

COVID-19 Q&A
Lung Cancer and Clinical Trials
with
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LUNGeivity spoke with Stephen Liu, MD, who answered questions from the lung cancer community about COVID-19 and clinical trials from his perspective as a medical oncologist. It is important to note that the conversation took place on July 3, as issues around the COVID-19 pandemic continue to evolve.

Dr. Liu is an associate professor of Medicine at Georgetown University, where he is director of the Thoracic Oncology Program and heads the Developmental Therapeutics Program. His focus is on the treatment of lung cancer and drug development, and he helps lead many of the clinical trials at Georgetown.

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

Are you still offering clinical trials as options for your patients right now?

We are. We firmly believe that clinical trials are a critical part of proper lung cancer care. In the research field, we often think of the importance of clinical trials in somewhat grand terms. Advancing the field, answering important clinical scientific questions, and making care better for future patients, but it's important to remember that in the moment for a given patient, participation in a clinical trial really may be the best immediate option. We've made tremendous strides in rational drug development to the point that even early-stage trials can have quite a high likelihood of success.

In many cases for patients with advanced lung cancer, the standard of care simply isn't good enough. We've strived to keep trials available, although certainly we did have to make adjustments to a lot of our standard procedures in the COVID-19 era. I will say that while we have kept our trials open, there is less overall trial availability as a direct result of COVID-19.

What factors do you take into account as an oncologist when you're offering clinical trials to your patients in this COVID era?

Our strategy has been to minimize exposure risk without compromising patient care. To make some of these decisions, I really have to consider responsibilities I have to multiple parties. Our focus is always with the patient, but if there is an exposure, there are consequences I have to keep in mind to the patient's family and caregivers, to other patients on the unit, to my research team and their families, and so forth. In the face of such a contagious virus, we did not take any of these decisions lightly. We always have to consider all of the options that a given patient has.

In some cases, we may have steered away from some options in terms of trials when there wasn't appropriate standard of care available. In years past, I would generally favor clinical trial participation. However, in the current climate, when there is a very effective available option as standard treatment,

then we may steer away from trials in those settings. For the trials that we had, we really try to prioritize the trials that had the greatest chance of delivering benefit to the patients, particularly those who did not have an acceptable alternative. As it turned out for lung cancer, these were largely targeted agents for genomically defined subsets of lung cancer.

What happens if a patient who is on a clinical trial gets diagnosed with COVID-19 while they are still on the trial?

It is a concern, and it actually has happened to one of my patients, unfortunately, whose family member was ill from, we think, a nursing home facility. With all of these cases, the priority is patient safety, much less so trial protocol. The specific actions are really going to depend on the drug being used, the specific trial, and the clinical circumstances. In most cases, we would hold treatment and really focus on helping a patient through this COVID infection. If it were a mild course and the patient recovered, we can then discuss how and when to resume therapy—certainly when we feel it's safe to do so, when it's in the patient's best interest.

Cancer treatment is not an elective process. This is therapy that the patient really needs, but most of the treatments we have can be held or delayed safely for a brief period. We follow the patients very closely. Of course, this has to be remotely. We would not want to bring patients with a confirmed COVID infection into contact with other vulnerable persons or our staff, and we try to do so remotely. We provide counseling about family members and caregivers, and how to do testing and how to try to minimize risk there. Because each trial is so different, the investigators really have to openly communicate with the study sponsor for specific guidance on how to proceed safely.

I've been very impressed by sponsors, including the FDA and NCI, regarding the flexibility we have, not only to minimize risks, but also to ensure patient safety in the face of a confirmed infection. It is not generally means for discontinuation completely of therapy, but we have to modify our treatment to make sure that the patients remain safe.

The next question is related to how your clinic is accommodating patients who are considering clinical trials as part of their treatment option. Do you have special practices in place? For example, do you have social distancing going on? Do people wear masks? Is there plexiglass?

We do have a lot of measures in place. These are not unique to clinical trial participation. These are really in place for all of our patients. Social distancing in the waiting room, masks for everyone, for all persons who enter the area. If they have any symptoms, if they have a fever, they're not really permitted into the hospital as a visitor. That applies to patient and staff alike. For everyone on the unit, though, we have adjusted the physical layout of our waiting rooms and of our unit to maintain those distances because we really do think that helps minimize risks.

