CMSS Presents:

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

August 12, 2020 | 1:00 – 2:30 pm ET

CMSS

CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

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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

CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

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

Host:

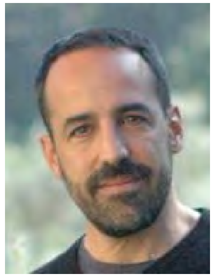
Helen Burstin, MD, MPH, MACP
Chief Executive Officer
Council of Medical Specialty Societies (CMSS)

Panelists:

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

Hannah Davis
Researcher with 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



Gary Wolf
Co-Founder, Quantified Self

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

#COVIDregistries | @susannahfox

Image: Michael
Swan on Flickr

@susannahfox

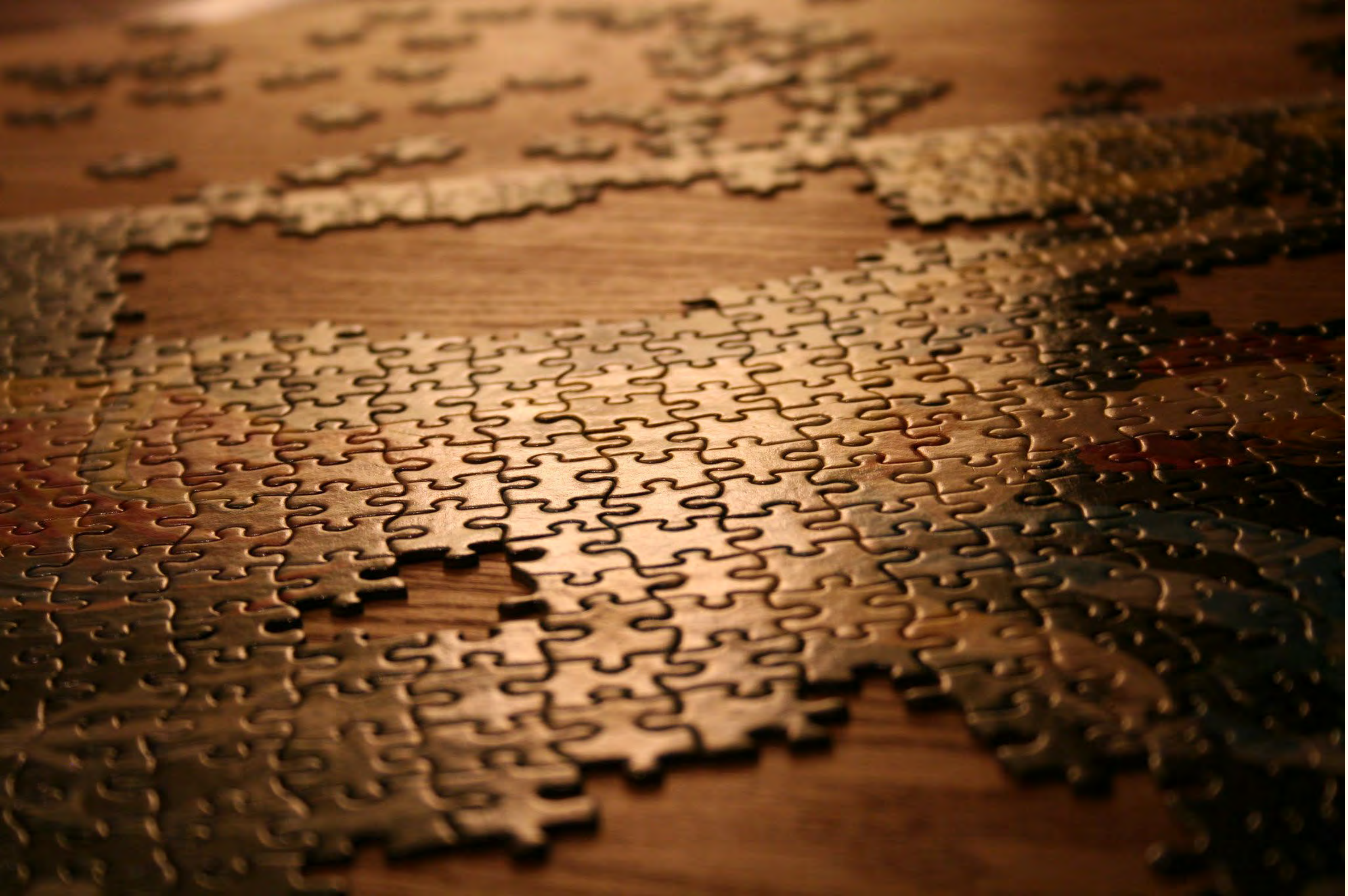


Image: Jolene
Faber on Flickr

@susannahfox

The Atlantic

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

https://www.autostraddle.com/the-soft-butch-that-couldnt-or-i-got-covid-19-in-march-and-never-got-better/

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 breaking out?

Why am I still sick?

How well am I recovering?

Where am I most tempted to smoke?

What triggers this arrhythmia?

What can I safely eat?

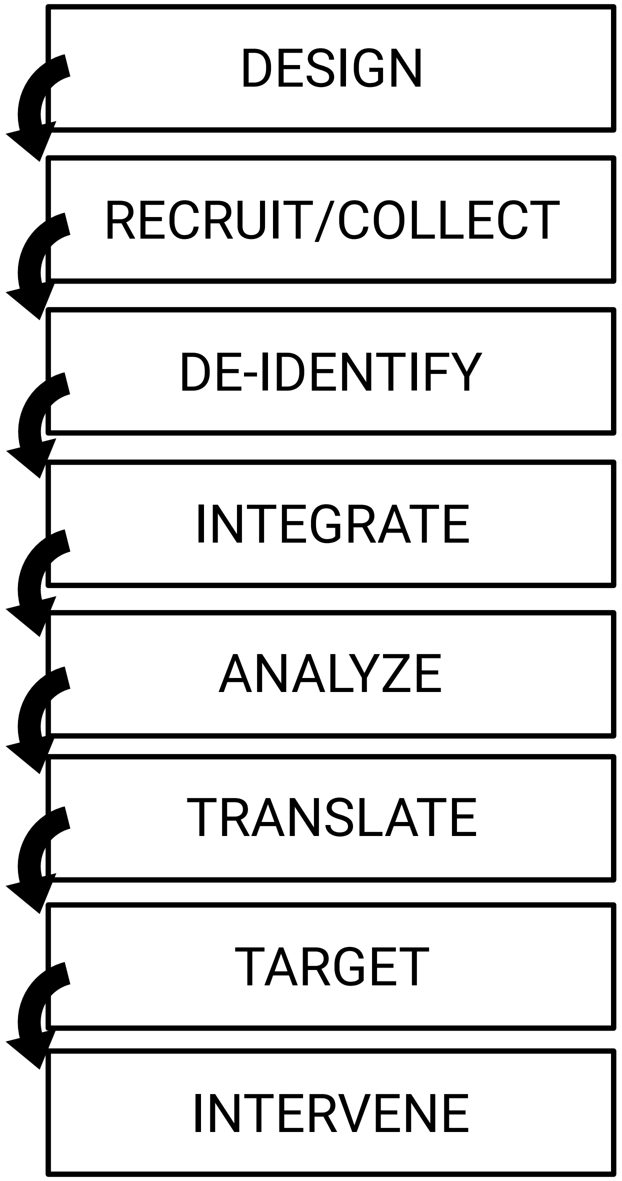
What lowers my blood sugar?

