

**COVID-19 Q&A**  
**with**  
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LUNGEvity spoke with David Carbone, MD, PhD, who answered several questions about COVID-19 and lung cancer trials and infusion-related treatments from his perspective as a medical oncologist at The Ohio State University. It is important to note that the conversation took place on April 6, as issues around the COVID-19 pandemic can change rapidly.

Below are the answers to the questions discussed in the accompanying video:

**What are the things that you tell your patients who are on clinical trials right now or who are considering a clinical trial in the era of COVID-19?**

I think that it really needs to be stated at the beginning that policies, procedures, approaches, and recommendations can change literally daily based on what's going on. They're also very regionally specific. For example, in a hot spot like New York City, they may have different policies—hospital policies, state policies—than we do here in Columbus, Ohio, which currently has far fewer deaths and cases. My answers will reflect the way it is right now, right here. We've talking about this at length, and I think that the current answer to that questions is that I've gone through all of our open clinical trials and I've selected the ones that are of clear clinical benefit for patients or involve no additional risk to staff compared to standard of care, such as the current first-line metastatic trial, the INSIGNIA trial. This trial basically has three arms, with standard-of-care arms that involve no additional risk to staff, and the research coordinators are being allowed to assess toxicities based on physician interactions rather than requiring an additional interaction.

I'm still encouraging patients to go on clinical trials of that sort, but there are also clinical trials that give access to clearly shown active agents that are not available as standard of care. There are drugs that have really excellent phase II data better than anything that you can get through standard of care that are still only available in clinical trials, so I'm still encouraging patients to consider those.

**The next question comes from a patient who is on a phase I clinical trial that requires her to travel. Is it safe for her to travel? What should she ask her doctor?**

Travel and exposure to other people are never completely safe in this environment, but cancer is bad for you, too. I don't think there is, again, a blanket answer to this question. I've assessed our own phase I trials for indications of real activity in settings where there are no other options for patients, and I've actually put on hold most of our phase I clinical trials for patients to start. However, if this person is already on a phase I trial, our current philosophy is that we continue to treat as per protocol some of the elective biopsies and those kinds of things we are willing to take a protocol deviation for, but we continue to offer treatment. A patient will have to make their own assessment about whether the risk of continuing participation is worth it in their case, but clearly travel to a large thoracic clinic with many patients in proximity does carry some level of risk.

**The next question comes from a phase III trial patient who is on a targeted therapy. Can she get her blood drawn at her local cancer center so that she doesn't have to travel? Can she do a scan locally as well?**

There has been some guidance recently about increased flexibility in this manner. Patients on national cooperative network trials are allowed now to get their treatments and their blood work and scans at another site if that site has the same trial open. This didn't use to be the case. It used to be difficult to do that. Often you can get scans locally, and I do that frequently as long as we can get digital copies of the scans. Blood work is a little bit more of a problem because of the fact that generally for trials a particular lab has to be registered for that participation. So, I think that what will be allowed depends upon whether it's a pharma study or a cooperative group study. If you violate a study, you may be taken off the study and restricted from access to your drug, which, if you're benefiting from the drug, would obviously be a huge problem. I think that this would be study-specific. There is more flexibility now than historically, but I would check with the study coordinators at the site where you are currently getting treatment to see what would be allowed with that study.

**You mentioned pharma trials and cooperative group trials. Is one more flexible than the other?**

I think that the NCI is really trying to be more flexible. Typically, trials are not very flexible. They have very strict criteria in order to maximize interpretability, but I think that both pharma and cooperative group studies are trying to be more flexible. And, again, the guidance changes rapidly, so you would have to check what the current situation is. I can't say in general whether one is better.

**The next question comes from a patient who had discussed starting a clinical trial early on this year and then COVID-19 happened. She's a stage IV non-small cell lung cancer patient. What should she do? Should she start on something like chemotherapy or wait for the trial to start? She's in limbo right now, and it is stressful.**

I often tell patients and other doctors that time is not your friend in metastatic lung cancer, and while you have to do the right tests and assess genetics and do all those kinds of things, waiting months for a trial to open is probably in general not a good idea. If you were offered participation in February and it is now April, I think that's pushing the limit of reasonableness for metastatic non-small cell lung cancer. Although everybody's case is different, I would say on average waiting more than a month or two for the possibility of a trial to start is probably a bad idea, especially because now it could be months before these kinds of things return to normal.

