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ASCO'S NEW CMO JULIE R. GRALOW WILL FOCUS ON EQUITY, ADVOCACY, AND GLOBAL HEALTH

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ASCO's new CMO Julie R. Gralow will focus on equity, advocacy, and global health

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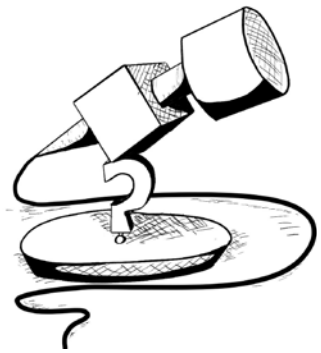
Q & A

Gralow spoke with Paul Goldberg, editor and publisher of The Cancer Letter.



CONVERSATION WITH THE CANCER LETTER

Julie R. Gralow, an expert in breast cancer, clinical trials and global health, was named chief medical officer of the American Society of Clinical Oncology.

She succeeds Richard L. Schilsky, ASCO's first CMO, who took the job in 2013 and will retire next February.

"When Rich came on, there was really no hard-and-fast rules around the job description. What's great about ASCO, I think, is its fluidity and its constantly looking at what's working and what's not," Gralow said to *The Cancer Letter*. "What I'm looking to add to it is, I think, part of the equity piece. I bring a lot of the patient advocacy perspective to it, and I will be working on the global piece."

Gralow is a professor of medical oncology and director of breast medical oncology at the University of Washington, Fred Hutchison Cancer Research Center, and the Seattle Cancer Care Alliance. She is also the SWOG Cancer Research Network's executive officer for the breast and lung committees.

Gralow will begin her new position on Feb. 15, 2021.

"Julie has all the qualities we were looking for in ASCO's new CMO," ASCO President Lori J. Pierce said in a statement. "She has a vision for the future of oncology backed up by a significant record of accomplishments in clinical cancer care and research. She knows how to lead large, multi-disciplinary teams. And she is a thoughtful and compassionate person. I know she will provide wise counsel as we work together to advance ASCO's mission."

The CMO position provides medical and scientific leadership for ASCO's research, public policy initiatives, and communications, and global programs—as well as fundraising for ASCO's affiliated foundation, Conquer Cancer. The CMO is a member of the executive leadership team and reports to the CEO.

"This is a pivotal time for ASCO and in the broader field of oncology," ASCO's CEO Clifford A. Hudis said in a statement. "The pace of scientific progress has never been greater, but COVID-19 has brought challenges to virtually every aspect of cancer research and care. I look forward to having Julie on our leadership team as we navigate these unprecedented times while remaining focused on improving the care of patients during the pandemic and beyond."

Gralow spoke with Paul Goldberg, editor and publisher of *The Cancer Letter*.

Paul Goldberg: First of all, congratulations. This is one of the most interesting jobs in the field.

Julie R. Gralow: I think it is, too. So, thank you very much. It's a terrific job, and I'm stepping into some big shoes.

One part of the job is to educate and explain, but there's also a component of moral authority. Isn't there?

JRG: I'm trying to process that. I think that my job will be to help serve our members so that they can better serve their patients, but that we've got to be broad. With respect to the moral authority, I don't think we're coming down from a top-down standpoint saying, "This is what's right," and all of that, but we are just trying to help make everybody do better. Do better for our patients. That's the goal in the long run.

I'm not sure if you meant something else by that.

> "I can create a lot of opportunities outside of Seattle, at the national level in serving our members, but also what I'm really very excited about is taking it to the global level."

Well, right now, delineating the truth from untruth, in this political environment, turns into more than just an education or an imparting of information. It's more like right and wrong.

JRG: I think ASCO has always been evidence-based, the source we go to, where we can trust it. I've always pointed my patients to Cancer.Net, for example, once Cancer.Net got started, saying, "There's lots of stuff out there on the internet, but I can tell you that Cancer.Net has been reviewed, it's evidence-based, it's science."

There are things we don't know for sure, because we haven't done the study, but you can trust that. I think the same is true for our members. They go to ASCO for the guidelines, for the recommendations, for the big annual meeting, where we present the scientific evidence, and ASCO is always in those oral sessions, and, increasingly, in poster sessions, with an independent discussant as well, which has always been an important piece.

You've got people up there on the platform, they can essentially say what they want about the research results, but you know it's going to be discussed by somebody who is going to reign them in, hold them accountable if they are overstating things.

All of this means that our members and attendees can trust us not just to deliver the content, but to put it in context.

How does this moment in history shape what you intend to do? And I'm talking about gender equality, racial justice, disparities.

JRG: There's a lot going on, isn't there?

It will be an interesting job.

JRG: Yeah. This is an exciting time with respect to equity and justice, because I think we're gaining a foothold, and it's going to be hard to go backwards.

For years and years, wearing my global hat, I've looked at this as equity across the globe. Why should your ZIP code determine whether you are going to live or die from cancer or whether you are going to get this treatment or not? That's a quote from Princess Dina Mired, who is the current president of the UICC.

ZIP code shouldn't determine whether you get treated for cancer, much less whether you live or die. So, from a global scale, I've been interested in that my whole career and, increasingly, I see the movement taking afoot that yes, inequities exist across the world, but they absolutely exist within our own country.

And maybe we can use some of the same tools for leveling the playing field and getting access to care and overcoming barriers to care right in our own backyard. So, we've got, as you say, the racial injustice and disparities piece that I really think the time is right to make some big changes.

We've got COVID-19. Hopefully, someday we'll have the recovery from the pandemic. We've learned a lot; haven't we?

Let's get to COVID in a moment. I want to stay on gender equality issues. There are many highly qualified women in this field, so gender equality should be an easy problem to fix, if there is determination.

JRG: Well, there are a lot of subtleties to it.

While we've got plenty of women, both community physicians and academics, in oncology, practicing oncology, it's at the leadership level where we still have some of those gender gaps. And when we look across medicine in general, the

Visiting medical students at a hospital in Thai Nguyen, north of Hanoi in December 1999.

percentage of women going to medical school now is at least equal if not, in some medical schools, even slightly higher than the ratio of men.

But those who rise through the ranks, at least in academics, and get promoted to full professor in the end, etc., drop out for a lot of reasons. And some of them are fine reasons, but we've got to get rid of the ones that aren't.

I'm hearing it said that this is a problem that can be solved tomorrow. I mean, just fix it.

JRG: It's very refreshing. There is a biotech in my region that you undoubtedly know about. And they made a commitment to have their board be at least 50% female, and to have their workforce be at least 50% female.

