



Empowering patient partnerships in clinical registries

...of the people, by the people, for the people

CMSS Summit: The Future of Clinical Registries | May 10, 2018

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Characteristics of old and new generation clinical registries

Patient expectations of clinical registries

Earning social license in a new era of mining...data

Case study: PatientsLikeMe

Next generation registries: of the people, by the people, for the people

A background graphic consisting of a network of interconnected nodes and lines. The nodes are represented by small circles in various colors: grey, yellow, and black. The lines are thin and grey, creating a complex web-like structure that is denser on the right side of the image.

Empowered Patients Are the Future of Health Care

"It's time for a new era of consumerism in health care, with patients at the center of the delivery system. Patients should be empowered to make the best decisions about their care..."

Seema Verma

May 3, 2018

Op-Ed Real Clear Health

Why a new generation of clinical registries?

Societies are well positioned to create new value for registry data by partnering with patients

Old Generation Characteristics

- Registries designed and developed by clinicians
- Prioritized culture of performance improvement in practice
- Measurement tools aligned to meet provider needs and objectives
- Major outputs centered on
 - Monitoring quality of care
 - Generating new clinical

New Generation Characteristics

- Registries designed and developed in partnership with patients
- Prioritize patient role in culture of performance improvement
- Measurement tools aligned to meet what matters to patients
- Major outputs centered on
 - Monitoring quality with patient input
 - Generating novel patient experience knowledge

Patient perspectives on participating in clinical registries

Seven themes emerged from focus groups

Patient Theme	Quote
Personalization/convenience of data collection	It makes it easy just to add on, you know, to make it part of your appointment
Trust and confidentiality	Sometimes by being told by many interpreters, sometimes they confuse you, and there are many interpreters that sometimes don't tell you the truth
Camaraderie	You might feel alone or isolated when you have some kind of chronic illness. But if you're in a community, it gets to different ears. It feels good.
Learning about yourself and your disease	It's asking questions about whether you can accomplish what you're doing, etcetera, etcetera, but I'm trying to understand how it feeds back to me.
Altruism	If not a cure, a better way of living for people who might have similar issues.
Material motivation	I was so excited for parking. That's all it takes. I would fill out that form every single time in the office to get my parking.

Source: Lee SB, Zak A, Iversen MD, Rolletta VL, Shadick NA, Solomon DH. Participation in clinical research registries: a focus group study examining views from patients with arthritis and other chronic illnesses. *J Arthritis Care Res (Hoboken)* 2016;68(7):974-980. doi: 10.1002/acr.22767.

Capturing elements of the lived experience
I have answered that question about how do you feel today and I'm like, well, today I feel fine but last week I was just feeling horrible

