COVID-19 Virtual Community Meeting: The Delta Variant and Staying Protected

September 24, 2021

9:00 AM PT, 10:00 AM MT, 11:00 AM CT, 12:00 PM ET
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Speakers

**Welcome**: Patricia Koffman  
Co-Founder and Communications Director  
CLL Society

**Moderator**: Brian Koffman, MDCM (retired), MS Ed  
Executive Vice President and Chief Medical Officer  
CLL Society

**Speaker**: Robyn Brumble, MSN, RN  
Director of Scientific Affairs  
CLL Society
Speakers

Daniel Engel, PhD
Professor of Microbiology, Immunology and Cancer Biology
University of Virginia School of Medicine

Sanjeet Singh Dadwal, MD
Chief, Division of Infectious Diseases
City of Hope National Medical Center

Deborah Stephens, DO
Assistant Professor of Hematology and Hematologic Malignancies
The University of Utah Health
The Huntsman Cancer Institute

Nicole Lamanna, MD
Associate Professor of Clinical Medicine
Division of Hematology Oncology
Department of Medicine
Columbia University Medical College
Agenda

12:00 PM ET Welcome, Overview, Panel Introductions, Audience Poll
12:05 PM   CLL Society COVID-19 Plan
12:10 PM   Panelist Comments
12:30 PM   Audience Q&A with Panelists
1:25   PM   Concluding Comments
Complete Prior to COVID-19 Exposure

Directions for Completing the COVID-19 Planning Checklist

1. Obtain an oxygen (O2) pulse oximeter (O2 saturation monitoring device) and have it readily available in your home. Inexpensive O2 pulse oximeters can be purchased on Amazon or from your local drug store.

2. Have a reliable digital thermometer available. If you only have oral thermometers in your home, consider purchasing one for each member of the household to prevent spreading the virus to other family members.

3. Know ahead of time where you will go to get tested for COVID-19, and confirm they will perform the necessary testing:
   - The location you choose should be willing to offer you both the rapid test and the PCR test at the same time. Remember, the Rapid test can indicate evidence of COVID-19 infection, but the PCR is typically more accurate. (Please also note, some rapid tests will not detect variants).
   - Always err on the side of caution and get tested right away should you experience any respiratory symptoms, or if you have known exposure to COVID-19. Do not dismiss allergy or cold symptoms!
   - The earlier you know, the earlier you can receive treatment, which is of utmost importance.

4. High titer convalescent plasma should be administered early after diagnosis and is authorized under the EUA (Emergency Use Authorization) for the treatment of hospitalized patients with COVID-19 and impaired immunity. That would include CLL patients. It is not used in severe COVID-19. Convalescent plasma may need to be administered more than once.

5. Monoclonal antibodies directed against the COVID-19 spike protein have proven to help high-risk patients and should be given within 10 days of diagnosis and can be given outpatient. The earlier the better! You must investigate ahead of time which hospitals in your area provide access to this critical COVID-19 treatment! COVID-19 monoclonal antibody therapies are not available everywhere and are most likely not available at your local small community hospital. So please spend time finding out exactly where you can access them quickly should you need them. It is also important to understand the criteria that make you eligible for receiving this critical COVID-19 treatment should there be any pushback when you advocate for receiving it:
   - Search this map to find the hospitals in your area that have monoclonal antibody therapy available, and make it part of your plan to visit their emergency room if COVID-19 treatment becomes necessary.
Known Exposure, Positive Result, and How to Quarantine

CHECKLIST FOR KNOWN EXPOSURE TO COVID-19 WITHOUT A POSITIVE TEST RESULT

READ THROUGH YOUR COVID-19 PLANNING FOLDER AND ACTIVATE YOUR HOUSEHOLD QUARANTINE PLAN

- Closely monitor for symptoms of COVID-19. Symptoms can appear anywhere from 2-14 days after exposure and may or may not include headache, fever or chills, cough, shortness of breath or difficulty breathing, increased fatigue, worsening muscle or body aches, headache, loss of taste or smell, sore throat, congestion, runny nose, nausea, vomiting, and diarrhea.
- Contact your healthcare provider(s) right away to arrange for possible urgent treatment with the anti-COVID-19 monoclonal antibodies, regardless of whether or not you have had a positive test or symptoms.
- Immediately schedule appointments for testing 3-5 days following the date of known exposure. Availability for testing can be limited during times of surge cases.

