Larry Saltzman: Welcome, this is Dr. Larry Saltzman for The Leukemia & Lymphoma Society and a presentation of the National Patient Registry project of the Michael J. Garil Patient Data Collaborative. Today is August 24, 2021.

The purpose of this webinar chapter is to provide you information regarding the recent approval of additional doses of COVID 19 vaccine for immunocompromised patients.

- LLS is not a medical provider, or an academic medical center
- LLS cannot recommend or comment on an individual's booster questions
- LLS is encouraging studies on boosters to assure vaccine safety in blood cancer patients
- LLS is funding a booster study at the Montefiore Medical Center in New York City and are looking for more centers
- LLS will follow closely the experience in foreign countries where boosters are being investigated (UK) or administered (Israel, France)
- LLS will monitor antibody responses in participants who notify us of their receiving such a vaccine
  - (observation – not intervention)
Now, to recap and to make sure we're all on the same page, LLS is not a medical provider or an academic medical center. LLS cannot recommend or comment on an individual's booster questions. LLS is encouraging studies on these boosters to assure vaccine safety in blood cancer patients.

LLS is funding a booster study currently at the Montefiore Medical Center in New York City, and we are looking for more of these centers. LLS will follow closely the experience in foreign countries where boosters are being investigated, such as the United Kingdom or administered in Israel and France, as well as others. LLS will monitor antibody responses in participants who notify us of their receiving such a vaccine. Please note, these are observational studies and not interventional studies.

So, here are some of the most frequently asked questions regarding this topic. Do I need a booster shot as a blood cancer patient? The CDC has given guidance that immunocompromised people may receive a third mRNA vaccine dose – essentially a series of three. These are now approved for Pfizer vaccine, ages 12 and older and Moderna vaccine, ages 16 and older.

The CDC has classified these immunocompromised people as the following. People in active treatment for hematologic malignancies. Those who have been in receipt of CAR T-cell or hematopoietic stem cell transplant within two years or taking immunosuppression therapy. Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, Cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Active treatment with high dose corticosteroids, in other words prednisone and a dose of greater than 20 milligrams or the equivalent each day. Those on what are called alkylating agents, antimetabolites, and transplant-related immunosuppressive drugs. And cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers which stands for tumor-necrosis blockers and other biologic agents that are immunosuppressive or immunomodulatory.
When should I receive a third booster? This can be given any time after the normal series recommendation. That means three weeks for Pfizer and four weeks for Moderna. How can I get a booster shot? Given the FDA/CDC approval, a person may self-attest to a vaccine distribution center and therefore will receive a vaccine.

This means a self-approval that you have a blood cancer or immunosuppressive diagnosis. The recommendations are to receive the same type of mRNA as the initial doses. However, if the same vaccine is not available, you may obtain the other mRNA vaccine.

Now that the Pfizer vaccine has received full approval by the FDA, and this just occurred yesterday, the 23rd of August, any doctor may write a prescription for the third dose to be given anywhere that has available vaccine.

Now is the LLS national patient registry providing follow up antibody testing? The answer here is yes. For those with previous testing and our sero-negative result, meaning no antibody seen, we suggest testing three to five weeks after the third dose booster. For those with previous testing and a response showing antibodies to the Spike antigen, in the best case we would prefer a test prior to the "booster" and then a test 3-5 weeks after.

We understand the stampede to the vaccines and will try to work as best as we can with all who contact us.

We will accept lab tests from your doctor what may have been done in the interim.
We will accept lab tests from your doctor for blood testing that may have been done in the interim, if they have not been done at the LLS LabCorp service centers.

Here’s some specific questions. What if I’m Wait and Watch? What if I’m taking Rituxan®? What if I’m taking BTK inhibitors? And can a booster make my lymphoma worse?

For all the above questions, we suggest you consult with your physician, as you are an individual with nuances that we cannot comment in generalities. Having said that, we have seen that Rituxan is a very long-lasting drug and the same for any CD20 inhibitors. These have long lasting effects, and we believe their effects may last as long as six to 12 months. So again, please talk to your physician.

If you’re on a BTK inhibitor, these are oral drugs that are given on a daily basis to suppress blood cancers. Again, talk to your physician. And our view is that we shouldn’t have you stop your cancer treatments, just to take a vaccine. So again, talk to your physician.

Now, how can I enroll in a clinical trial for boosters again? Again, the only center that we know of and LLS is funding is the Montefiore Medical Center in the Bronx in New York. Their phone number is 718-405-8404.

LLS will accept current registry participants for follow up testing. If you are new to our national patient registry, we will ask you to supply any antibody lab tests you may have previously
received. And the LLS Clinical Trial Support Center [LLS.org/CTSC] and its Informational Resource Center [LLS.org/InformationSpecialists] will monitor available trials.

This question comes up frequently—should a caregiver have a close family member living in the same household receive a third vaccine dose? Again, this is an individual decision that you all should consult with your physicians, ask for their recommendations based on your personal situation. The anticipated recommendation will be that a normal, healthy adult should receive a third vaccine at an eight months timeframe after the primary COVID-19 vaccines series was completed.

So you would need to check your calendar for dates, you should talk to your physicians. And again based on the type of vaccine you're looking for, it should become available in September or your provider can now write a prescription for you to get a Pfizer vaccine, if that is the one in your series.

Now for additional registry questions, please contact us at PACT@LLS.org. We do have a voicemail box: 844-696-7228, where you can leave a message. It is not answered automatically.
You can visit LLS.org for COVID information. You can search the main website for the term COVID and things will pop up [LLS.org/Coronavirus]. Please stay tuned for future updates. And I thank you so much for your participation and your attention.