Virtual
FH Community
Gathering

COVID-19 + FH
What you need to know
Medical Advice Disclaimer

• Information in this webinar is for your information.
• The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment, and does not constitute medical or other professional advice.
• Medical information changes constantly. Information in this webinar could be updated or change.
• Please follow up with your doctor and medical team for specific recommendations pertaining to the treatment of you or your family.

March 25, 2020
Corona Virus Disease 2019 (COVID-19)
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CMO: The FH Foundation
Coronavirus Disease 2019 (a.k.a. COVID-19)

- COVID-19 is an ssRNA virus

- Spread primarily person to person
  - Can be spread by asymptomatic carriers
  - Possible that the virus can be spread via contact

- Viral particles enter the lung via droplets
Epidemiology or COVID-19

- Attack rate: 30-40%

- Incubation time: 4-15 days

- Viral Shedding: ~ 20 days but can be as high as 37 days
  - virus shedding can occur both before symptoms develop and after symptoms abate
Prevention – What can you do?

• Wash your hands: many online tutorials
  • Turn on the water
  • Wet your hands
  • Turn off the water
  • Apply soap
  • Rub vigorously – 20 seconds begins now
  • Be sure to get between every finger, the back of your hands, both thumbs, under all nails, fingertips & wrists
  • Rinse off all soap
  • Dry hands with a clean towel
  • Use the towel to turn off the faucet
Prevention – What can you do?

• Practice personal distancing
  • Stay 6 feet away from other people / stay home if you can
• Clean high touch surfaces daily with wipes or soap and water
  • Door knobs
  • Light switches
  • Refrigerator and microwave doors
  • Drawer pulls
  • TV remote
  • Counters and tabletops
  • Toilet and faucet handles
Symptoms COVID-19

• Cough: 80%

• Fever: 45% at presentation – 80% at some point in illness

• Shortness of breath: 40%

• Upper respiratory symptoms: 20%

• Gastrointestinal symptoms: 10%
How can I get tested for COVID-19

• If you have symptoms suggestive of COVID-19 call your health care provider (HCP) for advice on getting tested.

• Although in some places testing continues to be difficult to come by, it is getting better. You may be asked to go to a specific location for “drive by” testing.

• If you don’t have an HCP, call or go online to your state health department.
Risk Factors for Severe Disease: COVID-19

- Age > 55
- Chronic kidney or lung disease
- Diabetes
- Hypertension
- Cardiac Disease
- Human immunodeficiency virus (HIV)
- History of an organ transplant
- Use of biologics that suppress the immune system  
  (IMPORTANTLY: THIS DOES NOT INCLUDE PCSK9i)
Mortality in COVID-19 – may be different in the US

The older you are, the more deadly the virus

This data is from China – US experience may differ
Does Having FH Make Me More Vulnerable?

• Just having FH should not make you more vulnerable.

• If you have FH and underlying heart disease or other risk factors, you are likely at increased risk as are all people with underlying heart disease and/or other risk factors. If this is your situation, you should do your best to minimize contact with others.
  • Enlist friends or family to buy your groceries and drop off
  • Use grocery delivery service
  • Have a friend or family member pick up your medications
  • Use a mail order pharmacy
  • Stay home

• Ask your doctor if he/she has a telehealth option
Should I stop any of my treatments?

Will my center continue Lipoprotein Apheresis?

Should I continue:

• ACE inhibitors / ARBs (Blood Pressure Medication)?
• PCSK9 inhibitors (Lipid Lowering Therapy)?
• Statins (Lipid Lowering Therapy)?
Angiotensin-Converting Enzyme 2 (ACE2) Controversy

- Corona viruses bind to their target cells in the lung through angiotensin-converting enzyme 2 (ACE2) which is expressed in the lungs.

- ACE2 facilitates the uptake of the virus.

- ACE2 expression is increased in persons on ACE inhibitors (like lisinopril) or ARBs (like losartan) so theoretically treatment with an ACE inhibitor or ARB could facilitate uptake of the virus.

- However once a person is infected with a corona virus ACE2 expression decreases and can lead to more severe pulmonary infections so theoretically treatment with ACE inhibitors or ARBs could protect against severe pulmonary infections.
ACE 2 Controversy - Would an increase in pulmonary ACE2 be bad or good?