And from the beginning, they created a Women in Science lectureship that I was invited to speak at in the very early days, as one of the first speakers.

And they asked me to just tell my story, and how did I get here and who were my mentors, etc. And what was fascinating about it was that the audience was almost half men that came to this Women in Science lecture.

It was a real culture, because at the top they had committed to this. So, we can do things like that.

It's wonderful that it's happening. Can we talk about COVID for a moment? What's ASCO's role in COVID, and what is ASCO CMO's role, most importantly, in dealing with the pandemic?

JRG: Early on, ASCO served as a resource for latest updates and best practices. When things were changing so fast and nobody knew what was going on, and we didn't understand what we could do with telemedicine. We didn't understand what the best restrictions were. Should we be shutting down the ORs or infusion rooms?

So, ASCO created a hub. And then, because they had the CENTRA research infrastructure, they also were able to create a COVID registry that I think we are going to continue to do research from and learn from for years to come.

But as I see it, we've all in various ways figured out how to protect our patients.

What do you really need to come in for? I mean, as a clinical trialist, we really thought how we do clinical trials. Can we do consent by telemedicine? Do we really need to bring our patients in to come from a distance just to get vitals, or could they do that locally? And it wouldn't be a protocol deviation.

What are the things within clinical trials that we can ease up that will be sustainable in the long term and make it easier for patients to be on a trial, easier for us to accrue to a trial?

The telemedicine and the cross-state licensure is really complicated and it changes, it seems to me, almost weekly.

I sit here in Seattle. We're the only academic medical center for a five-state region: Washington, Wyoming, Alaska, Montana, and Idaho. I have patients all over, across states, and it's really tough to figure out on any given day what I need to do on a telemedicine visit in Montana versus Alaska versus Hawaii.

Montana decided that we could get pandemic provisional licenses if we had our own state license and filled out a form. I'm now licensed to also practice in the State of Montana during the pandemic. So, I can see my return patients. Otherwise, I'd be practicing outside my scope across state lines.

I think ASCO is going to have to play a role in helping what happens post-pandemic with telemedicine, with clinical trials, and with all of the things that have changed in our practice.

And I think ASCO is a good resource to be able to share what the practices are dealing with, and help our members in solving all of this and understanding what we can do, what we can't do, and updating, if something isn't making sense as the pandemic ends, something that was good that we think should continue.

But there are legal issues, and things that get in the way. ASCO can help advocate for that on a broader basis than any individual practice or state could.

So, that would be a part of your role as a CMO?

JRG: Yes.

Are you worried about becoming a leader at ASCO when it looks like work will be virtual for another year, and it's really not clear that there will be another face-to-face ASCO annual meeting?

JRG: For a while anyway. Am I worried about that? No. I mean, progress is being made in cancer.

Clinical trials are ongoing. For example, from my past as a breast clinician, I am excited that we've had five or six new drugs approved in the last 18 months.

And this is on pace to continue, as more practice-changing studies come to fruition. I'm looking at the agenda for the San Antonio Breast Cancer Symposium coming up in a few weeks. There's some really important practice-changing data that's going on there.

While we all miss the face-to-face, I think ASCO did a really good job of pulling together, at short notice, a virtual meeting that worked for the most part, that resulted in more "attendees" than ever.

What I'm hearing, with my global hat again, from all of my colleagues—especially those in low- and middle-resource countries and in some other countries, where only the very top leaders get permission to leave the country to come to a meeting like ASCO—I'm hearing about all kinds of people who were able to participate in the ASCO annual meeting this past year, who never would have been able to.

While I think there's no question that we will go face-to-face again when it is safe, I think there's going to be some component that helps with that virtual piece that engages all those people who were able to participate this past year, and really appreciated it and were excited about it and would not be able to participate in a regular year. We'll learn from that as well.

Why did you move from a conventional academic career to ASCO? What would you be giving up, what would you be gaining, and what can you accomplish at ASCO that you might not be able to accomplish in a conventional academic setting?

JRG: I'll be giving up my day-to-day patient practice. There's no way to safely treat a group of metastatic breast cancer patients where, at least post-pandemic, I'll be in Alexandria a good portion of the time.

I'll be giving up that day-to-day direct patient care, but I have a very strong connection built over the past almost three decades with the patient advocacy community. I don't expect that my interactions and relationships with the patients, who are always driving us to remember what our focus is, that I will lose that patient connection in that way.

I will lose it in terms of being their primary provider. In my SWOG executive officer role, I am very involved in the startup of a lot of clinical trials at a high level, the training of our young up-and-coming clinical trialists.

In moving over to the ASCO CMO role, I won't be as directly one-on-one involved in the young investigator training or the fellows, but I'll be able to much more broadly impact their opportunities, their networking, what happens as they move from fellowship into early career, into mid-career. I'll be able to really help at a higher level.

I won't be the PI on another trial, except for, ultimately, overseeing at a high level the TAPUR trial and perhaps those yet to come at ASCO. But with the goal being that there will be lots of other people who get the academic credit for that, and I serve as the facilitator for that, really.

I think I can create a lot of opportunities outside of Seattle, at the national level in serving our members, but also what I'm really very excited about is taking it to the global level.

In ASCO's five-year strategic plan, one of the four major goals is to make a global impact. We just published our ASCO Academic Global Oncology Task Force set of recommendations, which were presented to the board, and were approved by the board.

I'm super-excited about taking that and implementing it.

Let's get to that in a moment. Can we talk more about the role of the CMO? Because, well, Rich was the first CMO ASCO had. He defined the job as it currently stands. You will be redefining this job. What are your plans? What will you do that's not being done? How will you do it differently from Rich, if you're going to do it differently? What do you intend to pursue at ASCO?

JRG: You're correct that when Rich came on, there was really no hard-and-fast rules around the job description. What's great about ASCO, I think, is its fluidity and its constantly looking at what's working and what's not. It's very strategic with the board. Also, I think Cliff is a great CEO. Like anyone starting a new and complex role, I am sure I don't know everything about the role—yet. I will know more in a few months.

What I'm looking to add to it is, I think, part of the equity piece. I bring a lot of the patient advocacy perspective to it, and I will be working on the global piece. In addition to what Rich has set up—the research piece with CENTRA, which is an amazing clinical trials network—I agree with ASCO's board that we should not be competing with the National Cancer Institute, the cooperative groups in any way. That has not and will not be ASCO's role.

