



## **COVID-19 Evidence Accelerator Collaborative**

### **Lab Meeting # 27**

*Thursday, February 4, 2021 3 - 4:00 pm ET*

#### **Call Summary**

#### **Overview of Lab Meeting 27**

Therapeutics Lab Meeting 27 focused on ongoing work in the post-COVID space. First, we heard from Dr. Zijian Chen, Director of the Center for Post-COVID Care at Mount Sinai Medical Center, about his work in the post-COVID space since the Spring of 2020. Next, Diana Berrent of Survivor Corps and Dr. Natalie Lambert of Indiana University presented on how they used Survivor Corps' 150,000-person social media network to research the experiences of COVID survivors. Finally, Drs. Carla Rodriguez-Watson and Alecia Clary of the Reagan-Udall Foundation for the FDA presented a landscape analysis of initiatives and registries in the post-COVID space and introduced activities to be pursued by the post-COVID workgroup.

#### **Post-COVID Care – A One Year Journey**

*Zijian Chen, Mount Sinai Beth Israel*

#### **COVID-19: Early Experience**

- In NY State in May of 2020, there were 304,000 cumulative cases and 24,000 cumulative deaths. 20,000 of these patients (confirmed or presumptive positives) engaged with the Mount Sinai Health System, more than 8,000 were admitted.
- There was an emergence of patients that were too sick to go home but not sick enough to be in the hospital which required a new paradigm in COVID care.
  - Some of these patients had partially “recovered” from disease and in May 2020 the understanding was that after recovering from symptoms of COVID the individuals would be ok and could go home.
  - Need for a new paradigm in care for COVID patients that had recovered but still needed care → Center for Post-COVID Care

#### **Center for Post-COVID Care**

- **Multidisciplinary team** – A collaborative team approach to multidisciplinary care including primary care, specialty care, lab diagnostics & imaging.
- **Longitudinal care** – Patients followed over time to treat and evaluate the short and long-term impact of COVID-19.

- **Clinical Research, Epidemiology, Biomedical Research, and Health Policy** – Unique opportunity to provide comprehensive clinical care alongside research and clinical trials to define new standards of care.
- **Data Repository** – Collect data overtime on patient experiences.

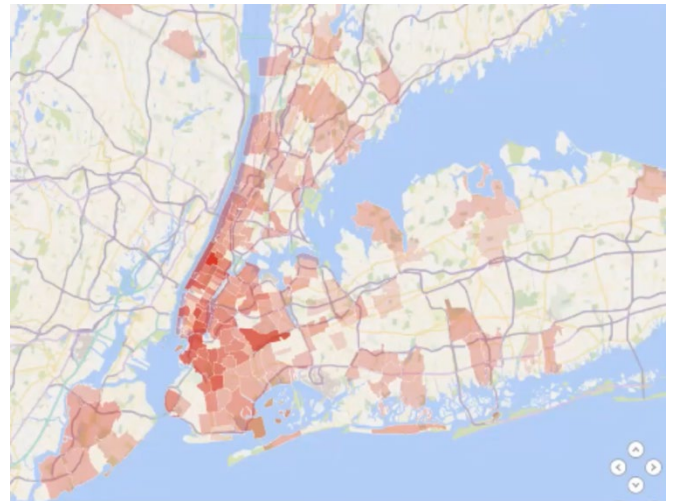
### Model for the Center for Post-COVID Care

- **Goal:** *Provide comprehensive care and a personalized treatment plan.*
- Medical home model centered around primary care, but engaging specialty providers when necessary.
  - Seamless hand off referral system ensures patients are connected with the specialist they need quickly.
  - Feedback from specialist to primary care to improve future workflows and clinical care. (i.e., How is the referral system working? How can it improve?)
  - Able to adapt quickly based on rapidly changing situation.

### Patient Characteristics

#### Zip-Codes

- Most patients come to the Center for Post-COVID Care are from the 5 boroughs of New York City, but there is a bit of incomplete data (i.e., reported patient addresses may be incomplete)
- Gaps in the map show there are underserved areas that are unable to get to us. Need to address this because we know these populations are disproportionately affected by COVID.
  - Currently building out our primary care site to ensure it is more accessible to these populations.

