

CMSS & PLRC PCORI Award

The Promise of Patient-Led Research Integration into Clinical Registries and Research

Conflict of Interest Disclosures

Gina Assaf - Nothing to disclose

Helen Burstin - Nothing to disclose

Susannah Fox - Nothing to disclose

Agenda

- Welcome & Introductions
- Context - CMSS + PLRC Collaboration
- Project Overview
- Background - Themes/Scorecards
- Historical Perspective of Patient-Led Efforts
- Value
- Next Steps

Welcome



**PATIENT-LED
RESEARCH
COLLABORATIVE**

This project was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Eugene Washington PCORI Engagement Award (21376-CMSS). The statements presented in this work are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.



Welcome & Introductions

Gina Assaf
Founding Member, PLRC



Helen Burstin, MD, MPH, MACP
Chief Executive Officer, CMSS



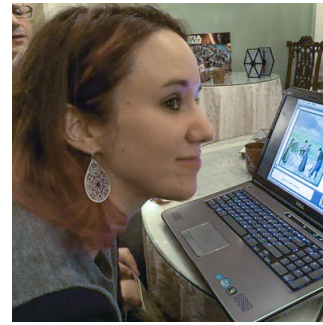
Susannah Fox
Principal, Internet Geologist LLC
Advisory Panel



Welcome & Introductions

CMSS-PLRC Project Team

Gina Assaf, PLRC
Hannah Davis, PLRC
Lisa McCorkell, PLRC
Hannah Wei, PLRC



Helen Burstin, CEO, CMSS
Elizabeth O'Keefe, CMSS
Suzanne Pope, Consultant, CMSS



Project Inception



Spring/Summer 2020

Patients were tracking symptoms, contributing data to the public conversation about COVID-19, and identifying an emerging threat: Long Covid.

CMSS invited patient-led researchers to present their findings as part of a webinar series.

