GREETINGS!

Dear CAB Members,

We hope you and your families are doing well and staying safe during this unprecedented time. The CTU team would like to share a special edition of The CAB Gab with you. During this challenging time, our team has been hard at work. The Center for Virology and Vaccine Research (CVVR) is actively involved in developing a COVID-19 vaccine and in testing a medication called Remdesivir for the treatment of COVID-19. In this edition, we share with you some of our updates from the front line. We hope to see you all at our virtual CAB meeting on May 20th, 2020.

-The CTU Team
WHAT IS COVID-19?
COVID-19 is an illness caused by a virus that can spread from person to person. The virus that causes COVID-19 is a new coronavirus that has spread throughout the world.

HOW DOES COVID-19 SPREAD?
You can become infected by coming in close contact (about 6 feet or 2 arm lengths) with a person who has COVID-19. COVID-19 is primarily spread from person to person. You can become infected from respiratory droplets when a person coughs, sneezes, or talks. You may also be able to get it by touching a surface or object that has the virus on it, and then by touching your mouth, nose, or eyes.

WHAT ARE SYMPTOMS OF COVID-19?
People with COVID-19 have a wide range of symptoms. The following symptoms may appear within 2-14 days after exposure to the virus:
- Fever
- Cough
- Shortness of Breath or Difficulty Breathing
- Chills or Shaking with Chills
- Muscle pain
- Headache
- Sore Throat
- New loss of Taste or Smell

HOW CAN I PREVENT THE SPREAD OF COVID-19?
Stay at home if you are sick, except to get medical care. Avoid public transportation, ride sharing or taxis. Separate yourself from other people in your home. If you are not sick, still try to stay at home as much as possible. If you do need to go out in public, wear a cloth face covering that covers your nose and mouth. Additionally, remember to wash your hands often with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer that contains at least 60% alcohol.
REMDESIVIR CLINICAL TRIALS

WHAT IS REMDESIVIR?
Remdesivir is an antiviral medication that is produced by the pharmaceutical company, Gilead Sciences. It was originally developed to see if it could help treat Ebola Virus. It has also been tested to see if it can help treat Marbug Virus, MERS, and SARS. Scientists now believe Remdesivir may be able to help treat COVID-19. Remdesivir is currently not approved anywhere globally for use.

HOW IS REMDESIVIR BEING TESTED AS A POTENTIAL TREATMENT FOR COVID-19?
Gilead Sciences has initiated two phase 3 clinical trials to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19. Both studies are randomized, open label studies being conducted at approximately 160 study sites globally. The studies began enrolling participants in March 2020.

The first remdesivir study is for patients who have severe manifestations of COVID-19. These participants have poor oxygenation and require supplemental oxygen. The second remdesivir study is for patients who have moderate manifestations of COVID-19. These patients have better oxygenation and may not require supplemental oxygenation. In these studies, participants are randomized to receive either 5 days of remdesivir or 10 days or remdesivir. In the moderate study, participants may also be randomized to a standard of care arm (i.e. a treatment other than remdesivir).

Beth Israel Deaconess Medical Center (BIDMC) is a site for both the severe and moderate protocols. Both trials are being led by the CTU's very own Dr. Katy Stephenson, who is acting as the principal investigator for these studies. As of April 28th, 2020, the CTU team has enrolled 34 participants into the severe protocol and 5 participants into the moderate protocol.

Additional study sites in Boston who are a part of the Gilead Sciences Remdesivir Trials include Brigham and Women's Hospital and Tufts Medical Center.

In addition to the Gilead Sciences studies, remdesivir is also being tested by the NIH. The National Institute of Allergy and Infectious Diseases (NIAID) launched a randomized, placebo-controlled trial to test remdesivir in hospitalized adults diagnosed with COVID-19. In Boston, Massachusetts General Hospital is a study site.
COVID-19 VACCINE

If there is anything that history has taught us, it's that vaccines have the ability to make deadly infectious diseases a thing of the past. Over the past two centuries, vaccines have effectively decreased mortality rates for diseases that once wrecked havoc on society. In 1796, Edward Jenner created the first smallpox vaccine. Over the course of the next 200 years, his vaccine technology helped to effectively eradicate the smallpox disease thus saving millions of lives. Jenner's work paved the way for development of other attempts to control infectious diseases. As of date, the World Health Organization (WHO) lists vaccines available against 26 different diseases.

While many different clinical trials are underway to test potential coronavirus treatments, most of the experts agree that an effective vaccine will be needed to control the pandemic. Scientists worldwide have begun the race to develop a COVID-19 vaccine. While the pace of vaccine development is impressive and far faster than the development of any previous vaccine, experts still estimate that it will be another 12-18 months before we see a licensed COVID-19 vaccine.

The CVVR is one of the latest sites involved in the development of a COVID-19 vaccine. On March 30th, 2020, Johnson & Johnson announced that they had selected a lead COVID-19 vaccine for development and committed one billion dollars in funds for this project. The vaccine chosen by Johnson & Johnson was the one developed right here at the CVVR!

