COVID-19 & COPD Webinar Series
How Has COVID-19 Impacted COPD Research?

June 16, 2020

COPD FOUNDATION

Introductory Remarks

Corinne Costa Davis
Chief Executive Officer
COPD Foundation

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DISCLAIMER

The information presented on this webinar should not serve as a substitute for medical advice and any content discussed should not be used for medical advice, diagnosis or treatment. Please consult with a physician before making changes to your own COPD management plan and if you have any concerns about COVID-19 symptoms.

The information presented on today's webinar about COVID-19 was current as of June 16, 2020. The information about the disease and the recommendations discussed today are changing rapidly and if you are viewing the recording of the webinar, this information may no longer be accurate.

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Today's Agenda

1. Introductions

2. Recent COVID-19 Updates

3. The NHLBI Response to COVID-19

4. The Impact of COVID-19 on COPD Research

5. The COPD Foundation Research Programs

6. Q & A

7. Resources and Conclusion

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TODAY'S SPEAKERS

Byron Thomashow, MD
Professor of Medicine,
Columbia University & NY Presbyterian Hospital
Chief Medical Officer,
COPD Foundation

Robert Wise, MD
Professor of Medicine,
Johns Hopkins University School of Medicine
Chair-Medical & Scientific Advisory Committee,
COPD Foundation

James Kiley, PhD
Director, Division of Lung Diseases, National Heart, Lung & Blood Institute

Ruth Tal-Singer, PhD
Chief Scientific Strategy Officer, COPD Foundation

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Recent COVID-19 Updates

Dr. Byron Thomashow

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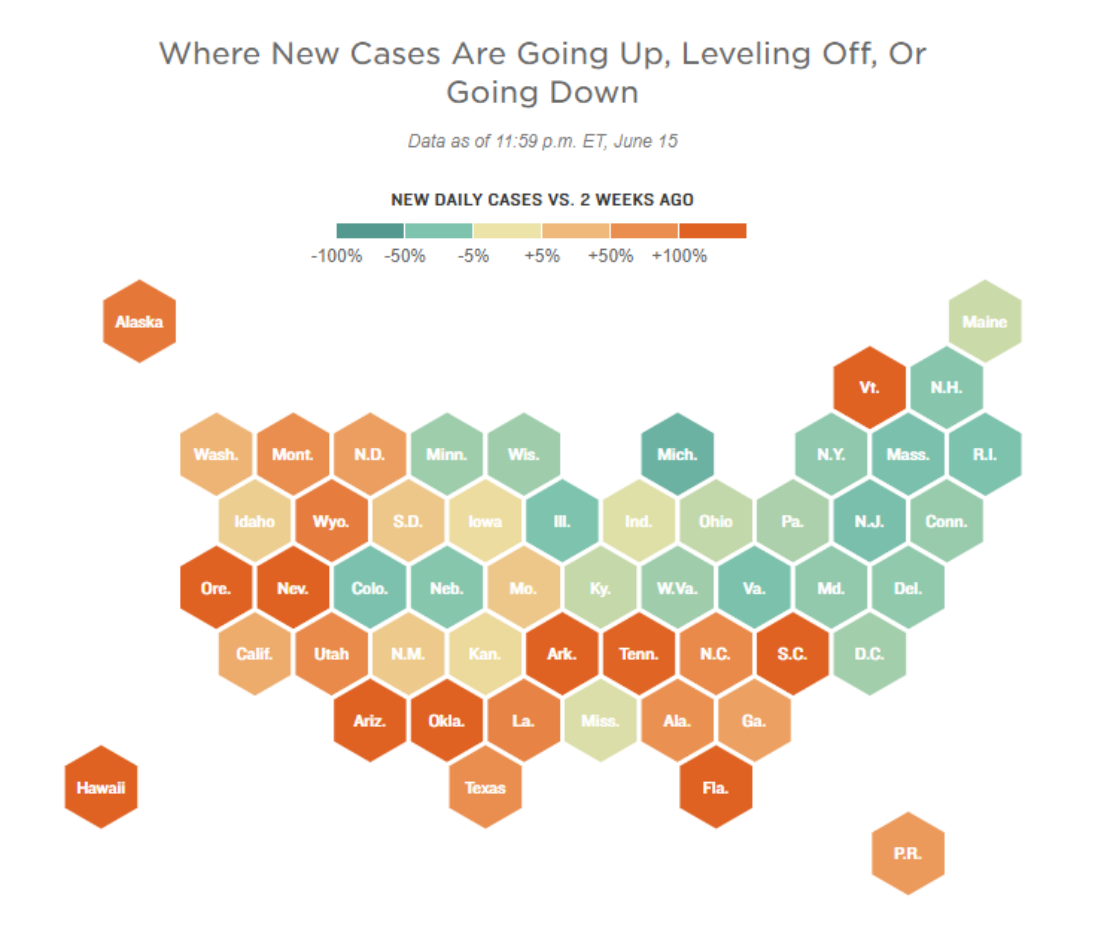
COVID-19 Situation Update

COVID-19 is a new disease caused by a **novel coronavirus** that is different than the common cold, flu or pneumonia. COVID-19 emerged in China in late 2019 and is now present in multiple other countries, including the U.S.



