

CLL Society's COVID-19 Virtual Community Meeting March 26, 2021

Audience Question and Answers

CLL PATIENTS AND CAREGIVERS WHO ARE FULLY VACCINATED

What can I do now? Still observe caution, wear a mask, social distance, and wash your hands.

Can I visit with adult friends or family who have been vaccinated? Same as above. Continue to observe caution and wait to do so until two weeks from the last dose of the vaccine.

What if my unvaccinated children or grandchildren go back to school? Maintain all precautions until the time comes that children start getting vaccinated.

Can I visit unvaccinated adult family or friends? Those with CLL should still avoid gathering with unvaccinated family and friends.

Should I go to my doctor's office? If deemed necessary by your provider that an inperson visit is necessary, then you have no choice. Otherwise, continue using telehealth appointments for remote consultations where available.

Should I go to my dentist appointments? If necessary, then go. But inquire if the dental staff has been vaccinated. Remember, they are the ones more at risk since they are working in patient's mouths!

Can I go shopping? Continue to limit exposure as much as possible by utilizing delivery services. If you absolutely must go out, be strategic by shopping at hours when shops will be less crowded.

Can I eat at an indoor restaurant? Please avoid eating indoors.

What about an outdoor restaurant? Continue to avoid unless necessary. If you do, only dine with people who live in your household.

I work with the public indoors. Can anything change? No. Continue to use full protection, such as a tightly fitted mask and eye shield.

Going to a hair or nail salon? If you must go, continue to use full protection, such as a tightly fitted mask and eye shield.



What about travel (such as flying, using a taxi or Uber, or public transit)? Continue to avoid if you can.

Attending a concert or sports event? Continue to avoid if you can.

Going to the gym or a public pool? Continue to avoid if you can.

RESPONSE TO THE VACCINE

How does my treatment affect my response to the vaccine, specifically if I am:

- Treatment Naïve There is a better chance of mounting a response based on data from other vaccines. However, at this time there is no data from EUA (Emergency Use Authorized) approved vaccines for COVID-19.
- 2) <u>Currently or Recently Receiving Chemotherapy</u> Depends on chemo and likely not to have a good response based on existing knowledge. Simply put, we do not have data on COVID vaccines in CLL patients.
- 3) On or Have Recently Received CD20 monoclonal antibodies for CLL There is no good data available. The response will likely be impaired.
- 4) On BTK Inhibitors There is likely to be a sub-optimal response based on previous hepatitis B and varicella-zoster (shingles) vaccine studies in CLL patients.
- 5) <u>Taking Venetoclax</u> There is not yet any clinical data available.

If possible, should CLL patients hold (temporarily discontinue) certain medications until after they are vaccinated? Specifically, if they are on:

- 1) Monoclonal Antibodies such as rituximab or obinutuzumab If it can be deferred, especially if this is being instituted for the first time, you are likely to have a better response to the vaccine. Honestly, we do not know how effective it would be.
- 2) <u>BTK Inhibitors</u> Response is sub-optimal with other vaccines; could be the case here too. There is simply no data at this time.

What do you recommend in terms of testing after being vaccinated? At present, NCCN and ASTCT/ASH do not recommend routine testing to determine vaccine response outside of clinical trials.

If my test indicates that the COVID-19 spike antibody was detected, does that mean the vaccine will be effective in neutralizing the virus if I am exposed? We do not know just yet!

If my spike antibody test comes back negative, does this mean the vaccine did not work, or is it possible that there may have been some protection given to my T cells? That is the exact concern that we do not yet have the answer to. It is important to recognize that when different therapeutic agents are used for CLL treatment (especially BTK Inhibitors), there is disruption of the cross-talk between various arms of the immune



system. Therefore, we cannot assume that T cell response will be intact or protective. Currently there is no data.

COVID-19 VARIANTS

How good are the vaccines against the new variants? New data are constantly emerging, but it appears that Moderna, Pfizer, and Johnson & Johnson are potentially effective.

Will monoclonal antibodies (mAbs) and convalescent plasma therapy still work against the new variants? The only guidance thus far has been that the mAb Bamlanivimab may not be effective in treating the California variant. CLL Society will update the guidance on variants as it becomes available. To read about the FDA's latest guidance please read this article.

VACCINE EFFICACY

Will a booster or a different vaccine be needed in the future? We do not have the data yet.

Is one vaccine preferable over another? No. Efficacy in clinical trials of the vaccines was based on the prevention of hospitalization and/or severe disease. Not based on immunogenicity.

What is the plan for CLL patients who do not get enough immunity after being fully immunized for COVID-19? Right now, the best thing to do is wait for the results of clinical trials so we can learn more about the COVID-19 vaccine in CLL patients. Specifically, we hope to learn more about the immunologic correlates of immunity, and perhaps even T cells.

If I have recently had COVID-19, do I still need to get a vaccine? Yes.

SIDE EFFECTS AND RISKS WITH VACCINE

My arm swelled up and I had other flu-like symptoms after receiving the vaccination. Is that a good sign that I have some immunity and would imply the vaccine is working? Possibly. Having these symptoms are suggestive of an immune system response.

If there was no reaction at all after receiving the vaccination, does that mean it did not work? No. The lack of symptoms does not mean the vaccine did not work.