TESTING RECOMMENDATIONS FOR COVID-19

- The CDC recommends testing 3-5 days following the date of the known exposure, even without symptoms. But if you begin to have symptoms, arrange to get tested right away.
- If possible, have both the rapid and PCR tests performed. If both are not available, the PCR test is much preferred due to increased accuracy. Know that if you test negative, you were not infected at the time your sample was collected. The test result only means that you did not have COVID-19 at the time of testing. Continue to take steps to protect yourself and others by wearing a mask and distancing.
- If symptoms develop, but you had a negative test, you should immediately get retested.
- If you test positive, refer to the COVID-19 Action Plan for the next steps.

QUARANTINE RECOMMENDATIONS FOR CLL

- If you received a negative PCR test result AND no symptoms have been detected during daily monitoring, quarantine can end after Day 10.
- For those that did not get tested and never experienced any symptoms of COVID-19, quarantine must last for the full 14 days following exposure.

HOUSEHOLD QUARANTINE PLAN

Why Is It Important To Have a Quarantine Plan in Place Before You Become Infected with COVID-19?

Receiving a COVID-19 diagnosis can be stressful and confusing, especially if you are not prepared. Having a well-thought-out quarantine plan will help everyone in the household know exactly what to do should the virus infect someone within the home. In addition to this checklist, learn as much as you can in advance about standard infection control precautions that may help decrease the possibility of spread. Place this document within your COVID-19 planning folder to refer to if needed.

- Have plenty of masks available. Everyone in the household should plan on wearing a tightly-fitting mask (preferably an N95) over their nose and mouth as much as possible, especially when in direct contact with anyone else in the home.
- Keep your distance from others. Stay in a designated room by yourself and use a bathroom separate from the one used by others in the household. Keep your bedroom and bathroom door closed whenever possible. Have someone else prepare meals and leave them outside your bedroom door.
- Do not leave your home (unless necessary for medical care), identify family, friends, or community groups to help deliver groceries, medications, and other supplies to your front door. Have their contact information readily available as part of your quarantine plan.
- If living with others, increase ventilation within your home. Open windows and outside doors (when the weather permits), operate attic/ceiling fans, or run a window air conditioner with the vent control open to increase the indoor/outdoor airflow.
- Have necessary supplies on hand. Consider creating a list that includes items such as thermometers for each person in the home, electrolytes, teas, over-the-counter medications, cleaning supplies, hand Sanitizer, disposable knives, Kleenex, etc. Speak with your healthcare provider about what vitamins or over-the-counter medications might be helpful to have readily available as well.
- Wipe down high-touch areas every day with a disinfectant. This includes doorknobs, light switches, phones, remote controls, appliances, sinks, toilet, countertops, etc. Let someone else disinfect high-touch surfaces in the common areas of the home. But you should also clean and disinfect your designated sick room and bathroom if possible.
- Do not share any items with others in your home. This includes clothes, drinking glasses, eating utensils, towels, or bedding. It is important to wash all items used by the infected person thoroughly with soap and water after using them.
What Do I Do If I Do Get COVID-19?

COVID-19 ACTION PLAN

Do These Things After Testing Positive for COVID-19

ACTIVATE YOUR PLAN! ACT EARLY-EVEN IF YOU FEEL FINE. REMEMBER, TIME IS OF THE ESSENCE.

☐ Access your COVID-19 Planning Folder.
☐ Read through your COVID-19 Planning Checklist and instructions again.
☐ Contact your healthcare provider(s) immediately to discuss arranging urgent treatment with the anti-COVID-19 monoclonal antibodies and any other possible early therapies as soon as possible.
☐ Activate your Household Quarantine Plan.

IMPORTANT PEOPLE TO CONTACT

☐ Contact anyone you have been around in the previous 48 hours and inform them of your positive test result. By notifying close contacts of possible exposure, you may be helping them prevent the spread of COVID-19 to their friends and family.
☐ Someone from the health department may call you. This is completely normal, and it is important to answer the call to assist with contact tracing, which may also help slow the spread.
☐ Call your healthcare provider(s) to notify them of your positive test result.
☐ Stay in touch with them periodically to ask questions and/or inform them of your status. And do not hesitate to call your healthcare provider(s) to report any symptoms that are severe or concerning to you.