When we're considering clinical trials, as always, we outline the risks and benefits of trial participation, and we have to weigh it against the available alternatives. We also work with trial sponsors to explore strategies to minimize risk as much as we can. We've been able to implement a lot of new practices to try to keep that risk as low as we can.

What new practices has your institution put in place to ensure that exposure to the COVID-19 virus is minimized for patients when they are considering clinical trials?

Some of the strategies are implemented for everyone, as we've mentioned. And as many have done, we do temperature checks at the door, have mask requirements, and use physical spacing in waiting rooms and infusion units—also decontamination and cleaning processes for CT scans and MRI machines, and spacing those areas out. We've really had to rework a lot of the infrastructure for some of our basic aspects of care. We're also trying to do as many visits as we can using telemedicine. As you know with clinical trial participation, some of the procedures and blood draws that we do are more for research than for patient safety.

We're looking at every visit at every time point and asking the sponsors, "How critical are these extra blood draws?" A lot of sponsors have agreed in light of the pandemic to omit some of the blood draws that may allow decreasing visits or decreasing exposure for trials that feature oral medications, such as a lot of our targeted therapies. If we can conduct our visit remotely, we can sometimes ship drugs directly to the patients. This will minimize risk and in a way also increase access to a lot of these trials. This does vary a little by specific trial, and there are factors that we may not immediately think of. For example, we have to consider temperature regulation, particularly in the middle of summer.

If extreme heat could impact the stability of the drug, then we have to consider whether it is safe to ship that drug. If it is, how do we do so in a safe manner and quickly? We're also in early talks to discuss home phlebotomy. Some of these blood draws are critical for patient safety or for development of the drug, but if someone's coming in for a pharmacokinetic blood sample, for example, it sure would be nice to have a phlebotomist maybe travel to the patient rather than them come in. We're in early talks for that. In the future, I would imagine even home infusion for some of these drugs may be common, although there are still a lot of barriers to do that in a safe manner.

What about local clinic infusions so that patients don't have to travel to the main trial site? Is that something that you are considering?

We are. A lot of trials won't permit that now, and part of it has to do with oversight and regulation, but we're going to need to rework a lot of our standard procedures. If it's safer in everyone's best interest to have some treatments delivered locally, we may be able to find ways to work around it. The challenge really is with newer medications, investigational drugs, where the processes aren't necessarily standard. The staff we have on trial units really is highly trained to monitor, to observe, and to deal with any unexpected problems. While that isn't often the case, it's good to have that type of trained personnel. We may not have that at every local center, so we'll have to take each case individually, but I think that sponsors and investigators are becoming more and more open to that.

Is it okay for caregivers to go with patients to the trial site and wait there? Is this something that your practice is allowing right now, especially for patients who have to go through four-hour long infusions? May caregivers wait, either in the infusion area or in the waiting areas?

Policies are going to vary by institution. Things are evolving rapidly. Certainly I would say that if a caregiver is ill or has a fever, they would not be permitted in as a visitor. Assuming the patient's caregivers are well, we still think there's value in maintaining physical distancing. We do have a fairly strict visitor policy. We currently do not allow visitors into our infusion areas, but a caregiver may

accompany a patient into the waiting area and into our outpatient clinic, provided they wear a mask and observe our distancing requirements.

This really is an aspect of our safeguarding policies that's difficult for patients and for investigators as well. We don't minimize the support of a caregiver. That's really an integral part of cancer care. Right now it is hard to take some of that away, but we do think it's in everyone's best interest for now. During the infusions, unfortunately, visitors are not permitted as of now. I hope we find safe ways to do that in the near future.

Because of the pandemic, does your clinic have the same process, or do they have new protocols for handling adverse event questions after hours?

At least at Georgetown, I'm quite proud to say the process is largely the same because we've always had staff on call 24 hours a day; we rotate those responsibilities among our division. A lot of my patients have also taken to emailing me directly with updates and questions, and we really strive to make ourselves as available as we can. I think it's especially important right now, if a patient were to be hospitalized or found to be COVID-positive, that the oncology team be alerted right away. This is particularly so if patients are on trial, so that we can provide specific guidance with respect to management of the cancer things to watch out for and how to really adapt their cancer treatment.