**The last question about clinical trials comes from a patient who goes to his cancer center every month for a blood draw. The center gives him his supply of pills when he checks in every month. Now that he's not visiting his cancer center, he's worried that he will not get his 30-day supply of pills. What are your thoughts on this?**

Specifically for clinical trials, it would depend on how flexible the sponsor is. If you're on a pill therapy that's working and it's only available in the clinical trial, then you will have to comply with the trial or you do risk getting cut off; that's just an unfortunate reality. Different sponsors are being more flexible in these times, so you may not find that to be a problem. With off-protocol patients on oral therapies who are stable, we've been doing telephone encounters and renewing their prescriptions, and they can get local blood draws just to assess toxicity, but this may not be possible in a clinical trial.

**The first question about infusion comes from a patient who is on an immunotherapy-chemotherapy combination, essentially the KEYNOTE-189 combination, and had their last infusion in March. Should they delay infusions, and what would happen if they delay infusions because they are scared of going to the infusion center?**

You only really know the answer to this question in hindsight. There have been patients who have gotten one dose of immunotherapy and have been apparently cured, but then there are patients who have stopped and progressed and not re-responded. The three-week interval between therapies is relatively arbitrary, and I would say, and I tell my patients this all the time, that if you're going on a holiday we can delay your therapy for a week. I'm totally comfortable with that. Many of the immunotherapy agents have long half-lives, so with a two- or three-week half-life, you will still have a reasonable level in your blood.

My recommendation in our clinic is to stay on schedule as much as possible, and we've been offering that option for our patients. In-between scans and when the patient's doing well, often I will allow a telephone encounter so that all the patient has to do is go to the infusion center. At most places, they are taking significant precautions to protect patients and staff, and it is relatively safe. As I said before, there's a risk from COVID-19 for sure and lung cancer patients are at special risk for these infections, but cancer is not good for you, either. The patient will have to make their own decision about how to balance those two things. A delay of a week or two should be okay. Some of the maintenance therapies are two weeks, for example, and we've converted most of those to four-week infusions with a different dosing regimen just to reduce infusion visits. With chemo-immuno like the KEYNOTE-189 regimen, I think it would be safe to go to four weeks, but beyond that I'm concerned.

**A small cell lung cancer patient who is receiving the chemo-immuno combination wonders whether they should stop treatment because they are scared to go to the infusion center.**

This is an example where you may be able to spread out the immunotherapy infusions after the chemotherapy is done for extensive-stage, and I think it is completely safe. A higher dose at longer intervals will be used, and that reduces your risk. Small cell is an awful disease, and, even with the best of therapies, more than half of people still progress. So I think that trying to adhere to the regimen, at least in the chemotherapy phase, is pretty important. The disease can come back rapidly and is often not as effectively treated the second time around with chemotherapy. The answer to this would be to encourage the chemotherapy and perhaps stretch out the immunotherapy infusions to four weeks after the chemo is done.

**A patient who lives in upstate New York and travels to New York City for the infusion wonders whether she can take her infusion at her local center and, if so, should she be worried about changing her place of infusion?**

I often tell patients that they shouldn't change their surgeon because surgery is a highly skilled procedure that really is better done by some surgeons than others. Similarly, highly technical radiation therapies are difficult to just transport to another center and have confidence that they'll be as effective. But I tell them my treatment is medical and that anybody can squirt something into a person's vein. The fact is that many of these treatments are expensive and require insurance approval. The biggest obstacle to doing what this person is suggesting is often that the approval for the infusions by the patient's insurance was for New York City, and you can't just show up at some other cancer center and have them write the order because that center does not have the authorization for the infusion.

