Prioritizing Patient Engagement and Inclusion of Patient-Generated Covid-19 Data

August 12, 2020 | 1:00 – 2:30 pm ET
CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

The series will address key questions related to the rapid development, deployment and implementation of Covid-19 focused clinical registries and clinical repositories by specialty societies and academia.

SUMMER 2020 | FREE TO ATTEND

About the Series:

- Made possible with funding from the Gordon and Betty Moore Foundation
- To foster collaboration between specialty societies and academia, we are grateful to collaborate with the Association of Academic Medical Colleges

Continue the Conversation:

- Use #COVIDRegistries when tweeting about the webinar series
- Follow @CMSSMed and visit CMSS.org for frequent updates
Today’s Webinar:

Prioritizing Patient Engagement and Inclusion of Patient-Generated Covid-19 Data

**Moderator:**

Susannah Fox  
Principal, Internet Geologist LLC;  
Former Chief Technology Officer,  
US Department of Health and Human Services

**Panelists:**

Gina Assaf  
Independent digital design consultant, Leading the Patient-Led Research Group within Body Politic

Emily Sirotich  
COVID-19 Global Rheumatology Alliance; Canadian Arthritis Patient Alliance; Department of Health Research Methods, Evidence, and Impact, McMaster University

**Host:**

Helen Burstin, MD, MPH, MACP  
Chief Executive Officer  
Council of Medical Specialty Societies (CMSS)

Gary Wolf  
Co-Founder, Quantified Self

Hannah Davis  
Researcher with the Patient-Led Research Group within Body Politic
Prioritizing Patient Engagement and Inclusion of Patient-Generated COVID-19 Data

#COVIDregistries | @susannahfox
The Coronavirus Is Never Going Away

No matter what happens now, the virus will continue to circulate around the world.

SARAH ZHANG   AUGUST 4, 2020
The internet gives us access not only to information, data, and tools, but also to each other.

How might we leverage peer-to-peer connections for pandemic response?
“I was the science.”

— Heather Hogan, who lives with LongCovid, writing about her odyssey

Self Registration

A person-centered approach to recording symptoms, observations, and outcomes.
Everybody has questions…

Wait are these really side effects?
When does my pain flare?
Why am I still sick?
Why am I breaking out?
How well am I recovering?
Where am I most tempted to smoke?
What triggers this arrhythmia?
What can I safely eat?
What lowers my blood sugar?
Does sleep affect my tremor?
...traditional research can’t answer.

Randomized Group Trials

• Powerful, expensive, slow
• High confidence about average effects.
• Outputs are products and standards of care

how to do a gold Standard clinical research trial
median cost $19 million

DESIGN

RECRUIT/COLLECT

DE-IDENTIFY

INTEGRATE

ANALYZE

TRANSLATE

TARGET

INTERVENE
...traditional research can’t answer.

Randomized Group Trials

- Powerful, expensive, slow
- High confidence about average effects.
- Outputs are products and standards of care

But what is true for me?

- Does sleep affect my tremor?
- When does my pain flare?
- Did it work last time?
- What triggers this arrhythmia?
- How are my feet doing?
- Wait are these really side effects?
- Why am I breaking out?
- How well am I recovering?
- Where am I most tempted to smoke?
- What can I safely eat?
- What lowers my blood sugar?
- Does sleep affect my tremor?

How to do a gold Standard clinical research trial

Median cost

$19 million
Background

**History:** The Quantified Self is a community of users and makers of self-tracking tools. First meeting in 2008. Spread to over 100 self-organized groups in over 30 countries.

**Organizational function:** Research, convening, funding, communication, advocacy, and technical development.

**Activities:** 11 international conferences, tool development, policy engagement, research innovation, and librarianship/archiving.
The First 1000 Discoveries

Gary Wolf – CMSS Webinar Series
Prioritizing Patient Engagement and Inclusion of Patient-Generated Covid-19 Data
Personal Science

Personal science is the practice of using empirical methods to explore personal questions.

33% of U.S. adults track health indicators like blood pressure, blood sugar, headaches, or sleep patterns. (Pew Research 2013)

30 million Apple Watches and 19 million Fitbit devices were sold in 2019. (San Jose Mercury News, Feb 6, 2020)

Duke, Scripps, UCSF, and Stanford currently using wearables data to provide "early warning" of COVID-19 detection.