Photo by Ted Eytan, MD

Advisory Panel Members

Donna Cryer, JD

Susannah Fox

Janna Friedly, MD, MPH

Harlan Krumholz, MD

Fiona Lowenstein

Monica Lypson, MD, MHPE

Greg Martin, MD, MSc

Karla Monterroso

Dona Kim Murphey, MD, PhD

Jaime Seltzer, MS

Craig Spencer, MD, MPH

Global Liver Institute

Internet Geologist, LLC

University of Washington

Yale University

Body Politic

Vagelos College of Physicians & Surgeons

Emory University/Society of Critical Care
Medicine

Brava Leaders

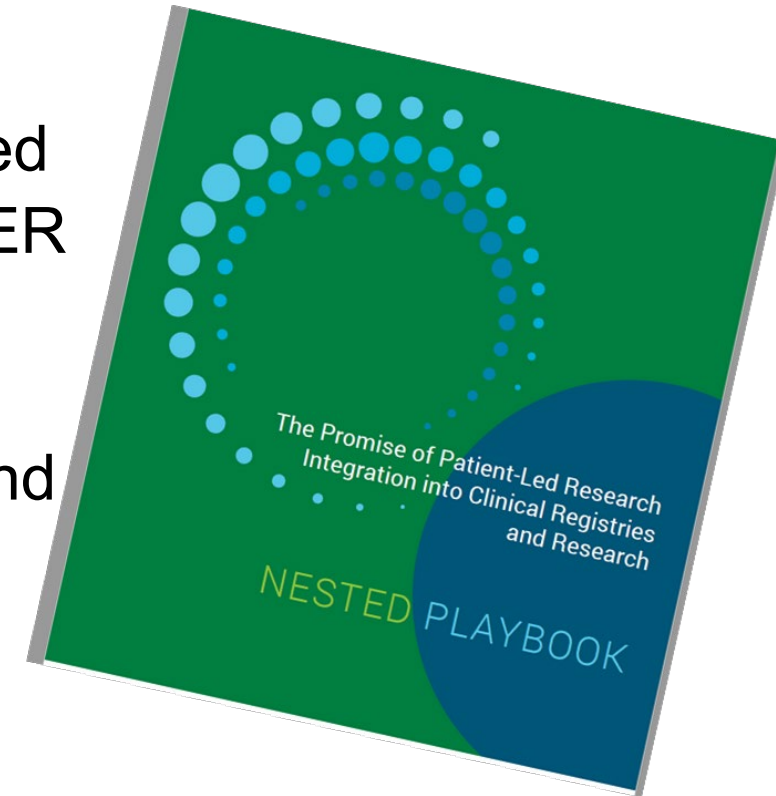
In Phase Neuro

#MEAAction

Columbia University Medical Center

Goals

- Support for patient-led outcomes research
- Incorporation of patient-led research and patient-generated outcomes data into clinical and research enterprise for CER
- Collaboration with diverse patient populations
- Patients leading CER efforts
- Pathways for sustaining patient-led outcomes research and CER – through specialty societies, clinical registries, research agencies, and academic medicine
- Lessons learned from COVID-19 patient-led outcomes research



Patient-Led Research Collaborative

45+ Long-COVID patient-researchers and advocates across **4 continents**. Met and formed in April 2020 in Body Politic COVID Support Group

Interdisciplinary team across sciences, technology, policy, media

IRB from University College London

10 PAPERS IN 21 MONTHS

3 patient-led papers, including an International study with 8,000+ Long COVID participants from **80+ countries in 9 languages**. 7 co-authored papers with **Yale, WHO, National COVID Cohort Collaborative, University of Toronto, Imperial College London, UCL**

POLICY DOCUMENTS

Our papers informed policy in the **US, UK, Belgium, Spain, Council of the European Union, World Health Organization, & others**.

800+ RESEARCH CITATIONS

Cited in international Long COVID research papers since May 2020. In **top 0.00003%** of papers on medRxiv. Published paper in the Lancet with over **260,000 views** by medical professionals and the public

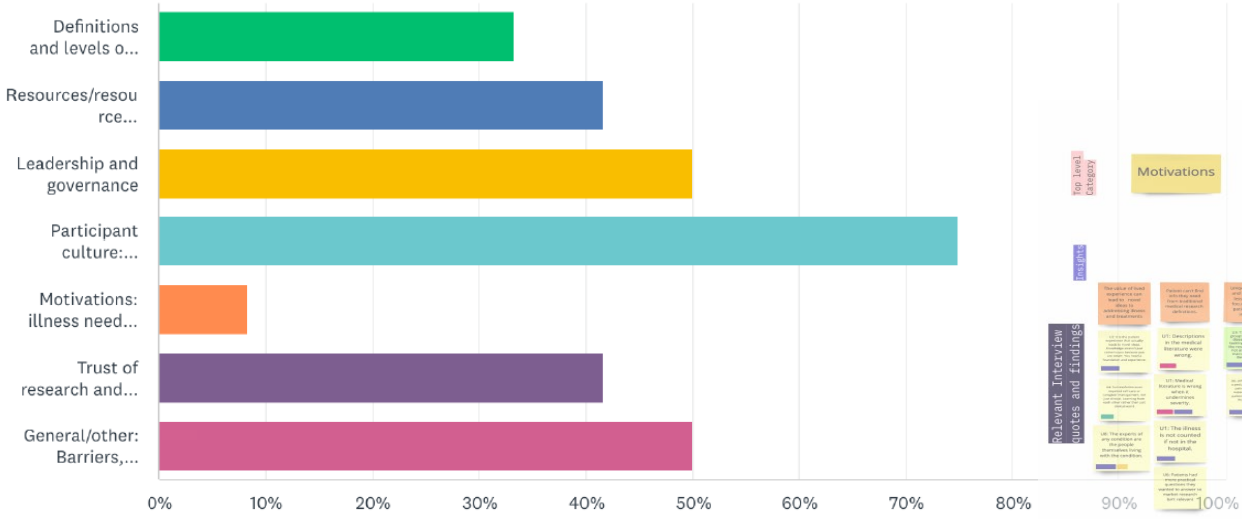
PUBLIC HEALTH GUIDELINES

Co-created **WHO Clinical Case Definition, CDC Long Covid guidelines, American Academy of Physical Medicine & Rehabilitation guidelines**, influenced **NIH \$1.15B funding**, & others.

Conducted In-depth Research

Choose 3 of the topics you think the group should focus the research:

Answered: 12 Skipped: 0



Key Informant Interviews

“The only thing better than a *voice* is a *vote*.”

“ You (as a patient) have to fight to say here is where the value is and convince people (researchers).”

“I not only understand research and I can read a protocol, but I can **tell my story effectively** and translate my lived experience strategically for a particular point...but nobody’s been trained. Teach patients both the substance and the technique of operating in these [research] environments.”