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



DESIGN
RECRUIT/COLLECT
DE-IDENTIFY
INTEGRATE
ANALYZE
TRANSLATE
TARGET
INTERVENE

how
to do a
gold
Standard
clinical
research
trial

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median
cost
$19
million

...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?

Wait are these really side effects?

When does my pain flare?

Why am I breaking out?

Did it work last time?

How well am I recovering?

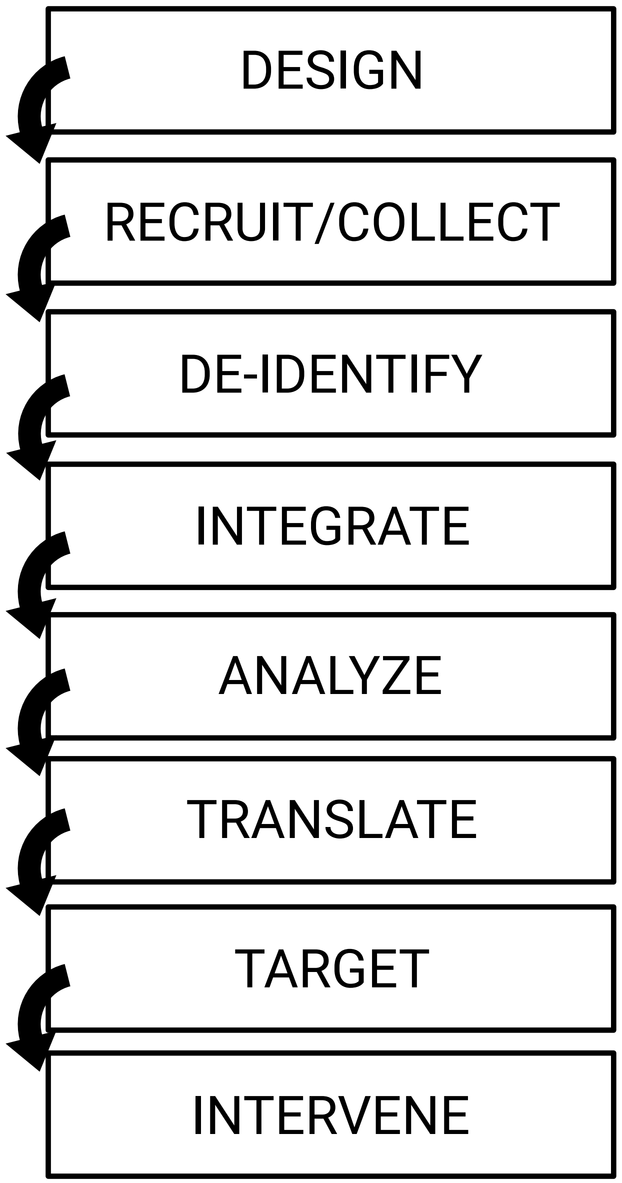
What triggers this arrhythmia?

Where am I most tempted to smoke?

What can I safely eat?

How are my feet doing?

What lowers my blood sugar?



DESIGN

RECRUIT/COLLECT

DE-IDENTIFY

INTEGRATE

ANALYZE

TRANSLATE

TARGET

INTERVENE

how to do a gold standard clinical research trial

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median cost $19 million

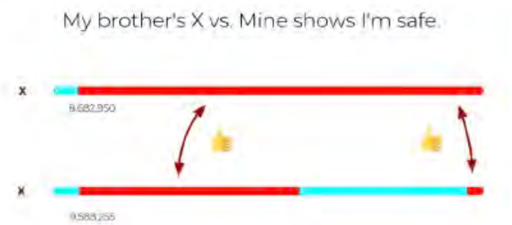
Background

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.

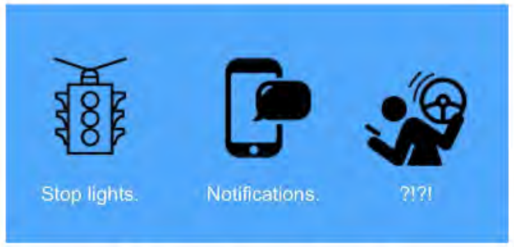
Organizational function: Research, convening, funding, communication, advocacy, and technical development.

Activities: 11 international conferences, tool development, policy engagement, research innovation, and librarianship/archiving.

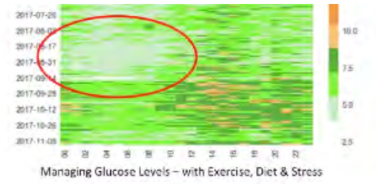
The First 1000 Discoveries



A SELF-STUDY OF MY CHILD'S GENETIC RISK
Mad Ball



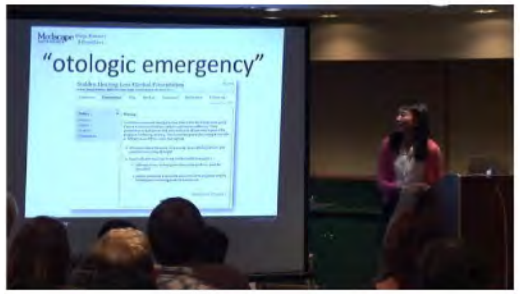
THE DATA IS IN, I'M A DISTRACTED DRIVER
Robert Macdonell



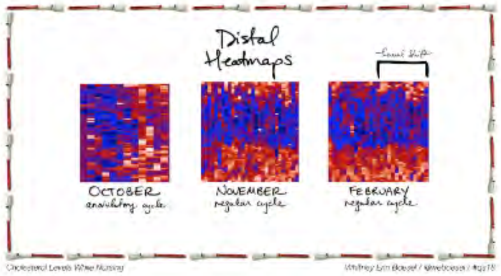
TRACKING GLUCOSE AS A PERSON WITHOUT DIABETES
Justin Lawler