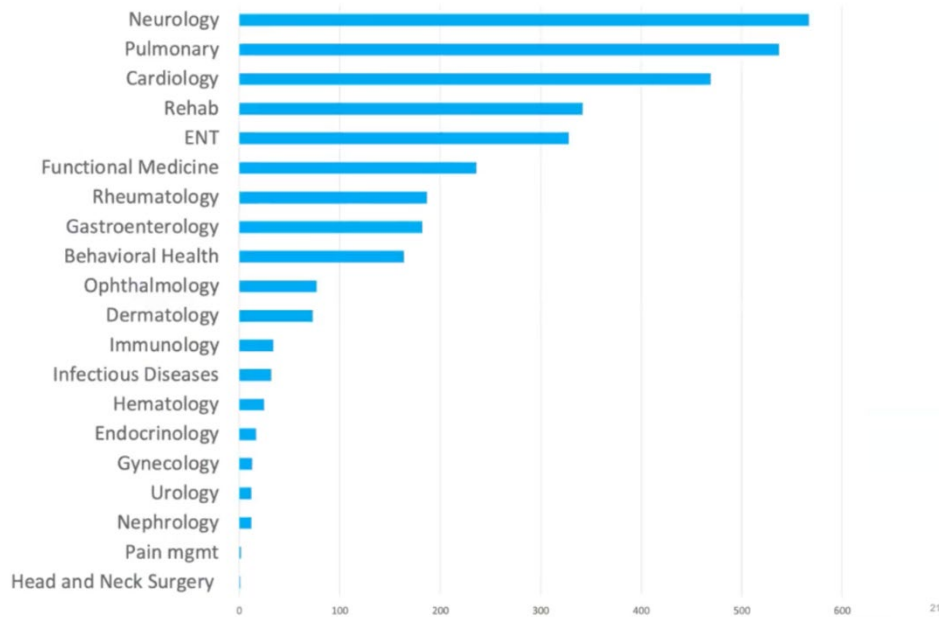


#### Patients by Race & Gender

- Majority white and female patients.

#### Service Utilization

- Utilization of services aligns with lasting symptoms of COVID (i.e., brain fog, tachycardia, etc.)



## Discussion

*Are there any tests you usually order and abnormalities you consistently see?*

- Some tests are standard for patients that come in such as panel to check liver function, EKG to check for arrhythmias, check blood counts, ESR & D-dimer, etc.
- Help give a baseline on organ system markers on all patients.

*What does follow-up generally look like?*

- 6-months (based on criteria for entrance into the registry)
- Many of these patients are invested in their care and reach out online to providers frequently.

*Seeing any patients who had asymptomatic COVID and now have post-COVID symptoms?*

- Yes. Patients who had very mild symptoms for an extended period of time and it got worse as they began to resume normal activity levels.

## **COVID-19 Health Impacts Research Using Real World Data (RWD)**

*Diana Berrent, Survivor Corps*

*Natalie Lambert, Indiana University School of Medicine*

### **Survivor Corps**

- Started before the understanding that some COVID patients are “long-haulers”
- 150,000 members (largest COVID movement in the world) with a large data set on non-hospitalized COVID patients

### **Lack of RWD for COVID-19 Patients Recovering at Home**

- Data is collected primarily on hospitalized COVID-19 patients while there is very little data collection on people with mild to moderate symptoms who are under minimal medical supervision.
- There are reports that those with COVID-19 symptoms seek care from their PCP, but do not receive the care they need.
  - PCPs do not recognize non-flu-like symptoms related to COVID-19
  - Many specialists' offices restricting examination of people who have tested positive for COVID

### **Study 1: "Long Haulers" Survey Posted by Survivor Corps on the Facebook Group Page**

- 1500+ survey respondents selected all long-term symptoms they have experienced in an open-ended poll
- **Key Findings**
  - Long-hauler reported a wide-range of long-term symptoms (n=98), many of which are not recognized by the CDC
  - Many long-term symptoms are painful (26.5%)
  - Attention needs to be given to symptoms experienced in every part of the body (including those in the brain, whole body, joints, hair, skin, and eyes)
  - Individuals frequently reported that they've been unable to receive treatment for long-term symptoms that do not require hospitalization

