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COVID-19 AND THE CANCER PATIENT: A CALL TO ACTION FOR BALANCING CANCER CARE AND VIRAL RISK

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Editor & Publisher

Paul Goldberg

Associate Editor

Matthew Bin Han Ong

Reporter

Alexandria Carolan

Designer

Jacqueline Ong

**Illustrator &
Operations Manager**
Katie Goldberg

Web Developer

David Koh

Editorial, Subscriptions and Customer Service

PO Box 9905 -
Washington, DC 20016

T 202-362-1809

F 202-379-1787

W www.cancerletter.com

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GUEST EDITORIAL

COVID-19 AND THE CANCER PATIENT: A CALL TO ACTION FOR BALANCING CANCER CARE AND VIRAL RISK

As COVID-19 has now officially been declared a source of the pandemic, with increasing incidence across the nation, it is without question that the needs of patients with particular vulnerabilities should garner particular attention.



By Karen E. Knudsen, MBA, PhD

*Executive vice president of oncology services, Jefferson Health;
Enterprise director, Sidney Kimmel Cancer Center;
Hillary Koprowski Professor and Chair,
Department of Cancer Biology, Thomas Jefferson University;
Chair, Cancer Biology*



By Roy Jensen, MD

*Director, The University of Kansas Cancer Center and
Kansas Masonic Cancer Research Institute;
William R. Jewell Distinguished Kansas Masonic Professor;
Professor of pathology and laboratory medicine, anatomy and cell biology, cancer biology
and molecular biosciences*

Given the specialized needs of cancer patients, it is imperative to consider how we, as the major cancer centers, may address and communicate how the impact of COVID-19 could impact the timing and delivery of cancer care, and to communicate this information to cancer patients.

At the time of writing, the catchment areas served by the cancer centers under our direction have reported 55 COVID-19 patients, some of whom have been diagnosed within our health systems. There are 50 patients in the Sidney Kimmel catchment areas in Pennsylvania and New Jersey, and five patients within KU's catchment area—Kansas and Western Missouri.

As such, discussions began centering on how our individual systems have begun to address the problem of COVID-19 in the backdrop of cancer care.

As cancer center leaders, we are responsible for delivering accurate information to our faculty and staff, and to our patients.

As the president and president-elect of the Association of American Cancer Institutes, we are pleased to announce that AACI is launching a platform for its members to share coronavirus experiences and best practices.

Details on accessing the platform will be made available to members of AACI, which comprises 100 of the leading academic and freestanding cancer research centers in North America, with the goal of sharing rapidly changing experiences and best practices for delivering cancer care in the backdrop of COVID-19.

In the spirit of sharing information, here is what the institutions we lead are doing to handle the COVID-19 cases:

The SKCC strategy

As part of a large, 14-hospital, two-state academic health system, the Sidney Kimmel Cancer Center at Jefferson Health follows enterprise guidance on limiting exposure to COVID-19.

Similar to other health care organizations, these guidelines include expanded strategies for exposure control, patient and caregiver education, domestic and international travel restrictions, remote work options, and additional measures to limit exposure across all sites of care.

Most critically, further protective procedures have been implemented with the unique needs of cancer patients in mind.

At SKCC, the cancer-focused effort is led by Dr. Neal Flomenberg, chair of the Department of Medical Oncology and a bone marrow transplant expert, in partnership with a number of key stakeholders, including Jefferson's infectious disease team, as well as collaboration with cancer leaders from the Fox Chase Cancer Center.

In alignment with overall guidance from Jefferson Health, the additional cancer-focused principles were developed for clear communication with patients and care teams.

Cancer-specific "contain and control" procedures were specifically geared toward: 1) patients undergoing active treatment, and 2) patients requiring bone marrow transplant.

For patients undergoing active treatment, the goal is to stay as close as possible to the intended treatment schedule.

Guiding principles and specialized programs for these patients are designed to:

- 1. Balance risk:** Understanding that long delays or interruptions in treatment could have significant consequences in terms of outcome, mitigating the risk of cancer progression remains the primary goal.
- 2. Limit cancer center visits for patients symptomatic for respiratory infection:** At SKCC, care teams are proactively calling patients 48 hours prior to visits, so that those with any concerning symptoms may be directed to an appropriate viral screening plan rather than presenting to the cancer center and potentially exposing patients or caregivers.
- 3. Enhance crowd-control in the Center through expanded hours:** Handwashing and crowd control is critical for reducing risk of viral infection. At SKCC, patients are encouraged to take advantage of the center's evening and weekend hours for infusion, including both Saturdays and Sundays. Receiving treatment at off-peak times has the potential to further reduce risk and exposure for vulnerable patients.
- 4. Follow-up by telehealth:** While use of telehealth visits has already been embedded in follow-up care for SKCC cancer patients, made possible through our JeffConnect Program, enhanced usage of the telemedicine program has been implemented to reduce the number of visits and resulting exposures for patients no longer on active treatment.

For patients requiring bone marrow transplant, additional consideration is merited.

Complementing the guidelines above, additional consideration was given for patients requiring bone marrow transplant.

For this class of patient, the following enhanced procedures were implemented:

- 1. Priority scheduling and proactive screening:** Given the difficulty in predicting the impact of the delay even in seemingly stable transplant patients, every effort should be made to ensure that transplants proceed as scheduled. Screening for influenza, RSV or other illnesses should be performed within seven days of admission.
- 2. Use of telehealth for pre- and post-transplant guidance.** At SKCC, telehealth communication has been enhanced for pre-transplant classes, and for post-transplant patients after discharge, again with the goal of limiting exposure.
- 3. Expanded visitor exposure limitation and guidelines:** Guidelines for BMT patients always include hand-washing, masks and gloves for anyone entering the room. During the pandemic it may be prudent to limit visitors to the rooms of BMT patients. At SKCC, visitors are limited now to 1 per day. There is also an education aspect, wherein visitors are reminded to wash both in and out of the room and to refrain from entering the center if respiratory tract or any other infectious disease symptoms are present.
- 4. Addressing special consideration for donors:** It goes without saying that for allogenic transplants, the health of both the donor and the recipient needs to be considered. Donors reporting symptoms of illness that could be consistent with COVID-19 should be tested and deferred until recovery if positive. Donors who are asymptomatic but reporting sick contact should be deferred for donation to reassess for symptoms. Travel restrictions to and from countries outside the U.S. may limit the availability of some unrelated donors and needs to be

considered in determining the best donor and transplant option for the patient. Haploidentical transplantation from a related donor should be strongly considered for these patients.

- 5. Refining care team visits:** During the pandemic, additional steps are being taken at SKCC to limit the number of individuals entering the patient’s room. For example, options include electing for a single physician to enter the room rather than the whole care team, and for transplant unit staff to carry food trays in and out of the rooms. Reducing the frequency of checking vital signs for patients who are feeling well and show no signs of neutropenia may be prudent, balanced with more frequent interviewing over the phone or intercom.

The KU strategy

The University of Kansas Cancer Center physician and administrative leadership, led by Dr. Steve Stites, executive vice president of clinical affairs and chief medical officer of The University of Kansas Health System and vice chancellor of clinical affairs at the University of Kansas Medical Center, developed precautions for COVID-19, given the unique vulnerability of cancer center patients. The cancer center leadership implemented the following measures to maximize the health and well-being of patients and care teams:

Cancer center leadership is recommending the deferral of all professionally-related domestic and/or international travel involving public transportation. Similar travel for personal reasons is strongly discouraged and is a personal judgment decision. Please consider the CDC-recommended travel precautions. Cancer center leadership is also recommending refraining from participation in any local, regional and/or national

professionally related meetings and conferences at this time. Virtual technological participation is strongly encouraged. Cancer center organized meetings and events are currently being rescheduled.

Within all cancer center locations, we are limiting patient-affiliated visitors and caregivers to one person that may accompany patients to cancer center appointments, assuming they undergo standard visitor screening. We are strongly encouraging other desired participants to use phone or other technology to participate in the appointment. New patients will be notified through cancer center nurse navigation, and patient in-clinic signage is being developed.

Non-employed personnel that are not absolutely essential for current active and specific patient care (i.e., vendors, MSL) shall not be allowed access to cancer center facilities. Access for employee and faculty candidates should be granted on a case-by-case basis, depending upon the judgment of the hiring supervisor or department/division chair, respectively. In-clinic signage is being developed.

Employees have been instructed that if they are feeling ill, they are to contact their health care provider and to stay home.

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Patient communication

Cancer center protocol for patients calling with symptoms:

- Calls and MyChart inquiries should be directed to the patient’s cancer center care team
- Nursing clinical assessment to include the coronavirus screening questions
 - ▶ Discuss assessment with physician or APP
 - ▶ If appropriate, schedule physician /APP appointment to address symptoms

- ▶ Follow health system protocols at arrival for screening and donning of face mask if patient acknowledges communicable symptoms.
- ▶ For more information, patients should be directed to information on the [health system website](#).

Ambulatory screening protocol at registration/arrival

Screening:

- Ask every patient to review the travel screening sign at the front desk and ask the patient, "Do you have any of the following symptoms including fever, cough, and difficulty breathing?"
- "Have you traveled internationally in the last month or had close contact with a person under investigation for COVID-19?"

Isolate—if the patient answers yes to these questions:

- Ask the patient to don a surgical mask (available at the front desk).
- Call/page your clinic or nurse manager (the manager will then isolate the patient in the designated room and call the health system infection prevention and control team).

Talking points to be used if patients ask whether it's safe to come for their appointment, or with other questions:

Q: Am I safe if I keep my appointment?

Yes, it is safe to be here. Our care team is following all recommended protocols from the Centers for Disease Control and Prevention. Our primary goals are to ensure the safety of everyone and to continue serving you with the best care.

Q: What are we doing to make sure the disease does not spread?

We have processes, supplies and areas of our facility that are designed to prevent the spread of the virus to other patients, visitors, staff and physicians. Our expert clinicians regularly care for patients with severe respiratory illnesses and other infectious diseases. They are well trained and follow specific procedures using equipment, tools and techniques in place to protect themselves and patients.

Q: Can I reschedule?

We want to assure you it is safe to be here. Although it is better for your health to proceed with your scheduled visit, if you are uncomfortable with keeping the appointment we can help you reschedule. We will likely consult with your physician or clinical professional to ensure your health is not compromised if you reschedule.

Q: Where is a trusted resource for information about this virus in the United States and Kansas or Missouri?

We highly recommend the websites for the Centers for Disease Control as well as the Kansas Department of Health and Environment. You can find links on our website kansashealthsystem.com.

Q: What should I do if I think I have been exposed to the virus and have symptoms of an upper respiratory infection?

Please call your physician's office and let them know ahead of your scheduled appointment time or ahead of an urgent care visit.

Talking points if employees are worried about their safety:

Q: Can I decline to see a patient with suspected or known COVID-19?