“When going to researchers, as a patient, I will always **just be a patient to them**, despite how much research experience I may have or what I’ve accomplished.”

“One of the biggest barriers of research is that you're inviting people to talk about *trauma* and then **leaving them with that trauma**.”

Key Themes

- **Motivations** of Involvement & Biases
- **Power Dynamic** in Collaboration
- Patient **Empowered** vs. **Patient-Led**
- Empowering Patients or **Reinforcing Problematic Dynamics**
- Skillset Required: Both **soft and hard skills**
- Losing Autonomy, Moral Alignment, and Insufficient Resources for Patient Groups



Deciding on a Scorecard for Evaluating Collaboration

The initial scorecard prototype was developed by the team following a synthesis of primary and secondary research

- Conducted a **literature review of existing models**, and evaluated several types of frameworks, their usefulness, and gaps.
- Decided on a **scorecard model for simplicity and immediate deployability and action oriented**

Scorecards

DIMENSION ANCHORS

Dimension to evaluate	What is unacceptable?	What is minimally acceptable?	What is ideal?
Patient/Partner Governance	Absence of patient involvement or token involvement.	Patients are provided a seat at the table of decision-making and are included in discussions/voting	Equal or more decision-making power is in the hands of patients
Integration into Research Process	Patients are used to recruit others as study subjects, without active engagement or compensation. No active involvement in study design and goals.	Patients give feedback on the study design, goals, methodology, and data collection methods. Patient feedback is integrated into the research process. If patients have capacity/skills, they are invited to conduct analyses and provide feedback on what is being reported and how it is disseminated.	Patients lead/co-lead at every stage of the research process, including equal or more decision-making power at every stage. Patients present hypotheses and research questions that should be investigated. Patients assess report format and analyses to ensure that it will be easily understood by the patient community and by the clinicians.
Patient Burden	Patients are expected to participate in research without recognition of their limitations and understanding of how research may lead to trauma, hardships, and impact on their illness. Patients are expected to participate without compensation in some form.	Follow the principle of "do no patient harm," including adequate compensation, flexible methods of participation, and recognition of the impact on vulnerable patients who may be most impacted.	The partner organization has the capacity and structure to support all patients, including those most impacted. The partner organization will conduct feedback sessions prior to launching study to understand the expected burden on patient researchers and how these burdens can be addressed.
Research Partner Readiness	There is no process, infrastructure, or dedicated resources for collaboration with patients. Patients' time and knowledge are not respected. Prior limited interaction with patients and patient organizations.	There is a process and infrastructure for collaboration with patients. Partner organization aware of existing biases, willing to invest time into building trustworthy relationships, and responsive to feedback.	Partner organization has at least one point of contact focused on meeting the needs of patients and patient groups. The entire partner team has a background and understanding of disability justice. Prior patient groups provide strong recommendations for the research team.



Research Partner Readiness

Research Partner Readiness	-2	Non-collaboration	-1	Minimal collaboration	0	Acceptable collaboration	1	Great collaboration	2	Ideal collaboration	
	Recognition of Biases										
	Research partner does not recognize bias and ignores feedback from patient group		Research partner has limited awareness of own biases and listens to some feedback from patient group		Research partner is aware of own biases and is open to feedback from patient group. Implements some of them		Research partner is aware of own biases and is open to feedback from patient group. Actively iterates on feedback given		Research partner is aware of own biases and is open to listening to feedback from patient group. Actively iterates on feedback given. Other patient groups can attest to a positive working relationship		
	Collaboration Process										
Research partner has no dedicated infrastructure for collaborating with patients.		Research partner has minimal resources/infrastructure for collaborating with patients; may have one coordinating personnel with minimal capacity to coordinate with patient group		Research partner has dedicated some resources and infrastructure for collaborating with patients (ie. patient panels); has at least one coordinating personnel focused on meeting the patient group's needs; conducts limited training to build skills to engage with patients		Research partner has an established infrastructure and process for collaborating with patients including at least one dedicated person focused on meeting the patient group's needs and advocating to rest of the partner organization; conducts routine training to build skills to engage with patients		Research partner has an established infrastructure and process for collaborating with patients that has been vetted by other patients / patient groups; has at least one dedicated person who is focused on meeting the patient group's needs. The partner is recognized as a patient ally vetted by other patients and patient groups with background in disability justice. Conducts extensive training on meaningful engagement with patients.			
Knowledge in Disease Subject											
Research partner has no knowledge/experience with the disease being researched		Research partner has minimal knowledge/experience with the disease state being researched		Research partner has some knowledge/experience with the disease being researched		Research partner has knowledge/experience of the disease being researched		Research partner has extensive knowledge and direct experience with the disease being researched and those with knowledge are in decision-making roles			