### **Long Haulers Need Recognition and Research**

- We don't yet know the full extent of COVID's impact on the body, patients are currently the experts as they've experienced the disease
- Many long haulers report their symptoms prevent them from being able to work
- Open-ended research that focuses on COVID patients' experiences is essential for pointing medical research in the right direction (i.e., research to capture ways in which long haulers' ability to work is hindered by their long-term COVID-19 sequelae)

### **Study 2: COVID-19 Symptom Impact Survey**

- Asks people who believe they have or ever had COVID-19 to report:
  - Demographic data
  - Medical history (prior flu/colds, SARS infection)
  - Onset of COVID symptoms, test results, hospitalizations for COVID
  - Underlying medical conditions & medications taken prior to COVID infection
  - Symptom specific questions related to timing of onset, duration, severity of discomfort, impact on ability to work, social functioning, etc.
  - Impact of COVID on stress and mental health
  - Patient experiences seeking care for COVID

- Results
  - Many people reported a variety of long-term symptoms occurred for over 100-days (e.g., Headache, shortness of breath, fatigue, confusion, difficulty concentrating)
  - Symptoms that are having an impact on survivors' ability to work include brain pressure, symptoms coming and going, etc.
  - Long-hauler symptoms appear 7-15 days after first symptoms
  - Individuals are turning to home-remedies for long-term symptoms

### **Analysis of Health Narratives**

- We are collecting and analyzing 2 million COVID-19 health narratives posted in the Survivor Corps Facebook group.
  - **Detect new covid-19 “signals” early on** – health impacts, health insurance coverage problems, health outcomes (medication/reactions), behavioral compliance problems, etc.
  - **Look for patterns in survivors’ experiences and compare to EHR data** – co-occurrence of symptoms, predictive models looking at underlying medical conditions and progression/severity of symptoms, compare survivors who obtained medical treatment and those who recovered at home
  - **Use NLP techniques to help prioritize development of standards of care and medical therapies for long haulers** – sentiment analysis, machine-learning based modeling to capture most persistent health impacts, etc.

### **Future Work & Partnerships**

- Conducting RWD research to align policy with COVID survivors’ medical and work support needs
- Develop a roadmap for post-COVID care centers
- Find funding to support analytics efforts
- Continue to produce educational resources needed by survivors and health practitioners
- Continue to mobilize 150k+ COVID-19 survivors to participate in research & share the results back to Survivor Corps community

### **COVID Patient Registries Current Landscape and Essential Elements**

*Carla Rodriguez-Watson & Alecia Clary, Reagan-Udall Foundation for the FDA*

### **Post-COVID Workgroup**

- The working group will conduct activities to:
  - Understand and begin to describe the taxonomy of post-COVID registries,
  - Identify standardizations or harmonization in outcomes of interest
  - Standardize terminologies
  - Identify data domains and core/optional data elements within those domains
  - Continue to catalogue and describe post-COVID registries

### **Landscape of Initiatives & Registries in the post-COVID space**

- An assessment identified 127 initiatives and 43 “registries” in the post-COVID space
- Populations represented in these initiatives include individuals that receive blood transfusions/donors, patients with cancer, pediatric patients with cancer, pregnant women 13+, patients with liver disease and/or transplant recipients that developed COVID, and COVID patients.
- Populations represented in the registries include COVID-19 patients with a current/prior cancer diagnosis, private cancer practices, patients with sickle cell disease, patients with MS and COVID
- Data Capture
  - Most registries capture age, sex, COVID-19 symptoms, hospitalizations, comorbidities
  - Others also capture disease specific information, US data, ex-US data, global data, etc.

### **Essential Registry Elements**

- Data domains and elements – Data must be relevant, scope and content must be adequate, and the data should be generalizable.
- Data standards – Data must be adequate to generate the information/evidence needed to answer the question at hand. (explicit data definitions, standardized collection, clear inclusion/exclusion criteria, etc.)
- Data quality assurance – Data collection processes must be systematic, consistent, reproducible, and reliable.
- Assurance of patient populations – Adequate patient privacy and protection of patient data.
- Governance – Expectations, policies, and procedures related to data governance should be developed to support stakeholder engagement and transparency.