We live in the era of participation

...but a clash of approaches stands between biomedicine and the potential for discovery in today's everyday tools.
Self-Registration

Patient Registry

• uniform data
• outcome focused
• particular disease
• predetermined scientific purposes

Self Registry

• accepts all data
• observation focused
• everyday living
• flexible self-directed purposes
Patient-Led Research for COVID-19

Gina Assaf and Hannah Davis

patientresearchcovid19.com
Who We Are

- **Gina Assaf** (COVID-19 on March 19), Washington, D.C
  - Design & Research Consultant for Technology for Social Impact
- **Hannah Davis** (COVID-19 on March 25), NYC
  - Research artist
  - Background in data analysis, machine learning

*Working with several other members of the Patient-Led Research team in Body Politic support group -> Community Driven process*
Our story and motivation

- Born out of **Body Politic (Slack)** Support Group
- Started research-group April 18th
- All patients/long haulers!
- **Multidisciplinary team:** All with directly applicable skills (research, analysis, data, health, policy)
First Survey: background

Saw need for systematic data aggregation and a Patient-Centric survey

Aggregated questions and symptoms from the group
First Survey: we were fast!

- Created Survey: April 18th
- Collected 640 Responses: May 2nd
- Analysis and Published Report: May 11th
First Survey: respondents

- **The ages of the respondents are varied**, with the majority of respondents between the ages of 30 and 49 (62.7%).
- **Most respondents are from the U.S.** 71.9% (NY specifically) followed by the U.K., Netherlands, Canada, Belgium and France.
- Majority of respondents are **white** 76.5% and identified as **cisgender female** 76.6%.
Captured common phenomena discussed in the support group(s)

- **Many symptoms** reported outside of the CDC list and medical community awareness including many neurological symptoms
- Lack of Medical & public health groups' responses to these patients with prolonged symptoms and recovery
Symptomatic people who tested negative had the same symptom frequency as people who tested positive, but tested later on average. Relapses and new symptoms are common.
What Does COVID-19 Recovery Actually Look Like?

An Analysis of the Prolonged COVID-19 Symptoms Survey by Patient-Led Research Team

Generated from survey data organized by decentralized team of COVID-19 patients, exported on May 2, 2020 (640 Responses)


Report created and written by volunteers from the COVID-19 Body Politic Slack Group including: Gina Assaf, Hannah Davis, Lisa McCorkell, Hannah Wei., O'Neil Brooke, Athena Akrami, Ryan Low, Jared Mercier, and Adetutu A.

Survey Authors and Contributors Include: Gina Assaf, Tina L., Annie C., Monica S., Jared Mercier, Lauren N., Noel H., JD Davids, and Susie.
First Survey: response

- **Appreciation** messages from many other patients
- Connection with the ME/CFS groups
- **Press/general** awareness of Long Covid
- **Cited in medical/health journals**: British Medical Journal 3x and Fatigue journal
- **CDC** circulated our report internally & requested a meeting
First Survey: what citations look like

- Cited in medical/health journals: British Medical Journal 3x and Fatigue journal

Fatigue:


British Medical Journal:

Second Survey (in progress)

Comprehensive IRB approved Survey with focus on topics Important to Long Hauler Patients:

1. Antibody testing
2. Neurological symptoms
3. Mental health
4. Symptoms over a longer time period
5. Diagnostics

For wider reach will be translating and recruiting participants both internal/external to Body Politic Support group
Questions and Tradeoffs

- Value of IRB/Formal Publication/ Is it worth it?
- Do we prioritize speed/getting information out there quickly or formal publishing processes?
- Which researchers do we partner with? What do partnerships look like? What is the benefit?
Lessons from doing this type of research

Benefits
- Patient-led research lets us ask the right questions earlier/better understanding of the illness
- Multidisciplinary effort
- Get answers earlier
- Motivation is not ego/profit, it’s our own health

Challenges
- Energy levels → We are all sick
- Funding/organizational/governance structure
- Methodological challenges
- Outside of the “normal” research system
Thank you!

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Methods, Relevance and Lessons from the COVID-19 Global Rheumatology Alliance Patient Experience Survey

Emily Sirotich, PhD Student
Department of Health Research Methods, Evidence, and Impact; McMaster University
Patient Engagement Lead; COVID-19 Global Rheumatology Alliance
Disclosures

ES is a Board Member of the Canadian Arthritis Patient Alliance and COVID-19 Global Rheumatology Alliance, whose activities are largely supported by independent grants from pharmaceutical companies.
Objectives

- Partnership with patients improves design of clinical registries
- Research driven by key partners and data providers amplifies reach of clinical research
- Patient-reported outcomes are reliable and valuable indicators of health, particularly in the investigation of complex and novel diseases
COVID-19 Global Rheumatology Alliance

Our Mission:
• To collect, analyze and disseminate information about COVID-19 and rheumatology to patients, physicians and other relevant groups to improve the care of patients with rheumatic disease.