Patient perspectives on clinical registry recruitment and retention

Literature reveals little is known about patient experiences in registries

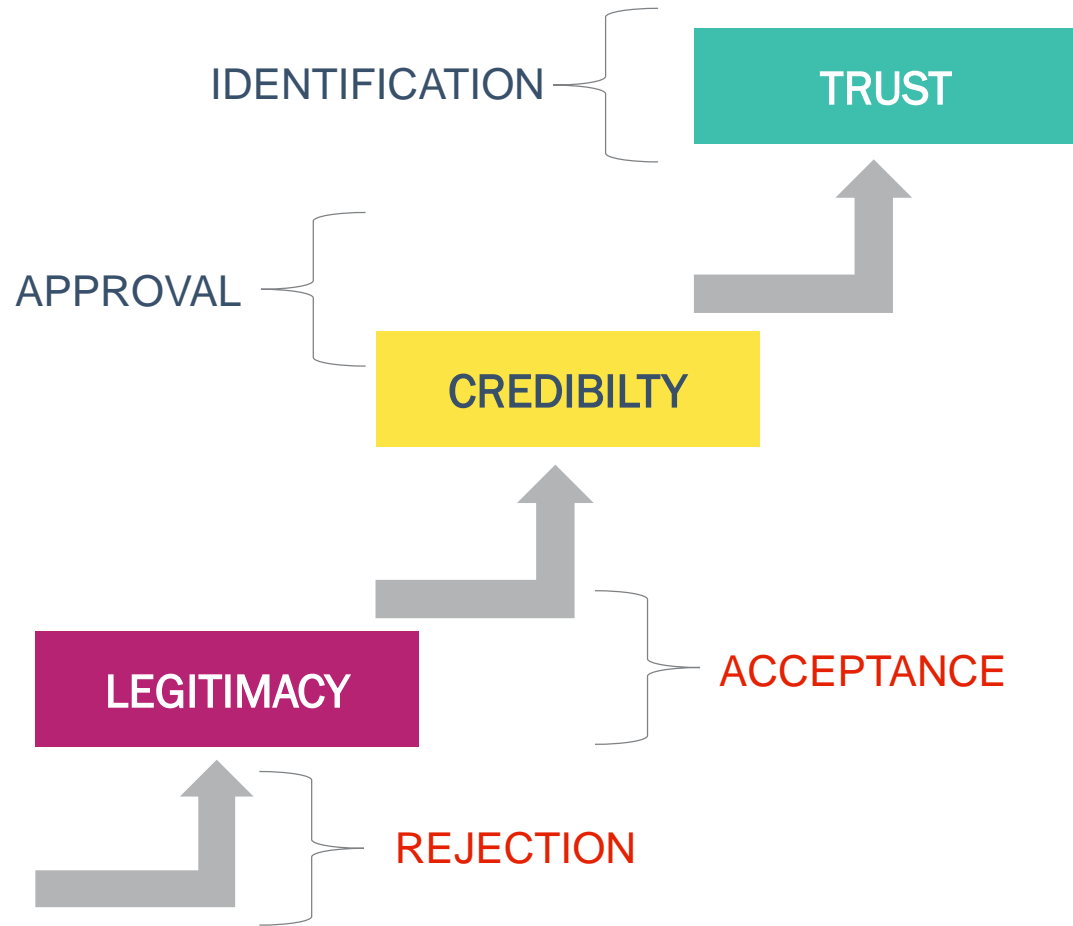
On enrollment

- Desire to help others
- Hope that participating will help them manage their condition
- Ease of participation
- Preferred method of participation:
 - Younger patients prefer email and digital options such as apps
 - Older patients prefer to have surveys mailed to them

On staying involved

- Most surveyed said they'd stay involved but would like:
 - To receive general information about their condition
 - Feedback about their survey responses
 - Receive some form of payment / gift
- Most willing to respond to questions frequently

Introduction to social license concept – its a new era of mining



- Social License to Operate arose from the mining industry
- Broadly defined as:
 - the extent to which an entity is constrained to meet societal expectations and avoid activities that people and their communities deem unacceptable.
- Three essential preconditions
 - Legitimacy
 - Credibility
 - Trust

Earning social license through patient partnerships in registries

Create added value for your registry by prioritizing patient perspective and experience

- **Inclusiveness** (*increases legitimacy*)
 - People who represent the registry population should participate in the registry design or repurposing process
- **Evaluation of materials** (*establishes credibility*)
 - A representative sample of potential registry participants are best suited to offer opinions and perspectives on the information provided about the registry
 - Opportunity to illuminate whether certain people will need more robust description and/or customization of information about registry's goals and objective
- **Consistency of evaluation** (*builds trust*)
 - People for whom the registry matters will bring relevant issues to table
 - For people considering joining the registry it matters that others like them were included in all phases of design, material development and evaluation

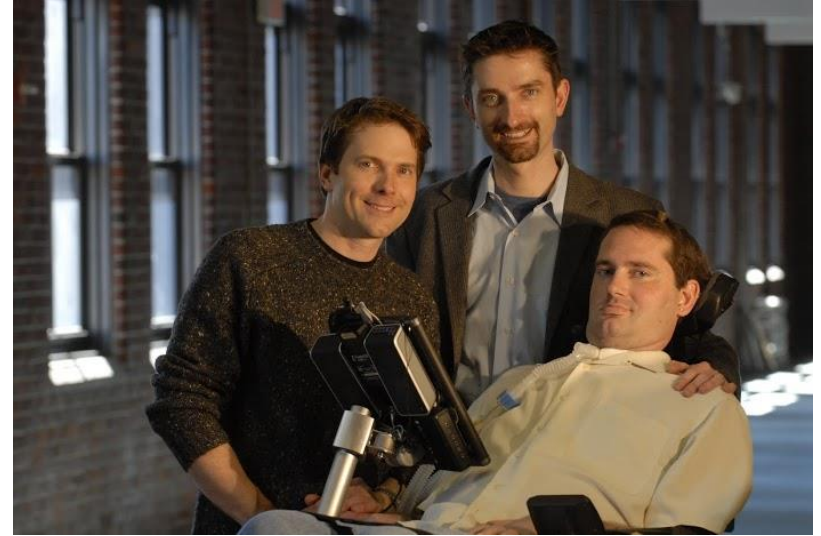
A complex network graph background with nodes of various sizes and colors (gray, yellow, black) connected by thin lines. The graph is more dense on the right side of the slide.