It is safe to see patients while wearing proper protective gear. We see highly infectious patients every day (influenza, TB, measles, etc.). **The expectation is that our medical professionals will not refuse to see any health system patient.** If individual departments, divisions or service lines would like to prioritize who of their specialty sees patients, that's perfectly acceptable. In an effort to preserve resources, residents and students should not routinely be seeing these patients unless there is an urgent medical or procedural need. **It is important to note that at the hospitals located in the epicenter of the outbreak in Washington state, there has been no known patient-to-patient or patient-to-provider transmission.**

Q: Testing is becoming more widely available. Who should get tested?

With this anticipated increase in availability of testing, we are aware there will be questions about clinical guidelines for appropriate testing. We will be sharing an internal testing guideline early tomorrow. A few important points: an order will be required for testing, and we will limit collection at our sites to those with an order from one of our health system providers. We will not collect specimens for orders from other systems or offices.

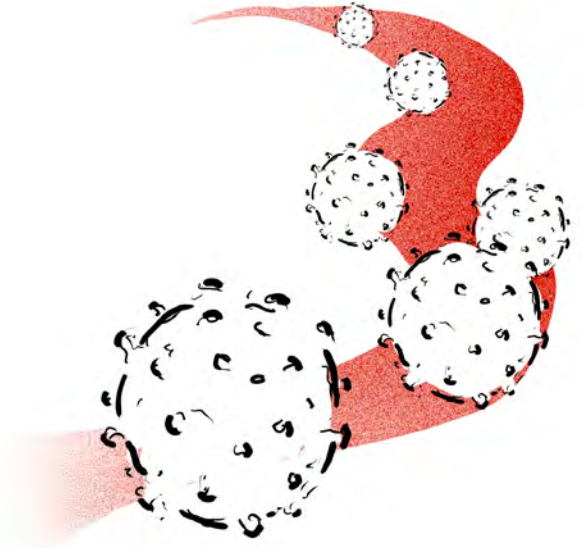
Q: Do I need to wear a PAPR for every patient with a cough?

We know that SARS-CoV-2 is likely transmitted like other coronaviruses—by droplets. We are continuing to place known or suspected patients on airborne and droplet precautions including PAPR, gowns and gloves where available (which is an abundance-of-caution recommendation). **The CDC changed their guidelines and now recommend if airborne precautions are not available it is safe to assess/treat patients wearing surgical masks, eye or face shields, gloves and gown.**

Pandemic: Bracing for coronavirus surge

By Alexandria Carolan and Matthew Ong

The COVID-19 pandemic will affect every aspect of cancer care and cancer research.



- Cancer centers in the United States are racing to protect patients most vulnerable to the expected surge—elderly cancer patients and those with suppressed immune systems.
- Many worry that the pandemic will confound clinical trials, too, potentially affecting drug approvals for years to come.
- In preparation, centers are instituting travel bans and work from home policies, and professional societies are re-scheduling or cancelling annual meetings. The 2020 annual meeting of the American Association for Cancer Research was postponed, and the American Society of Clinical Oncology is weighing a digital annual meeting instead. *The Cancer Letter's* running list of cancelled meetings appears [here](#).

To gauge the impact of COVID-19 on oncology, *The Cancer Letter* spoke with leaders at Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center, MD Anderson Cancer Center, University of California, Los Angeles, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, the University of Kansas Cancer Center, and Sidney Kimmel Cancer Center at Thomas Jefferson University.

Their responses appear on [page 15](#).

In Washington state, hit hardest—with 420 cases and 31 deaths at this writing—the Seattle Cancer Care Alliance and Fred Hutch faced the landfall of the pandemic.

“Seattle Cancer Care Alliance has had to make the very difficult decision to reschedule non-essential patient visits for the time being out of concern for our patients’ health—and to make sure that we are well-positioned to care for our patients in active treatment and prepare as the number of COVID-19 cases in

our area continues to grow,” said Steve Pergam, medical director of Infection Prevention at Seattle Cancer Care Alliance and clinical and infectious disease researcher at Fred Hutch.

NCI Director Ned Sharpless said the institute is developing strategies for minimizing disruption to clinical trials as well as preparing contingency plans for safeguarding its workforce.

“We believe we will be able to do the things that we really need to do, like support clinical trials externally or provide grants to extramural awardees, or even keep intramural activities going, to the extent possible,” Sharpless said in a March 12 meeting of the NCI Clinical Trials Advisory Committee. “I want to assure you that we are prepared. And we have given thought to how to deal with the impact of the coronavirus epidemic on clinical trials.

“We’ve been discussing how clinical trials, in particular, could be affected by, say, decreased ability of patients to get

MEETING CANCELLATIONS, POSTPONEMENTS, CHANGES: AN UP-TO-DATE LIST OF ONCOLOGY CONFERENCES

Status	Meeting	Details
Postponed	Flatiron Health research summit	March 10-12, Washington, DC. New date TBA
Canceled	Healthcare Information and Management Systems Society	March 9-13, Orlando, FL
Virtual	ENETS Conference for the Diagnosis and Treatment of Neuroendocrine Tumor Disease	March 11-13.
Postponed	European Association of Radiology	March 11-15, Vienna. Rescheduled to July 15-19
Canceled	AACR-Prostate Cancer Advances	March 12-15, Denver, CO
Canceled	National Association of Community Health Centers	March 16-19, Washington, DC
Canceled	Children's Oncology Group Spring Meeting	March 17-20, Chicago, IL
Postponed	European Breast Cancer Conference	March 18-20, Barcelona, Spain. Postponed to Sept. 30–Oct. 2
Canceled	St. Gallen International Gastrointestinal Cancer Conference	March 19-21, St. Gallen, Switzerland
Postponed	The National Comprehensive Cancer Network	March 19-22, Orlando, FL. New date TBA
Postponed	European Association of Urology	March 20-24, Amsterdam. Postponed to July 2020
Postponed	1st Translational Research Conference: Chronic Lymphocytic Leukaemia	March 20-22, Paris, France. Postponed to Nov. 17-19
Virtual	American Society of Preventive Oncology annual meeting	March 22-24, Tucson, AZ
Canceled	AMIA Informatics Summit	March 23-26, Houston, TX
Canceled	The International Papillomavirus Conference	March 23-27, Barcelona, Spain
Postponed	The First International Summit on Interventional Pharmacoeconomics	March 25-27, Tel Aviv, Israel. New date TBA
Postponed	The Society of Surgical Oncology meeting	March 25-28 in Boston, MA. Postponed to Aug. 17-20
Postponed	Journées Francophones d'Hépatogastroentérologie et d'Oncologie Digestive	March 26-29, Paris, France. Postponed to June 25-28
Canceled	Society for Healthcare Epidemiology of America	March 26-30, Atlanta, GA
Canceled	Society of Gynecologic Oncology 2020 Annual Meeting on Women's Cancer	March 28-31, Toronto, Ontario
Canceled	Society of Interventional Radiology	March 28-April 2, Seattle, WA
Virtual	Cholangiocarcinoma Foundation annual conference	April 1-3, Salt Lake City, UT
Postponed	Summit on National and Global Cancer Health Disparity	April 3-4, Seattle, WA. Postponed to Fall 2020.
Canceled	Roche Tissue Diagnostics Tucson Symposium	April 21-22, Tucson, AZ
Canceled	SWOG spring meeting	April 22-25, San Francisco, CA
Canceled	American College of Physicians Internal Medicine Meeting	April 23-25, Los Angeles, CA
Postponed	AACR Annual Meeting	April 24-29, San Diego, CA. New date TBA
Virtual	ECOG-ACRIN Cancer Research Group's Spring 2020 Group Meeting	April 29–May 1 in Baltimore, MD
Canceled	Oncology Nursing Society (ONS) Congress	April 29-May 3, San Antonio, TX
Postponed	MD Anderson Multidisciplinary Therapy of Pancreas Cancer symposium	May 8-9, Houston, TX. New date TBA

This list is current as of March 12. For the most up-to-date list, [click here](#).

to treatment or infusion centers in the community, for example.”

Based on previous, more limited, emergency situations, NCI anticipates that there will be “disruptions in the continuity of care for patients currently enrolled on clinical trials as well as decreased accrual to trials as health care providers try to ensure appropriate care for their patients,” Margaret Mooney, acting associate director of the Cancer Therapy Evaluation Program, chief of the Clinical Investigations Branch in CTEP in NCI’s Division of Cancer Treatment and Diagnosis, said to *The Cancer Letter*.



We believe we will be able to fully do the things that we really need to do, like support clinical trials externally, or provide grants to extramural fundees, or even keep intramural activities going, to the extent possible.



— Ned Sharpless

“This is a far more challenging situation in that it spans the entire country, older adults and those with serious underlying medical conditions are at higher risk of getting sick from the illness, and we do not know how COVID-19 outbreak will evolve or the extent of the stress it will be put on the health care system and the families, caregivers, and com-

munities that support cancer patients,” Mooney said.

FDA has postponed all foreign inspections not determined to be critical, a move that could potentially delay drug approvals and other regulatory functions.

The novel coronavirus will be deadly for many cancer patients. Patients with blood malignancies are at particularly high risk.

“Many of our therapies compromise the immune system, and particularly in the blood cancers—where it’s the immune system itself and parts of it that are cancerous,” said Joseph McGuirk, professor of medicine, Schutte-Speas Professor of Hematology-Oncology, director of the Division of Hematologic Malignancies and Cellular Therapeutics, and medical director of the Blood and Marrow Transplant Program at The University of Kansas Cancer Center.

“We suppress the immune system on purpose, and that sets our patients up for risk for infections—including [COVID19],” McGuirk said during a Facebook Live event on the subject March 11.

Older patients, bone marrow transplant recipients, and solid tumor patients who actively or have recently received chemotherapy should adhere to the same guidelines provided by CDC for the general public—avoid touching areas of the face, practice social distancing, washing hands thoroughly and often, avoiding coming into contact with high-touch public surfaces, said Dana Hawkinson, medical director for infection prevention and control, The University of Kansas Health System, and an assistant professor specializing in infectious diseases at University of Kansas Medical Center.

Canceling follow-up appointments isn’t on the table yet, Hawkinson said. “Individually, I would say, continue to be vigilant, talk with your provider, get

good guidance. And by all means, if it’s safe and you’ve talked with your provider, please come in to your clinic visit—because missing a clinic visit could be even worse.”

The transcript of McGuirk’s conversation with Hawkinson and KU Cancer Center Director Roy Jensen appears on [page 25](#).

A guest editorial by Karen Knudsen, executive vice president of Oncology Services at Jefferson Health, enterprise director at Sidney Kimmel Cancer Center at Jefferson, Thomas Jefferson University, and chair & Hilary Koprowski Endowed Professor in the Department of Cancer Biology, and Jensen appears on [page 4](#). Jensen is president of the Association of American Cancer Institutes and Knudsen is president-elect.

“Given the specialized needs of cancer patients, it is imperative to consider how we as the major cancer centers may address and communicate how the impact of COVID-19 may impact the timing and delivery of cancer care, and to communicate this information to cancer patients,” Knudsen and Jensen wrote.

