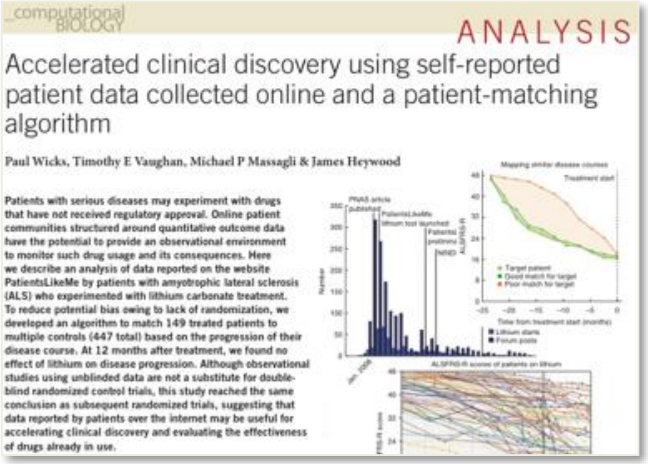
Steps in Continuous Engagement	Purpose of Patient Engagement	Patient Activities	PLM Research
Topic Solicitation	Define potential research topics that are relevant to patients	Contribute real world research questions Input on challenges / facilitators in patient disease journey that require further investigation	Ask patients to provide research questions at the end of surveys – we have obtained over 1000 questions Community build interviews
Prioritization	Determine relative importance of potential topics	Determine topics of greatest urgency and impact on patients Determine questions that have greatest impact in patients' daily lives	Forum events to determine key research questions in managing Type II diabetes – comorbidities, lifestyle, social contexts Evaluation of cognitive symptoms as a target in antidepressant treatment
Framing the Question	Define research questions with a "real world perspective"	Structure questions in the voice of the patient so that real world impact is addressed	Elicited research questions from Mood Community, e.g., "What were you diagnosed with before bipolar?"
Selection of comparators and outcomes	Determine treatment comparators and outcomes that match real world research questions	Act as patient representatives to help finalize research questions Assure inclusion of real world outcomes Determine most realistic treatment comparisons (re: affordability, access, and burden)	Found that different "shapes" of nausea per disease and drug, e.g. duration, severity, timing, amelioration Different perceptions of insomnia re: stage of sleep disruption Fatigue (e.g., RA) is consistently an important outcome across diseases and studies
Creation of conceptual framework	Determine potential hypotheses and research questions	Gather peer perspectives Communicate on social media Review proposed research questions and suggest possible factors and barriers that might affect results	Concept mapping to develop a conceptual model for provider performance quality metrics

Steps in Continuous Engagement	Purpose of Patient Engagement	Patient Activities	PLM Research
Analysis plan	Determine the data sources most likely to deliver "real world" patient perspectives	Provide input on importance of key factors and variables Assist in selection of valid measures that reduce participant burden Review of informed consent materials for comprehension and burden Feedback on logistics of study	Clinical trial optimization to assess study logistics Feasibility evaluation to assess PLM study logistics, e.g., app study
Data collection	Determine sources and methods of data collection	Assist is defining potential real world data sources Pilot testing of measures and surveys Craft study name and materials to reduce stigma	Pilot testing of a survey for patients with major depression
Reviewing and interpreting results	Determine meaningful results	Input on relevance of findings Provide feedback on believability of results	Patient-led study to develop a patient-reported outcome instrument for pain (RWJF)
Translation	Define results with highest impact for professional and patient audiences	Integration of the patient voice in linking findings to real world experience Assist in development of dissemination plan	Patient givebacks
Dissemination	Distribute findings to professional and patient communities	Plain language summaries Participate as authors on publications	Open access publishing Follow-up interviews after studies/blogs Patient participation in publications and conference presentations (e.g., sleep data at AMIA)

Patient-Driven Study: ALS Lithium Study

Background

- Fornai *et al.* [PNAS **105**(6): 2052:2057] results motivated patients to take lithium
- PatientsLikeMe provided tools to enable sharing of information on lithium use and FRS progression



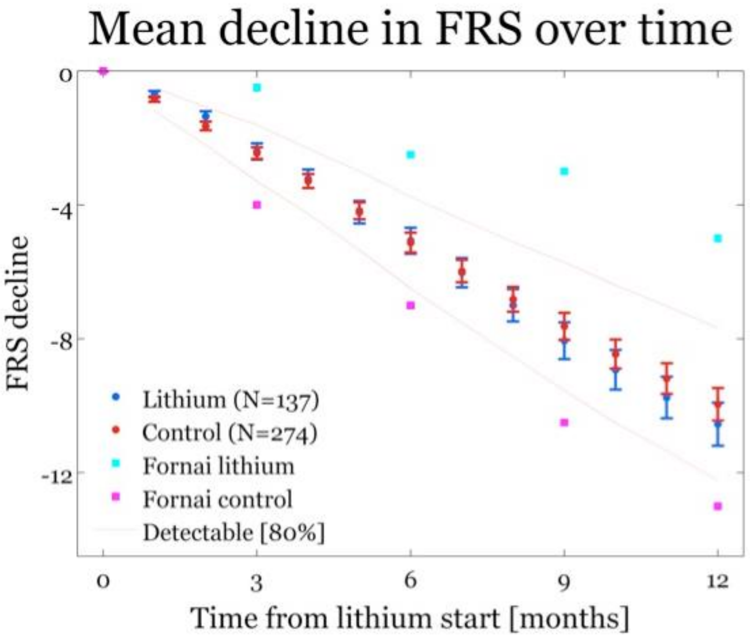
computational BIOLOGY

ANALYSIS

Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm

Paul Wicks, Timothy E Vaughan, Michael P Massagli & James Heywood

Patients with serious diseases may experiment with drugs that have not received regulatory approval. Online patient communities structured around quantitative outcome data have the potential to provide an observational environment to monitor such drug usage and its consequences. Here we describe an analysis of data reported on the website PatientsLikeMe by patients with amyotrophic lateral sclerosis (ALS) who experimented with lithium carbonate treatment. To reduce potential bias owing to lack of randomization, we developed an algorithm to match 149 treated patients to multiple controls (447 total) based on the progression of their disease course. At 12 months after treatment, we found no effect of lithium on disease progression. Although observational studies using unblinded data are not a substitute for double-blind randomized control trials, this study reached the same conclusion as subsequent randomized trials, suggesting that data reported by patients over the internet may be useful for accelerating clinical discovery and evaluating the effectiveness of drugs already in use.



Wicks P, Vaughan TE, Massagli MP, Heywood J. Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm. Nat Biotechnol. 2011 May;29(5):411-4. doi: 10.1038/nbt.1837.

Quality of Care in Long-Term Care Facilities

Steve was diagnosed with ALS in 2006. He used his expertise as an architect and his interest in technology to spearhead the ALS Residence Initiative (ALSRI), starting with the Steve Saling ALS Residence at the Chelsea Jewish Foundation's Leonard Florence Center for Living in Chelsea, Mass. The ALSRI has grown into a series of fully automated residences – now in multiple cities nationwide – that allow pALS the freedom of independent living alongside 24-hour care.

http://blog.patientslikeme.com/tag/steve-saling-als-residence/

patientslikeme®

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