But as I view the work of CENTRA, it's clearly a service in a way to our members. I look at the TAPUR trial and all of

the genomics and the matching of drugs and ASCO's ability to bring a bunch of industry together to have access to their drugs with the right genomic alteration.

In my clinical practice today, for a lot of those I'd have to either enroll in the MATCH trial, which is very complicated and usually it doesn't have an arm that matches, or do single-patient INDs, which my clinical trials group has the money and the resources to do, but a community oncologist group, unless they're quite large, doesn't.

This is, in a way, getting access to genomics and drugs, and then collecting it in a way that will be publishable, where we will be gaining evidence, where we can get it into our guidelines, and all so that then we can have it covered under whatever insurance scheme the patient has, because we've provided the evidence.

I think the research piece will go on, as I talked about the COVID registry. There are several COVID registries out there and they all have their own unique features. ASCO's is very valuable because there's going to be a very long-term follow up of these patients in this registry plus insights into the practices themselves.

The equity piece, the patient advocacy piece, the global piece, the post-COVID piece. I think those will all be things that I'll be adding on top of what Rich has created.

Let's back up a little bit to Big Data. What about CancerLinQ, for example? How should that be done, or is it going to be changed?

JRG: CancerLinQ is really a valuable resource, both for the practices that participate in it, as well as the researchers, and at all levels to get data back out to share with its users and others.

The whole idea of seeing what you're doing, what your outcomes are, how compliant are you with pathways, how do your outcomes compare, I think it's really important. It helps us do our best work, right?

It helps us with the best quality if we see what we're doing and we compare ourselves to others. I think CancerLinQ is serving that important role in an increasing way and I am excited by what is ahead.

So, it remains unchanged. What do you see as the greatest opportunities for ASCO in the years ahead?

JRG: We've got a strategic plan to 2023. We need to meet the needs of our members, number one, so they can best meet the needs of our patients.

That starts with how we help them optimize quality of care. CancerLinQ falls in there. It also includes how we steward our resources and help them do the same. Oncology care is very expensive, and financial toxicity to our patients is real. And it also extends to our desire to have a global impact.

Thinking about quality and cost, we've got to tackle that.

As I said, in breast cancer we've had five or six new drugs approved in the last 18 months and they're all exorbitantly expensive. We've got to best figure out how to practice quality care, but also care that doesn't bankrupt our patients and our country.

Globally, I see a real opportunity for collaboration across other societies outside of ASCO, with ESMO for sure and the European societies. AORTIC, the African Organization for Research and Training in Cancer, and the Asian societies.

We've been doing some of that, but I think partnering more globally, we are going to come together, we're going to collaborate, and we're going to be better partners and collaborators.

Just this week, WHO announced their global campaign to eliminate cervical cancer.

I would view, with my ASCO CMO hat on, we should be at the table on that, because even though cervical cancer mortality is currently not high in the US because we do screening, we certainly still have populations that have very high rates. We don't have good uptake of HPV vaccines for a variety of reasons.

We should look at innovative ways for screening. I'm very excited about doing studies and getting approval for an HPV self-swab. Now we have new guidelines that if you're HPV negative, you only need to come in every five years. And you would only do a pelvic examine and cytology, a Pap smear.

If the HPV was positive, we have the potential, if it works, to do HPV self-swabs, so women don't even need a pelvic exam. And that really removes a lot of barriers, especially in some of our racial, ethnic minority groups. You ask, what the vision would be. I would view that we can partner better with our global community in, for example, this eliminate cervical cancer campaign.

I hear back from patients that ASCO seems to be a lot about treatment, but not as much about the prevention. I think we need to be more visible in the prevention piece as well.

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We can partner with all the efforts going on at the UN level and the WHO level in healthier lifestyles, and smoking cessation, and all of those things that are part of the UN's current NCD strategic plan. And we're not promoting that as much in the U.S.

So, I think that's another opportunity.

Especially now. It's a new day. Can we talk about international oncology? For you, this has been a career-long interest. Can we talk more about how it began, how you see it, how your interest has evolved, and how that would affect ASCO?

Kyiv, Ukraine – March for Life and Hope, 2003, with breast cancer support group Amazonki.

JRG: Well, it wasn't on my radar even when I came in fellowship and I arrived in Seattle. And then, in about 1997, I was approached by a Seattle-based NGO, PATH, that used to be called the Program for Appropriate Technology in Health. Now it's just PATH, kind of like SWOG. It used to be Southwest Oncology Group, but now it's just SWOG.

PATH, which had expertise and structure in many countries, mostly related to infectious disease. So, post-Chernobyl, USAID, with the U.S. Congress providing money, wanted to do something in Ukraine. And they looked and saw that post-Chernobyl exposure, we expected that certain cancers might increase years later, like breast cancer, as we saw post-Hiroshima, for the young women exposed.

And so, Congress voted. USAID put out an RFA for a Ukraine breast cancer assistance project in conjunction with Ukrainian ministry of health. PATH won the contract, because they had infrastructure already set up through Ukraine, through Eastern Europe for infectious diseases, for vaccines, essentially.

They were trying to get together a group of breast cancer experts, and they thought we'll just select a group from Seattle, so we don't have to pay a lot of extra expenses of flying people around and all. I was pretty young in my career. I was junior faculty, but they said, "Would you like to do a three-year consultancy on this Ukraine breast cancer project?" And I said, "Sure, that sounds interesting."

And we did it.

I helped collaborate and run a clinical trial in Odessa, in conjunction with the chemotherapist there. That served a couple purposes. One was to help teach them how to do clinical trials. The other was, it was a preoperative chemo trial to show the surgeons that chemo actually worked.

So, we chose the preoperative setting so everybody could see the tumor shrink and show that chemo worked.

At the time in Ukraine, the surgeons ran the show. The chemotherapists were just kind of handed the patients after surgery and didn't have the same status and respect. And so, that little clinical trial that we did in Odessa set them up so that they got a clinical trials infrastructure. They now, as do a lot of other sites in the country, participate in a lot of industry-sponsored trials.

We had a big national meeting. The surgeon saw the value of chemotherapy, the value of even discussing it preoperatively when the disease is locally advanced. And so, just through that little project, I said, "This is amazing how with proper respect and partnership and being safe, we can actually help change."

They used results from the various projects that we did in that PATH project to rewrite what their pathways were essentially, and how they treated breast cancer.

And a big piece that came out of it was that there was another group—and I did not lead this—that was interested in creating dialogue between the healthcare professionals, the doctors, the nurses, and the patients.