Today, Italy has the greatest number of COVID-19 cases outside China, and if the situation in Italy’s cancer centers today is indicative of what’s about to happen in the U.S., extreme concern would be justified. In Italy, more than 10,000 people have tested positive for COVID-19 and more than 1,000 have died. The country is on a travel lockdown.

“What are we doing in Italy in order to reduce the risk of our patients? We stopped follow-up visits,” said Giuseppe Curigliano, associate professor of Medical Oncology at University of Milano and the head of the Division of Early Drug Development at European Institute of Oncology, Italy, who is based in the Lombardy region—the epicenter of the outbreak. “Any patients that were supposed to visit our comprehensive

cancer center for follow up, we decided to stop the visits. We decided to give priority to patients with active disease over patients who are treated in the curative setting.”

Italy has 4.1 MDs per 1,000 people, and 2.4 hospital beds per 1,000 people. By comparison, the U.S. has about half that—2.6 MDs per 1,000 people, and 2.9 beds per 1,000 people, according to data from [The World Bank](#).

“The more you’re high at risk, like our cancer patients, the more probability you have of dying. There is a high fatality rate in cancer patients,” Curigliano said.

Faculty and staff at the European Institute of Oncology in Milan check in with patients one day before their scheduled visit. Do they have a cough, fever, or a runny nose?

“They can come directly to the hospital only if they have no symptoms related to coronavirus,” Curigliano said. “Once they arrive in the hospital, there is a checkpoint, external to the hospital, where temperature is measured and an exam is done. If everything is OK, they come directly into the hospital.”

In China, Curigliano estimated that 5% of patients who tested positive for COVID-19 have cancer—data that’s not yet available in Italy.

“It’s like being in a war or under a terrorist attack, when usually 15% of people go in intensive care. This is exactly the atmosphere that we are living in,” Curigliano said. “It’s a complete lockdown. Universities are closed, schools are closed, any other activity that is not a hospital, a food market, or a pharmacy is closed.”

Curigliano’s conversation with *The Cancer Letter* appears on [page 21](#).

At least 33 states and the District of Columbia have declared a state of emer-

gency at this writing. Nearly 1,800 people in the U.S. have tested positive for coronavirus, and 41 have died.

Aggressive respiratory viruses are always a danger to cancer patients, KU’S McGuirk said. “It’s always critically important that we know about that, and we can guide our patients in terms of coming in, taking special precautions,” he said. “For example, and coming to clinic to minimize exposure to others—regardless of what type of virus it is—and then isolating those patients as soon as they come in so that we can investigate what’s going on with them.”

AACI is launching a platform for its members to share coronavirus experiences and best practices, Knudsen and Jensen wrote.

“As cancer center leaders, we are responsible for delivering accurate information to our faculty and staff, and to our patients,” they wrote.

NCI: The list of items is enormous

NCI has set up a task force to prepare contingency plans for the institute. Also, the NCI Clinical Trials Advisory Committee is expected to issue a guidance for adapting clinical trials to the outbreak to ensure that NCI’s networks can be flexible enough to cope with issues of patient access, while minimizing protocol deviations that could present problems during the auditing phase of the trials.

“Our goal is to help physician and health-care providers address some of the current challenges in providing care to patients enrolled on NCTN and NCORP clinical trials,” CTEP’s Mooney said. “We are looking at changes we can make in our usual procedures such as allowing sites to ship oral investigational agents to patients directly, instead of requiring

patients to come to the site given travel restrictions during this period, extending use of local healthcare providers for routine study follow-up visits, and if needed and feasible, helping transfer patient care to other participating sites in the NCTN/NCORP network.



Continue to be vigilant, talk with your provider, get good guidance. And by all means, if it’s safe and you’ve talked with your provider, please come in to your clinic visit—because missing a clinic visit could be even worse.



– Dana Hawkinson

“We will continue to monitor closely the trials being conducted across the network with the NCTN Groups and NCORP Research Bases and their investigators to see if there are additional accommodations that can be made to help maintain continuity of care for patients on clinical trials as much as possible in this challenging situation.

“The recommendations provided by the CDC and other public health experts to mitigate risks to people at high risk are the best guide currently on how to protect patients. As more information becomes available on mitigation strategies from physicians directly caring for cancer patients, that information will be able to be shared broadly in the oncology community.”

Following are remarks from NCI Director Ned Sharpless, addressing CTAC members at a meeting March 12:

I would say a word about the ongoing impact of the coronavirus planning on the National Cancer Institute. As you can imagine, NCI is a large federal agency with lots of employees and contractors and a really important mission. The continuance of operations towards that mission is of utmost priority to the NCI and the American public. So, we've done a lot of planning around how we can continue to carry out our mission should this epidemic continue.

We believe we will be able to do the things that we really need to do, like support clinical trials externally or provide grants to extramural awardees, or even keep intramural activities going, to the extent possible. I want to assure you that we are prepared. And we have given thought to how to deal with the impact of the coronavirus epidemic on clinical trials.

The operational challenges provided by COVID-19 are significant, and, working closely with the NIH, we have instituted a number of measures to try and get a handle on this proactively. The NCI has set up a task force that meets daily to discuss topics like our teleworking policy, school closings, as well as what will happen to the intramural program in terms of feeding cells and animal care, should there be limited access to campus.

First, as for contingency planning, one of the things we talked about, is that we have a large workforce

and a number of contractors whose safety and ability to work are our utmost priorities. I think one of the areas where I'm more optimistic is in our ability to issue grants, even under fairly difficult circumstances, so I expect that we will be able to continue operations of disbursing funds to extramural grantees, even should the situation at NIH become significantly worse than it is today.

Right now, we're limiting meetings and limiting travel, limiting group sizes. Work is, to date, not dramatically affected, although we are considering contingencies where necessary.

Second, we are also very much interested in what cancer patients should do who are undergoing therapy at this time. This is the reason for planning discussions with ASCO and other similar organizations about how we can provide useful advice during this time, in this fast-moving situation where data are somewhat unclear as to how to handle this situation, as a clinical matter, for the benefit of patients.

And lastly, we've been discussing how clinical trials, in particular, could be affected by, say, decreased ability of patients to get to treatment or infusion centers in the community, for example.

So, the list of items that we have to think about and plan for is enormous. As you can imagine, patient safety is our top priority. The ability to do clinical trials in a way that decreases patients' need to travel as well as their exposure, and allows for good clinical trials practice, is what we're working on

Meeting cancellations, travel restrictions

Dozens of organizations in oncology have postponed or canceled annual meetings to prevent spread of the virus, and a Biogen conference in Boston Feb. 29 has proven to cause upwards of 70 cases of coronavirus in the U.S.

Whether meetings in oncology will take place is mostly no longer a question. They will likely not happen as scheduled (*The Cancer Letter*, [March 4, 2019](#)).

The American Association for Cancer Research postponed its annual meeting April 24-29 until later this year, and the American Society of Clinical Oncology has said it's considering a digital format for its May annual meeting.

"If the meeting is moved to a digital format, ASCO will be able to offer a rich program online, with tools that allow attendees to connect and participate," ASCO said in a statement. "A final decision on the meeting format will be made by the end of April if not sooner to allow participants adequate time to adjust their plans."

The Cancer Letter is tracking canceled meetings in oncology, travel advisories, and confirmed cases in the U.S., [here](#).

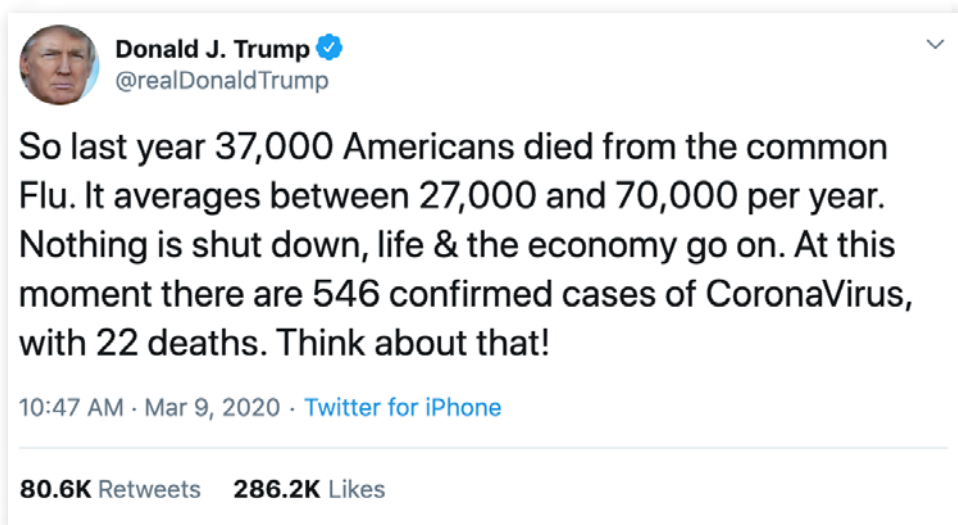
Numerous cancer centers in the U.S. have instituted work from home policies and travel restrictions.

Cary Gross, professor of medicine and of epidemiology, founder and director of Cancer Outcomes Public Policy and Effectiveness Research Center at Yale School of Medicine; and director of Adult Primary Care Center, Quality Improvement; chair and director of the National Clinician Scholars Program, began a crowdsourcing document of [institutions with travel restrictions](#).

Testing still inadequate

The mortality rate for COVID-19, at about 2% to 4%, is much higher compared with the seasonal flu, which generally has below a .1% mortality rate, according to the [World Health Organization](#). The basic reproduction number (Ro) for the novel coronavirus is also nearly double that of the flu.

On March 11, the WHO declared COVID-19 a pandemic. On the same day, President Trump instituted a travel ban for Europe (excluding the United Kingdom). However, his tweets about the virus have understated the threat.



On March 12, Vice President Mike Pence—responding to a loss of 11 years of stock gains stemming from investors bailing due to the rapid uptick in U.S. cases and lack of an early national containment and response plan—is now saying there has been “irresponsible rhetoric” from those who have downplayed the seriousness of coronavirus.

Trump and Pence have reportedly been exposed to the virus but refused testing.

“Both the President and Vice President had almost no interactions with the individual who tested positive and do not require being tested at this time,” the White House said in a statement March 12.

Testing for the virus in the U.S. has been slower than in other countries. CDC has tested 3,791 specimens, and public health laboratories have tested 7,288 specimens as of March 11, according to [CDC](#).

“The system is not really geared to what we need right now, what you are asking for. That is a failing,” Anthony Fauci, director of the National Institute of Al-

lergy and Infectious Diseases, told the House Oversight and Reform Committee March 11 at a hearing on the nation’s preparedness for the outbreak. “The idea of anybody getting it easily the way people in other countries are doing it, we’re not set up for that. Do I think we should be? Yes. But we’re not.”