Current Global Situation:
Total Cases: 8,065,966
Total Deaths: 437,603

https://www.npr.org/sections/health-shots/2020/03/16/816707182/map-tracking-the-spread-of-the-coronavirus-in-the-u-s

New Learnings: Prevention

The risk of contracting COVID-19 lies on a spectrum:

There are four major risks:

1. Enclosed spaces
2. Large crowds
3. The Amount of time you are exposed
4. Exposure to people coughing, sneezing, shouting, singing

Facemasks and social distancing works. Large systematic review and meta analysis reinforce this.
(Chu et al Lancet)

The World Health Organization announced new facemask guidelines: *The general public should wear cloth masks in public spaces where physical distancing is not possible. In addition people over 60 or with preexisting conditions should wear medical masks in areas where there is community spread and distancing not possible.*

PRESYMPTOMATIC

Someone who IS infected, DOESN'T currently have symptoms, but DOES develop symptoms at a later point

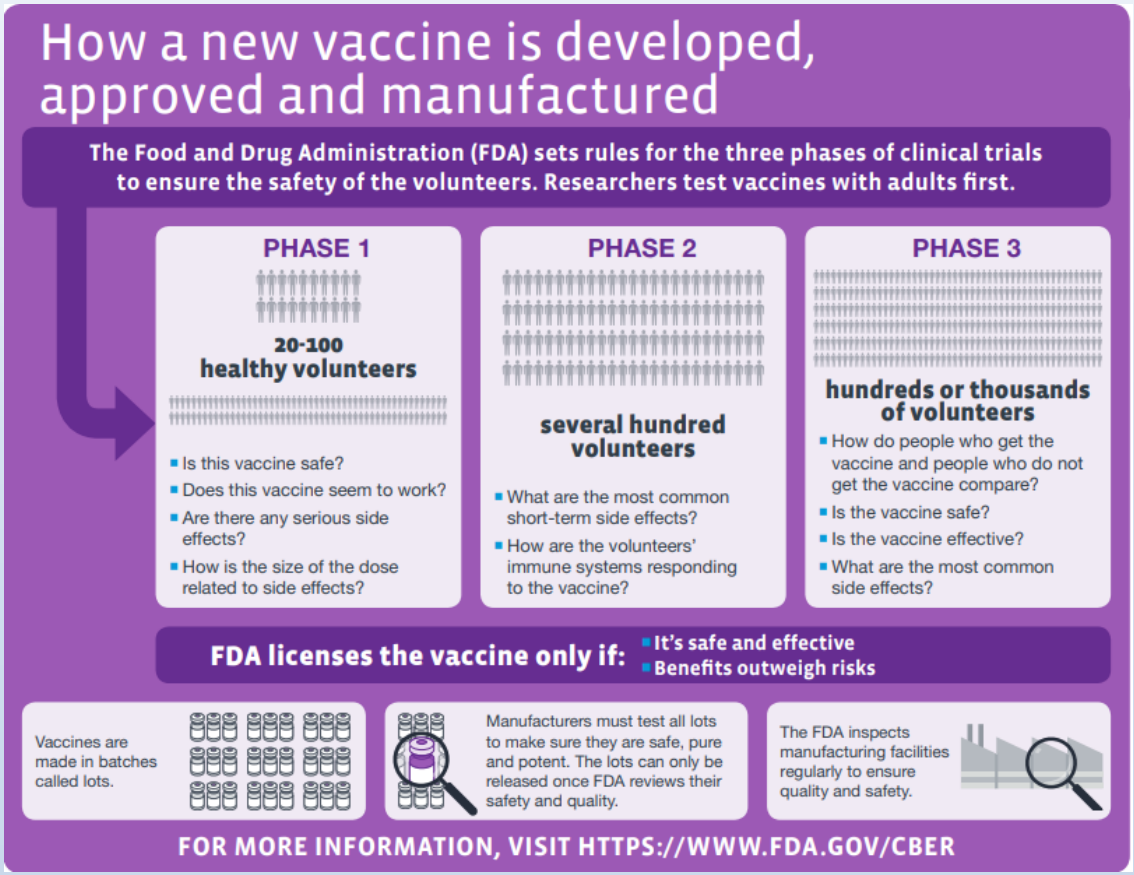
VS

ASYMPTOMATIC

Someone who IS infected, but NEVER develops symptoms

New Learnings: Vaccines

- Currently there are **10** vaccine candidates in development around the world that are **beginning human trials.**
- Reports suggest that some of these could be ready for large scale testing as soon as July.
- Phase 3 trials involve some 30 thousand volunteers for each candidate vaccine. Half receive placebo.
- The goal of these larger trials is to define safety, and potential effectiveness based upon level of antibody formation.
- The hope is to have at least one effective and safe vaccine by 2021.



New Learnings: Remdesivir

- Antiviral agent
- Preliminary results indicate that patients treated with Remdesivir had a 31% faster time to recovery than those who received placebo. The median time to recovery was 11 days on Remdesivir, 15 days on placebo. This was statistically significant. The results also suggested a potential survival benefit. Mortality rate 8% with Remdesivir vs 11.6% with placebo. (https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19)
- Based on this and other studies Remdesivir received FDA **emergency use authorization** for treatment of COVID-19. Patients receive either a 5 day or 10-day regimen depending on severity of disease.
- Availability of the drug is an increasing concern. Reports suggest that Gilead the company that makes the drug is ramping up to make more but it is unclear how much will be available this summer.

New Learnings: Other Medication

Hydroxychloroquine

- Several published papers have been retracted because of concerns about the data. However **none of the large published studies have confirmed any significant benefit and have stressed potential adverse effects.**
- A recent publication showed no evidence that hydroxycholoroquine is helpful in preventing COVID-19. Study looked at 821 participants all with direct exposure-2/3 health care providers, remainder household contacts. Volunteers received either 5 days of drug or placebo. 49 treated with drug and 58 with placebo developed infection-no statistical difference.(Rajasinghamet al NEJM)
- On June 15, The FDA revoked the Emergency Use Authorization it had previously issued for hydroxychloroquine use in treating COVID-19.

Famotidine

- In a small case series of non hospitalized patients with COVID-19 symptoms, patients felt better after taking 1-2 days of Famotidine and symptoms cleared within 14 days without apparent side effects.
- In computer models, Famotidine was identified as a potential inhibitor of 3-chynotypsion like protease suggesting a potential mechanism for action in Covid 19. But very small study, results very preliminary and drug given in high doses.