IMPROVING MY BLOOD PRESSURE WITH ANAEROBIC INTERVAL TRAINING
Siva Raj

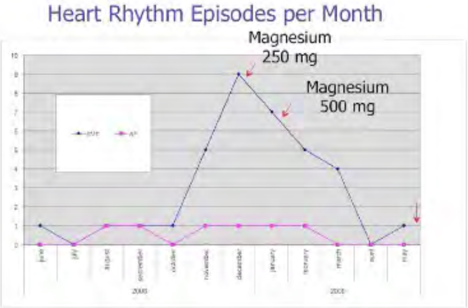
MY HEADACHES FROM TRACKING HEADACHES
Jakob Eg Larsen



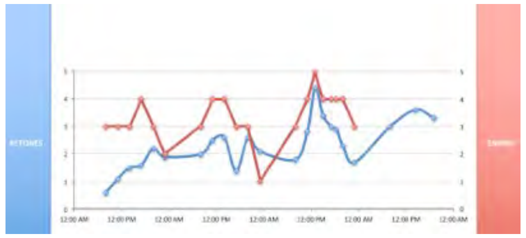
TRACKING MY HEARING LOSS
Lindsay Meyer



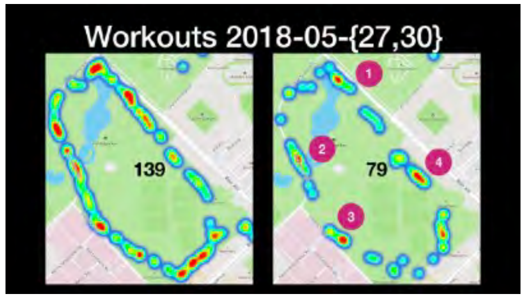
CHOLESTEROL LEVELS WHILE NURSING
Whitney Erin Boesel



WHAT CAUSES MY HEART RHYTHM DISORDER?
Mark Drangsholt



BLOOD KETONES DURING REGULAR FASTING
Mark Moschel



WHICH GRASSES AGGRAVATE MY ALLERGIES?
Thomas Blomseth Christiansen

USING SELF-TRACKING TO HACK MUSCULOSKELETAL PAIN
Bryan Ausinheiler

BUILDING MYSELF BACK UP
Maggie Delano

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.

NBA Central
@TheNBACentral

NBA players will wear a 'smart ring' at Disney world, per CNBC.com

The Oura smart ring is capable of predicting COVID-19 symptoms up to 3 days in advance with 90% accuracy. The ring can measure body
temperature, respiratory functions and heart rate.

10:22 AM · Jun 18, 2020

23.1K See the latest COVID-19 information on Twitter

Wolf, Gary Isaac, and Martijn De Groot. "A Conceptual Framework for Personal Science." Frontiers in Computer Science, vol. 2, June 2020, p. 21
Heyen, Nils B. "From Self-Tracking to Self-Expertise: The Production of Self-Related Knowledge by Doing Personal Science." Public Understanding of Science, vol. 29, no. 2, 2020, pp. 124–38

We live in the era of participation

ARDUINO
vimeo
Khan Academy
GitHub
WIKIPEDIA
The Free Encyclopedia
YouTube
reddit

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

Self-Registration

Patient Registry	Self Registry
• uniform data	• accepts all data
• outcome focused	• observation focused
• particular disease	• everyday living
• predetermined scientific purposes	• flexible self-directed purposes

Patient-Led Research for COVID-19

Gina Assaf and Hannah Davis

patientresearchcovid19.com

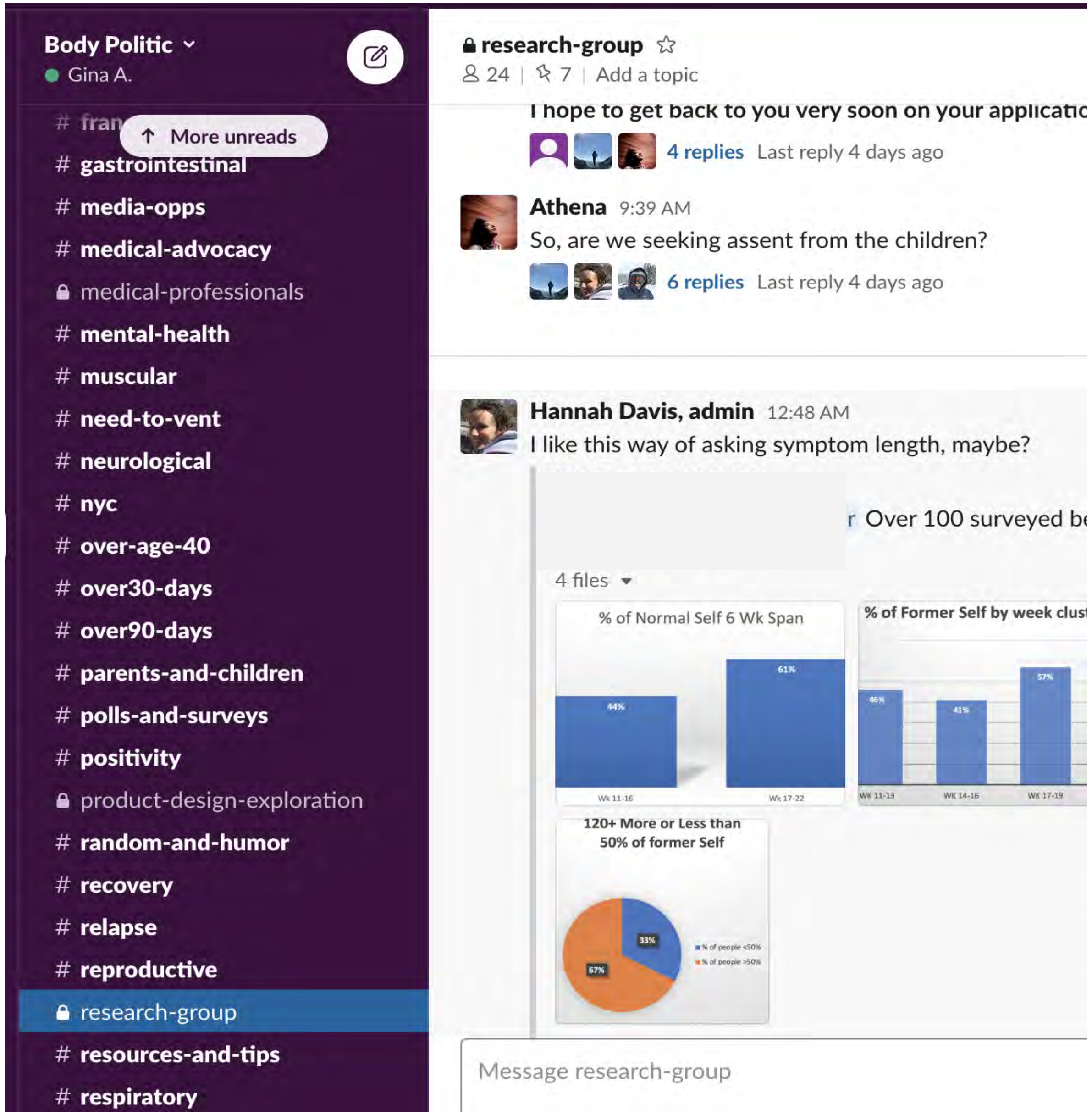
Who We Are

- **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)



I hope to get back to you very soon on your applicati

4 replies Last reply 4 days ago

Athena 9:39 AM

So, are we seeking assent from the children?

