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

June 16, 2020
Introductory Remarks

Corinne Costa Davis
Chief Executive Officer
COPD Foundation
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.
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
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
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Ruth Tal-Singer, PhD
Chief Scientific Strategy Officer, COPD Foundation
Recent COVID-19 Updates

Dr. Byron Thomashow
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

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.

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**How a new vaccine is developed, approved and manufactured**

*The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.*

**Phase 1**
- 20-100 healthy volunteers
- **Questions:**
  - Is this vaccine safe?
  - Does this vaccine seem to work?
  - Are there any serious side effects?
  - How large is the dose related to side effects?

**Phase 2**
- Several hundred volunteers
- **Questions:**
  - What are the most common short-term side effects?
  - How are the volunteers’ immune systems responding to the vaccine?

**Phase 3**
- Hundreds or thousands of volunteers
- **Questions:**
  - How do people who get the vaccine and people who do not get the vaccine compare?
  - Is the vaccine safe?
  - Is the vaccine effective?
  - What are the most common side effects?

**FDA licenses the vaccine only if:**
- It’s safe and effective
- Benefits outweigh risks

Vaccines are made in batches called lots.

Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.

For more information, visit HTTPS://WWW.FDA.GOV/CBER
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 hydroxychloroquine 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. (Rajasingham et al NEJM)

**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-chynoptysion 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)

- 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

COPD Foundation Webinar

COVID Updates: Impact of COVID on COPD Research

June 16, 2020
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**: NHLBI and trans-NIH COVID-19 strategy discussions
- **Mar 17**: 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**: 1st NHLBI Clinical Study Launched
- **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)

**Key Events and Trials**

- **ORCHID Trial**: First patient recruited April 9
- **COLUMBIA 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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Compelling and Diverse Portfolio Responsive to Public Health Challenge of COVID-19

From Research Community Engagement to Strategy to Research Solicitation

<table>
<thead>
<tr>
<th>Solicitation Mechanism</th>
<th>Type of Research</th>
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<tr>
<td>NOSI*</td>
<td>All types of research (basic → preclinical → clinical)</td>
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<tr>
<td>NOSI</td>
<td>Phase I – IIa Clinical Trials</td>
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<tr>
<td>NOSI**</td>
<td>Behavioral and Social Sciences</td>
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<tr>
<td>OTA</td>
<td>Phase IIb – III Clinical Trials</td>
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<tr>
<td>OTA (in process)</td>
<td>Cohort and other Longitudinal Studies, Community-based Interventions</td>
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Our Challenge: Enabling a Nimble, Integrated, and Adaptive Approach Across Networks and Cohort Studies
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

A Diverse, Connected Community Collectively Creating a Healthier Future

- Patients
- Citizen-Science
- Researchers
- Policymakers & Government Agencies
- Academic Health Centers
- NIH
- National Heart, Lung, and Blood Institute
- Professional Societies/Foundations
- Private Sector / Industry
- Primary Care
- Community Organizations
- International Organizations

American Lung Association
Sleep Research Society
ACTIV PARTNERSHIP
FNHIH
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:

- **ACTIV**: Learn more about the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV):
  https://www.nih.gov/research-training/medical-research-initiatives/activ
The Impact of COVID-19 on COPD Research

Dr. Bob Wise
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
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
COPD360® mobilizes partnerships between patients, caregivers, health care professionals, researchers, academic institutions, government agencies and industry leaders with a common mission.
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

Surveys and analytics supported by grants from AstraZeneca, GSK, Teva, Pfizer, and Mylan
COVID-19 Survey 2 Highlights

- Launched May 1st and closed May 31st

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<thead>
<tr>
<th></th>
<th>US</th>
<th>Europe</th>
<th>Canada</th>
<th>Other countries</th>
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<tr>
<td></td>
<td>726</td>
<td>18</td>
<td>15</td>
<td>11</td>
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<table>
<thead>
<tr>
<th>COPD (Emphysema or Chronic Bronchitis)</th>
<th>A1AT Deficiency</th>
<th>Bronchiectasis /NTM</th>
<th>Caregivers of an individual with COPD</th>
</tr>
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<tbody>
<tr>
<td>634 (87 without COPD)</td>
<td>31 (19 with COPD)</td>
<td>211 (130 with COPD too)</td>
<td>13</td>
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COVID-19 Survey 2 Highlights: COPD Responses

- 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
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
Many Individuals with COPD are taking positive measures 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.”
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
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%)

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

“I sing very loud and deep. Works better than breathing treatments”
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**.

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

“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 Highlights: COPD Responses**
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.*
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

COPD FOUNDATION
IS HERE FOR YOU!
Other Resources for COVID-19 Information

1. The Centers for Disease Control and Prevention:

2. The World Health Organization:

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