New Learnings: Other Therapies

Convalescent Plasma: (plasma donated by people who have recovered from COVID-19)

- Open label multicenter randomized trial in Wuhan China. (Li et al JAMA doi:10.1001/Jama.2020.10044)
- Among patients with severe or life threatening COVID-19, convalescent plasma therapy added to standard therapy, compared with standard therapy alone did not reveal a statistically significant improvement in 28 days.
- Interpretation is limited by early termination of trial so only 103 of planned 200 cases recruited because COVID-19 epidemic had improved and new cases not available.
- The study did suggest that the plasma therapy was associated with some clinical improvement in severely ill but not critically ill.
- More studies underway.
- U.S. Government awarded AstraZeneca 23 million dollars to develop antibody therapy

The NHLBI Response to COVID-19

Dr. James Kiley

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Rising to the Public Health Challenge of COVID-19: NHLBI's Research Response Strategy

COPD Foundation Webinar

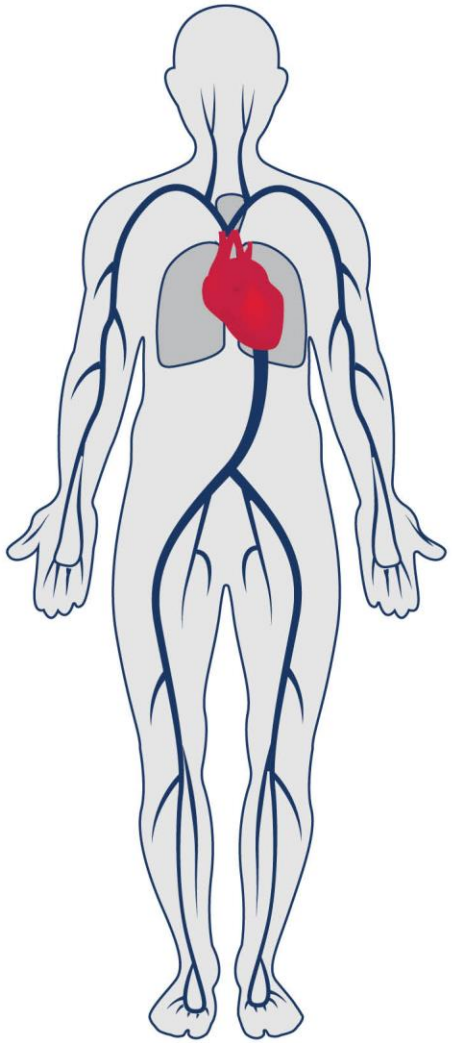
COVID Updates: Impact of COVID on COPD Research

June 16, 2020

James Kiley, MS, PhD
Director, Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health

National Heart, Lung, and Blood Institute

NHLBI's Role in Combating COVID



COVID-19 can have severe effects on the lung, the heart, and blood coagulation.

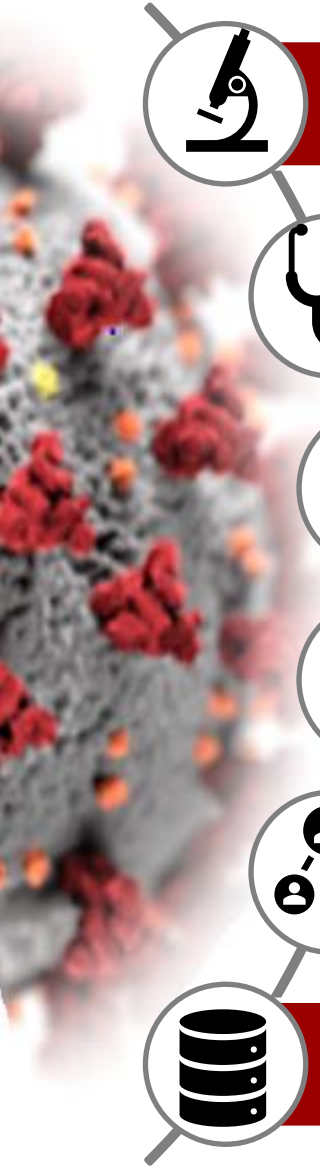
HEART
Cardiovascular Complications

LUNG
Acute Respiratory Distress Syndrome (ARDS)
Acute Respiratory Failure

BLOOD
COVID-19 associated coagulopathy (CAC)

Those with underlying health conditions, such as chronic lung disease, cardiovascular disease, and diabetes mellitus, appear to be at higher risk for severe COVID-19–associated disease.

NHLBI COVID-19 Response: Research Strategy



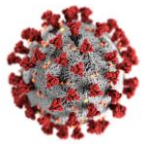
- Understand pathophysiology and identify new potential treatments
- Test host-directed interventions and provide evidence base for clinical practice
- Promote blood safety, sero-surveillance, and new blood-derived therapeutics
- Conduct longitudinal/cohort studies to understand natural hx and risk factors
- Test behavioral, social, and community-based interventions
- Provide data and biospecimen resource

NHLBI Response: A Timeline of Key Events

Feb 28

Clinical Characteristics of COVID-19 in China

The NEW ENGLAND JOURNAL of MEDICINE



Mar 17

NHLBI and trans-NIH COVID-19 strategy discussions

NOSI supporting all COVID-19 research (NOT-HL-20-757)

Mar 25

Roundtable: RCTs in COVID-19 Patients

Mar 27

CARES Act passed

Apr 3

Roundtable: Acute Care Cohort / Longitudinal Cohort / National Registry of COVID-19 Patients

Apr 9

1st NHLBI Clinical Study Launched

Apr 13

NOSI supporting COVID-19 observational research (NOT-OD-20-097)

Apr 17

Public-Private Partnership

Apr 27

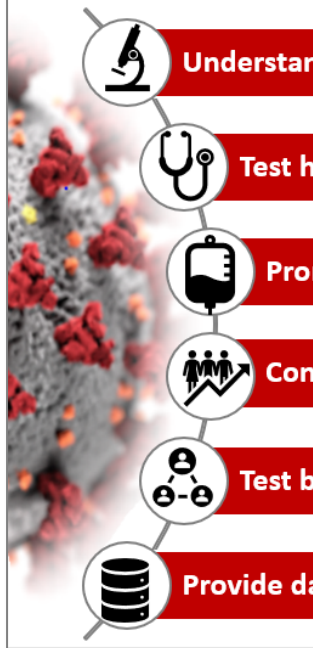
NOSI supporting COVID-19 clinical research (NOT-HL-20-782)