Activities:
1. Physician-reported registry of people with rheumatic disease and COVID-19 infections;
2. Patient Experience Survey to collect data about the patient experience during the COVID-19 pandemic;
3. Evidence synthesis; and
4. Dissemination of information to patients and health professionals.
Limitations of a Physician Registry

- Patient-reported outcomes not sufficiently captured
- Physician registry does not capture behavioral changes of patients regardless of infection status
- Physician registry does not include data from patients with mild symptoms who do not seek medical care
COVID-19 Global Rheumatology Alliance Patient Experience Survey

This international, anonymous, patient-facing survey is intended for adults and parents of children with rheumatic diseases, whether or not they have contracted COVID-19

Current Respondents of Patient Survey = 13,110

• Includes 787 with COVID-19 diagnosis
• Over 100 countries are represented
• Survey translated into 9 languages
Research Design and Methods

Patients
Patients with rheumatic and autoimmune conditions with or without COVID-19 infection are invited to participate

Patient Health Information
PHI such as patient names or date of birth will not be collected

Data Collected
Collect clinically relevant data and patient-important outcomes

Data Hosting
De-identified patient data will be entered into a web-based survey developed and hosted by Boston Children’s Hospital

PHI: patient health information
Rapid Engagement with Patients, Patient Organizations, and Rheumatologists

Patients involved in generating research questions, study design, measuring instruments, etc.

Survey sent to physicians, patients, and patient groups for further review and translated into 9 languages.

Survey deemed exempt as it was to be anonymous and excluded PHI.

Survey dissemination led by patients and patient organizations supplied with social media kits.

IRB: Institutional Review Board; PHI: patient health information
Data Elements Captured

- PATIENT BEHAVIOUR
- EMPLOYMENT
- DECISION TO CONTINUE IMMUNOSUPPRESSION
- ABILITY FOR PATIENTS TO CONNECT WITH THEIR RHEUMATOLOGISTS
- PATIENT-REPORTED OUTCOME MEASUREMENT INFORMATION SYSTEMS (PROMIS) MEASURES
Advantages of Patient-Integrated Registries

Informing the prevention and treatment of COVID-19 and understanding the impact of the pandemic on all patients

Rapid mobilization of the rheumatology community through web-based communication

Questions were developed by patients and addressed the knowledge gaps that were prioritized by patients
Meet the COVID-19 Global Rheumatology Alliance (GRA) Patient Board

To further support the mission of the GRA, this patient board was established with a vision to represent a culturally and regionally diverse patient voice and expand the reach and visibility of the GRAs work to the broader patient and caregiver community. This group serves to amplify the patient’s perspective by sharing ideas, initiatives, and feedback with the GRA Steering Committee.

MEMBERS

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Lessons from the Patient Experience Survey

• Partnership with patients improves design of clinical registries
  • Relevant patient outcomes were collected

• Research driven by key partners and data providers amplifies reach of clinical research
  • 11,000 responses in 1 month
  • 9 languages and 100 countries

• Patient-reported outcomes are reliable and valuable indicators of health, particularly in the investigation of complex and novel diseases
  • Rapid mobilization of the patient community
Thank you!

Emily Sirotich, PhD Student
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Website:
https://rheum-covid.org/

Patient Survey:
https://rheum-covid.org/patient-survey/
Questions & Answers

Please submit all questions through the question box.
Summary & Evaluation

• Thank you to all our panelists.
• A recording of the webinar will be available on the CMSS website in the coming weeks.
• Please compete a short evaluation following the webinar.
• For more information, contact info@cmss.org.
Upcoming Webinar:
Using Clinical Registries to Address Disparities in Covid-19
September 1
2:30 - 4:00 pm ET

Moderator:
Helen Burstin, MD, MPH, MACP
Chief Executive Officer
Council of Medical Specialty Societies (CMSS)

Panelists:
Kirsten Bibbins-Domingo,
PhD, MD, MAS
Professor and Chair, Department of Epidemiology and Biostatistics; Lee Goldman, MD Endowed Chair in Medicine; Vice Dean of Population Health and Health Equity, School of Medicine UCSF

Eliseo Perez-Stable, MD
Director of the National Institute on Minority Health and Health Disparities (NIMHD), National Institutes of Health (NIH)

Bill Wood, MD, MPH
Chair, Data Hub Oversight Group, ASH Research Collaborative; Associate Professor of Medicine, Division of Hematology, University of North Carolina at Chapel Hill

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