Getting that transfer of authorization is possible, but it requires legwork from the insurance company and from the treating doctor. If someone is not on a protocol and if they can accomplish that transfer of authorization, it's reasonable to get these treatments at a local center. I'm not entirely sure that the risks would be any different, but in New York City right now, things are pretty bad. A rural center may have a lower risk of infection, and pembrolizumab at one site or another should be pretty much the same.

**If you are on immunotherapy, are you at higher risk of getting a more severe form of COVID-19?**

That is a really good question, and one that I really don't know the answer to. It's even conceivable that the disease severity could be less if you're on immunotherapy. There's now an international consortium, which I think originated in Italy, to actually collect data on lung cancer patients undergoing various therapies. As I said, right now, you have a higher risk of dying from lung cancer than from COVID-19. I would do the best you can to treat the lung cancer, and what happens with COVID-10 will happen.

**The next question comes from a patient who used to travel to a comprehensive cancer center for their chemotherapy infusions. Can they receive their infusion at a local center, and should they be worried about changing their place of chemotherapy infusion?**

One good thing about chemotherapy now is that we've learned how to give it, and the side effects really are not all that common. Probably the most worrisome thing would be febrile neutropenia, where the patient would have to be admitted for antibiotics, for example. This can be serious, and how a hospital responds to such a patient really varies, depending upon the locality. Right now in our hospital, for example, patients aren't allowed visitors or guests. The patient would have to go into an emergency room, which is a high-risk environment for infection. They could potentially be admitted and cared for at least right now as would anyone else as they would have been in the past, but they wouldn't be allowed visitors. This is a concern, especially with a frail patient who's having serious problems. Potentially, they should discuss the precise chemotherapy regimen with their doctor. If they have a tendency to neutropenia with previous cycles, maybe the doctor could reduce the dose or stretch the intervals to reduce the risk of that happening. But really, it's uncommon in my practice that we have to admit patients for side effects. Probably the worst one is baldness from Taxol, and you don't have to be admitted for that.

**What do you tell your patients who are stressed or anxious in this time of COVID-19, and what are the stress management tips that you share?**

Lung cancer patients are stressed to begin with. When I see a new lung cancer patient, we always talk about what it means to be diagnosed with lung cancer and how that transforms your whole life in a way that you never could have predicted and affects your family and your children and everything else. So to some degree, stress and anxiety are normal responses to their diagnosis. I honestly think that it's a mistake to think that we should medicate away a normal and productive response. I try to engage their families in the discussion. I try to assure them that treatments are better now than they used to be, that the side effects are much better managed. On top of that, these patients who are hit with a diagnosis of lung cancer have to worry about COVID-19, and that is something that's out of our control. This is not something we would have wished for.

What I tell them is that it depends on the exact clinical situation, but often the risk to their livelihood, their well-being, and their life is much higher from the cancer than from the virus. We need to do

everything we can to properly treat their cancer with a minimum number of visits with a minimum exposure to staff with maximum care in the clinic per sterilization and hand washing, masks, and those kinds of things. Right now we need to focus on their cancer, and it's reasonable to be concerned about COVID-19, but assure them that all reasonable measures are being taken to minimize their exposure to the virus. In our clinic, for example, we prescreen everybody who comes into the clinic for symptoms, and we check their temperatures. If they have any symptoms or fever, they are not allowed in our clinic. We have spaced our waiting room chairs apart, we have private infusion rooms for patients, we will issue masks if they need them, and I think we've done that, and we do more sterilization procedures than we've ever done before. The real elephant in the room is their cancer, and we need to focus on that.

**What is your message of hope for our community during these times?**

Lung cancer patients now have more and better options for a good high-quality life than ever before, and patients should keep that in mind. They're hit with this terrible diagnosis, and they have news programs every hour telling them how awful the virus is, but the fact is that they still have a better outlook for their disease than they've ever had in the past. They should be hopeful that with the measures of mitigation for the virus and application of the best possible therapies, which is still possible in most centers, including ours, that they will have a good outcome from all of this and that their doctors will work with them to do their best for that to happen.