Apr 29

ROA for Host-targeting Therapies for COVID-19 (OTA-20-11)

- **ORCHID Trial** hydroxychloroquine
  First patient recruited April 9
- **COLCORONA Trial** effects of colchicine on cardiopulmonary complications
- **CORAL Study** long-term observational, collect outcomes data
- **REDS Sero-Surveillance** & Biospecimen Repository
- **C3P0 Trial** convalescent plasma

NHLBI Research Response Strategy



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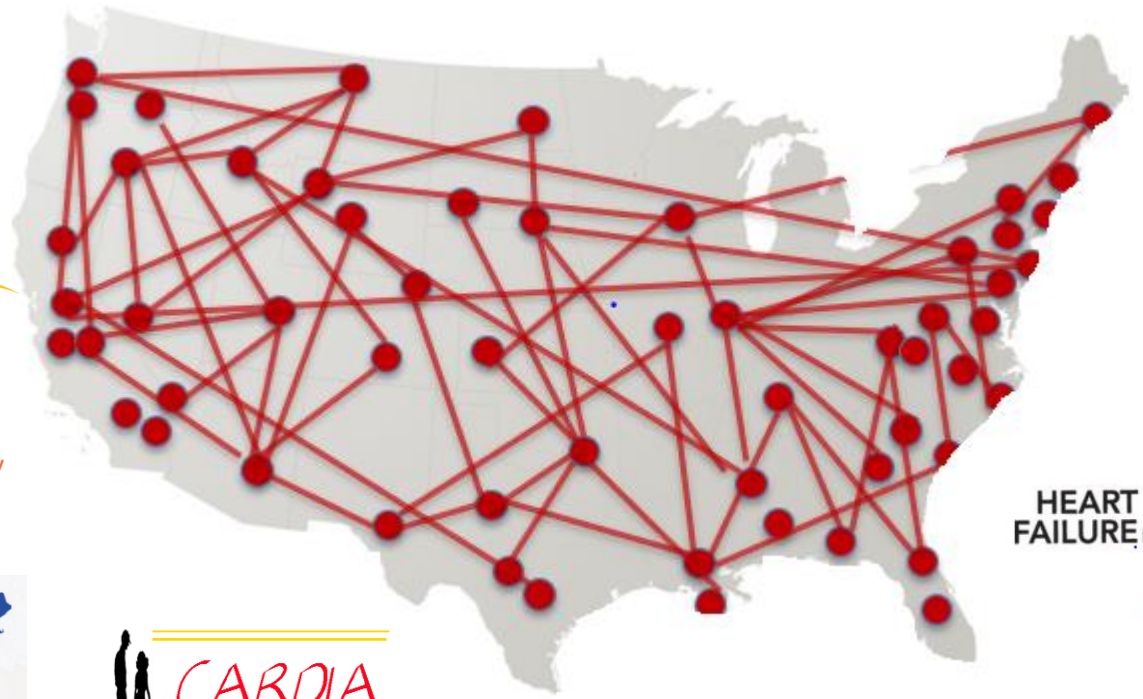
From Research Community Engagement to Strategy to Research Solicitation

Solicitation Mechanism	*Type of Research*
NOSI*	All types of research (basic → preclinical → clinical)
NOSI	Phase I – IIa Clinical Trials
NOSI**	Behavioral and Social Sciences
OTA	Phase IIb – III Clinical Trials
OTA (in process)	Cohort and other Longitudinal Studies, Community-based Interventions

Compelling and Diverse Portfolio Responsive to Public Health Challenge of COVID-19

Our Challenge: Enabling a Nimble, Integrated, and Adaptive Approach Across Networks and Cohort Studies



TACTIC

CHS

SIREN

PETAL NETWORK
Prevention & Early Treatment of Acute Lung Injury

MESA

SOL STUDY OF LATINOS
Hispanic Community Health Study

CTSN
CARDIOTHORACIC SURGICAL TRIALS network

FRAMINGHAM HEART STUDY

JACKSON HEART STUDY

HEART FAILURE NETWORK

Nurses' Health Study 3

STRONG HEART STUDY

RURAL
Risk Underlying Rural Areas Longitudinal Study

CARDIA
Coronary Artery Risk Development in Young Adults

ARIC

WOMEN'S HEALTH INITIATIVE

COPDGene

PrecISE
PRECISION INTERVENTIONS FOR SEVERE ASTHMA

SPIROMICS

REDS-IV-P
Optimizing Transfusion Across the Lifespan

NIH National Heart, Lung, and Blood Institute

All-Hands Approach: Integrating Longitudinal and Other Cohort Studies

Leverage existing assets of clinical networks and longitudinal cohort studies to better define the clinical course of COVID-19 and identify predictive risk factors

Goals

- Enable research on natural history, predictive biomarkers, patient stratification, optimal clinical management, new therapeutic targets
- Leverage EHR/digital platform in context of direct patient care using CDEs, FHIR standards
- Follow SARS-CoV-2 infected donors from community-based sero-surveillance networks prospectively to define immune and virologic parameters over time
- Establish biospecimen repository for research community

OTA for Coordinating Center
Maximizing Flexibility in Funding Support

NHLBI & Trans-NIH Circle of Partners: A Diverse Ecosystem Enabling Innovation to Combat COVID-19

Researchers
Policymakers & Government Agencies
Academic Health Centers
International Organizations
Community Organizations
Primary Care
Private Sector / Industry
Professional Societies/ Foundations
Patients Citizen-Science