Case Study: 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 one family's experience with ALS
- In 2006 the website was launched as an online, open, patient registry community for patients with many life changing diseases
- The platform was expanded to all conditions in 2011
- In 2017 joined with others to form Digital Life



Alliance

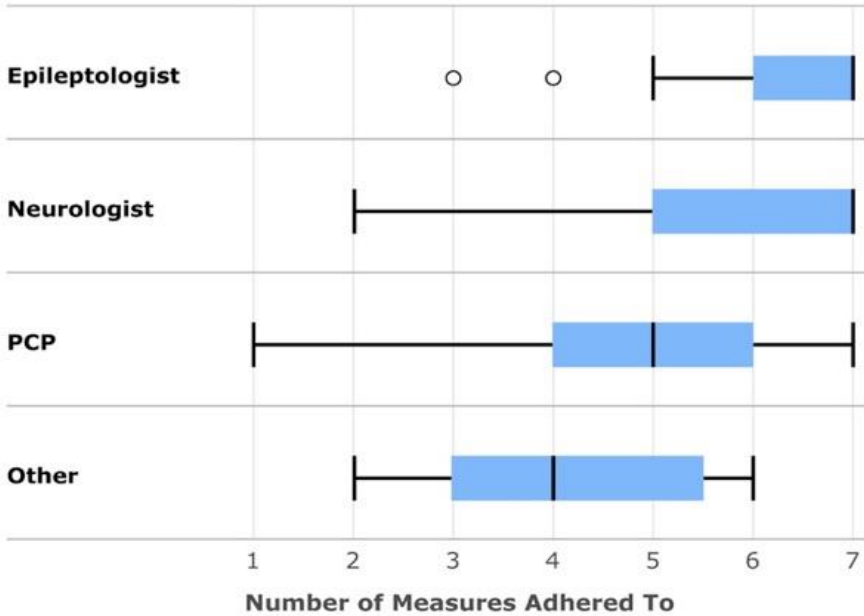
- 630,000+ members
- 2700+ conditions
- Peer-to-peer network
- 40+ million data points
- 4+ million posts
- 15+ PROs
- Data mapped to UMLS taxonomies
- 100+ publications, most peer-reviewed
- Research, bioinformatics, data scientists, clinicians
- Safety monitoring platform
- FDA Research Collaboration
- Digital phenotyping
- Digital Life Alliance
- Empowering patients
- Advancing knowledge
- Improving treatments
- Improving care

Patient perspective on quality of care

Essential element of trustworthy guideline development



Specialty of Treating Physician



Neurology® Clinical Practice

Patient assessment of physician performance of epilepsy quality-of-care measures



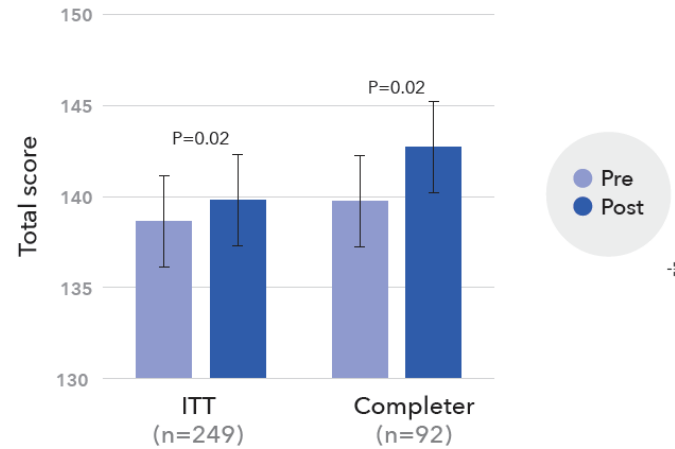
- The AAN developed epilepsy quality measures to raise the standard of care in epilepsy
- We partnered with AAN to develop a self-report instrument that would establish the current state of the art
- In a survey of 221 epilepsy patients we found significant differences between treating physician types, with patients treated by non-specialists receiving poorer care
- We identified care gaps around side effect management, surgery referral, reproductive issues in women
- **Impact:** Lead to changes in neurology training and informed NQF quality measures in epilepsy