The Soviet-era teaching was, you don't tell a patient they have a fatal disease, because they'll go and kill themselves before dying of the disease. So, don't tell a patient they have cancer. They're going to go commit suicide. And if you read Solzhenitsyn's "Cancer Ward," that's the era, essentially.

These patients were sitting in a cancer hospital, on a chemotherapy ward, and yet they would say to their doctor or their nurse, "I have cancer; don't I?" And they would be told, "No, you don't. You have a very bad infection of your breast. So we had to remove it. And now you need very potent antibiotics that are going to make your hair fall out."

It was done in a way where they thought they were protecting the patient. But, of course, everybody knew the patient had cancer. They were on a chemotherapy ward, labeled chemotherapy ward in a cancer hospital, labeled cancer hospital. And they didn't have the opportunity to talk about it, or to be connected with others or to get information.

One of the projects was related to talking to some interested doctors and nurses who were willing to help start giving some education and having that dialogue and learning how to have that back and forth, and some patients who were interested in doing the same.

And by the end of that three-year period, there were actually breast cancer support groups popping up around Ukraine.

In 2001, the Amazonki, which were named after the mythologic Amazonian women who cut off one breast to better be able to use a bow and arrow, actually got permission to shut down the main street in Kyiv, the Khreshchatyk Street, to have a "march for life and hope," with pink balloons and a marching band for the daughters, so that the daughters could learn about their cancer risk. And so that people could see survivors. "Yep, I had breast cancer and I'm alive."

And back in that era, in 2001, to get a permit to do a march down the main street in a former Soviet country was a big, big, big deal.

So, that's how I got involved. That was a very long answer, but that's what started it.

And then I said, "Wow."

It didn't take much to really change, in a very good way, some things that were happening in Ukraine, and build relationships, and build dialogue that has persisted to this day.

And you're doing this, of course, elsewhere around the globe. You've mentioned Africa.

Gralow's first trip to to Uganda Cancer Institute for teaching in 2009, before construction of a new outpatient/research building of the joint UCI-Fred Hutch cancer center.

JRG: Well, the Fred Hutch has a relationship with the Uganda Cancer Institute that basically started with HIV-related cancers: Kaposi sarcoma, lymphomas, cervical cancer side to that as well.

It was really our infectious disease people. There was a lot of HIV money out there, not much cancer money. So, they got a big grant with HIV-related cancers and set up a true collaboration, a partnership with our Ugandan colleagues.

We started having some of the Ugandan oncologists come over to Seattle, some for short periods of time just to see what our clinics look like, and others to get a master's or even get a PhD. They didn't have a formal oncology fellowship training program in that era.

Several of them, when they came over, said breast and cervical cancer are the

most common cancers in our women. We want to spend time in breast cancer.

That's how I got to meet them and establish relationships and create some projects with them and got to know them. As the years evolved, we added breast and certain other cancers that were common there. I'm now on the steering committee for a formal adult hematology/oncology fellowship program that the East Africa Development Bank is paying for at the Uganda Cancer Institute.

I've watched what's happened there. What happened in Eastern Europe, Central Asia was with these support groups starting.

I told them that I'd come back every once-in-a-while, and bring them together, give a talk. And that's how my weekend project, the Women's Empowerment Cancer Advocacy Network, got started. Every two years since 2003, we've facilitated getting together between 12 and 15, mostly former Soviet, but other Eastern Europe countries, bringing the patient advocates together.

Then I started meeting Ugandan patient advocates, and they said, "Can we do something in Africa like what you're doing in Eastern Europe, Central Asia, to promote the patient advocacy movement?"

I said, "Well, I think it's going to be a lot different, but let's try it."

In 2013, we hosted the first of our annual series of East Africa weekend meetings, in which we bring together, again about 12 to 15 countries, the leading patient advocates who have their own nonprofits.

We do some education—they want to make sure that they're promoting evidence—but also a lot of networking and learning from each other, which is the best part of it all. We missed this year.

Lagos, Nigeria – World Cancer Day activities, February 2016.

It was supposed to be in Malawi, but COVID hit, and I'm not sure we're going to be able to do one face to face, but we've got some ongoing.

We're working with the NCI's Africa ECHO project, with a forum for having regular meetings. We're working on a big women's cancer survivorship effort in Africa right now with the NCI Center for Global Health at ECHO Africa, with key leaders in Africa.

> I hear back from patients that ASCO seems to be a lot about treatment, but not as much about the prevention. I think we need to be more visible in the prevention piece as well.

And we are going to kind of translate the Breast Health Global Initiative survivorship guidelines and the NCCN harmonized guidelines for Africa into some survivorship guidelines specific for Africa, designed by Africans, agreed to by the African community, and then promote survivorship efforts within Sub-Saharan Africa. That's a big project going on now even though we're not able to meet face to face.

I've never understood why there are so few clinical trials being done through the cooperative groups, for example, internationally. It's very rare. I get the bureaucratic explanations, which get me only so far.

JRG: Well, it's because of the rule. For the NCI to pay for a trial through the cooperative groups, it has to be open in the U.S., as well as the other countries.

A lot of the trials that we would propose aren't exactly the leading questions in the U.S., or wouldn't be standard of care. SWOG has a Latin America initiative, and we just spent last week having a virtual meeting in Santiago.

The first meeting was actually canceled at the last minute due to political unrest a year ago, and then it was rescheduled, and then postponed due to COVID. And now we just decided we're going to do it virtually.

I spent last week virtually in Santiago with the SWOG Latin America network, but the problem is there are great researchers there, there are great questions, but for the U.S. government, the NCI, to pay for them, they have to be open, not just in the Latin America countries, but in our U.S. site. And a lot of them are really, really, really important questions, but they just are not the same questions and the same standard of care as we would have in the U.S.

So, we have to find external sources of funding if we're doing a trial exclusively in our Latin America network. And we do have some examples of that.

Also, they can join on any of our other trials that the NCI is paying for, but there are complicated issues with even just getting them study drug. The shipping of drug across borders, of drugs being provided by a company. If we've got the U.S. side of a company giving us free drug, then we want to open it in Latin America, and it's a totally different group of people to work with.

We try to do studies with China, for example, and they have prohibitions on shipping any biologic specimens out of the country. So, there are a lot of issues.

There's another Seattle group called BIO Ventures for Global Health that works with industry. And they've created a couple of things.

One's called the Africa Access Initiative, but more relevant to your question, they have something called AC3T Africa Consortium for Cancer Clinical Trials, and [they are] going in and finding sites in Africa that they fill out surveys.

