

Update for Week of April 20, 2020 to the Joint Statement on COVID-19
From Lung Cancer Advocacy Groups

As of April 18, 2020, the Centers for Disease Control and Prevention (CDC) reports [661,712 cases of COVID-19 and 33,049 COVID-19-associated deaths](#). A recent [study](#) conducted by researchers at Stanford University suggests that this number is an underrepresentation of the total number of infected individuals. We must urge caution with interpretation of this study, which is still undergoing peer-review. Some are interpreting the findings to mean we should accelerate loosening of social distancing policies across the country. However, researchers still do not know if the presence of [antibodies](#) confers protection or how long such immunity might last. Further, in the absence of any effective therapeutics or a vaccine, local flare-ups are still a risk, as has been witnessed in [other countries](#). Social distancing is working and should be maintained for now.

In this week's update, we address the following important topics:

Role of telehealth in the era of COVID-19

1. What is telehealth?
2. How is the use of telehealth changing during the COVID-19 pandemic?
3. What are some of the barriers to broad uptake of telehealth during the current crisis?
4. How do I know if I am eligible to obtain telehealth services?

Impact of COVID-19 on lung cancer clinical trials

1. How is the FDA allowing the use of telehealth for lung cancer clinical trials?
2. If a patient is receiving their drug through a pharmacy at the clinical trial site, can they now receive the drug through home delivery without having to change the protocol?
3. If a patient is receiving a drug given through infusion, can they now receive the clinical trial treatment through home infusion?

Role of telehealth in the era of COVID-19

1. What is telehealth?

The terms “telehealth” and “telemedicine” are used interchangeably to describe using telecommunications technologies to deliver health care. It includes a variety of services that deliver health care, public health, and health education, and ranges from methods as simple as telephone calls and email to live video, mobile apps, remote patient monitoring and uploading scan images. The Center for Connected Health Policy (CCHP) provides an excellent overview of telehealth [here](#).

2. How is the use of telehealth changing during the COVID-19 pandemic?

In light of the COVID-19 pandemic, federal and state policies are rapidly adapting to allow for greater utilization of telehealth services. The Centers for Medicare & Medicaid Services (CMS) have created some useful fact sheets highlighting various policy changes, including this [one](#) summarizing Medicare telemedicine services and this [one](#) addressing

sweeping regulatory changes to meet patients' needs during this time. Private health insurance companies are also modifying their policies to enable greater use of telehealth. CCHP is maintaining an updated [list](#) of COVID-19 telehealth coverage policies.

3. What are some of the barriers to broad uptake of telehealth during the current crisis?

The challenge with adapting telehealth policies in real-time to address an unfolding and unprecedented public health crisis is that, in a pre-COVID-19 world, federal and state policies varied widely in how telehealth services were provided and covered. Most of the current challenges relate to regulatory and reimbursement issues, including licensure requirements. Even as the popularity of telehealth among patients grows, private healthcare [payers](#) have been slow to embrace the technology. The Federation of State Medical Boards is maintaining an updated [list](#) of states currently waiving telehealth licensure requirements.

The “[digital divide](#)” is also a barrier to accessing telehealth. Patients who are elderly, in areas with poor Internet or cellular coverage, or economically disadvantaged, may not be able to access the technology necessary to telehealth.

4. How do I know if I am eligible to obtain telehealth services? What can I do to ensure broader access?

Again, laws vary by state regarding how telehealth is being implemented and what health insurance companies and providers can do. **Review your health insurance plan benefits and policies frequently to learn how they may be changing.** This CCHP [list](#) of COVID-19 state actions may also be helpful.

CCHP also monitors state and federal telehealth legislation to provide a clear overview of policy across the nation. As a citizen, you can monitor [legislation](#) that has been introduced in your state and testify to show your support or opposition. You can call your legislators to ensure your needs are being heard.

For a great overview and more in-depth discussion on all of these points on telehealth, please check out GO₂ Foundation for Lung Cancer's [Rapid Response Living Room](#) from April 14, 2020, featuring Dr. Joelle Fathi.

Impact of COVID-19 on lung cancer clinical trials

The United States Food and Drug Administration(FDA) has issued [guidance](#) to clinical trial sponsors (pharmaceutical companies and government agencies), institutional review boards (IRBs), and researchers on how to adapt lung cancer clinical trials in the era of COVID-19. The FDA emphasizes that [patients' safety should be at the forefront of considerations at all times](#). Below, we answer three important questions for patients (and their caregivers).