COVID-19 vaccine development efforts at the CVVR began in January 2020 under the direction of CVVR director, Dr. Dan Barouch. The vaccine is expected to be ready for testing in a clinical trial by September 2020 with hopes that the vaccine could be licensed for emergency use sometime in early 2021. The COVID-19 vaccine candidate developed by the CVVR is based off of a viral vector called adenovirus 26 (Ad26). This Ad26 vector was originally developed for HIV vaccines and is the construct for the HIV vaccines currently being tested by the CTU team. Having this solid foundation from the HIV trials has allowed the CVVR research team to work at a faster pace in the development of a COVID-19 vaccine. Without the dedication of our research participants in our HIV trials, we wouldn't have some of the baseline data needed to show the safety and efficacy of vaccines developed with an Ad26 viral vector. So a special thank you is in order for our participants and their continuing contribution to science!

We will continue to keep CAB members updated on the progress of our COVID-19 vaccine and upcoming vaccine trial. If you know of anyone interested in participating in the trial, please have them email us at CVVRtrials@bidmc.harvard.edu.
HIV AND COVID-19: WHAT YOU NEED TO KNOW

For more information visit: https://www.avert.org/coronavirus/covid19-HIV

Avert.org is a website that provides global information and education on HIV and AIDS. They have recently added helpful information to their website about how people living with HIV may be affected by COVID-19.

Is Coronavirus-19 worse for people living with HIV?
People living with HIV who are on effective antiretroviral therapy (ART) are currently not at increased risk of getting coronavirus or developing severe symptoms. People living with HIV who are not on ART treatment or not virally suppressed may be at a greater risk and should speak with their HIV provider. As with the general population, older people living with HIV and those with underlying health conditions should take extra precautions to prevent illness.

I am living with HIV. How can I prevent COVID-19?
The advice for people living with HIV is mostly the same as for everyone else. Some steps you can take to prevent infection include:

- Wash your hands frequently with soap and water for at least 20 seconds
- Use an alcohol based hand sanitizer for situations where you do not have access to soap and water
- Avoid touching your face
- Avoid being around people who are feeling unwell
- Cover your nose and mouth with a clean tissue when you sneeze and cough. After, throw it away and wash your hands

Tips on COVID-19 for people living with HIV

- Try to stock up on antiretroviral medication (ART) so you have enough for 30 days, or ideally for three months
- Ensure your vaccinations are up to date (i.e. influenza, pneumococcal)
- Make sure you know how to get in touch with your healthcare facility and that you have a plan in place if you feel unwell and need to stay home
- Make sure you are eating well, exercising (as best you can at home) and looking after your mental health

Preparing for COVID-19 if you’re living with HIV

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<thead>
<tr>
<th>TAKE ACTION TO AVOID COVID-19</th>
<th>CONTINUE YOUR TREATMENT</th>
<th>STOCK UP ON ART</th>
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<tr>
<td>Follow the general prevention advice.</td>
<td>Take your ART to keep your immune system healthy.</td>
<td>Have a 30-DAY supply of your ART, ideally 3 months.</td>
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Avert.org www.avert.org/coronavirus
Interested in hearing more about the ongoing COVID-19 work in the CVVR? Check out some of the press releases below featuring our lab, CVVR Director Dr. Dan Barouch, and the CTU's fearless leader, Dr. Katy Stephenson.

"Beth Israel is working with Johnson & Johnson on a Coronavirus Vaccine"
Boston Globe Article, March 12, 2020, featuring the CVVR laboratory

"Massachusetts life sciences industry at forefront of worldwide fight against Coronavirus"
Boston Globe Article, March 19, 2020, featuring the CVVR laboratory

"Why are some with COVID-19 getting seriously ill and others feel fine?"
Boston 25 News Interview April 9, 2020, featuring Dr. Katy Stephenson
https://www.boston25news.com/video/?id=4881827

"Bidmc launches clinical trials evaluating anti-viral drug remdesivir as treatment for COVID-19"
BIDMC.org article, March 24, 2020, featuring Dr. Katy Stephenson
https://www.bidmc.org/about-bidmc/news/2020/03/remdesivir

"Beth Israel launches drug study to help COVID-19 patients"
NBC 10 News Article, March 25, 2020, featuring Dr. Katy Stephenson
CVVR PRESS RELEASES

"How does the Coronavirus behave inside a patient?"
The New Yorker, March 26, 2020, featuring Dr. Dan Barouch

"Researchers, healthcare experts working to develop COVID-19 vaccine as death toll surges."
7 News Boston article, March 31, 2020, featuring Dr. Dan Barouch

"US and J&J commit $1b to coronavirus vaccine codeveloped by Beth Israel"
Boston Globe Article April 4, 2020, featuring Dr. Dan Barouch

"In it together, 4/9/2020 Episode"
WBGH Radio Interview, April 9, 2020, featuring Dr. Dan Barouch

"No evidence yet for effective COVID-19 treatments, review shows"
ABC News article, April 14th, 2020, featuring Dr. Katy Stephenson
https://abcnews.go.com/Health/covid-19-treatments-effective-review-shows/story?id=70140442
CVVR PRESS RELEASES

"The race to develop a Coronavirus Vaccine"
WBUR Radio Interview, April 14, 2020, featuring Dr. Dan Barouch
https://www.wbur.org/onpoint/2020/04/14/coronavirus-vaccine

"Here's what scientists still wish they knew about coronavirus"
LA Times article, April 21, 2020, featuring Dr. Katy Stephenson

"Genetic engineering could make a COVID-19 vaccine in months rather than years"
Scientific American, April 21, 2020, featuring Dr. Dan Barouch