Former FDA Commissioner Scott Gottlieb surmised that there are two paths the U.S. can follow to mitigate

COVID-19: That of South Korea, which has been largely successful in containing the virus and has tested more than 100,000 specimens, and that of Italy—which has upwards of 10,000 cases that grow by the day.

“We probably lost chance to have an outcome like South Korea,” Gottlieb wrote in a [tweet](#) March 12.

CDC can produce between 300 and 350 tests a day, CDC director Robert Redfield said at the hearing. Private labs LabCorp and Quest have the capacity to test at a large scale—more so than public labs, Redfield and Fauci said.

Some have called for academic health centers to take the lead. Cleveland Clinic has developed its own test that gives results within eight hours, rather than the 2-3 days it can take for other tests to show a result, according to [reports](#).

Health care workers at M Health Fairview, of Minnesota Medical Center, MN, have begun offering curbside COVID-19 testing outside their facilities, according to [reports](#).

“It starts with aggressive screening to get people diagnosed,” Gottlieb wrote. “While testing capacity expands, it’s not evenly distributed to places most needed, we’re far behind current case-loads. Too many people still can’t get screened. So, we can’t identify clusters and isolate disease.”

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Pergam, Pisters, Platanius spoke
with Alexandria Carolan, a
reporter with The Cancer Letter.

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CONVERSATION WITH
THE CANCER LETTER

Is your cancer center ready for COVID-19?

The Cancer Letter spoke with leaders at Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center MD Anderson Cancer Center, University of California, Los Angeles, and Robert H. Lurie Comprehensive Cancer Center of Northwestern University to gauge the impact of coronavirus.



Steve Pergam

*Medical director, Infection Prevention at Seattle Cancer Care Alliance
Clinical and infectious disease researcher at the Fred Hutchinson Cancer Research Center*



Peter WT Pisters

President, MD Anderson Cancer Center



Leonidas Platanias

Director, Northwestern's Robert H. Lurie Comprehensive Cancer Center

“We don’t want to be alarmist, but we do want to be truthful. The truth is that all cancer patients should be concerned about COVID-19 because they are at higher risk,” said Steve Pergam, medical director of Infection Prevention at Seattle Cancer Care Alliance and clinical and infectious disease researcher at Fred Hutch, which does not provide patient care on its campus. “We are taking numerous precautions, such as screening all patients, staff and providers for respiratory symptoms (including runny nose, congestion, fever or shortness of breath) upon arrival at the clinic.”

Washington state has 420 confirmed cases of COVID-19 and 31 deaths—the highest of any state.

“With a virus that is unpredictable and rapidly changing, we must do everything we can to keep our patients safe,” said Peter WT Pisters, president of MD Anderson Cancer Center. “We also have a responsibility to advise on other proactive measures that can be taken at a community level to slow down the spread of the disease within our community and across the nation.”

Even now, patients are worried about coming in for their regular clinical care.

“We hear concerns from patients, and we are working hard to minimize their time spent in hospital facilities,” Leonidas C. Platanius, director of Northwestern’s Robert H. Lurie Comprehensive Cancer Center, said to *The Cancer Letter*. “We are being proactive and have in place new procedures specifically addressing COVID-19 issues. For instance, patients calling for an appointment are being screened for fever, cough and recent international travel.”

Patients at Lurie Comprehensive Cancer Center are screened for coronavirus prior to their appointments. There’s a COVID-19 nurse hotline, and a specific COVID-19 response team.

Illinois has 25 confirmed COVID-19 cases and no deaths.

“Our caregivers are being asked to remain vigilant with infectious disease protocols—evaluate symptoms, take travel history, and contact the emerging infectious disease team regarding any potential COVID-19 cases,” a spokesperson for UCLA Health said to *The Cancer Letter*. “If a patient meets criteria for testing established by the CDC, biological samples are taken to determine an accurate diagnosis.”

California, has more than 200 cases and four deaths.

“Staff caring for patients suspected of carrying any contagious disease take all appropriate precautions to contain transmission,” the UCLA spokesperson said. “Our overriding priority at all times is to provide high-quality patient care while ensuring employee safety at all UCLA Health hospitals and clinics.”

Cancer center leaders spoke with Alexandria Carolan, a reporter with *The Cancer Letter*.

Alexandria Carolan: How are cancer patients affected by this outbreak? Are they disproportionately at risk because they require more consistent care?

Steve Pergam (Seattle Cancer Care Alliance/Fred Hutch): We don’t want to be alarmist, but we do want to be truthful. The truth is that all cancer patients should be concerned about COVID-19, because they are at higher risk. Bone marrow transplant patients and those with blood malignancies such as non-Hodgkin lymphoma, chronic lymphocytic leukemia, acute myeloid leukemia, acute lymphoblastic leukemia and multiple myeloma are at even

greater risk because their immune systems are most compromised. Any cancer patient in active treatment—this includes surgery, radiation, chemotherapy and/or immunotherapy—is also considered high-risk. And cancer patients who are over 70 face an elevated risk due to their age.

Peter WT Pisters (MD Anderson): Ensuring the safety of our patients and the health of our workforce members remains our highest priorities during this pandemic. Research shows that patients currently receiving cancer treatment, cancer survivors, older patients, and those with weakened immune systems or serious medical conditions are uniquely vulnerable to the 2019 novel coronavirus disease (COVID-19). Because of these factors, we have an even greater obligation to implement proactive efforts that go above and beyond CDC guidelines in order to protect our patients and employees.

Leonidas Platanius (Lurie Comprehensive Cancer Center): Many of our patients with cancer are at higher risk in terms of morbidity and mortality than the general population due to the treatments they receive, including chemotherapy and radiation therapy. Patients with hematological malignancies who receive intensive chemotherapy or patients undergoing stem cell transplant are particularly high-risk groups. In addition, patients undergoing cancer treatment are at higher risk for exposure to the virus because they have to travel to and from the facility to get their care, interact with a large team of health care providers when on-site, and visit facilities where patients with COVID-19 are also receiving care.

How do you communicate with cancer patients about this outbreak?

SP: It is our job to be open and transparent with our patients about COVID-19 and the impact it has on our patient community. At Seattle Cancer Care Alliance, we have a dedicated [webpage](#), which has become a repository of patient-facing communications. There, patients will find our most up-to-date information related to COVID-19 and the measures we're taking to ensure the health and safety of our patient community. We have protocols and systems in place to keep all patients, visitors and healthcare workers safe. We have also established a nurse triage line for patients to call with their COVID-19-related concerns. We are asking patients to call that line in advance of their appointments if they are experiencing symptoms related to the virus. Our trained nurses will provide guidance about whether the patient needs to reschedule or cancel their appointment.

PP: As an institution, we are committed to providing frequent and transparent communications so that our patients and workforce members have up-to-date, factual information about this rapidly evolving outbreak. A [dedicated page](#) on our external website explains the proactive measures MD Anderson is taking to prevent the introduction or spread of COVID-19 at any of our campuses. These same messages are shared across MD Anderson's social media channels and my own Twitter account (@ppisters), through patient portal notices directly to patients, and with our care teams and staff through daily emails and alerts.

At MD Anderson, we believe communication is everyone's responsibility, and I take my role as "Communicator in Chief" seriously. With information evolving daily, it is important to separate facts from fear. I have started a [series of short videos](#), available on MD Anderson's [YouTube channel](#), to inform all of our stakeholders about MD Anderson's plans to protect our patients, workforce and community. Key precautions, including

enhanced screening protocols and visitor limitations, also are highlighted in multiple languages on signage throughout our campuses.

LP: We have a website specifically dedicated to providing COVID-19 information and answers to frequently asked questions. We have also set up a COVID-19 hotline. Of course, our physicians and nurses also spend time with our patients and their families directly addressing their questions.

Have patients expressed concerns about coming in, because they don't want to be exposed to the virus?

SP: We have had patients express their concerns and, as always, planning and preparedness are essential to maintaining our high levels of care as we navigate this pandemic. Seattle Cancer Care Alliance has an extensive infection prevention protocol in place to prevent the spread of illness among patients and staff. We are taking numerous precautions, such as screening all patients, staff and providers for respiratory symptoms (including runny nose, congestion, fever or shortness of breath) upon arrival at the clinic. We are also continuing routine cleaning of high-touch surfaces such as door handles and elevator buttons and using disinfectants that are effective at killing COVID-19. We have a responsibility to the community to continue to provide top-notch cancer care, and we take that responsibility very seriously.

PP: Many patients and their caregivers have questions and concerns about COVID-19, including questions about the risk of travel. We understand these concerns and recommend patients follow the advice of their care teams and guidance from CDC. We ask that patients

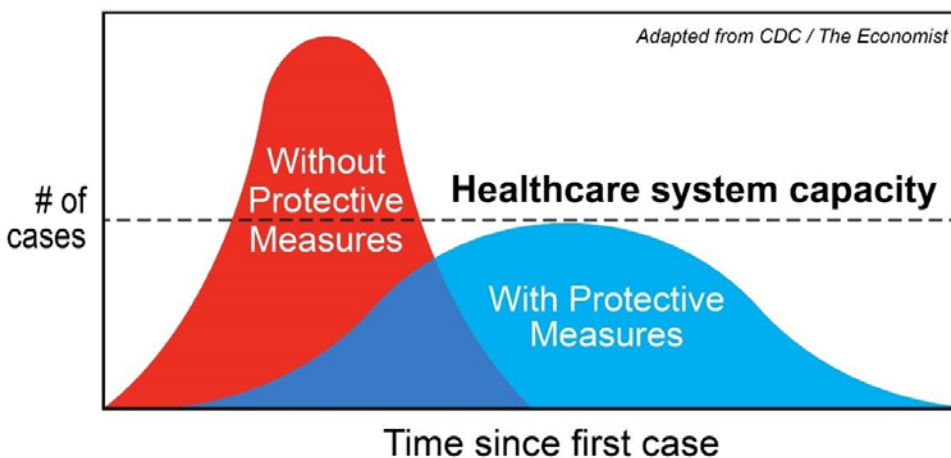
who need to fly to Houston contact their care team first. We are making recommendations on a patient-by-patient basis, considering treatment timeline, type of treatment or appointment, patient age, other health conditions and any current symptoms or side effects. We are also encouraging everyone to take everyday preventive actions to stop the spread of respiratory infections by washing their hands often for at least 20 seconds, avoiding touching their face and reconsidering participation at crowded events.

LP: Yes, we hear concerns from patients, and we are working hard to minimize their time spent in hospital facilities. To minimize potential COVID-19 exposure, we are being proactive and have in place new procedures specifically addressing COVID-19 issues. For instance, patients calling for an appointment are being screened for fever, cough and recent international travel. Depending on the answers to the screening questions, they are being triaged to a COVID-19 nurse hotline or are scheduled for their visit with instructions to wear a mask and take other precautions, if necessary. We also have established a COVID-19 response team that is activated if any patient arrives after failing the screening questions. In this case, the patient and their companions are given masks and brought to the closest negative airflow room for further assessment. We work closely with the Northwestern Medicine Infection Prevention team on these measures.