SCHEDULED APPOINTMENTS

☐ If you have an in-person medical appointment that cannot be avoided, call the office ahead of time to remind them you have been diagnosed with COVID-19. This will help the office put measures in place to protect the staff and other patients when you arrive.

KEEP A LOG OF YOUR VITAL SIGNS AND SYMPTOMS

☐ Begin recording a list of all measured vital signs, especially oxygen saturation levels and temperatures.
☐ Keep track of when you experience any new symptoms such as cough, chills, shortness of breath, fatigue, muscle/body aches, vomiting, diarrhea, or loss of taste/smell.
☐ Include the time and date when you are logging them.
☐ Call your healthcare provider(s) to inform them if your oxygen saturation is consistently reading below 95%, fever >100.4, or with worsening symptoms.

SEEKING EMERGENCY CARE

☐ Call 911 immediately if emergency warning signs for COVID-19 develop such as difficulty breathing, rapid breathing, oxygen saturation consistently reading <95%, persistent pain or pressure in the chest, difficulty staying awake, confusion, or discolored lips/nails/beds.
☐ Should you need to seek emergency care via ambulance, you must request to be taken to the hospital that you have already determined ahead of time can provide you with rapid access to critical COVID-19 therapies. If they are not informed, they are required to transfer you to the nearest local hospital.
☐ Take your COVID-19 Planning Folder along with you to the hospital so you have quick access to the important documents (the “Official Statement for Prioritizing CLL Patient’s Emergency Room Care”).
☐ Most importantly, ADVOCATE for your best care! Remember, EARLY administration of critical COVID-19 therapies, such as convalescent plasma and SARS-CoV-2 monoclonal antibodies, is extremely important for those who are immunocompromised (as recommended by Emergency Use Authorization and other clinical guidelines). Data shows both reduced mortality and mortality in CLL patients with both of these treatments.

AFTER YOUR DISEASE HAS RUN ITS COURSE

☐ Please consult with your healthcare provider(s) to find out when you can safely be around others. If you have any symptoms, it is important to get tested again. Routine testing after COVID-19 is not advised in the general population. However, your healthcare provider may recommend repeated testing, as some CLL patients have difficulty clearing the virus that causes COVID-19 and may remain contagious after symptoms resolve.
Where to Find the COVID-19 Action Plan
On CLL Society’s Website
Important Takeaways

• Complete the checklists ahead of time - BE PREPARED!

• Keep them in an easily accessible place, such as a folder

• Discuss your plan with others within the household

• If you have known exposure, symptoms, or a positive test result - pull out the plan and act fast! Time is of the essence.
What to Know About SARS-CoV-2 Variants

Dan Engel, PhD
University of Virginia
Topic: Variants of SARS-CoV-2

- A few words about how variants arise
- Will there be new variants?
- Is there anything we should do to stay protected against new variants?
- Variants and vaccination
- Variants and monoclonal antibody therapy
- Mask, mask, mask
American Society for Virology
COVID-19 Vaccine Education
VIRTUAL TOWN HALL

Please visit asv.org/education for more information, and to register
COVID-19 Vaccine Response in CLL

Deborah Stephens, DO
The University of Utah Health
The Huntsman Cancer Institute
Response to COVID-19 Vaccine

• Responses to Pfizer Vaccine
  • Overall response (detected by antibody) was 40% in CLL Patients
    • Patients in Remission: 79%
    • Patients on “watch and wait”: 55%
    • Patients on any kind of treatment: 16%

Herishanu, Blood 2021
Response to COVID-19 Vaccine

• Responses to Pfizer or Moderna Vaccine
  • Antibodies Detected: 52% in CLL Patients
    • Patients Never Treated: 94%
    • Patients with Prior Treatment: 23%
      • Ibrutinib/acalabrutinib Treatment: 21%
      • Rituximab/obinutuzumab within 12 months: 14%
      • Rituximab/obinutuzumab + venetoclax within 12 months: 0%
  • Younger (<70) or no prior treatment: more likely to develop antibodies
Different Parts of Immune System Needed for Vaccine Response

Antibodies are easiest to measure

Jiskoot, Pharmaceutical Biotechnology 2019
Recommendation

• Likely responses outside of antibodies that are not easily measurable

• Risks of severe complications of COVID-19 outweigh any risks of vaccination

• Recommend all CLL patients receive a COVID-19 vaccine
  • If initially received Pfizer/Moderna: Recommend a booster shot of same vaccine (Pfizer/Moderna)

• Must continue to be vigilant with masking, washing hands, social distancing (without social isolation)
What If I Am Infected with COVID-19?