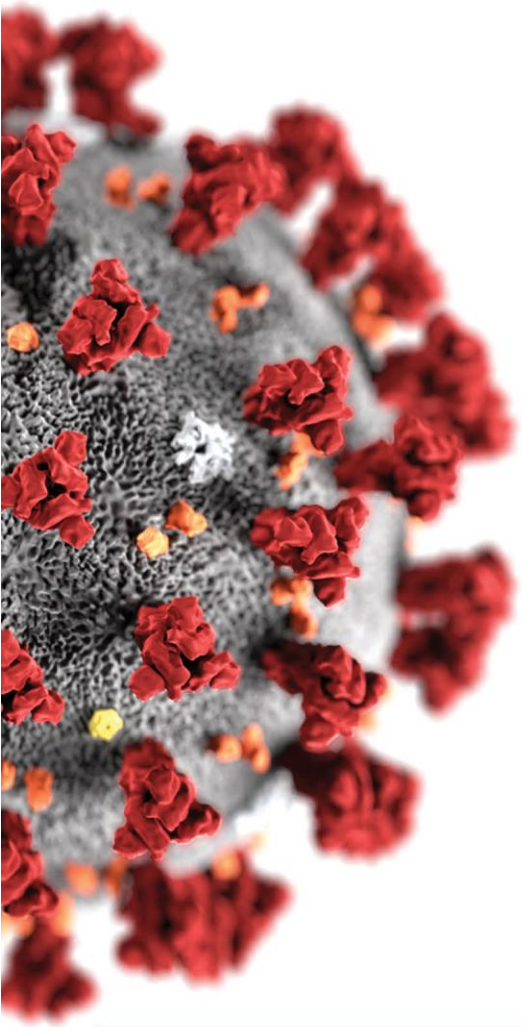
NIH National Heart, Lung, and Blood Institute

A Diverse, Connected Community Collectively Creating a Healthier Future

ACTIV PARTNERSHIP

FNIH Foundation for the National Institutes of Health

Links and Resources



- Get the latest research information from NIH:
  https://www.nih.gov/coronavirus
- Visit the NHLBI COVID-19 webpage for information for researchers, practicing clinicians, and the general public:
  https://www.nhlbi.nih.gov/coronavirus
- Get the latest public health information from CDC:
  https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html
- **ACTIV:** Learn more about the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV):
  https://www.nih.gov/research-training/medical-research-initiatives/activ

National Heart, Lung,
and Blood Institute

The Impact of COVID-19 on COPD Research

Dr. Bob Wise

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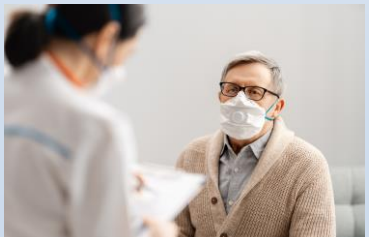
How Did Research Institutions Respond?

1. No in-person study visits unless necessary for patient safety
2. Study visits exploring life-saving clinical outcomes were prioritized (e.g. COVID-related research, advanced cancer)
3. Study sites that continued implemented appropriate prevention practices (e.g. limited waiting room, patients call from car, everyone wears PPE)
4. Studies already underway started using telemedicine to conduct visits and to collect outcomes wherever possible
5. Home-based visits were stopped
6. Aerosol generating procedures were stopped (e.g. nebulizer treatments, spirometry & CPAP/BiPAP use)

How Did the Study Teams Adapt?

- Transition to all digital study visits
- Bloodwork & other measures only if needed for safety
- Begin surveillance for COVID-19
- Begin surveillance for adverse effects of COVID-19 lockdown



CAPTURE™ COPD

How Will We Restart Research?

Step 1 Reopening basic science labs with appropriate preventive practices

Step 2 Return to clinical research in phases with appropriate preventive practices guided by local policies and patient safety

Therapeutic trials in conditions that have no standard of care (e.g. no existing approved treatments)	Therapeutic trials in conditions where there IS a standard of care (e.g. comparative effectiveness trials)	Non pharmacologic Interventional trials(e.g. behavioral interventions, pulmonary therapy)	Observational Studies (e.g. studying progress of disease over time, COPDGene)

Of 6 drug and device companies that indicated they had paused interventional trials;
1 had restarted but not in the U.S.
1 had restarted including the U.S.
1 was close to restarting
3 have not yet restarted

What Does This Mean for COPD?

Many COPD studies involve aerosol generating procedures as outcome measures and are tougher to restart

Local issues are important to determining how and what restarts (extent COVID-19 community spread, local attitudes, institutional requirements)

COVID-19 has resulted in promising changes in the way treatment and device research and review is conducted, hopefully speeding up non-COVID related efforts in the future (digital outcome measures, more real-world evidence use, flexible trial designs, increased speed of review)

We will need to advocate for Congress to provide more funds to help complete NIH funded studies that have been delayed and advocate for the FDA to adopt some of the new approaches permanently

So Is Research Safe?

Decisions to restart clinical research are being driven by the safety and wellbeing of patients and the study team.

We still encourage voluntary participation in clinical research when it has been deemed safe by local study teams. When in doubt, talk to your healthcare professional and ask the study team what they are doing to keep participants safe so you can make an informed choice.