Does leadership foresee a surge of patients coming in for emergency care and taking up beds, potentially even disrupting the regular care of cancer patients?

SP: As an outpatient clinic, Seattle Cancer Care Alliance is not equipped to serve patients who need emergency care. This is a fluid, everchanging situation and our leadership has certainly had discussions about the potential for this. That said, we are operating as normally as possible and continuing to care for those patients who are in active treatment.

PP: We know health care systems that put diligent protective measures in place early in the course of an epidemic are more successful in containing infection and ensuring that the system has the capacity to serve patients if severe cases arise. In public health, this concept is known as “flattening the curve” (see graph). We actively are collaborating with health systems leaders in our region as well as city, county and state officials to take proactive measures now to help protect against a scenario where regular care is disrupted.



LP: Yes, we expect a surge of patients and are working closely with others across the health system to develop contingency plans designed to minimize any impact on patients who need cancer treatment. We have particular concern about the availability of ICU beds and respirators that may be needed. This is important, because if the system is overwhelmed, it will affect patients

who need intensive care management for cancer. Plans are being developed and space identified for additional respirators and intensive care equipment if necessary in the near future.

Are there concerns about disruptions to drug supply?

SP: Drug shortages have not been a serious concern for our organization yet. Our main concern now is maintaining a reliable supply of cleaning products, masks and other personal protective equipment, all of which are key to prevent the spread of the virus among our patients and staff.

Our leadership is also paying close attention to blood supplies. As people adopt social distancing practices, we are

noticing a drop in blood donations. We are encouraging people who can to donate blood so we can avoid a shortage.

PP: Our leadership team is proactively working to ensure we have the necessary supplies, equipment and training in place to prevent the spread of infection and to continue patient care without interruption. We are monitoring the situation

closely and are not currently concerned about disruptions to the drug supply.

LP: Yes, there are concerns, especially as a significant number of drugs come from China. For instance, 80% of the U.S. antibiotic supply is made in China, and there may be disruptions because of the intensity of COVID-19 there. Working closely with the Northwestern Medicine health system and our hospital pharmacy, we have a plan in place to ensure that all important medications for the treatment of cancer will continue to be available.

Has your cancer center updated its staff and faculty policies because of coronavirus? I mean, for travel, work from home, etc.

SP: Seattle Cancer Care Alliance has had to make the very difficult decision to reschedule non-essential patient visits for the time being out of concern for our patients' health—and to make sure that we are well-positioned to care for our patients in active treatment and prepare as the number of COVID-19 cases in our area continues to grow.

PP: MD Anderson already has restrictions in place for all employee business travel, domestic and international, through April 29. We have also asked employees to refrain from personal travel to areas with a Level 2 and Level 3 travel advisory based on federal guidelines. As an additional precaution, our Information Security team developed a COVID-19 Travel Registry (CTR) aimed at preventing the introduction or spread of the novel coronavirus at any of our campuses. With the CTR, employees have the opportunity to share details of recent personal travel, as well as the travel of their household members, with our Office of Employee Health and Wellbeing. All of the information is confidential.

Additionally, we have empowered and encouraged our workforce to utilize Skype, WebEx and other remote participation tools to conduct meetings, when possible. These technologies still allow for engaging discussion during events like institutional and external grand rounds, as I experienced firsthand when leading a virtual lecture with Harvard School of Public Health this week. In the near future, some employees will be asked to work from home and some will be redeployed to help carry out operations on campus. We have chosen to go above and beyond CDC-recommended guidelines from the beginning and we will continue to closely monitor this pandemic.

LP: Yes. All business travel outside of our state is banned by Northwestern



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– Steve Pergam

Medicine, and we advise our faculty and staff to minimize their personal travel as well. We have also cancelled all Cancer Center seminars and grand rounds. Yesterday, we announced that the monthly meetings for the different Cancer Center Support Grant programs will no longer take place in person; we will be conducting them online, via teleconference. These precautions will be in place for the next two months, and we

will reassess the situation then. In general, we have been promoting social distancing, and have asked our faculty and staff to minimize unnecessary in-person meetings. We are also in the process of defining a policy regarding interactions with vendors visiting us and the ability for our staff to work off-site.

How does your cancer center anticipate responding to COVID-19 if the outbreak continues to worsen?

SP: Currently, our focus is on taking care of patients in active treatment while also being incredibly vigilant about preventing the spread of COVID-19 among our patient and staff community. Our infection prevention team is having ongoing discussions with leadership and our state and local public health officials in anticipation of the outbreak worsening. We are continually adapting as the situation evolves. We communicate with our patients about any changes to our policies and operations via the COVID-19 webpage on the [SCCA website](#).

PP: With a virus that is unpredictable and rapidly changing, we must do everything we can to keep our patients safe. We also have a responsibility to advise on other proactive measures that can be taken at a community level to slow down the spread of the disease within our community and across the nation. We are collaborating with other institutions in our region and working with city, county and state health officials to monitor updates, develop community screening protocols and expand access to testing.

Our emergency plan includes detailed actions for outbreaks like COVID-19. We are prepared to take additional steps to ensure the safety of our patients as the situation progresses. MD Anderson

began limiting visitors and expanded screening on campus the first week of March. Starting March 13, patient visitors (already limited to two people who are not showing symptoms) must be age 18 or older.

Throughout all of this, we strive to keep in mind our core value of Caring, using our expertise and best judgement to allow for compassionate exceptions on a case-by-case basis. Visitors who are not caregivers and who do not have mission-critical business with MD Anderson are restricted from campus. All volunteer shifts have been canceled as a significant portion of our volunteer population are cancer survivors or elderly adults at greater risk. Going forward, employees, patients and caregivers will only have access to limited entry points on our campuses.

Our testing capacity for COVID-19 is currently reserved for patients as testing kits remain in high demand. However, we are dedicated to providing a pathway for employee testing as well. We are preparing one of our Houston-area diagnostic imaging clinics to become a future testing site for MD Anderson patients and employees. I am inspired by the way the MD Anderson community has come together to protect the patients we serve. We will continue to provide clear and consistent communication to all stakeholders as we implement additional measures to mitigate the impact of the COVID-19 pandemic.

LP: We have been working closely with Northwestern Medicine to optimize and update plans as needed. We will intensify the measures mentioned above and we will consider further escalations as needed. The next step will be to have all of our staff working remotely. For now, we don't plan to suspend the research operations of our labs, but this may be something that we may have to face in the future. Our priority is the safety and the well-being of our patients.

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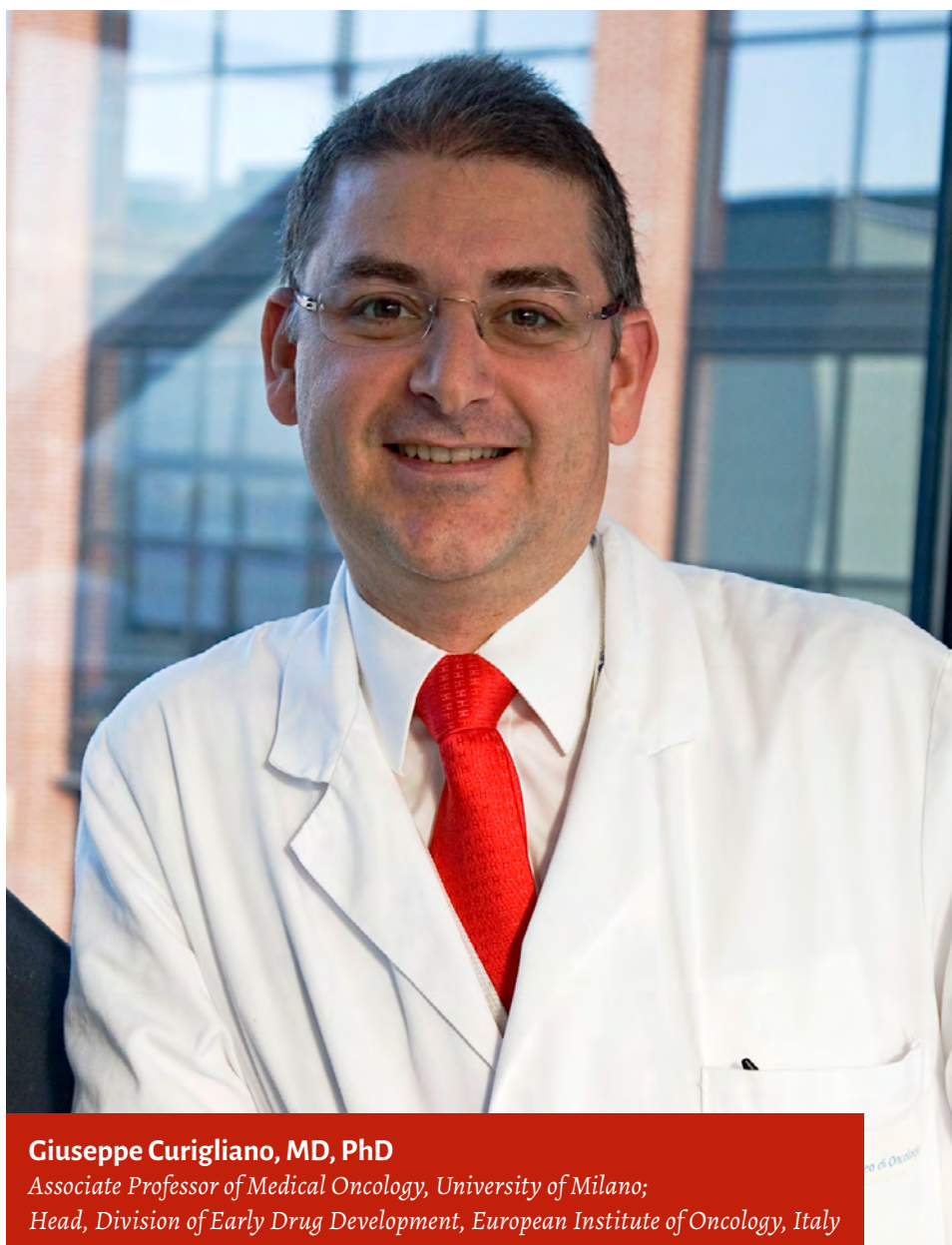
What to expect: Oncology's response to coronavirus in Italy

"It's like being in a war"

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The more you're high at risk, like our cancer patients, the more probability you have of dying. There is a high fatality rate in cancer patients. My advice is to be very careful, because this is not the flu.

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Giuseppe Curigliano, MD, PhD

Associate Professor of Medical Oncology, University of Milano;
Head, Division of Early Drug Development, European Institute of Oncology, Italy

To get a sense of how COVID-19 will affect oncology in the U.S., *The Cancer Letter* called Giuseppe Curigliano, associate professor of Medical Oncology at University of Milano and the head of the Division of Early Drug Development at European Institute of Oncology, Italy, who is based in the Lombardy region—the epicenter of the outbreak.