Nicole Lamanna, MD
Columbia University Medical College
If a CLL Patient Becomes Infected with COVID-19, What Are the Immediate Next Steps? What Treatments Should They Be Asking For?

• STAY CALM!
• Contact your treating physician (CLL doctor, or other)
• Make arrangements to receive monoclonal antibody therapy!
  • Antibodies approved through EUA include: Regeneron, Eli-Lilly, GSK (availability may differ depending upon location)
  • Need to receive in a timely fashion after positive test results OR recent post-exposure prophylaxis (ideally within 24-72 hours)
• Self-quarantine except to get tested/receive antibody therapy (if you are living with other individuals, they should be tested and self-quarantine as well)
How Do Monoclonal Antibody Therapies Work Against COVID-19?

• Monoclonal antibodies against COVID-19 attach to the virus to block it from entering human cells

• The monoclonal antibody protein also “marks” the virus to be broken down by the immune system and cleared from the body.
Monoclonal Antibody Therapies for COVID-19
(Regeneron, Eli Lilly, GSK)

FDA emergency use authorization (EUA) of this treatment for:

1. Mild-moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing.

2. Adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis with Regeneron or Eli Lilly monoclonal antibodies of COVID-19 in individuals who are:
   - Not fully vaccinated OR who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
   - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) OR
   - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)
Monoclonal Antibody Therapies for COVID-19
(Regeneron, Eli Lilly, GSK)

• Typically given as IV infusion (approximately one hour for infusion, but whole process 2-3 hours for monitoring etc.); some can be given subcutaneously (SQ)

• These infusions are generally well-tolerated!

• An infusion-related reaction could occur and symptoms may include:
  o Fever; chills; nausea; headache; shortness of breath; low blood pressure; wheezing; swelling of your lips, face, or throat; rash, including hives; itching; muscle aches; and/or dizziness
Management of COVID-19 in Hospitalized CLL Patients: What to Expect

Sanjeet, Dadwal, MD, FACP
City of Hope National Medical Center
Treatment Recommendations from Infectious Diseases Society of America (IDSA)

- Treatment guidance is for general public – lack of data/recommendations in immunocompromised patients

- Treatment guidance is lacking for immunocompromised patients due to lack of clinical trial data

- Treatment based on disease severity:
  - Mild to moderate
  - Moderate to severe
  - Critically ill
  - Severe illness (defined as oxygen saturation less than 94%)
Treatment Options

• Anti-viral drugs:
  • Remdesivir is the only FDA approved anti-viral drug
  • Ongoing studies:
    • Molnupiravir – in phase 3 trial treating non-hospitalized patients with intent to prevent progression to severe disease and hospitalization. This may become available under EUA by end of this year

• Anti-inflammatory approach:
  • Reserved for severe and critically ill (requiring supplemental oxygen)
    • Decadron
    • IL-6 inhibitors: Tocilizumab or Sarilumab or Baracitinib or Tofacitinib
**Monoclonal Antibodies/ High Titer COVID-19 Convalescent Plasma (CCP)**

- Monoclonal antibodies (3 are EUA approved):
  - EUA for use in post-exposure prophylaxis (only Casirivimab/Imdevimab)
  - EUA for treatment of mild to moderate non-hospitalized patients or if hospitalized for reasons other than COVID-19
  - Not recommended for patients hospitalized for COVID-19, especially severe illness. Discussion can be done with FDA and the sponsor for emergency IND to treat in special situations

- CCP, COVID-19 Convalescent Plasma:
  - Not recommended for severe disease in general population
  - Small studies suggest benefit in immunocompromised patients, especially those receiving anti-B cell therapies (e.g., CLL, lymphoma patients)
Ask for Clinical Trials if Available

Ask your treating MD

www.clinicaltrials.gov
Audience Questions & Answers
This program was made possible by grant support from

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Thank You for Attending!

Please take a moment to complete our post-event survey, your feedback is important to us.

Join us on October 15th for the CLL Society Ed Forum: The Right Tests at the Right Time

CLL Society is invested in your long life. Please invest in the long life of the CLL Society by supporting our work.

cllsociety.org/donate-to-cll-society/