They go in and inspect them, and they certify them as being a site that could do a clinical trial, and they're creating a network so the industry can come in and have the assurance that BIO Ventures for Global Health knows these people. They've certified them. They have the ability to do blood draws, do the biopsy, and deliver the drug safely with supportive care meds.

There's some people working on very good opportunities to do more of that, but with respect to the cooperative groups, which is what you asked about, we have big barriers in place from our own how we get our money from the government.

It says it comes with a statement that this has to be done in U.S. patients. And if you can figure out how to add on some others, that's fine, but it's got to be predominantly benefiting Americans, is kind of the current ties to that money.

I guess the industry has been able to figure out how to do this well enough. There are a lot of drugs being approved based on non-U.S. data, but can ASCO play a role in making it work better?

JRG: I think in terms of the ease of doing clinical trials across multiple countries and multiple sites and all of that, ASCO can certainly use its voice in terms of some of the policy, some of the gravitas that comes along with being ASCO and collaborating.

I don't know that we're going to be able to turn around things as easily with respect to when money comes out of our own government, what NCI can do with it. I think there are certainly people in the NCI Center for Global Health who would like to ease that up a lot, too.

So, I think I need to learn more about that piece of it, and how ASCO can help with it, because we certainly have some barriers there.

Well, the president-elect really gets it.

JRG: Well, and he is interested in cancer; right? So, we may have a new era coming.

Yeah. Is there anything we forgot to talk about? Anything we forgot to mention?

JRG: I think we talked about a lot of things.

Thank you.

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Cancer hospitals stay open as COVID-19 cases skyrocket

By Alexandria Carolan

The United States faces the worst-yet surge of COVID-19, but cancer hospitals have learned to adapt to the pandemic, opting to continue cancer services at an unchanged pace.

"Treatment, surgeries, procedures are still occurring with minimal delays. Worst case, we are triaging who gets treated and who doesn't," Howard H. Bailey, Andy and Susan North Professor of Cancer Research, professor of medicine, obstetrics and gynecology, director of University of Wisconsin Carbone Cancer Center and associate dean of oncology at the University of Wisconsin School of Medicine and Public Health, said to *The Cancer Letter.*

To gauge how cancer hospitals are responding to this new wave of infections, *The Cancer Letter* posed the following questions to leaders of cancer institutions across the U.S.:

1. How do you expect this new surge to affect cancer care? What's your best-case and worst-case scenario?
2. What have learned over the spring and summer that you're implementing now? What are some of the tools you have now that you didn't have during the first wave?
3. Are you going to be able to provide cancer services? Do you expect patient volume to be as low as it was in the spring?
4. What are your recommendations to patients, faculty, and staff on how to spend the holidays?

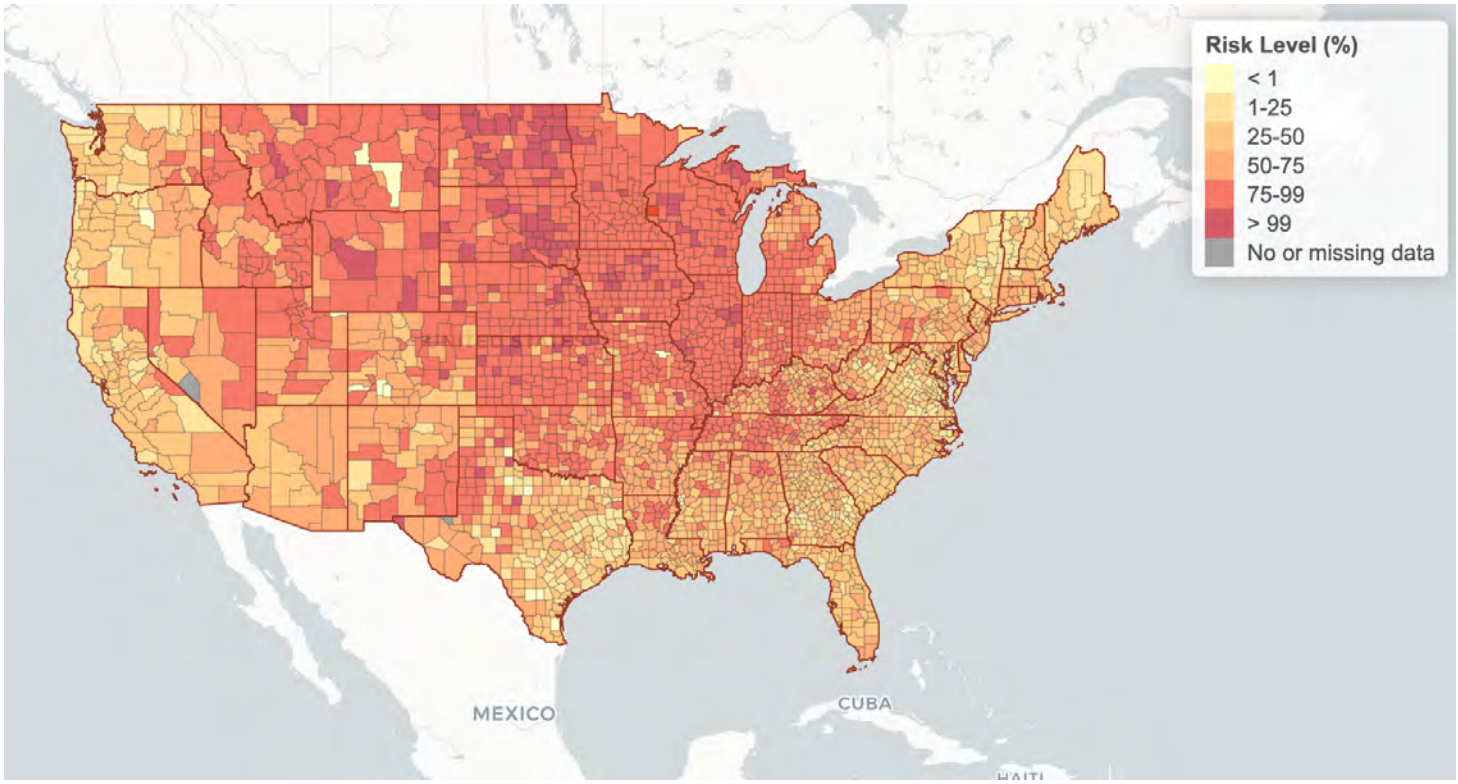
When the crisis first hit in the spring, many U.S. cancer hospitals decided to delay or postpone treatments for cancer patients. When the rate of new infections decreased over the summer, cancer hospitals resumed operations and started to work through the backlog of delayed treatments.