COVID-19 Impact-COPD Foundation Research Perspective

Ruth Tal-Singer, PhD
Chief Scientific Strategy Officer
COPD Foundation

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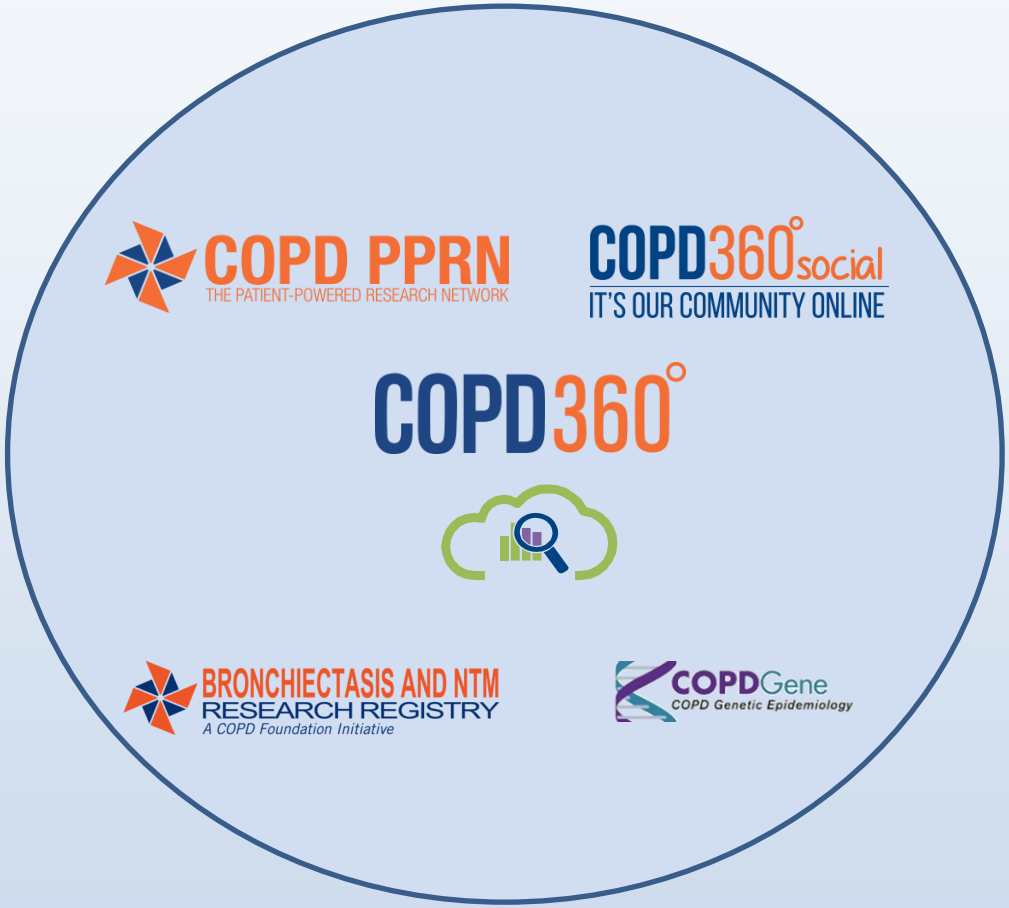
COPD360 is the engine driving our scientific research

COPD360^0 mobilizes partnerships between patients, caregivers, health care professionals, researchers, academic institutions, government agencies and industry leaders with a common mission



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COPD360 Research Response to COVID-19

- We are using surveys to learn how the ongoing pandemic is affecting our community
- The results help us develop resources and programs that address the needs of our community of patients, families, caregivers, health care professionals and researchers

COPD360social

BRONCHIECTASIS AND NTM RESEARCH REGISTRY
A COPD Foundation Initiative

March Survey 1
- 566 COPD
- Published online April 22nd
- Webinar presented April 28th

May Survey 2
- 776 survey participants
- First Results online June 11th

TBD Survey 3
- Planned
- Post reopening Aug/ Sept

Surveys and analytics supported by grants from AstraZeneca, GSK, Teva, Pfizer, and Mylan

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COVID-19 Survey 2 Highlights

COPD360social
IT'S OUR COMMUNITY ONLINE

BRONCHIECTASIS AND NTM RESEARCH REGISTRY
A COPD Foundation Initiative

PULMONARY EDUCATION AND RESEARCH FOUNDATION

NTMir
Nontuberculous Mycobacteria

COPD PPRN
THE PATIENT-POWERED RESEARCH NETWORK

- Launched May 1st and closed May31st

US	Europe	Canada	Other countries
726	18	15	11

COPD Emphysema or Chronic Bronchitis	A1AT Deficiency	Bronchiectasis /NTM	Caregivers of an individual with COPD
634 (87 without COPD)	31 (19 with COPD)	211 (130 with COPD too)	13

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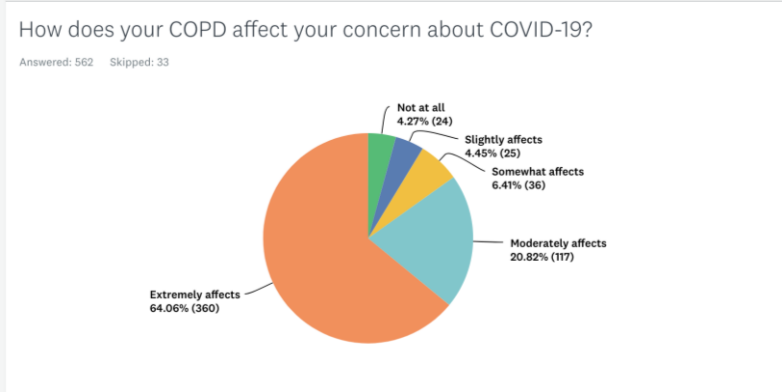
COVID-19 Survey 2 Highlights: COPD Responses

Results available here:
https://bit.ly/3fggIGy
COPD Digest Prieto et al.