My lymph nodes swelled up after the vaccine. Should I worry? No, you should not. Unless there isn't any improvement over the next few weeks. Then you should consider discussing with your healthcare provider.

I have heard that the vaccine can cause immune thrombocytopenia (ITP) and lower my platelet count. Is that true? The condition known as ITP can occur in anyone with any vaccination. The rare incidence of this happening in response to the COVID-19 vaccine will likely occur at the same rate as with all other vaccines. There is zero evidence that CLL patients are more at risk for developing ITP in response to vaccines, even though they are more at risk of ITP in general.

What is a pulse oximeter? Should I have one at home? Yes, it is not a bad idea to have one at home. Please review this article on pulse oximeters for more information.

Has the pandemic slowed down among CLL patients? Yes, it seems to have. Patients are more well informed about COVID-19 and are still taking precautions.

Has the death rate dropped for CLL patients who contract COVID-19? Yes, it has. How important is early diagnosis? Very important, as it can allow for early use of monoclonal antibodies and/or participation in clinical trials. Please see this <u>article</u> for more information.

If we are following the science, why have cancer patients not been prioritized for vaccinations? Specifically, CLL patients or patients in active treatment. This is an important question that the CLL Society asked of the CDC! CLL Society joined with other blood cancer organizations to advocate for prioritization. Now 46 states in the US have changed their vaccination plans to prioritize cancer patients as part of their high-risk criteria. Please see this <u>article</u> on the topic.

Has anyone become very sick with long COVID-19 consequences despite having already received the vaccine? We do not have any data on this.

Can a healthy vaccinated person infect a CLL member of their household via asymptomatic transmission? There are no data indicating if a healthy vaccinated person has ever transmitted COVID-19 to a CLL patient. However, there is some level of concern. Minnesota state recently reported COVID-19 developing in ~80 people after they had been fully vaccinated. So, there is a risk. We need to remember, vaccines are not 100% effective in preventing infection or risk of transmission. But they are extremely effective in preventing severe disease and resulting hospitalization in patients without active cancer or transplant.

Have there been any confirmed deaths despite being fully vaccinated? No. There have been no deaths confirmed by the CDC that were caused by the COVID-19 vaccine.



Should I continue getting Immunoglobulin injections at the time or around the time of getting vaccinated against COVID-19? Yes. There is no data that IVIG will limit the anticipated response. However, since CLL causes B cells not to do their job of producing antibodies there is the potential to have a lower response to the vaccine.

My oncologist mentioned that over time, the IVIG infusions might be infused with enough antibodies that I may receive some COVID-19 immunity as a result. Is this likely to be true? No. Because the effects of IVIG are not long-lasting. Antibodies decline over time, which is why repeated doses are needed when undergoing treatment.

MISCELLANEOUS

Is there concern for the vaccines (either mRNA or adenovirus) to cause antibodydependent enhancement (ADE)? My concern, as a CLL patient currently on a BTKi, is that I will only produce a low titer of antibodies, and thus produce a nonneutralizing response that could lead to ADE if infected with the virus. Does recent data refute this concern? This remains a theoretical concern, as there is no evidence to support this so far.

I heard somewhere that should I test positive for COVID-19 and require treatment, the timing of when to receive the various COVID-19 treatments is critical, and getting the wrong treatment at the wrong time might make things even worse. Can you please explain? Even though the antiviral drug Remdesivir is FDA approved for moderate to severe disease, healthcare providers must decide when (or if) to use it. Additionally, the steroid dexamethasone should not be used if your oxygen saturation is within normal limits. This is because steroids dampen the ability of T-cell immunity function, which can result in a prolonged period of shedding the virus and in higher numbers. Monoclonal antibodies (MAB) should be used early on when there is mild to moderate disease, as there seems to be no benefit when used later in the disease process when cases become more severe.

I was just exposed to COVID-19, are there any medications that I can take to help prevent me from getting severely ill? None have been approved by the FDA just yet. But some are being studied in ongoing clinical trials, so stay tuned.

I just tested positive for COVID-19, but I feel fine. I know I should quarantine, but what else should I do? Who should I contact on my healthcare team? Contact your oncologist as soon as you are diagnosed to find out if there are any available treatments from a clinical trial standpoint.

If I get COVID-19, when should I go to the emergency room or urgent care clinic, if at all? If you have any symptoms check your oxygen saturation level if you have the pulse oximeter device on hand. If oxygen levels are low (<94%), you need to go



immediately so you can receive antiviral therapy. If your symptoms are mild and oxygen levels are normal, then request monoclonal antibody (mAb) therapy. This treatment has shown to be effective when given early, although data are from non-cancer patients.

What will happen to me if I go to the emergency room? You will receive an examination, chest X-ray, blood test, be swabbed for COVID-19, and be checked to rule out other infections.

I just tested positive for COVID-19, should I stop any of my CLL medications? No. Please consult with your oncologist as soon as possible.

Has the prognosis and mortality rate improved for CLL patients who become infected with COVID-19 since the studies that first came out with data in March 2020? To date, there has not been any CLL-specific dependent data comparing early pandemic prognosis to recent. Overall, the mortality rate has been decreasing and there have been improvements in supportive care while managing COVID-19. While there is no official data yet, CLL experts agree anecdotally that the rate which was reported in March 2020 is no longer representative of the present-day mortality rate.