Having MORE ACE2 could lead to increased susceptibility to viral entry

Having MORE ACE2 could be helpful in minimizing severity of pulmonary infections

University of Minnesota evaluating losartan 25 mg vs placebo in persons with COVID-19 diagnosis who don’t require immediate hospitalization. Groups will be compared on:
1. Need for hospitalization
2. SOB
3. Ability to perform daily activities
4. Fever on day 3,5,7,10
5. Severity of symptoms if hospitalized
NCT04311177
## Current Consensus

### March 17, 2020

The AHA, the HFSA and the ACC recommend continuation of angiotensin converting enzyme inhibitors (ACE-i) or angiotensin receptor blocker (ARB) medications for all patients already prescribed for indications such as heart failure, hypertension or ischemic heart disease.

<table>
<thead>
<tr>
<th>Society</th>
<th>Summary of recommendations</th>
<th>Last Statement Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Society of Hypertension</td>
<td>Recommend continuing ACEIs/ARBs due to lack of evidence to support differential use in COVID-19 patients. In those with severe symptoms or sepsis, antihypertensive decisions should be made on a case-by-case basis taking into account current guidelines.</td>
<td>March 12, 2020</td>
</tr>
<tr>
<td>European Society of Cardiology Council on Hypertension</td>
<td>Strongly encourage continuing ACEIs/ARBs due to lack of evidence to support discontinuing.</td>
<td>March 13, 2020</td>
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<tr>
<td>Hypertension Canada</td>
<td>Recommend continuing ACEIs/ARBs due to lack of evidence that patients with hypertension or those treated with ACEIs/ARBs are at higher risk of adverse outcomes from COVID-19 infection.</td>
<td>March 13, 2020</td>
</tr>
<tr>
<td>Canadian Cardiovascular Society</td>
<td>Strongly encourage continuing ACEIs/ARBs and Angiotensin Receptor Neprilysin Inhibitors due to a lack of clinical evidence to support withdrawal of these agents.</td>
<td>March 15, 2020</td>
</tr>
<tr>
<td>The Renal Association, United Kingdom</td>
<td>Strongly encourage continuing ACEIs/ARBs due to unconvincing evidence that these medications increase risk.</td>
<td>March 15, 2020</td>
</tr>
<tr>
<td>International Society of Hypertension</td>
<td>Strongly recommend that the routine use of ACEIs/ARBs to treat hypertension should not be influenced by concerns about COVID-19 in the absence of compelling data that ACEIs/ARBs either improve or worsen susceptibility to COVID-19 infection nor do they affect the outcomes of those infected.</td>
<td>March 16, 2020</td>
</tr>
<tr>
<td>American College of Physicians</td>
<td>Encourage continuing ACEIs/ARBs because there is no evidence linking them to COVID-19 disease severity, and discontinuation of antihypertensive therapy without medical indication could in some circumstances result in harm.</td>
<td>March 16, 2020</td>
</tr>
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Monoclonal Antibodies

- Monoclonal antibodies (mAbs) are large molecules that bind to specific targets often expressed on the immune system aimed at treating immunopathological conditions. Some mAbs can have the potential for immunotoxicity (immune suppression, immune stimulation and for hypersensitivity reactions [this is also known as immunogenicity]).
PCSK9 Inhibitors are Monoclonal Antibodies

• What about PCSK9 inhibitors which are Monoclonal Antibodies?

• Researchers from the Karolinska Institute in Stockholm, Sweden have documented that PCSK9 inhibitors can have a positive impact on the immune system. Oxidized LDL (which is commonly found in people with atherosclerosis) can activate certain immune cells including dendritic cells and T cells.

• PCSK9 inhibitors were shown to inhibit this process leading to an anti inflammatory state.
The researchers hypothesize that PCSK9 inhibitors may protect against atherosclerosis both by lowering LDL and positively impacting the immune system.

It is notable that statins also have anti inflammatory and immune modulatory roles in addition to their LDL lowering effects.

The bottom line ..... PCSK9 inhibitors may positively impact the immune system.
With regard to PCSK9 inhibitors, such as evolocumab, there is no information on the incidence and impact on the risk of contracting coronavirus (COVID-19). Evolocumab is a fully human monoclonal antibody that inhibits the interaction between the enzyme proprotein convertase subtilisin/kexin type 9 (PCSK9) and low-density lipoprotein receptors (LDL-R).\(^1\) Results from phase 2, 3 and open-label extension clinical studies did not find any safety risk of immunosuppressive effects in patients receiving evolocumab, with the longest study duration being out to 5 years.\(^2,3,4\) Across Amgen clinical trials, over 27,000 patients have been exposed to evolocumab.\(^5\) Patients should always consult with their healthcare provider if they are considering stopping treatment or altering their treatment plan.