Patient Burden

	-2 Non-collaboration	-1 Minimal collaboration	0 Acceptable collaboration	1 Great collaboration	2 Ideal collaboration
Patient Burden	Flexible Engagement				
	Patients have minimal choice in how to engage (e.g. sent a meeting link without discussion, a request with a hard deadline); accommodations come at a high time, effort, or monetary cost to the patient.	Patients have limited flexibility in how to engage, and minimal accommodations are offered. No justification is offered for inflexibility.	Patients have flexibility in how to engage. Partner organization offers most or all accommodations that patients request, and provides justification for those it doesn't offer.	Partner organization offers most or all accommodations requested, and provides justification for those it doesn't offer. Patients co-design engagement to minimize patient burden in future studies.	Patients co-design the study from the ground up and are given a decision-making role in providing flexibility. Partner organization offers most or all accommodations requested before and during the study, and provides justification for those it doesn't offer.
	Trauma				
	Research team does not consider the trauma, pain, or setbacks that the study might cause.	Patients' trauma/pain may be considered by the partner org, but justification, recognition, and mitigation are not provided.	Researchers consider the trauma burden during study design, and put some mitigation or care strategies in place.	Partner organization is open to co-running a session with the explicit goal of reducing trauma before the study launches where reducing trauma is an explicit goal. Some mitigation and care strategies are practiced. Research team understands the trauma burden and justifies its necessity.	Patients co-design the study and run feedback sessions, and have a decision-making role in mitigation/care strategies, as well as deciding whether the research potential justifies the trauma burden. All participants are informed of the study's results so they see the payoff of their efforts.
	Responsiveness to Patients				
Partner organization does not address patient concerns on flexibility or trauma burden.	Partner concerns may be taken into consideration, but without a specific plan to incorporate changes into current or future engagements.	Partner organization hears patient feedback and makes a specific plan to incorporate accommodations/trauma mitigation or care into future engagements.	Researchers incorporate patient feedback into the current study, and patients co-design engagement to minimize patient burden going forward.	Patients co-design the study from the ground up, including running feedback sessions before launching study to minimize patient burden, anticipate and mitigate trauma, and provide accommodations. Patients are given a decision-making role throughout the study and in future engagements.	
Compensation Rate					
Patients are not compensated	Patients are compensated minimally or below market rate and patients are not given options for how to be paid. See: Fair Market Value Calculator .	Patients are compensated at a fair rate and are given options for how to be paid. See: Fair Market Value Calculator .	Patients are compensated at a fair rate relative to their domain expertise and experience level and are given options for how to be paid.	Patients are compensated at a fair rate relative to their experience level and domain expertise AND patients are able to negotiate type of payment	