"This time will be different—in the spring the state and the country stopped, and it allowed us to catch our breath, so to speak," Hannah Hazard-Jenkins, director of West Virginia University Cancer Institute, associate professor, and associate chair of surgery for cancer services at J.W. Ruby Memorial Hospital, said to *The Cancer Letter.* "We will not have that this time, and it will pose very different challenges moving forward."

At this writing, 250,000 people in the U.S. have died from the disease caused by SARS-CoV-2. Incidence of COVID-19 continues to rise, with every state reporting exponential spread of the virus.

As a result of delayed diagnoses and cancelled treatments, NCI CISNET modelers predicted that COVID-19 is going to increase cancer mortality in breast and colorectal cancers by about 10,000 deaths. NCI Director Ned Sharpless warned that this likely applies to other cancers as well (*The Cancer Letter,* June 19, 2020).

"This time, the number of cases we are seeing is much higher, and what drives our decisionmaking is no longer highly



The COVID-19 Event Risk Assessment Planning Tool shows the risk level of attending an event, given the event size and location.

dependent on PPE, but on bedspace in the hospital and the availability of key personnel who are contracting the virus through community spread," Hazard-Jenkins said.

The upcoming holidays are a concern for these hospitals. The Centers for Disease Control and Prevention Nov. 19 urged Americans not to travel for Thanksgiving.

To present the risk of gathering in groups, Georgia Institute of Technology has created a map describing the chances of exposure based on event size and location.

"It's not your chance of getting infected with COVID. That's not what the map is showing. It's just a chance that one or more people there may have been infected with COVID," Clio Andris, who co-developed the project, said to *The Cancer Letter.*

According to the map, states in the middle of the country have it worst. If you were to attend an event with 10 people in several counties in the Midwest, there would be a 99% chance that you would encounter at least one infected person.

"More recently, along with North Dakota, South Dakota and Wisconsin had a big surge as well. But before that, we were looking more at Arizona and Florida as having these surges," said Andris, also assistant professor of city and regional planning and interactive computing at Georgia Tech. "We're seeing that things are getting worse and worse and worse. And so, back in September, things had gotten a bit better, and the risk was lower. But seeing towards the end of October, things started to get worse. And now, late November, it's the worst it's been in a long time."

Andris said she expects the risk to increase.

"It's spiraling out of control a bit, it seems, as somebody who's looking at the data, and not as an expert epidemiologist," Andris said. "We're not seeing the behavioral changes that would be needed to really mitigate it from a public health standpoint. We need to rely on the government to create rules and laws that help, because people don't seem to be taking the initiative on their own.

Leaders of cancer hospitals are heeding these warnings.

"Patients should not gather outside their bubbles during the holidays. They should remain in small family units and follow the recommendations for social distancing," D. Neil Hayes, scientific director of the University of Tennessee West Institute for Cancer Research and Van Vleet Endowed Professor in Medical Oncology at the University of Tennessee Health Science Center, said to *The Cancer Letter.*

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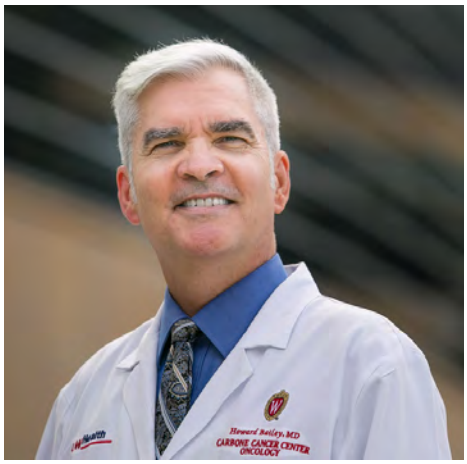
Howard H. Bailey

Andy and Susan North Professor of Cancer Research, Professor of medicine, obstetrics and gynecology, Director, University of Wisconsin Carbone Cancer Center; Associate dean of oncology, University of Wisconsin School of Medicine and Public Health



It is altering how we "follow" our patients, primarily through remote. Our active cancer (whether newly diagnosed or being treated for advanced disease) patient volumes decreased slightly in the spring, and are slightly reduced now.

The number of patients undergoing chemotherapy is down slightly. Relative to our ongoing surge—best case is the current: Treatment, surgeries, procedures are still occurring with minimal delays. Worst case, we are triaging who gets treated and who doesn't.

We have had a more rapid switch to remote visits and have limited clinic exposures, and have better COVID testing now than in spring.

We expect to continue cancer services. I expect volumes to be slightly diminished. We are anecdotally noticing, in some disease areas, more new diagnoses through the Emergency Department, rather than primary care—implying patients are waiting until they can't wait.

For the holidays, limit travel if desiring to meet with family/friends—wear masks throughout, and limit contact. For our profoundly immunocompromised—we are advising against gatherings of any kind.

> Relative to our ongoing surge—best case is the current: Treatment, surgeries, procedures are still occurring with minimal delays. Worst case, we are triaging who gets treated and who doesn't.
>
> *– Howard H. Bailey*

Richard Barakat

Physician-in-chief, director of cancer, Northwell Health Cancer Institute

In some ways, I believe that we are still feeling the effects of the initial wave of COVID-19 infections, so that a new surge will actually be more of a ripple effect—the difference being that we are much better prepared to handle whatever comes our way. Since we have learned a lot, we do not believe that we will need to shut down services to the degree we did in the early stages of the pandemic.

The best case scenario is that we will have a safe and effective vaccine before the end of the year, but it will take some time before they are widely available and distributed. Until then, our most effective weapons against preventing the spread of COVID-19 remain the proper and consistent use of face coverings and PPE, maintaining social distancing, and engaging in proper hand hygiene.

As we prepare for a second COVID-19 wave, we are better equipped to care for these patients. One of the major lessons learned was the need to decrease the flow of traffic in our ambulatory centers to decrease transmission rates, while recognizing the hardships this places on patients and their families.

With the widespread availability, we are judiciously testing our patients for COVID-19. All solid tumor patients are tested prior to their initial chemotherapy and undergo repeat testing based on screening with a symptom checklist. Patients with hematologic malignancies are tested at initiation of therapy then every three weeks.

We were able to continue treating patients with radiation at the start of the pandemic and expect that to remain the same. Patients undergoing radiation do not require testing unless symptomatic or if they have a history of exposure. All patients undergoing surgery require negative testing within 72 hours.

Equally important was the realization that we must take care of our front line workers and prepare for the emotional and psychological toll that a second wave of COVID-19 may cause.