Patients partnering in care

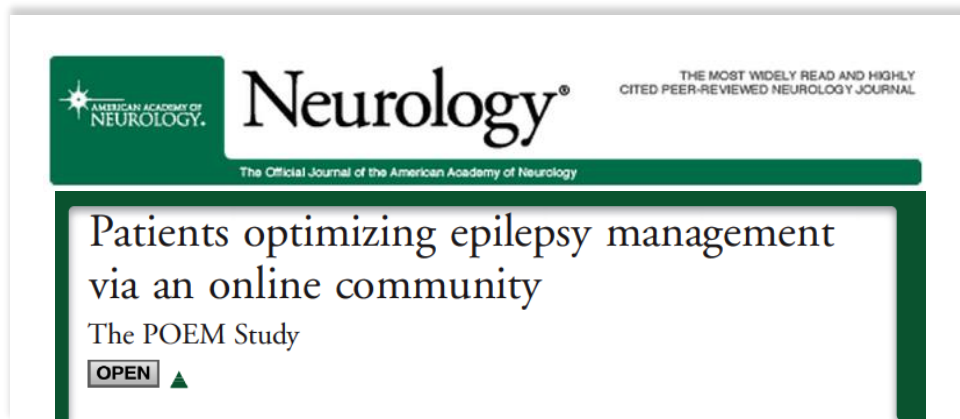
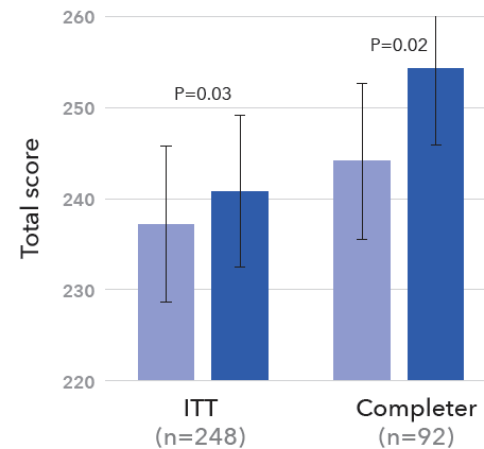
Improving self-efficacy and self-management



Epilepsy Self-Management Scale (ESMS)



Epilepsy Self-Efficacy Scale (ESES)



- Veterans living with seizures due to epilepsy or TBI are isolated, face stigma, and struggle to manage condition
- In a joint study we offered access to the standard PatientsLikeMe platform to ~250 veterans with epilepsy
- After just 6 weeks of interacting with their peers and tracking their seizures, we identified significant improvements in self-efficacy and self-management
- **Impact:** Demonstrated potential of PLM to improve patient outcomes

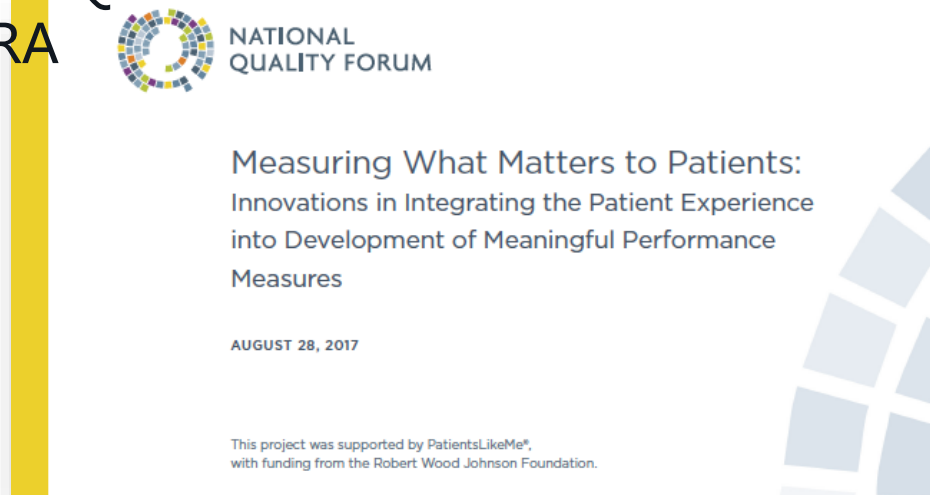
Patient perspective on what matters:

Patient Experience Reports



Objectives:

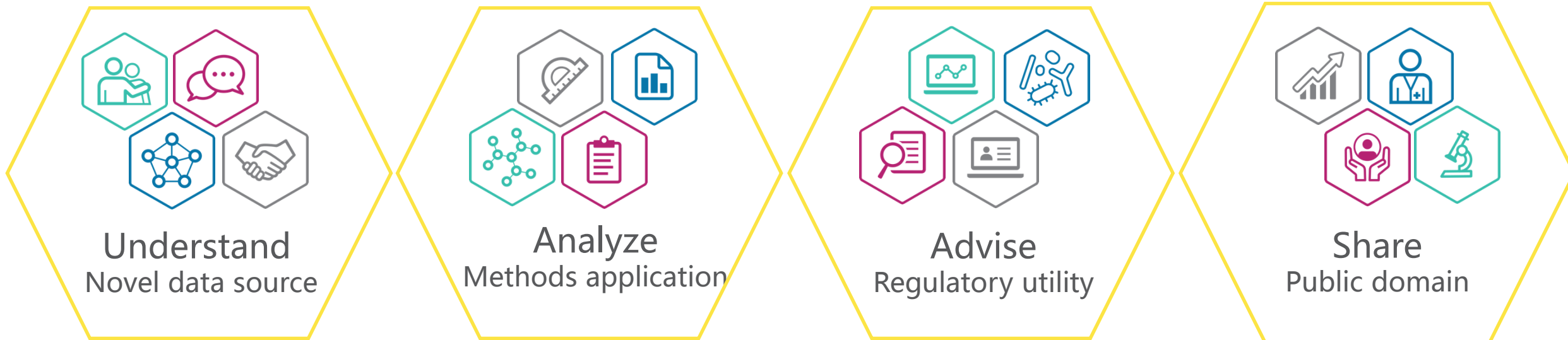
- To explore and evaluate a novel approach to inform the development and refinement of patient reported outcome performance measures (PRO-PM)
- Identify, prioritize, and contextualize health related QoL and functional status in COPD, MS, and RA



- Must shift performance measures to focus on patient priorities
- Online patient communities can provide access not otherwise available by offering:
 - Virtual "town halls" with global reach
 - Improve data quality
 - Represent real time patient experience
 - Identify unmet patient concerns
 - Prioritize symptoms
 - Focus on outcomes longitudinally

PatientsLikeMe / FDA Research Collaboration

Advancing use of patient experience data in support of FDA's mission



Patient Voice at FDA

- Patient Perspectives on:
 - REMS impact
 - Opioid access
 - MedWatch Form
 - Medication Label
- PFDD PDUFA Public Meetings
- PFDD Guidance Development for 21st

PLM Data Characterization

- PLM Data aligns well with FDA analytics:
 - AE MedDRA coding
 - Treatment coding
 - ICSR Content Quality

Real World Data to Evidence

- Drug Safety Communications
- Off label safety and efficacy
- RWE Advisory Board Member
- Digital Health Team Advisor

Knowledge Advancement

- *Patient Experience Reports:*
 - Parkinson's disease
 - IPF
 - Fibromyalgia
- Dissemination for 2018:
 - 4 manuscripts in process
 - 5 panels and/or posters (DIA, ISPOR, AHA, Duke)

Next Generation Registries...

...of the people, by the people, for the people

- Patients are ***interested in knowing how the information*** they provide to a registry is interpreted
- Patients also want to know ***how their individual disease course*** compares with others and whether the provided data accurately depict their disease experience.
- Offering social support from peers with similar conditions ***may motivate registry*** participation.
- Be wary of a ***viewing technology as the solution*** for registry engagement – it may introduce new disparities and vulnerabilities. Offering communication and data collection options may appeal to a broader group.
- Continue to ***learn from the experiences of registry participants*** about quality of care, preferred outcomes and performance improvement opportunities
- Give back - ***share what you learn*** with registry participants

Reference materials

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- Measuring What Matters to Patients: Innovations in Integrating the Patient Experience into Development of Meaningful Performance Measures. National Quality Forum Washington, DC. August 2017.