“So this is actually the perception that I have—it’s like being in a war or under a terrorist attack when usually 10% of people go in intensive care,” Curigliano said to *The Cancer Letter*.

“I am not scared about this because we are doctors, so this is our job,” Curigliano said. “But, you know, it’s really impressive how many new patients every day arrive in many hospitals in the city with the possibility of coronavirus, with symptoms of coronavirus—and you know already that 8%-10% of them will go into intensive care.”

Italy, which has the most cases of COVID-19 outside China, has instituted a mandatory quarantine and ban on travel for the 60 million people within the country.

Curigliano spoke with Alexandria Carolan, a reporter with *The Cancer Letter*.

Alexandria Carolan: How are you handling things in Milan?

Giuseppe Curigliano: First of all, I have to review the numbers, because it is quite important. Looking at the data, we have actually, in Italy, 10,140 COVID-19 cases out of 60,671 tested subjects [as of March 10]. And in the last three weeks, 631 patients died. This is quite important to be known.

Actually, at 6:00 p.m. on March 10, we had the new data of the day. We have

877 patients in intensive care for acute respiratory distress syndrome (ARDS), which means 8%–10% of positive cases are at risk to develop acute respiratory distress, conditioning the need for respiratory support.

There are 5,077 patients hospitalized for mild symptoms. I personally don’t have the data for cancer patients. I can tell you that some of my patients are positive for COVID, and some of them are actually hospitalized for ARDS. But the global number of cancer patients in Italy is not known. Of those with who tested positive for COVID-19 in China, almost 5% of them are cancer patients, with a very high fatality rate.

So, what are we doing in Italy in order to reduce the risk of our patients? We stopped follow-up visits. Any patients that were supposed to visit our comprehensive cancer center for follow up, we decided to stop the visits. We decided to give priority to patients with active disease over patients who are treated in the curative setting.

We give high priority to patients receiving treatment for an active disease. If they have to receive a neoadjuvant treatment or an adjuvant treatment, or treatment for metastatic disease, we reorganized the clinical activity to confirm the visits and the treatments. The same priority was given to patients receiving experimental treatments in clinical studies. But, you should know that some of these patients are coming from geographical areas where travel is banned. So it’s quite difficult for them to reach here.

In some of these patients, we delayed the treatment until quarantine was expired. Of course, we have to protect patients because some of them have leukopenia, lymphopenia, due to active treatment. For each patient who comes into the hospital, we test the temperature, we ask if they have

coughs or symptoms that are related to coronavirus, and then we give them masks and gloves before entering in the hospital to guarantee that the hospital is a clean hospital. And the same thing for doctors.

Actually, I have some symptoms. I did the test and I am coronavirus-negative, but I protect myself with a mask, in order to also protect the patients.

When you mentioned travel restrictions, are patients now unable to travel to your cancer center?

GC: No, no, actually the travel restriction is for all people in my country, with the exception of people moving for health reasons.

Oh, so they are able to travel.

GC: For cancer patients, there is no travel restriction.

They need a permit to travel. Is that correct?

GC: Yes. Correct.

You mentioned how you protect yourself with masks when you treat patients. Could you talk about that a bit more? How do you ensure that these patients won’t be infected while they’re in the hospital?

GC: Now, you know, if we are symptomatic, we have to be tested for coronavirus. So in case we are positive, we cannot work. Any coronavirus-positive doctor should stay at home for at least two weeks.

And all the people working in the same team that had face-to-face contact, they should also be tested for coronavirus. In the experience of the hematological department, I can mention that all the doctors are tested every week, because patients in the hematological context are more frail, and so you have to be careful because they receive high-dose chemotherapy, and they can't really defend infections that are very serious.

They do the test every week. Also hematological patients, for example, with leukemia, are tested for coronavirus before starting any treatment.

Have patients expressed concerns about coming into the hospital because they don't want to get the virus?

GC: No, because in my geographical area, Regione Lombardia—that is an area with a high rate of infection—we decided to have at least two hospitals, my hospital (European Institute of Oncology), and the National Cancer Institute, which are the hub hospitals for medical oncology patients. We are taking care of new cases, of our patients, and all the patients who are coronavirus-negative of the other hospitals in Regione Lombardia.

In our hospital, only patients who are coronavirus-negative can enter.

If you are a cancer patient who tests positive for coronavirus, can you not go into that hospital?

GC: No, because there are some hospitals that are COVID hospitals. All patients who are positive can go just to hospitals in which they are awaiting patients that are coronavirus-positive. And the two hubs, that are my hospital and the National Cancer Institute, should be clean. So it's mandatory that we are clean.

Do you find that cancer patients are more at risk to catch the coronavirus than others?

GC: Yes, they are. Just today, a patient of mine with lung cancer receiving a treatment with a RET inhibitor, so with an experimental agent, developed a coronavirus infection because he's living in the Bergamo city, where there is a spread of the virus, and he was just hospitalized for pneumonitis induced by coronavirus.

We have to be very careful because we do a lot of education with patients, but sometimes, of course, the risk is very high for them because they have lymphopenia or leukopenia.

How are you communicating with patients about the virus? What do you tell them?

GC: What do we do every day? Patients are very aware, actually, because there is a national campaign against the coronavirus. But every day we call all the patients who have to visit the next day. We ask them by phone if they have fever, if they have coughs or any symptoms—and they can come directly to the hospital only if they have no symptoms related to coronavirus.

Once they arrive in the hospital there is a checkpoint, external to the hospital, where temperature is measured and an exam is done. If everything is OK, they come directly into the hospital. They are very happy about this because they know very well that if we deliver any treatment inducing leukopenia, and they are positive for coronavirus, they are at risk, of course.

There are two hospitals in your region that will take care of coronavirus negative patients?

GC: Yes, in Regione Lombardia, not in all of Italy. We decided to have two hub hospitals for new patients with cancer, and so there are many hospitals in which you had hospitalized a lot of patients with coronavirus, that are not cancer patients. For Regione Lombardia, it is two hospitals—one of these hospitals is my hospital. It must be a clean hospital to take care of all the cancer patients, the new cancer patients of Regione Lombardia.

If you have a new cancer patient in Bergamo, he cannot be treated in a hospital in Bergamo because there are many patients with coronavirus. Who will take care of him? He will come to our hospital. We are the hub for many hospitals

that actually are fighting against the coronavirus in intensive care, in order to get a clean hospital for new cancer patients.

Could you describe the atmosphere in your city and your institution? What is it like?

GC: You know, the atmosphere in Milan is spectral. There is no one walking in squares and roads. Doctors, we are working—we are at risk, of course. My wife is an intensive care doctor. Every week she undergoes a coronavirus test, and we wait during the weekend for the results. And I know very well that if she will be positive, I have to be tested also, and if I would be positive also, I will go into quarantine.

I am not scared about this because we are doctors, so this is our job. But, you know, it's really impressive how many new patients every day arrive in many hospitals in the city with the possibility of coronavirus, with symptoms of coronavirus—and you know already that 8%-10% of them will go into intensive care.

So this is actually the perception that I have—it's like being in a war or under a terrorist attack when usually 10% of people go in intensive care.

This is exactly the atmosphere that we are living in, and there is no one working overall. When I come to the hospital at 7 a.m., usually, in the past, you need more than half an hour due to traffic. Now, I actually arrive at the hospital in 10 to 15 minutes.

It's a spectral atmosphere where no one is walking or working, because, in Milano, the only activities that open are the

hospital, the store where you can buy food, and the pharmacies. Nobody else is working for 15 days. It's a complete lockdown. Universities are closed, schools are closed, any other activity that is not a hospital, a food market, or a pharmacy is closed. It's like being at war.

How do you plan to respond as this progresses? Do you see the situation changing soon?

GC: Social isolation and containment is the only way. Social isolation and containment.

You should know that 12% of coronavirus-positive are doctors and nurses. The only way to stop these epidemics is to stay at home, don't go around. If we stay at home, we can stop this.

And do you have any advice for oncologists and doctors in the U.S. as we respond to this here?

GC: To be prepared. The only thing that is very important is to be prepared. My advice is—in case you have specific areas of the country where there is an increase of the spread—to start social isolation and containment measures as soon as possible, to recommend to cancer patients to be careful, to protect themselves and to protect their family, in order to avoid the spreading that is so high like in Milano and the Regione Lombardia area.

We did not start the social isolation as soon as possible like they did in China. And we hope that measures that we

did now will reduce the spread in the next weeks.

Is there anything else you'd like to add?

GC: You know, the only thing that I would like to add, is that coronavirus is not a simple flu. It's a severe, very serious disease in which you have a risk of 10% to go into an intensive care unit, with the median of hospitalization of three weeks.

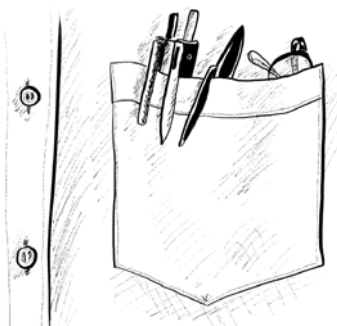
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THE CLINICAL CANCER LETTER



TRIALS & TRIBULATIONS

A conversation about COVID-19: Reflecting on first cases in Kansas



By Roy Jensen, MD

*Director, The University of Kansas Cancer Center and
Kansas Masonic Cancer Research Institute*

The following is a transcript of a weekly Facebook Live program, where Roy Jensen, director of The University of Kansas Cancer Center and Kansas Masonic Cancer Research Institute, interviews cancer researchers, clinicians, and patients.

On March 11, Jensen, who is also William R. Jewell Distinguished Kansas Masonic Professor and professor of pathology and laboratory medicine, anatomy and cell biology, cancer biology and molecular biosciences, focused on COVID-19.

Jensen spoke with:



Dana Hawkinson, MD

*Medical Director for Infection
Prevention and Control,
The University of Kansas Health System;
Assistant professor,
University of Kansas Medical Center*



Joseph McGuirk, DO

*Director, Division of Hematologic
Malignancies and Cellular Therapeutics,
Medical Director, Blood and
Marrow Transplant Program,
The University of Kansas Cancer Center;
Professor of Medicine, Schutte-Speas
Professor of Hematology-Oncology,
University of Kansas Medical Center*

At this writing, there are five cases of COVID-19 in Kansas. One patient has died.

A video of the conversation can be found [here](#).

Roy Jensen: Dr. Hawkinson, could you first tell us about the current state of the virus, not only here locally, but nationally. What are the risks? What do we know, what we don't know and how are things changing?

Dana Hawkinson: Yes. As a quick overview of novel coronavirus or SARS-CoV-2, obviously most people know this was a virus was discovered originally in December 2019, in China. There were multiple infections, there continued to be widespread infection and now it's reached around the globe.

Currently, there is no local spread. In the United States there are some communities that have had person-to-person and community spread, but this number and these infections are changing daily. So, a lot of what we're saying is, at this point in time or at the current state, this virus is similar to the SARS virus, which was originally discovered in 2002.