6 replies Last reply 4 days ago

Hannah Davis, admin 12:48 AM

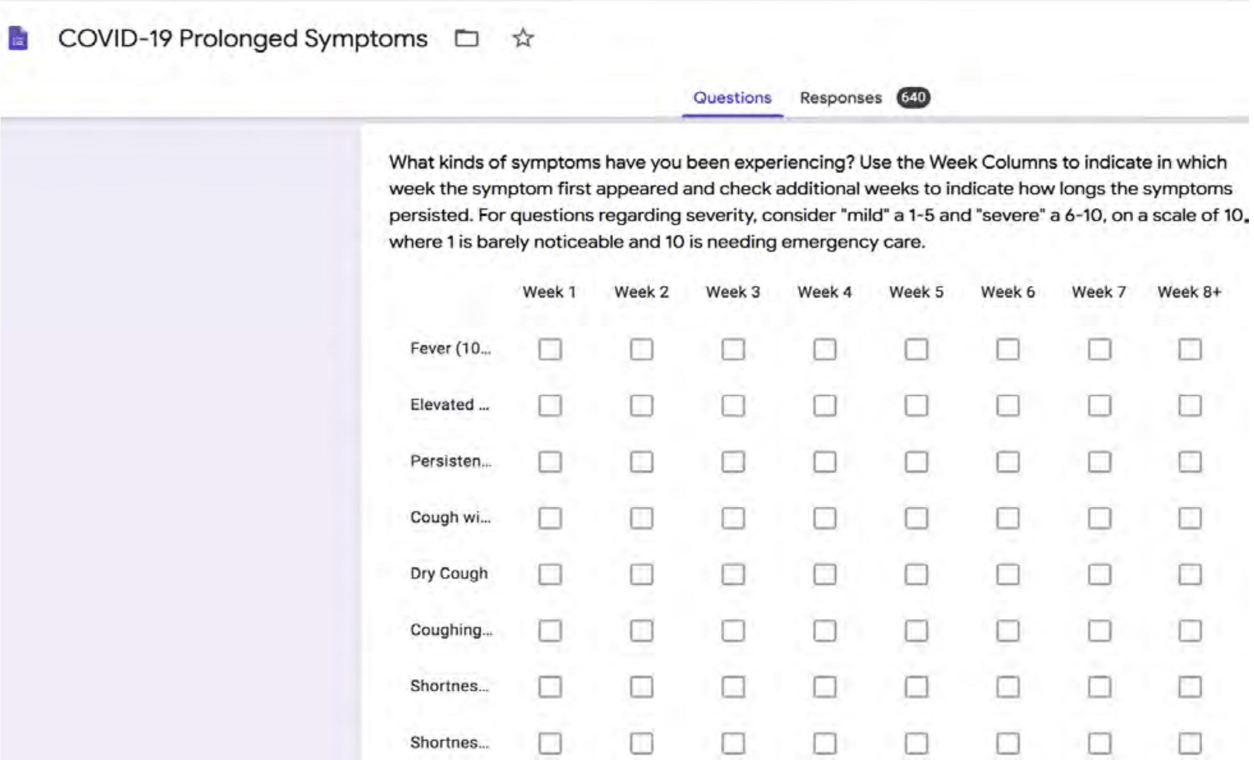
I like this way of asking symptom length, maybe?

r Over 100 surveyed be

First Survey: background

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

Aggregated questions and symptoms from the group



COVID-19 Prolonged Symptoms

What kinds of symptoms have you been experiencing? Use the Week Columns to indicate in which week the symptom first appeared and check additional weeks to indicate how longs the symptoms persisted. For questions regarding severity, consider "mild" a 1-5 and "severe" a 6-10, on a scale of 10, where 1 is barely noticeable and 10 is needing emergency care.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8+
Fever (10...	☐	☐	☐	☐	☐	☐	☐	☐
Elevated ...	☐	☐	☐	☐	☐	☐	☐	☐
Persisten...	☐	☐	☐	☐	☐	☐	☐	☐
Cough wi...	☐	☐	☐	☐	☐	☐	☐	☐
Dry Cough	☐	☐	☐	☐	☐	☐	☐	☐
Coughing...	☐	☐	☐	☐	☐	☐	☐	☐
Shortnes...	☐	☐	☐	☐	☐	☐	☐	☐
Shortnes...	☐	☐	☐	☐	☐	☐	☐	☐

First Survey: we were fast!