1. How is the FDA allowing the use of telehealth for lung cancer clinical trials?

The FDA allows for changes to be made to the clinical trial protocol without prior FDA review or approval if the change is intended to protect the life and well-being of the patient. Therefore, changes in protocol conduct necessary to immediately assure patient safety, such as use of telehealth for safety monitoring instead of on-site visits, can be immediately implemented once the new protocol has been approved by an IRB. The FDA can then be subsequently notified. It is important to note that the consult is just one part of patient safety monitoring. The patient's clinical trial team and the clinical trial sponsor will also need to have a clear plan in place to ensure that patient safety is prioritized in case routine monitoring such as blood tests and heart function exams are unable to be conducted.

2. If a patient is receiving their drug through a pharmacy at the clinical trial site, can they now receive the drug through home delivery?

The FDA understands that there may be a risk of exposure to SARS-CoV-2 when a patient visits a clinical trial site. In case a patient is receiving their drug (such as a targeted therapy pill) through their clinical trial site pharmacy, the clinical trial sponsor now has the option of directly mailing the drug to the patient's home as long as the following conditions are met:

- The patient already takes the pill at home as part of the trial protocol
- The shipment of the drug to the patient's home does not affect the chemical nature of the drug
- The sponsor keeps a clear track of number of pills shipped to the patient's home and is able to share this information with the FDA when asked

3. If a patient is receiving a drug given through infusion, can they now receive the clinical trial treatment through home infusion?

This is an extremely important question for the lung cancer community --- where clinical trials often require an infusion of a chemotherapy, an immunotherapy, an angiogenesis inhibitor, or a combination of the above.

The FDA understands and appreciates that a patient may be exposed to SARS-CoV-2 when they travel to their routine clinical trial infusion center. Therefore, the FDA is open to alternative sites for administration (e.g., home nursing or alternative sites closer to a patient's home where the infusion is given by trained medical personnel who are not part of the study team). The ultimate decision to allow this switch to home infusion or local infusion is based on the following criteria:

- The shipment of the drug to the local infusion center or to the patient's home does not affect the chemical nature of the drug
- The sponsor keeps a clear track of the amount of shipped to the patient's home and is able to share this information with the FDA when asked

Another option is delaying or discontinuing infusion for a period of time while the patient continues to be on the study. This decision needs to be made jointly by the clinical trial team and the patient.

Note: The ultimate decision on whether to allow a home infusion or local infusion is highly dependent on the drug being tested. Some infusions cannot be given at a local infusion center or through home infusion. Examples include drugs that require ability to manage potential [infusion reactions](#) with specific medication, or treatments such as gene therapy or cell therapy that require exacting handling procedures and patient monitoring.

LUNgevity Foundation recently conducted an **Oncology Center of Excellence (OCE)** listening session with FDA leadership and lung cancer patients. Stay tuned for the recorded webinar that can be accessed [here](#).

Resources and websites:

1. [IASLC's Guide to COVID-19 and Lung Cancer](#)
2. The National Cancer Institute has a special website for COVID-19 and emergency preparedness. [COVID-19: What People with Cancer Should Know](#)-
3. We are following updates provided by the [World Health Organization \(WHO\)](#) and the US [Centers for Disease Control and Prevention \(CDC\)](#)
4. Johns Hopkins [COVID-19 Resource Center](#)
5. Interactive map of US COVID-19 cases by state
6. [The One-Two Punch: Cancer And COVID-19](#) (an important perspective for cancer patients)
7. You can find information specific to your state or city or town on your health department's website.
 - Directory of state department of health [websites](#)
 - Directory of local health department [websites](#)
8. **American Medical Association** [resources](#) for healthcare providers.
9. If you cannot avoid air travel, check out "[Dirtiest Places on Airplanes: How to Avoid Germs](#)"



GO2 Foundation for Lung Cancer (Amy Moore, PhD - amoore@go2foundation.org)
LUNgevity Foundation (Upal Basu Roy, PhD, MPH - ubasuroy@lungevity.org)
Lung Cancer Foundation of America (Kim Norris - KNorris@lcfamerica.org)
Lung Cancer Research Foundation (Cristina Chin, LMSW, MPH - cchin@lcrf.org)
LungCAN (Kimberly Lester - kimberly@lungcan.org)