It has about 70 to 80% homology with that virus, that means it's similar. In most people, in 80% of people, it causes very mild illness in which you don't need hospitalization

It doesn't seem to affect children or patients under the age of 19, in fact, I think it's about 2% of cases or less from the published reports.

But in general, if we're talking about other patient populations such as anybody with underlying co-morbid illnesses like

heart failure, diabetes, underlying lung disease, and, of course, any neoplastic or oncologic disease, certainly they can develop and progress to severe disease in a higher probability than other patients who don't have those underlying diseases.

So, Dr. McGuirk, in regard to cancer patients, which ones would you say are at greatest risk for major complications for COVID-19? And I suspect that many of the patients that you care for fall into that category.

Joseph McGuirk: Yes, very much so. And so many of our therapies compromise the immune system, particularly in the blood cancers, where it's the immune system itself, and parts of it that are cancerous. And so, we suppress the immune system on purpose. And that sets our patients up for risk for infections, including this organism as well.

Many of our patients are of advanced age, and that, in and of itself, appears to be a risk factor for the acquisition and becoming quite ill in a threatening way with this virus. And patients who have received, in general, beyond those particular populations, bone marrow transplant, blood cancer patients, but even solid tumor patients who are actively receiving or relatively recently have received chemotherapy. Those are vulnerable populations of patients in particular with this virus.

So, Dr. Hawkinson, what is your general advice for cancer patients in regard to exposure to this virus and how to prevent that?

DH: First of all, I want to say I echo everything that Dr. McGuirk has said. It's all absolutely true. As far as protecting yourself, again, individual vigilance has been most important and that includes appropriate hand-washing.

Certainly, in patients who are older or have an underlying cancer diagnoses or on chemotherapy, trying to social distance, keeping yourself, not necessarily isolated or quarantined, but trying to avoid areas where there are mass groups or mass gatherings. This includes anything from possible sports events to bus stations, to airports, sometimes even grocery shopping or churches.

It's important to understand those risks, and, in doing so, also, because we are touching surfaces all the time—door handles, railings—and this disease is really caused by droplets, but also fomites, which are inanimate objects, such as high touch surfaces. We touch those surfaces and then we're touching our eyes, our nose or mouth. That is the main way that we contract this disease.

So, staying vigilant in hand hygiene, trying to avoid putting your hands in your eyes, nose, mouth, social distancing as much as possible—those are really the main ways that we can stay healthy, especially if we do have underlying malignancy or chemotherapy or otherwise immunocompromised state.

At this point in time, locally, it doesn't seem like there's community spread, but things can change rapidly in the next week, in the next two weeks, three weeks. And so, it's important to stay vigilant on the news, keeping up with the accurate websites such as the CDC and the Kansas Department of Health, and local health departments for their news and advisories on travel, and other things to do to protect yourself.

So, that advice sounds very similar to what we're giving to the general public. I'm sure that one of the specific questions that cancer patient has is around their appointments and coming in to see the physicians. Is there any advice around that situation that either one of you have, say, in the first case, where someone is just concerned about being exposed to the virus, and in the second case where they may be exhibiting symptoms that cause them to be concerned?

DH: I'll just start by saying as an individual you are probably more at risk of complications or problems by not seeing your physician. So, if you think there are issues, absolutely call the clinic, absolutely call the physician, and try to get some guidance at that point, because there are other things out there as well.

Locally, there's not a lot of community spread. The disease rate is not high for COVID-19, but there are certainly other things that are still important and can cause severe illness.

Influenza activity around here is still very high. We diagnose multiple cases of influenza every day here at the health system, both in the inpatient setting and outpatient setting. So, individually, I would say continue to be vigilant, talk with your provider, get good guidance, and by all means, if it's safe and you've talked with your provider, please come into your clinic visit because missing a clinic visit could be even worse. And I'll let Dr. McGuirk speak on the global issues.

JM: I completely concur. That's exactly right, and that is the straightforward, sensible advice to contact the treating team, the health care team.

There are, as Dr. Hawkinson just mentioned, the majority of our patients who have respiratory viral symptoms, and it's common that this time of year we're seeing these patients every day in our cancer center and our bone marrow transplant clinic, are influenza, respiratory syncytial virus, parainfluenza, and some of these viruses can be very aggressive in our population of patients and we have treatments, effective treatments, for some of them, not all of them.

And so, it's always critically important that we know about that and we can guide our patients in terms of coming in, taking special precautions for example, and coming to clinic to minimize exposure to others regardless of what type of virus it is, and then isolating those patients as soon as they come in, so that we can investigate what's going on with them.

The audience wants to know: Can you have the flu and coronavirus at the same time? Dr. Hawkinson?

DH: Initial reports and anecdotal reports and the data would suggest that with other infections, other viral infections you certainly can have co-infections and sometimes those percentages of people that have co-infections can be fairly high. With COVID-19 and other infections, such as influenza, it doesn't seem like there is a high rate of co-infection. So, at this point in time what we are telling patients is if you have tested

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— Joseph McGuirk

positive for influenza, you're positive for influenza. There's at this point in time, no need to further test for COVID-19.

What about traveling, or attending sporting events, or concerts or large crowds? What approach should cancer patients in particular take in regard to those types of events?

JM: We're currently—and I would be interested to hear what Dr. Hawkinson says about this approach.

We're currently being very prudent and very conservative in our cancer center and recommending that our patients, particularly those who are most vulnerable, patients in active treatment or relatively recent treatment, all of our patients with blood cancers, that they not travel, unless it's absolutely essential, and then that we help coordinate that effort for them, that they stay away from large crowds, that they even consider, during this particular time, avoiding church, going to the grocery store in the off-hours.

But, as Dr. Hawkinson pointed out earlier, when they go to that grocery store, being mindful of what they're touching, keeping their hands away from their face, taking Purell, for example, with them and washing their hands frequently. So, some practical measures, with regard to even our staff, our physicians.

As you know, Dr. Jensen, we've canceled and rescheduled a number of really important meetings that people worked on all year long, because if our health care providers become ill, first and fore-

most, they won't be able to care for the patients that we need to be caring for.

But, secondly, they may have an asymptomatic phase, and they can spread that virus, potentially.

I think we're pulling out all the stops in our institution to mitigate a rapid expansion of this virus in our community. And part of that traveling, self-imposed traveling restrictions, not just on our patients and their families, but also on our faculty, and not having large groups of people get together. It has been a very important issue over the last couple of weeks.

So, Dr. Hawkinson, could you talk a little bit about the steps that have been taken to ensure that [for] any patient that would come here to be treated for coronavirus at our institution has the infrastructure and the support that they need, but also what we've done to protect our staff and our other patients from becoming infected with the virus.

DH: We have had a multidisciplinary approach at the health system for many years now to dealing with emerging infectious diseases. So, we have had multiple service lines available to help to formulate plans.

This includes emergency management, the emergency department, the supply chain, making sure we have enough supplies and resources to be used. We have protocols for bringing patients in in a controlled manner, getting the patients to the correct isolation or precau-

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– Dana Hawkinson

tion rooms, and then thereby keeping our other patients safe as well as our health care providers.

We take that with utmost importance and we feel that we have worked on these processes and procedures for the past few years. We tried to smooth them out as much as possible. We've been hoping for the best and preparing for the worst and we continue to streamline these processes, and this includes not only the hospital but also the clinics including the Westwood Cancer Clinic as well.

So, it sounds like we have a question from our audience: "What should you do if you think you might be infected?"

DH: The first thing to do is probably call your primary care provider or your treating team, especially if you are one of the cancer center patients. Call the treating team first. Get some information from them.

At this point in time, the testing is certainly done through the state, and so any testing would be performed through the state and we would get the testing performed should you need it.

There are still screening criteria which we need to abide by, but I think the first thing to do is call the treating team, get information from them, and then they are able to relay it to the infection prevention team, and we will determine: should we be testing for COVID-19 or is it another illness?

And, as Dr. McGuirk pointed out, there are certainly other respiratory viruses still going on. There are still other ill-

nesses out there. And so, I think getting that information from your treating team, from your treating physician is probably the first step.

It looks like we have an additional question: Where should you go for more information about the coronavirus?

DH: The best places to go are accurate and informative websites. The best is probably CDC, so [cdc.gov](https://www.cdc.gov). Another important one is probably your state health department, whether it's Kansas Department of Health Environment, or Missouri State Health Department. I would say start there, because we all know that there's plenty of information out there on the internet, but those are probably the most reliable resources for COVID-19.

I think one of the most encouraging things that I've heard about the COVID pandemic is that there's been one report out of China [and] one report out of Seattle, that infection control protocols within health care systems work against this virus. And the two reports that I'm referring to, and while this is early, there's been no transmission to health care workers that have taken the appropriate precautions, either in China or in Seattle. And so, I think that that's an extraordinarily positive development.

DH: It certainly reinforces the fact that simple measures help constrain this virus. Simple measures such as hand washing, proper equipment, the gloves, the gowns, the droplet precautions. Again, it's important for us to keep our health care workers safe so they can treat ill patients and keep other patients safe. So, I would agree 100% with what you said.

It sounds like we have another question. The audience wants to know, what are your considerations for the rural community regarding coronavirus?

DH: I think at this point there is not a large, or any community spread around this area. The rural community still seems to be safe. Obviously, being rural, you are not interacting with many other people in general. So, I think it's just a matter of keeping an eye on your own health and continuing to monitor for any community spread or activity of the virus at this point in time. And just monitoring.

What about the prospects for a vaccine against COVID?

DH: I know people are working on it. Labs are working on a vaccination as well as therapeutics. There are no treatments for this virus. It's probably at least one to two years away for a vaccine. For other therapies, those are currently in trials, either anecdotally or through government trials as well, but right now, there's really nothing else to use other than supportive care.

CLINICAL ROUNDUP



FDA encourages inclusion of older adult patients in cancer clinical trials

FDA issued a draft guidance document, “[Inclusion of Older Adults in Cancer Clinical Trials Guidance for Industry](#),” to provide recommendations to sponsors and institutional review boards for the inclusion of older adult patients, ages 65 years and older, in the clinical trials of drugs for the treatment of cancer.

The draft guidance recommends enrolling older adults in early phase studies of cancer clinical trials, if appropriate, to obtain information to better inform later phase studies. It also includes additional recommendations intended to facilitate a better understanding of the benefit-risk profile of cancer drugs in older adult patients regarding trial design, recruitment strategies, information collection and developing and reporting more discrete age groups.

“Enrolling a broad representation of patients in clinical trials is an import-

ant tenet of clinical research as it facilitates a better understanding of the drug’s benefits and risks across the patient population likely to take the drug,” Richard Pazdur, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research, said in a statement. “However, because cancer incidence increases with age, and given the aging U.S. population, it’s particularly important now more than ever to ensure that older adults are also enrolling in cancer clinical trials.”

It is important to have older adult patients in clinical trials because differences may exist between younger and older patients in drug response and toxicity. Older adults often have other diseases or conditions and may be taking medications that could impact the efficacy of either the cancer drug or other drugs they are taking and may also impact the incidence and the severity of adverse events.