Created Survey

April 18th

May 2nd

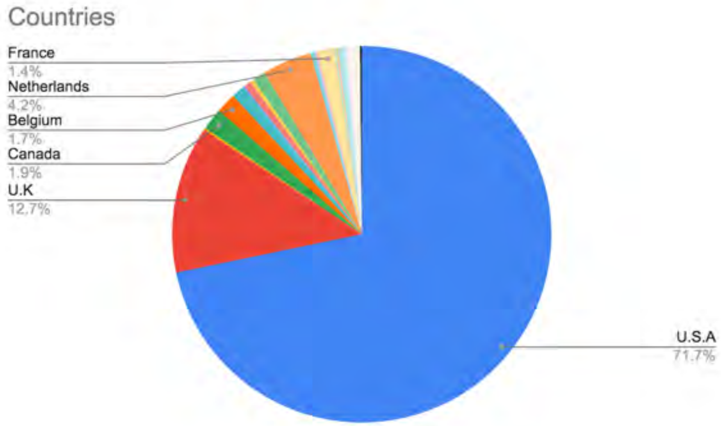
Collected 640 Responses

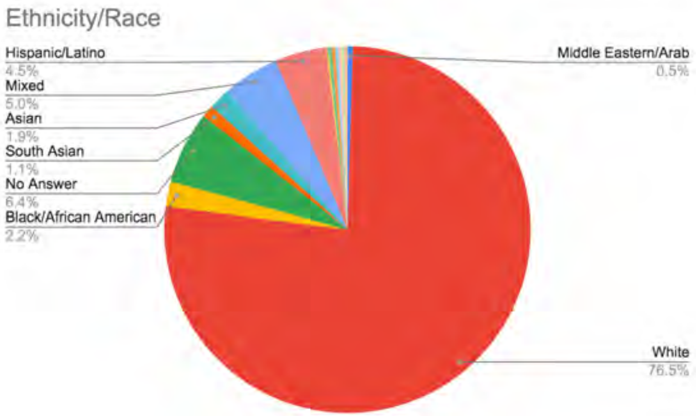
Analysis and Published Report

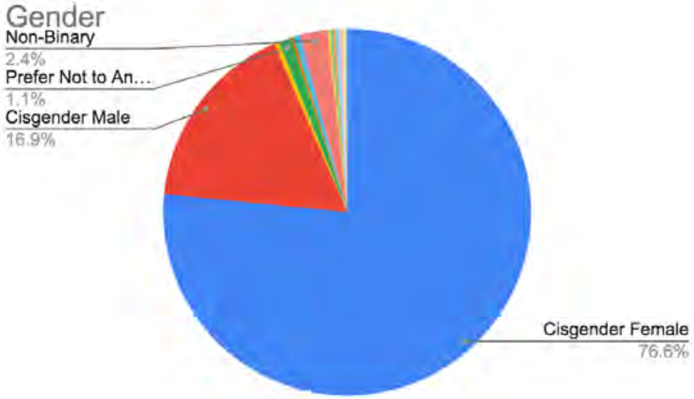
May 11th

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.% (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%