- 37 (6.4%) of 595 COPD respondents were told by a health care professional that they had COVID-19
  - Symptoms most frequently reported:
    88% shortness of breath, 71% cough, 35% fever
- 16 Individuals with COPD were tested and 2 reported a positive test
  2 were hospitalized for over 1 week
- 126 experienced COPD exacerbations in the 5 months of 2020 (186 in 2019)

Nearly 98% (553) with COPD expressed concern for COVID-19, 58% indicating they were "extremely concerned" about COVID-19



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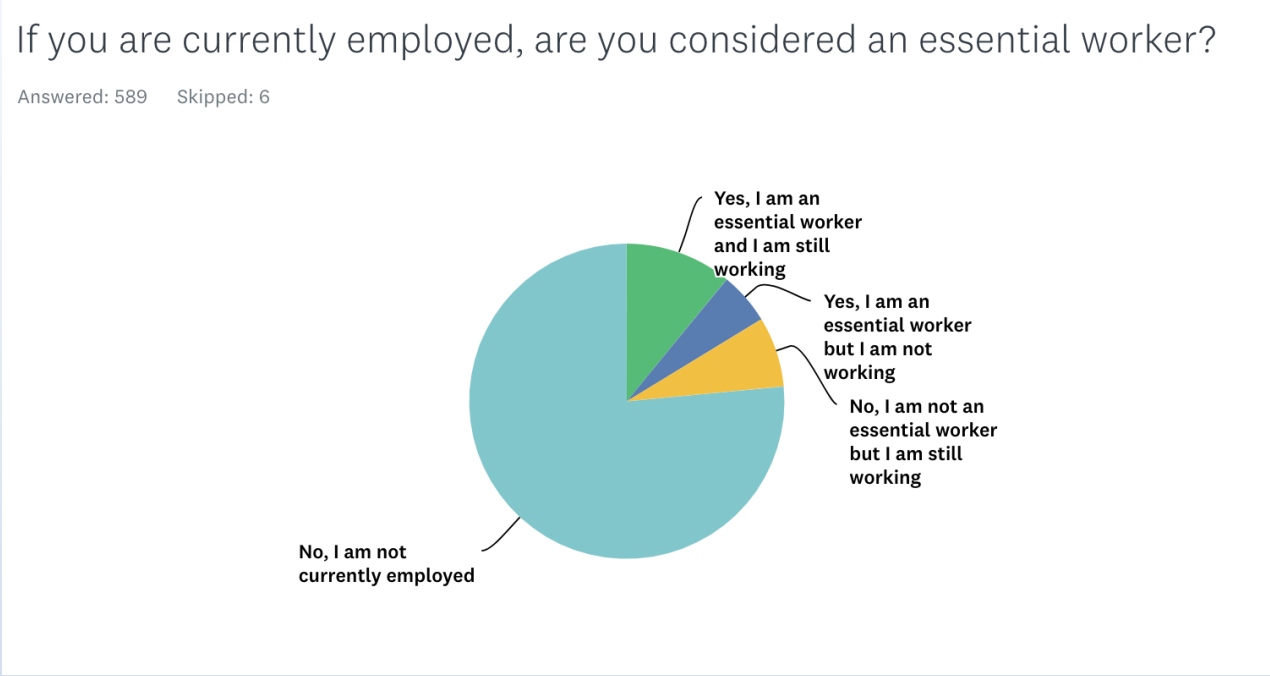
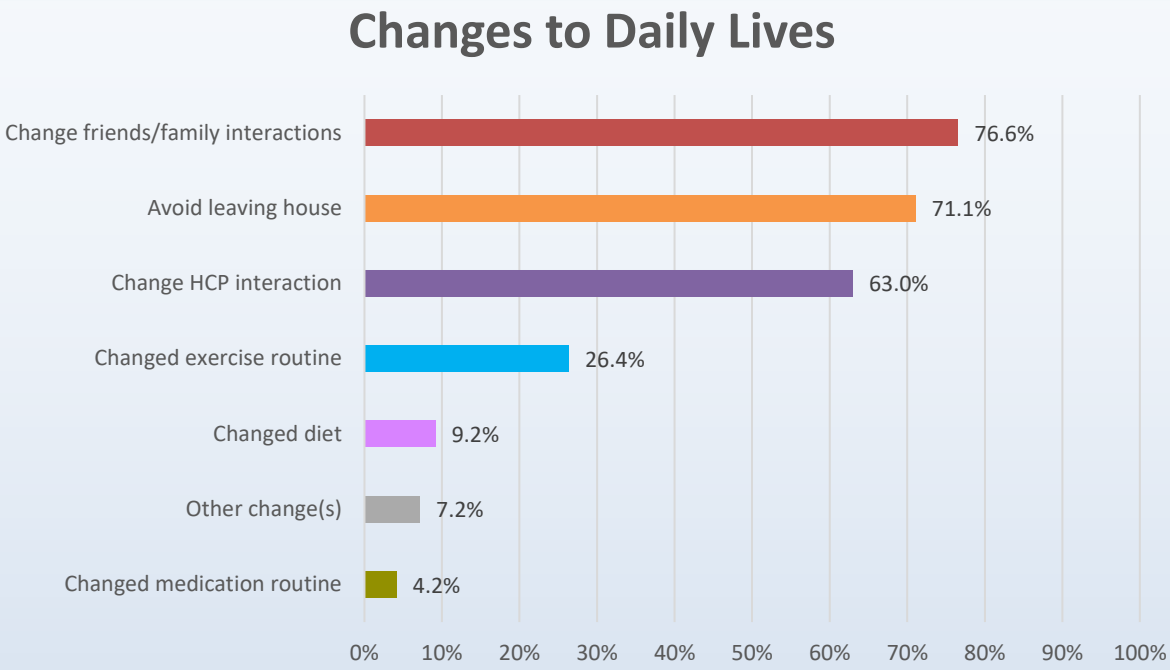
COVID-19 Survey 2 Highlights: COPD Responses

Employment information helps inform our public policy and advocacy efforts for COPD community members in the workforce



- 79 (13.4 %) of COPD are considered "essential workers" (53 actively working)
- 35 are working but considered themselves "non-essential workers."
  - 20% of them reported still working during the survey (some from home).
- 371 (63%) reported not being employed some retired or on disability

COVID-19 Survey 2 Highlights: COPD Responses



Many Individuals with COPD are taking <u>positive measures</u> to stay safe but remain worried:

"I'm scared and I lack knowledge about my disease and the pandemic"

" Home confinement is increasing my depression and consequent fear for life."

Example for Caregiver Perspective: being away from family is stressful

"I have two elderly parents that are not in assisted living, therefore need my help. This is extremely difficult for me and them. They need so much assistance and I cannot be there very often."