“Unfortunately, adults aged 65 years and older, and especially those over 75 years old, are currently underrepresented in cancer clinical trials despite accounting for a growing segment of the cancer patient population.

“This has been a persistent issue in oncology and the FDA is engaged with stakeholders to improve the representation of older adults in cancer clinical trials. That is why today, we are providing recommendations on increasing the enrollment of older adults in cancer clinical trials, when appropriate,” Pazdur said.

Furthermore, there may be important differences in efficacy in older adult patients compared to the younger or general population, and information describing such differences should be

conveyed to patients and health care providers where appropriate.

Phase III GY004 for Cediranib and Lynparza doesn’t meet PFS endpoint in ovarian cancer indication

The phase III GY004 trial examining primarily the efficacy and safety of investigational medicine cediranib in combination with Lynparza versus platinum-based chemotherapy in patients with platinum-sensitive relapsed ovarian cancer failed to meet its primary endpoint of progression-free survival.

The trial was conducted by NRG Oncology. AstraZeneca and Merck sponsor the trial.

The trial did not meet the primary endpoint in the intent-to-treat population of a statistically significant improvement in progression-free survival with cediranib in combination with Lynparza vs. platinum-based chemotherapy.

Cediranib is an investigational oral vascular endothelial growth factor receptor inhibitor.

“Despite these disappointing results, we remain committed to expanding on the benefits already demonstrated with Lynparza for patients with advanced ovarian cancer,” Jose Baselga, executive vice president of oncology R&D, AstraZeneca, said in a statement.

The safety and tolerability profiles observed in GY004 were generally consistent with those known for each medicine.

Copper IUDs less likely to contribute to cervical cancer than hormonal IUDs

Patients who used copper intrauterine devices were found to have a lower risk of high-grade cervical neoplasms compared to users of the levonorgestrel-releasing intrauterine system, according to a Columbia study recently published in *Obstetrics & Gynecology*.

Studies from the 1980s suggested reduced risk of cervical cancer among women who used an intrauterine contraceptive, though those studies did not differentiate between the varying types of IUDs. Furthermore, much of the data from those studies was collected prior to the availability of most hormonal IUDs (LNG-IUS).

By standardizing four decades' worth of data from the Columbia University Irving Medical Center database through the OMOP Common Data Model and using high-level analytics developed within the Observational Health Data Sciences and Informatics (OHDSI) collaboration, the research team ran a retrospective cohort analysis of more than 10,000 patients who received IUDs.

The diagnosis of high-grade cervical neoplasia was 0.7% in the Cu IUD cohort and 1.8% in the LNG-IUS cohort.

"Copper and hormonal IUDs may have different physiological effects on the female genitourinary system," says Matthew Spotnitz, MD, MPH, a Postdoctoral Research Scientist within the Department of Biomedical Informatics and lead author of this study. "Consequently, the risk of cervical neoplasms may be different for copper and hormonal IUD users. Our findings may help

patients and healthcare providers make informed decisions about whether the benefits of hormonal IUD use, compared to copper IUD use, are greater than the risks."

Spotnitz noted that the research team hopes to lead a network study across other databases within the OHDSI network, which spans 19 countries, 133 unique databases converted to the OMOP CDM, and more than one billion patient records.

"The proportions of women who use copper and hormonal IUDs may vary among institutions," Spotnitz says. "Overall, IUD use has become more popular over the past 20 years. Copper IUD use has remained constant whereas hormonal IUD use has increased. The rising popularity of hormonal IUDs may be related to the fact that they decrease the pain and bleeding of menses."

The study notes that more than 100 million women use IUDs as contraception around the world, and these findings have implications for the larger population of current IUD users.

The full study is entitled "Relative Risk of Cervical Neoplasms Among Copper and Levonorgestrel-Releasing Intrauterine System Users."

DBMI assistant professor Karthik Natarajan, PhD, DBMI adjunct professor Patrick Ryan, PhD, and Epidemiology, Population and Family Health professor Carolyn Westhoff, MD, collaborated on this study. Natarajan is also affiliated with the Columbia Data Science Institute.

OHDSI is an international, open-science collaborative that looks to improve health by empowering a community to collaboratively generate the evidence that promotes better health decisions and better care.

DRUGS & TARGETS



FDA grants accelerated approval to nivolumab and ipilimumab combination for hepatocellular carcinoma

FDA granted accelerated approval to the combination of nivolumab and ipilimumab (Opdivo and Yervoy) for patients with hepatocellular carcinoma who have been previously treated with sorafenib.

Bristol-Myers Squibb Co. sponsors the drugs.

Efficacy of the combination was investigated in Cohort 4 of CHECKMATE-040, (NCT01658878) a multicenter, multiple cohort, open-label trial conducted in patients with HCC who progressed on or were intolerant to sorafenib. A total of 49 patients received nivolumab 1 mg/kg in combination with ipilimumab 3 mg/kg every 3 weeks for four doses, followed by single-agent nivolumab 240

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mg every 2 weeks until disease progression or unacceptable toxicity.

The main efficacy outcome measures were overall response rate and duration of response as determined by blinded independent central review using RECIST v1.1. ORR was 33% (n=16; 95% CI: 20, 48), with 4 complete responses and 12 partial responses. Response duration ranged from 4.6 to 30.5+ months, with 31% of responses lasting at least 24 months.

FDA accepts BLA for biosimilar MYL-1402O in cancer indications

FDA has accepted Mylan's Biologics License Application or MYL-1402O, a proposed biosimilar to Avastin (bevacizumab), for review under the 351(k) pathway.

Mylan and Biocon sponsor MYL-1402O.

The BLA seeks approval of bevacizumab for first-line and second-line treatment of patients with metastatic colorectal cancer in combination with fluorouracil-based chemotherapy; first-line use for patients with non-squamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma in combination with interferon alfa; and persistent, recurrent or metastatic cervical cancer.

The FDA goal date set under the Biosimilar User Fee Act is Dec. 27, 2020.

Mylan and Biocon's proposed biosimilar bevacizumab is expected to be the third biosimilar from the partnered portfolio for cancer patients in the U.S. It is currently available in India and other developing markets.

FDA grants Breakthrough Therapy Designation for JNJ-6372 in NSCLC indication

FDA has granted Breakthrough Therapy Designation for JNJ-61186372 (JNJ-6372) for the treatment of patients with metastatic non-small cell lung cancer with epidermal growth factor receptor Exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.

Janssen Pharmaceutical Companies of Johnson & Johnson sponsors JNJ-61186372.

JNJ-6372 is an EGFR-mesenchymal epithelial transition factor bispecific antibody that targets activating and resistant EGFR and MET mutations and amplifications. Currently, there are no FDA-approved targeted therapies for patients with lung cancer who have EGFR Exon 20 insertion mutations.

Patients with NSCLC and EGFR Exon 20 insertion mutations have a form of disease that is generally insensitive to EGFR tyrosine kinase inhibitor treatments and carries a worse prognosis compared to patients with more common EGFR mutations (Exon 19 deletions/L858R substitution).

The current standard of care for this patient population is conventional cytotoxic chemotherapy.

The Breakthrough Therapy Designation is supported by data from a phase I, first-in-human, open-label, multicenter study (NCT02609776). The study evaluates the safety, pharmacokinetics

and preliminary efficacy of JNJ-6372 monotherapy and in combination with lazertinib[1], a novel third-generation EGFR TKI, in adult patients with advanced NSCLC.

The study seeks to determine the recommended Phase 2 dose in patients with advanced NSCLC. Enrollment into the Part 2 dose expansion cohorts is ongoing, as the study evaluates JNJ-6372 monotherapy activity in multiple NSCLC sub-populations with genomic alterations such as those with C797S resistance mutation or MET amplification.

Thermo Fisher Scientific collaborates with Janssen to co-develop companion diagnostic for cancer

Thermo Fisher Scientific and Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, signed an agreement to co-develop a companion diagnostic in oncology.

The CDx will support clinical trial enrollment globally.

Under the agreement, Thermo Fisher Scientific will collaborate with Janssen Research & Development, LLC scientists to validate multiple biomarkers for use with Thermo Fisher's OncoPrint Dx Target Test, which will be used to identify variant-positive patients for enrollment into clinical trials focused on non-small cell lung cancer. Additional indications in oncology may follow as part of the agreement.

OncoPrint Dx Target Test is a next-generation sequencing assay that contains

46 cancer-related biomarkers and a workflow that features a fast turnaround time and the lowest sample requirements on the market for detection of both DNA and RNA variants.

Since its approval by the U.S. Food and Drug Administration in 2017, OncoPrint Dx Target Test has been the focus of multiple drug development and clinical trial support agreements between Thermo Fisher and international pharmaceutical companies.

European Commission approves Venclyxto in CLL indication

The European Commission has approved Venclyxto in combination with obinutuzumab for the treatment of adult patients with chronic lymphocytic leukemia, who were previously untreated.

The approval is valid in all 27 member states of the EU, as well as Iceland, Liechtenstein, Norway and the United Kingdom.

AbbVie sponsors the drug.

"This approval underscores the growing utility of Venclyxto in treating CLL and demonstrates its clinical benefit as a chemotherapy-free combination therapy option for CLL patients in Europe who have not yet been treated," Neil Gallagher, chief medical officer and vice president of development at AbbVie, said in a statement.

This is the third approval for Venclyxto, a first-in-class B-cell lymphoma-2 inhibitor. BCL-2 is a protein that prevents cancer cells from undergoing apoptosis, the process that leads to the natural death

or self-destruction of cancer cells. Venclyxto is also approved in combination with rituximab for the treatment of adult patients with CLL who have received at least one prior therapy, and as a monotherapy for the treatment of CLL in the presence or absence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor.

This most recent approval is based on results from the phase III CLL14 clinical trial primary analysis (median follow up of 28 months), which demonstrated superior progression-free survival (PFS; the time on treatment without disease progression or death) as assessed by investigators in patients treated with VENCLYXTO plus obinutuzumab compared to patients who received a standard of care chemotherapy regimen of chlorambucil plus obinutuzumab (hazard ratio 0.35; 95% CI (0.23,0.53), $p < 0.0001$, medians not yet reached).

At an updated CLL14 efficacy analysis (median follow-up of 40 months), the median PFS had not been reached in the Venclyxto + obinutuzumab arm and was 35.6 months [95% CI: 33.7,40.7] in the obinutuzumab + chlorambucil arm (hazard ratio 0.31; 95% CI: 0.22, 0.44). The 36-month PFS estimate in the venetoclax plus obinutuzumab arm was 81.9% [95% CI: 76.5, 87.3] and in the obinutuzumab plus chlorambucil arm was 49.5% [95% CI: 42.4, 56.6]. Additionally, after completing one year of treatment, patients treated with the VENCLYXTO combination experienced deep response as measured by higher rates of undetectable minimal residual disease or complete response as compared to patients receiving a standard of care regimen.