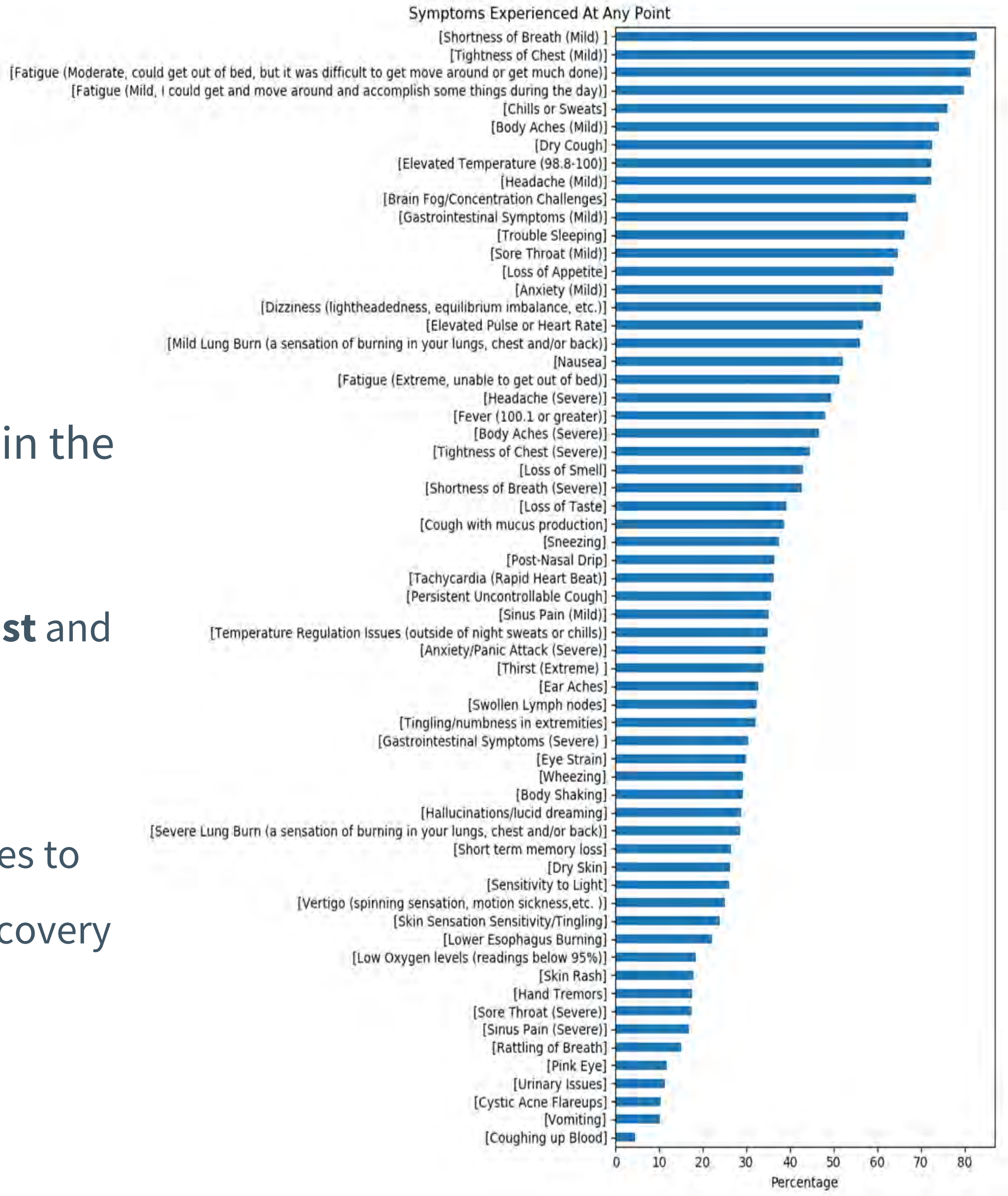




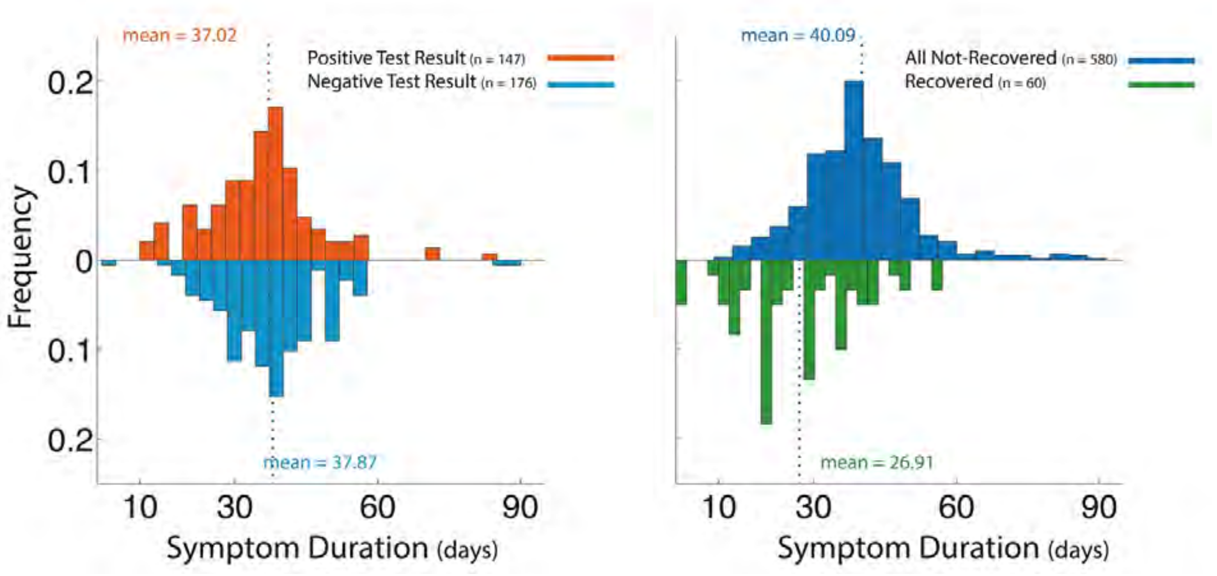
First Survey: what we learned

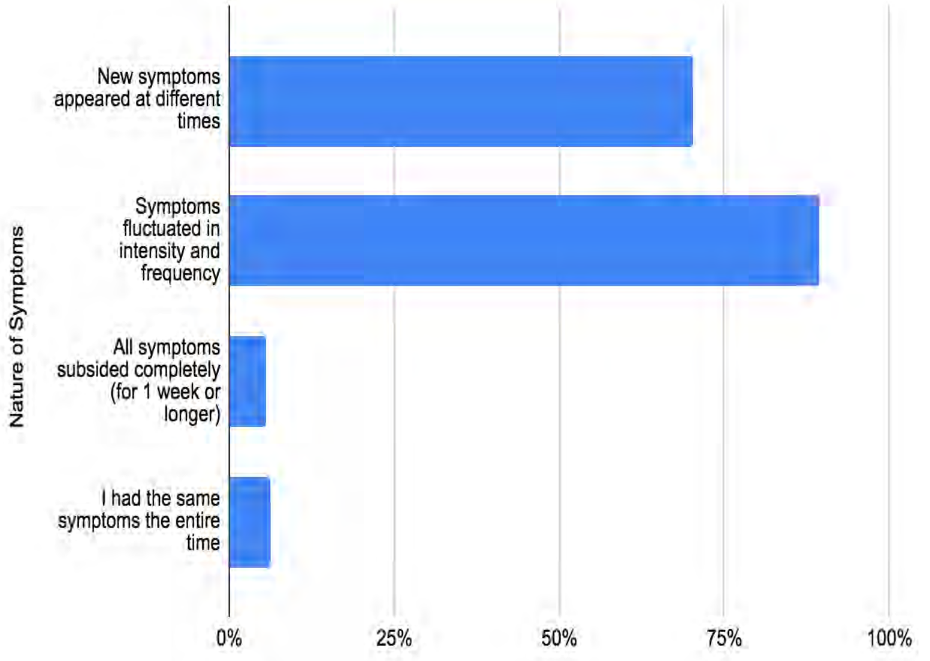
Captured common phenomena discussed in the support group(s)

- **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



First Survey: what we learned, continued

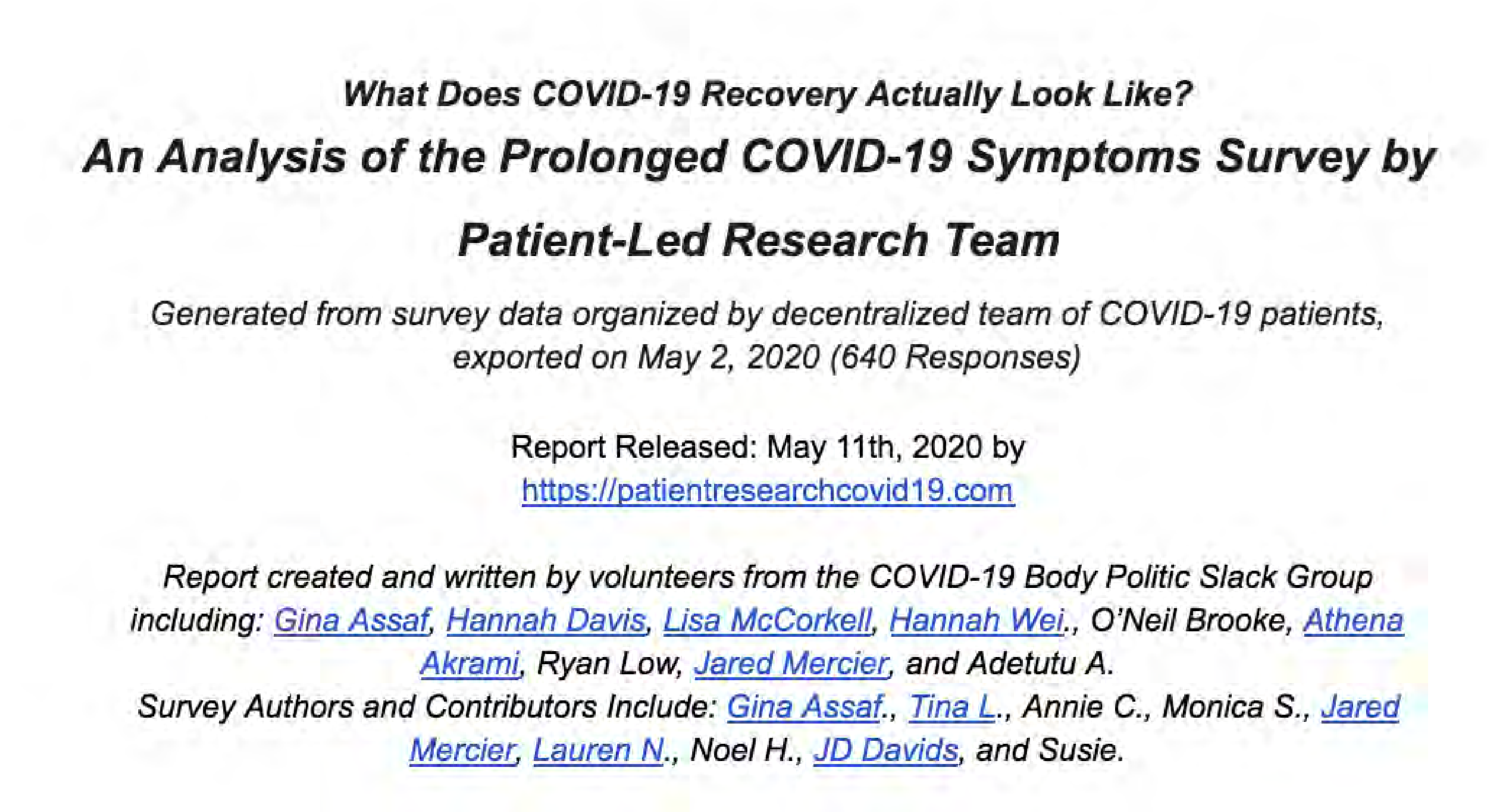




Symptomatic people who tested negative **had the same symptom frequency** as people who tested positive, **but tested later on average**