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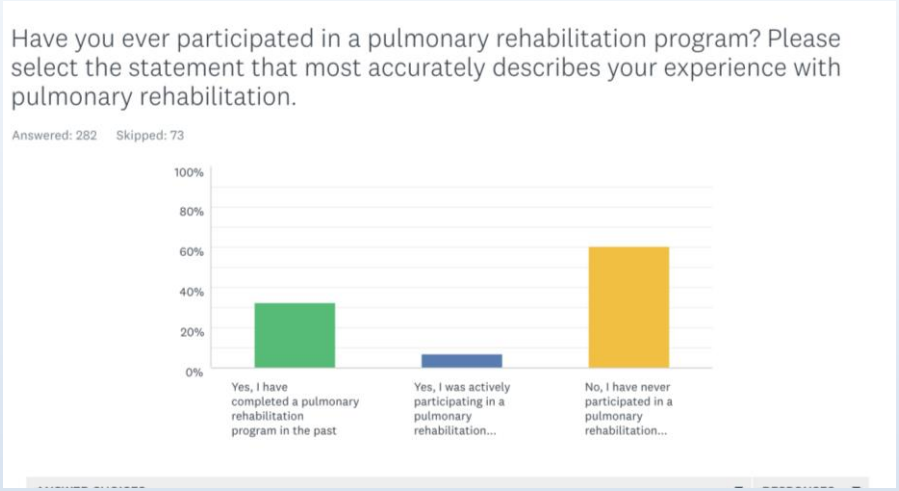
COVID-19 Survey 2 Highlights: COPD Responses

Pulmonary rehabilitation can improve the quality of life of people with COPD and other lung diseases and prevent hospitalization. The ongoing pandemic has significantly affected the availability of supervised exercise programs, and pulmonary rehabilitation programs.



- 7.4% (35) reported actively participating in a pulmonary rehabilitation program before it was closed due to COVID-19
- Comments highlight concern about access to supervised exercise programs
- Some were able to do telehealth pulmonary rehabilitation.

"I used to go to the gym approximately 5x a week for treadmill and weights, and socialization….. I am afraid I am slipping backwards in my breathing."

Impact:

- We partnered with experts on grant applications that focus on improving the efficiency of virtual/telehealth pulmonary rehabilitation with COPD360 peer coaching support.
- We added information to our website about maintaining an exercise routine at home

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COVID-19 Survey 2 Highlights: COPD Responses

Airway mucus can be a problem for many with COPD, especially individuals with chronic bronchitis, and bronchiectasis.
Airway Clearance Techniques (ACTs) are associated with aerosol generation and many individuals are concerned during COVID-19

- 60% (n=356) of those with COPD reported doing at least one ACT including mostly huff cough (43%)
- *77% of the Bronchiectasis/NTM respondents reported conducting at least one ACT including mostly the huff cough (37%)*

"I sing very loud and deep. Works better than breathing treatments"

Impact:

- We are planning educational activities on doing airway clearance techniques while reducing potential COVID-19 exposure to others
- We added a dedicated COPDF Coping with Airway Mucus web page

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COVID-19 Survey 2 Highlights: COPD Responses

What Would Help Those with COPD Cope Better with COVID-19?

- The most common response to this question was the need for help with selecting/getting the **best face coverings/masks.**

Needs Reported by COPD Survey Respondents	Percentage	Number
Help with selecting/obtaining the best face coverings/mask	52.1%	252
Guided physical therapy/pulmonary rehab/exercise at home	34.7%	168
Ways to get household supplies	32.3%	156
Access to virtual support groups, book clubs, guided meditation	18.8%	91
Other (comments provided)	18.4%	89
Assistance with writing a COPD action plan	13.2%	64
Assistance with technology, video calls, and/or social media	12.6%	61
Assistance carrying oxygen tanks in/and out of home	5.0%	24

"Difficult to be active and breathe while wearing a face mask, blood pressure rises, get hot, have to stop a lot, and I love being out, and doing my own shopping and bits of travel. Very sad."

Impact:

- The mask issue has been addressed in the April 3rd update of the COVID-19 Blog post being updated regularly
- We addressed coping at a recent webinar on "Maintaining Good Health Through COPD Management".

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COVID-19 Survey 2 and COPD360 Research: Next Steps

- Analysis of text responses and Medications using Machine Learning ongoing
- Text responses also being reviewed by COPD patient Investigators on the BRIDGE Project
- Results from the Bronchiectasis/NTM community are like those of the COPD community –an article with highlights will be posted this week
- We partnered with COPDGene and other academic experts to work on scientific publications that will hopefully improve access to better care
- COVID-19 surveys will continue as long as this pandemic remains an issue
- Working with the PPRN in developing "The Patient Journey" project questions related to impact of COVID-19 on individuals with COPD

Question and Answer Period

Please submit your questions in the control panel. In the likely event that we are unable to answer all the questions, we will work to post answers to questions on our website next week.

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Visit us at www.COPDFoundation.org

- Ask and answer questions from peers on COPD360social
- Check-in and share how you are coping
- Read updates on our COPD Digest Blog
- Tune in for future webinars and Facebook Live chats

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Other Resources for COVID-19 Information

1. The Centers for Disease Control and Prevention:
https://www.cdc.gov/coronavirus/2019-ncov/index.html
& added guidance for people who need extra precautions: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html

2. The World Health Organization:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen

3. Johns Hopkins University:
https://coronavirus.jhu.edu/

4. Public Health On Call Podcast:
https://www.jhsph.edu/podcasts/public-health-on-call/

5. COPD Foundation-COVID-19 Page:
https://www.copdfoundation.org/Learn-More/I-am-a-Person-with-COPD/Coronavirus-Information.aspx

6. COPD Foundation-COVID-19 Blog Updates:
https://www.copdfoundation.org/COPD360social/Community/COPD-Digest/Article/1553/A-Coronavirus-Update-for-the-COPD-Community.aspx