Integration into Research Process

Integration Into Research Process	-2	Non-collaboration	-1	Minimal collaboration	0	Acceptable collaboration	1	Great collaboration	2	Ideal collaboration	
	Hypothesis Generation										
	Research goals are siloed from patients' priorities. Patient org's questions and experiences are not included and/or dismissed when generating research hypotheses.	Research goals attempt to involve patients' priorities but is limited by communication or collaboration. Patients org's inquiries and lived experiences are rarely included when generating research hypotheses. Patients may have suggested the research question with no further involvement.	Research goals take into account patients' priorities. Patient org's inquiries and lived experiences are included when generating research hypotheses.	Research goals proactively address patients' priorities with sufficient ongoing collaboration. Patients org's inquiries and lived experiences are included when generating research hypotheses.	Research goals are based on patients' priorities and co-written by patient organization or patient-researchers. Patients organization's inquiries and lived experiences share an equal weight with research organization's interests when generating research hypotheses.						
	Study Design										
	No involvement of patients in the study design process. Patients do not have the opportunity to review and comment. Patient groups may be contacted only for study recruiting.	No involvement of patients in the study design process. Patients may be invited to review study design but feedback is mostly ignored by research organization and no functioning accountability system is in place. Patient groups may be contacted for study recruiting purposes only.	Select patient voices are approached to inform the study design. Patient orgs are invited to review study design and have an impact on the study design.	Patient organization and their community's input is proactively invited to help inform the study design. Patient organizations are invited to review study design and patient feedback changes the study design.	Study design is co-written and reviewed by patient-researchers. If applicable, protocol testing is done by the patient community.						
	Analysis										
	Patients have no say in what data to prioritize for analysis and methods of analysis.	Patients are asked to review drafts but have little say in what data to prioritize for analysis and methods of analysis.	Patients or patient organization is involved in interpreting data and carrying out analysis in some capacity.	Patients or patient organization is involved in interpreting data and carrying out analysis anywhere in the study.	Patient-researchers lead on the interpretation and analysis and/or work concurrently with partner org's research team to carry out analysis						
	Publication										
	Study results are inaccessible to patients and/or behind an academic paywall. Findings are not communicated in lay terms.	Study results are inaccessible to patients and/or behind an academic paywall. Findings are summarized in lay terms.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms in ways that are informative to the patient population.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms and are actively disseminated to patient population.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms and are actively disseminated to patient population. A channel of communication is available for patients to ask questions of the research partner.						
	Attribution										
Patients' work is attributed to others and/or patients are not attributed at all.	Patients are listed as being involved without a description of how they were involved. Patient group was not consulted on how they prefer to be attributed.	Patient group is acknowledged/credited in major public facing communication (press, announcements, papers), to the extent that patient group wishes to be named. Patient group was consulted on how they prefer to be attributed.	Patient group is credited in all public facing communication and included as authors on papers, to the extent that patient group wishes to be named. Patient group was consulted on how they prefer to be attributed.	Patients are acknowledged specifically for what they did throughout the engagement process, are credited in all public facing communication, and included as authors on papers, to the extent that patient group wishes to be named. Patient group was consulted on how they prefer to be attributed.							

Patient/Partner Governance

Patient/Partner Governance	-2	-1	0	1	2
	Non-collaboration	Minimal collaboration	Acceptable collaboration	Great collaboration	Ideal collaboration
	Meaningful Decision-making between groups				
	Decision-making for significant decisions (funding, study design, publication, etc.) is not communicated or the partner group decides the decision making process and patients don't have any decision-making power.	Decision-making process for significant decisions (funding, study design, publication, etc.) is not communicated or agreed upon, patients have limited or not meaningful decision-making power	Decision-making process for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patient and partner group.	Decision-making for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patient and partner group, with deference given to patient group	Decision-making for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patient and partner group, with deference given to patient group with sufficient support to make the decisions.
	Accountability between groups				
	Lack of understanding of the rules of engagement/culture and no written agreement and no defined consequences for not following through	There is an understanding of the rules of engagement/culture but no written agreement and/or defined consequences for not following through between groups.	Shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups.	Shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups. Deference is given to patient groups to define the engagement.	Shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups. Deference is given to patient groups to define the engagement with sufficient support.

Status of Scorecards: Ever-Evolving

- 4 scorecards - semi-final version; will continue to iterate in future
- Patient Burden - conducted additional testing and iteration
- Further evaluate the other scorecards and implement
- Intended as dynamic tools



Patient-Led Historical Perspective

1935: Alcoholics Anonymous

1948: Fountain House – people with serious mental illness

1953: Narcotics Anonymous

1956: La Leche League – peer mentoring for breastfeeding

1963: Weight Watchers

1970: Boston Women's Health Book Collective

1971: Black Panther Party's peer-led sickle-cell anemia screening initiative

1972: Berkeley Center for Independent Living – people with disabilities

1983: MHP Salud – peer health promotion among farmworkers

1983: Denver Principles – people with AIDS demanded fair treatment

1992: ACT UP (the AIDS Coalition to Unleash Power) – therapies for HIV

Value Proposition



Photo by Ted Eytan, MD

Webinars

- Thursday, January 19, 2023, 2 pm CT- Topic: Research Partner Readiness and Integration into the Research Process
- Thursday, January 26, 2023, 2 pm CT- Topic: Patient/Partner Governance and Patient Burden
- Thursday February 2, 2023, 2 pm CT- Topic: How to Improve Your Score/Q&A Session

Thank You

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