> We plan to continue to treat cancer patients despite a new surge, while doing everything to ensure their safety, but this, of course, will depend on the level of the surge that we experience.
>
> *– Richard Barakat*

We also learned that a lot could be achieved by the use of telehealth, and this is something that will definitely continue. In addition, we were also able to treat some COVID-19 positive patients with modified chemotherapy regimens as well as radiation. For cancer patients with COVID-19 infection, new treatment protocols coupled with scientific advances and newly approved therapeutics will enable us to deliver even more effective care to these patients.

We plan to continue to treat cancer patients despite a new surge, while doing everything to ensure their safety, but this, of course, will depend on the level of the surge that we experience. We will utilize COVID-contained zones with increased use of testing—and this will include sites for surgery, as well as chemotherapy and radiation, so we don't anticipate the level of decreases that occurred in the spring.

We have also developed emergency response standard operating procedures to continue to provide cancer clinical trials that may benefit our patients. This will require the use of telehealth and remote consenting procedures. We also need to continue to provide screening procedures, such as mammography and colonoscopy, to avoid the increase in projected cancer deaths that avoidance of screening may lead to.

We encourage all to continue adopting COVID-19 safety precautions with their families, friends and social networks, especially as people prepare to potentially gather indoors during the holiday season. We wish everyone a safe, happy and healthy holiday season.

Michael J. Birrer

Vice chancellor,
University of Arkansas for Medical Sciences;
Director, Winthrop P. Rockefeller Cancer Institute;
Director, Cancer Service Line

The best-case scenario is that the surge does not materialize, or if it does, it's limited, and our health systems are able to handle it. The worst-case scenario is that it overwhelms the system. In this case, triage and prioritization will become important. In addition, we will enlarge our intensive care beds along with available ventilators. I think, in the end, we will meet all of the challenges of the COVID pandemic

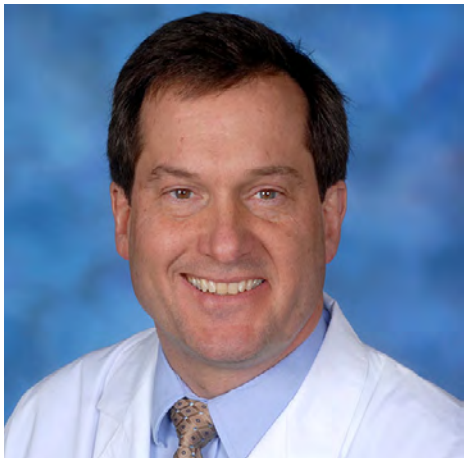
COVID is important, but so is caring for cancer patients. They expect prompt diagnosis, timely effective therapy, including chemotherapy. We have streamlined our screening process and are now allowing visitors, which greatly helps the quality of life for our cancer patients.

We will continue to meet our Arkansas cancer patients' needs. Our clinics are fully open and our volumes remain strong.

Enjoy family and friends during the holidays—it's important, but also stay safe. Maintain social distancing, and use masks when you can't.

John F. Deeken

President, Inova Schar Cancer Institute;
Medical director,
Inova Schar Head and Neck Cancer Program



We have learned so much over the past seven months in how to contend with this pandemic, from patient screening, testing, and triaging patients based on COVID infection severity. We also rapidly pivoted to using telemedicine when possible and appropriate.

In the best-case scenario, we adjust our outpatient clinics and treatments, including chemotherapy and radiation, to enable cancer care to continue despite rising infection rates. We use what we have learned about COVID treatments to do far better than the 16% mortality rate we saw in the spring in cancer patients who become infected with COVID.

In the worst-case scenario, our inpatient hospitals become overwhelmed with COVID patients, our cancer patients again refuse to go to the ER when their medical condition warrants, and cancer screening efforts are again put on hold.

We learned how to protect cancer patients and safely treat them with our comprehensive cancer center policies, including our COVID testing clinic—separating COVID patients from other immunosuppressed patients, testing patients prior to starting chemotherapy, home remote monitoring of cancer patients with COVID who have mild to no symptoms, use of PPE including face shields as well as masks, and providing telemedicine services when appropriate. All of these tools will be put to good use as we enter the difficult season ahead.

We never saw a drop in active cancer patient treatments in the spring—in fact, our volumes grew by 10%. We maintained active treatments, and even kept our clinical trial program fully open. We did see a dip in breast surgery clinic visits in May and June, due to decreased screening studies being done—but that now has more than rebounded.

We rapidly moved toward telemedicine visits, and at one point had about 80% of our clinic visits done via telemedicine. Now, that is about 20%. We expect to see that gradually move toward more telemedicine percentages if the situation significantly worsens.

We learned a great deal in the spring on how to continue cancer care despite COVID, and will continue to refine our processes going into the winter to maintain our patient care. As long as the people in our community continue to safely distance, wear masks, and wash hands frequently, we hope to not see the overwhelming experiences that Seattle and New York City saw early in the pandemic. Be safe. Wear a mask. Maintain social distances. Follow the guidelines of the CDC as well as the elected and health officials in your state and county. Be especially careful with older family members and anyone with a cancer diagnosis, to get them successfully through this time period until the anti-COVID vaccines become widely available.

Wafik S. El-Deiry

Director, Cancer Center at Brown University;
Director, Joint Program in Cancer Biology, Brown University and Lifespan Cancer Institute;
Attending physician, hematology/oncology, LCI;
Mencoff Family University Professor,
Associate Dean of oncologic sciences, Warren Alpert Medical School, Brown University;
American Cancer Society Research Professor

There will be more telemedicine visits. This is mostly to reduce the numbers of patients on site, if they don't absolutely need to be seen in person. Patients who need to be seen on site will be seen as we consider those situations low risk with current PPE use by both our care team and patients.

There are plans in our state to open up facilities at various sites as our hospitals fill up and additional capacity is needed. There are now some therapy options that could be helpful such as antibody therapies that can be used for the most high risk patients.

This includes a recent emergency use authorization for bamlanivimab and recent guidance from the CDC for the high risk individuals for whom its use is being prioritized. Anything that can prevent worsening of symptoms can help and we didn't really have these or other capabilities (availability of data with remdesivir or steroids in COVID) months ago.

We intend to continue caring for patients. The patients who need active treatment need to get it. There will continue to be an impact on cancer screening as patients weigh the risks while the pandemic is surging. We have encouraged patients to not put off cancer screening or care and we will do everything possible to facilitate their care. Our clinical trials kept going and enrolling patients through the spring and we expect that to continue as long as staff are available.