Relapses and new symptoms are common

First Survey: for other insights read full report



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)

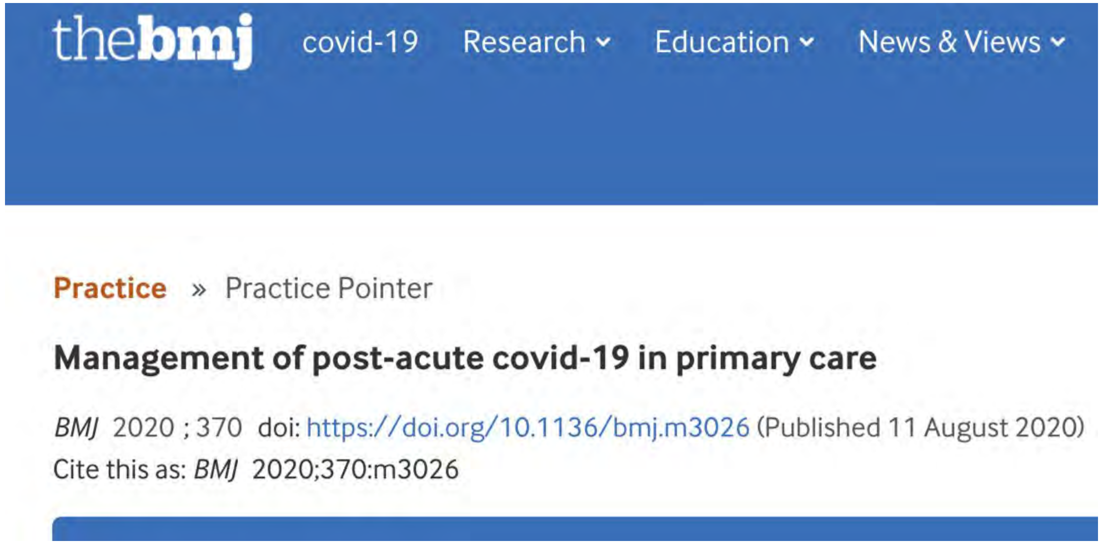
Report Released: May 11th, 2020 by
https://patientresearchcovid19.com

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


COVID-19 Can Last for Several Months
The disease's "long-haulers" have endured relentless waves of debilitating symptoms—and disbelief from doctors and friends.
theatlantic.com



Practice » Practice Pointer

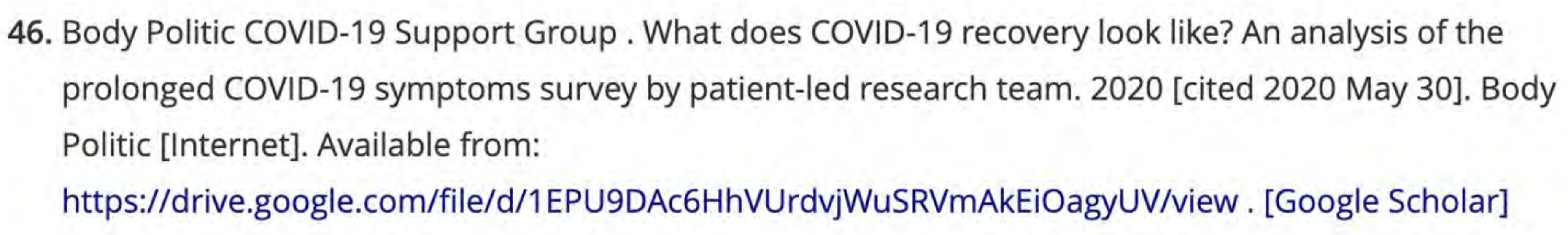
Management of post-acute covid-19 in primary care

BMJ 2020 ; 370 doi: https://doi.org/10.1136/bmj.m3026 (Published 11 August 2020)
Cite this as: *BMJ* 2020;370:m3026

First Survey: what citations look like

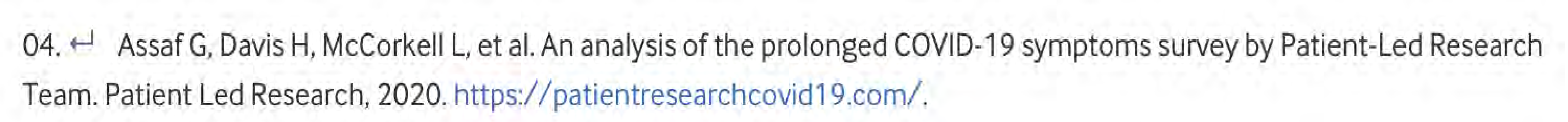
- **Cited in medical/health journals**: British Medical Journal 3x and Fatigue journal

Fatigue:



46. Body Politic COVID-19 Support Group . What does COVID-19 recovery look like? An analysis of the prolonged COVID-19 symptoms survey by patient-led research team. 2020 [cited 2020 May 30]. Body Politic [Internet]. Available from: https://drive.google.com/file/d/1EPU9DAc6HhVUrdvjWuSRVmAkEiOagyUV/view . [Google Scholar]

British Medical Journal:



04. ↵ Assaf G, Davis H, McCorkell L, et al. An analysis of the prolonged COVID-19 symptoms survey by Patient-Led Research Team. Patient Led Research, 2020. https://patientresearchcovid19.com/.

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!

@ginaassaf

@ahandvanish

patientresearchcovid19.com

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

CMSS Webinar Series: Covid-19 and Clinical Registries. August 12, 2020

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

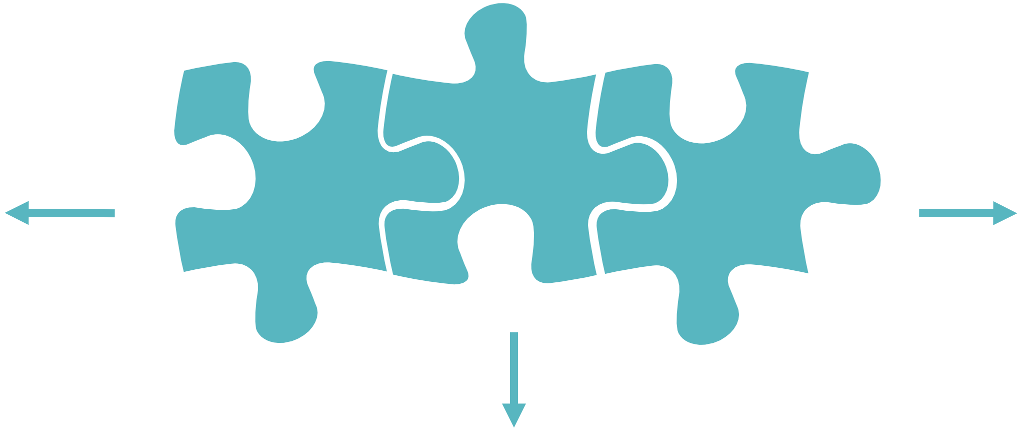
Our Mission:

- 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 include data from patients with mild symptoms who do not seek medical care

Physician registry does not capture behavioral changes of patients regardless of infection status

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

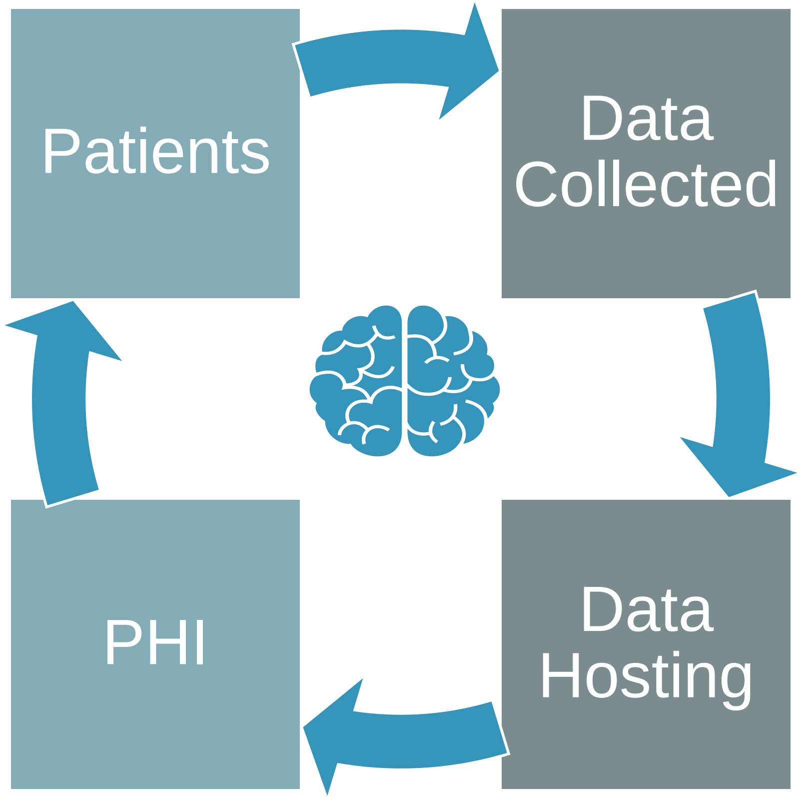
Research Design and Methods

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

Patient involvement

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

Survey review

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

IRB review

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

Survey communication

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

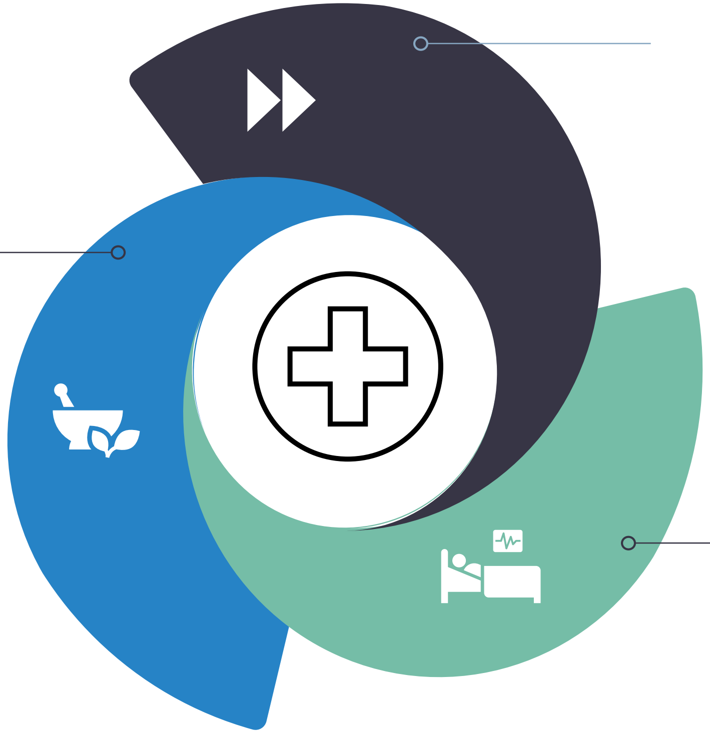
EMPLOYMENT

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 GRA's 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

Emily Sir Sirotch
PATIENT ENGAGEMENT CO-LEAD
Toronto, Canada
@emilysirotich

Wendy Costello
PATIENT ENGAGEMENT CO-LEAD
Ireland Chair of iCAN and ENCA
and PReS Council Member
@wendycostello2

Naira Ikram
Duke University,
"Psychoneuroimmunology:
Causes and Consequences."
Major, USA
Patient Board—Research and Communications
@NairaIkram

Evelyn Olmedo
SLE & SCLE Advocate,
El Salvador
Patient Board—Research
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Richard A. Howard, MBA
Chief Mission Advancement
Officer, Spondylitis
Association of America, USA
Patient Board—Patient Outreach
@RichAHoward

Monique C. Gore-Massy
aka "The LemonadeMaker"
Global Lupus Advocate /
Patient Consultant, USA
Patient Board—Communications
@GoldenMoe

Laura-Ann Tomasella
Arthritis Kids South Africa,
South Africa
Patient Board—Communications and Outreach
@arthritiskidssa

CONTACT US Online: rheum-covid.org Email: Rheum.covid.patient.board@gmail.com Instagram: @rheum_covid

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
rheum.covid@gmail.com

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.

CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

Upcoming Webinar:

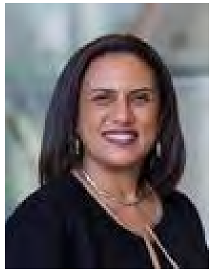
Using Clinical Registries to Address Disparities in Covid-19

September 1
2:30 - 4:00 pm ET

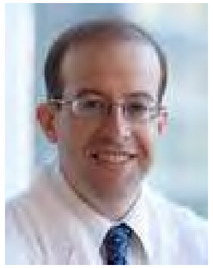
Moderator:

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



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

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

Clyde Yancy, MD, MSc, MACC, FAHA, MACP, FHFSA
Vice Dean, Diversity & Inclusion, Magerstadt Professor of Medicine, Professor of Medical Social Sciences, Chief, Division of Cardiology Northwestern University, Feinberg School of Medicine