If there are further questions or inquiries about this or other topics, please feel free to check or direct others to this Amgen website. [https://wwwext.amgen.com/covid-19/](https://wwwext.amgen.com/covid-19/)
Statement from Regeneron

PCSK9 inhibitors are monoclonal antibodies that bind to circulating PCSK9 (proprotein convertase subtilisin kexin type 9) in the liver. Through this mechanism, the number of functioning LDL receptors increase in the liver and decrease circulating LDL cholesterol (LDL-C) levels. This pathway is completely separate from the body’s immune response. Over 30,000 patients were observed for as long as five years across more than 25 Phase 3 trials in the Praluent® (alirocumab) ODYSSEY clinical study program.

No data are available on COVID-19 transmission or in COVID-19 patients, but there is also no evidence that Praluent would have any impact on the risk of transmission or contraction of COVID-19 or related illnesses.
Statement from Regeneron

Influenza or “flu-like symptoms” have been reported with PCSK9 inhibitors at a higher rate than placebo in clinical studies and in the post-marketing setting. Influenza diagnoses were based on symptoms and in most cases not confirmed by a flu test. In the ODYSSEY clinical study program, all Praluent cases were of mild or moderate intensity and were more commonly seen within the first six to twelve months of therapy.

No data are available on COVID-19 transmission or in COVID-19 patients, but there is also **no evidence that Praluent would have any impact on the risk of transmission or contraction of COVID-19 or related illnesses.**

If there are further questions or inquiries about this or other topics, please feel free to check or direct others to these Regeneron websites:  
https://www.regeneron.com/covid19 for COVID 19 information
https://www.regeneron.com/medical-inquiries for questions from patients or HCPs
Statins in COVID-19 Infection

- Statins have many positive attributes including:
  - Anti-inflammatory effects
  - Positive immunomodulatory effects
  - Antioxidant effects
  - Improvement in endothelial function
  - Antithrombotic effects
- Based on these benefits some hospitals have protocols for treating persons hospitalized with COVID-19 with statin therapy unless they have liver function test abnormalities
Are there any approved treatments for COVID-19?

- All current treatments are supportive:
  - Tylenol
  - Oxygen
  - Antibiotics if suspect a bacterial pneumonia on top of COVID-19 viral pneumonia
  - Ventilator support if needed
Experimental Therapies in Hospitalized Patients

- World Health Organization (WHO) launching a study (SOLIDARITY) using a cocktail of drugs including:
  - Persons hospitalized with confirmed case, sign informed consent, physician goes into WHO website notes which drugs available at his/her hospital – website randomizes patient to an available drug or if none available to local standard of care. Physician subsequently records day patient left hospital or died and if oxygen or a ventilator was required.
  - Hydroxychloroquine and Chloroquine (antimalarial drug with antiviral activity)
  - Remdesivir (experimental anti-viral used unsuccessfully in Ebola this agent shuts down viral replication)
  - Lopinavir & ritonavir (agents used to treat HIV) will be used alone or with interferon-beta (an immune system messenger that can cripple viruses)
Telehealth

- Medicare telehealth coverage that will enable beneficiaries to receive a wider range of healthcare services from their doctors without having to travel to a healthcare facility. Beginning on March 6, 2020, Medicare—administered by the Centers for Medicare & Medicaid Services (CMS)—will temporarily pay clinicians to provide telehealth services for beneficiaries residing across the entire country.
Commercial Insurance Coverage

• Many plans have waived copays and prior authorization requirements for COVID testing and treatment. Check with your insurance provider.

• Many, but not all, are covering telehealth for any reason (not just COVID). Some have their own platforms. Check with your insurer.

• Many are allowing for a 90 day supply of prescriptions, some by mail, some early refills. Check with your plan.

• FH Foundation is signed on to a letter asking insurers to allow 90 day refills, off-formulary prescriptions, ensure Prior Authorization requirements don’t impede access to care, and other flexibilities at this time.
QUESTIONS?
Ways to Get Involved with the FH Foundation

- Join our online discussion groups
- Become an FH Advocate for Awareness
- Share your story
- Volunteer
- Make a donation

Visit our website to learn more:
www.theFHFoundation.org/get-involved
Thank you!