During the surge of this pandemic, everyone must use caution in situations where risk is increased. This means avoiding large gatherings, maintaining social distancing, using PPE, and strong consideration of staying home and not traveling or having holidays turn into spreader or superspreader events. If we can all be patient long enough for a vaccine to become available, this period will pass and hopefully later in 2021 more things will be back to normal.

I would like to add that we've been actively doing research so we can learn more and develop new approaches to deal with COVID-19. Our first study was just published and made the cover of the Nov. 17, 2020 issue of the journal *Oncotarget*. This paper culminates several months of intense effort by a very

talented multidisciplinary group of collaborators.

We discovered in our preclinical studies that MEK inhibitors as a class have effects that are relevant to COVID-19 and worth testing further. For example multiple MEK inhibitors suppress SARS-CoV-2 infectivity factors, boost natural killer cell killing and attenuate cytokines. We showed that MEK inhibitors reduce a SARS-CoV-2 Pseudovirus infection of human lung and small airway epithelial cells.

We hope to see further effort in clinical trials for example looking at whether MEK inhibitors might add something useful to remdesivir in slowing progression to severe COVID particularly in COVID-positive patients who are hospitalized but don't require much oxygen or ICU care. There are many clinical trial opportunities and we think with the surge, trials will help us learn more quickly what may be helpful to patients.

In addition, we have a manuscript under review that should appear on the preprint server BioRxiv soon where we tested plasma samples from COVID-positive versus COVID-negative individuals. This analysis from a large panel of cytokines, chemokines and growth factors in a good-sized patient cohort points to macrophage activation syndrome as an important lead in predicting COVID disease severity and which could be helpful in monitoring the effects of therapeutics. We believe this type of collaborative research is very important at this time to complement other efforts in the field to develop therapeutic antibodies and vaccines.

Mark B. Evers

Professor of surgery, Mark McDowell Cancer Foundation Chair,
Lucille P. Markey Cancer Center;
Director, Markey Cancer Center;
Physician-in-chief, Oncology Service

Best case: All operations continue unchecked with continuation of our clinical research, non-urgent surgical cases, and uninterrupted screening services. Also, maintaining visitor accessibility to in- and out-patient care settings and maintaining healthy and productive staffing levels.

Worst case: Restrictions to clinical research, delays to non-urgent procedures and screening services. Removing visitor accessibility to in- and out-patient care settings. Reduction to productive staffing levels due to compromised health conditions.

[What we learned over the spring and summer was to implement] efficient daily screening of patients and staff, limited visitation, mandatory masks, and distancing at all times. In addition, we effectively utilized telehealth services for care when indicated. Currently, there is a better understanding by faculty and staff of the disease and its behavior. All inpatients and all surgical patients are COVID screened. Rapid changes in operations are ready for implementation when indicated.

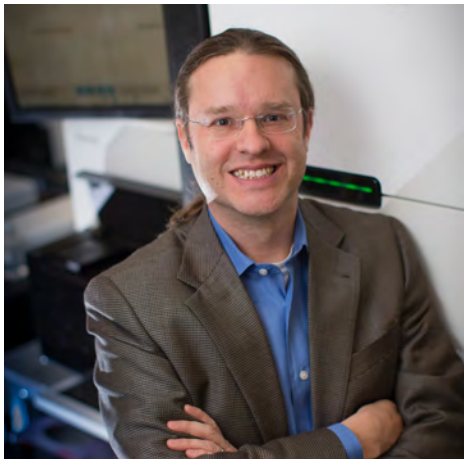
Even though infection rates are higher in the community, we do not expect volumes of ambulatory visits or surgeries to decrease to spring levels. COVID screening of all surgical patients means that indiscriminate canceling of elective surgeries will not be necessary. Unfortunately, preventative services are likely to be negatively impacted with a rise in COVID-19 numbers.

However, our ability to manage and maintain a safe care environment for all our patients, caregivers, and clinical team will ensure cancer care continues for those with new disease or under active treatment. New telehealth services will allow providers to manage surveillance and long-term survivors until the pandemic subsides.

[For the holidays, practice] distancing, small groups, wear masks, and don't travel unless absolutely necessary.

D. Neil Hayes

Scientific director,
University of Tennessee West Institute for Cancer Research;
Van Vleet Endowed Professor in Medical Oncology,
University of Tennessee Health Science Center



My expectation is as follows:

COVID has impacted our ability to treat patients who normally travel for their care. Usually, we have housing for out-of-town patients, but this is greatly reduced because of restrictions in our ability to supplement costs for traveling patients. This is especially bad for inten-

sive treatments, like radiation, where they need daily treatment, but cannot travel the distance involved, and cannot get local housing.

COVID has hit our ability to treat patients in nursing homes. Nursing homes are fearful of transporting patients back and forth for chemotherapy or radiation because this creates a hole in their bubble. They are worried about such patients bringing in COVID. Nursing home patients are finding it harder to get treatments and are being directed toward more palliative approaches. Many of them are sick, and a hospice decision is reasonable—but it is not what would happen normally.

Many patients are deferring the initial visits to the surgeons or other providers that would have diagnosed the initial cancer, and I think some diagnoses are being delayed.

Once patients are in treatment, COVID is causing some delays in things like routine X-rays and procedures, because of the requirement to get screened before the procedure can occur.

Our clinic closed one day per week, which complicated things for us. This was a money decision, not so much because we were losing money, but because the hospital was.

I think we learned that if we take the common precautions of masks, hand washing, and other proven techniques, the transmission rates in the hospital are not terrible. I am not an expert in this per se, but it does appear that we are not seeing lots of in-house transmission. We have also tried to adapt to all of the issues above to do the best to manage patients.

For the moment, outpatient cancer care remains on track, although hindered as described above. I think we are likely to see some older patients shifted toward simpler treatments or hospice, because of the added burden of cancer. We are likely to see some delays in diagnosis because of patients and provider behaviors. We are likely to see some delays because of slowed services.

Patients should not gather outside their bubbles during the holidays. They should remain in small family units and follow the recommendations for social distancing.

Hannah Hazard-Jenkins

Director, West Virginia University Cancer Institute; Associate professor, associate chair of surgery, Cancer Services, J.W. Ruby Memorial Hospital

This surge is different for the WVU Cancer Institute and West Virginia. In the spring, we were driven to act based on minimal understanding of the disease, limited PPE and testing for the disease. The number of COVID cases in our state remained relatively low in the spring.

This time, the number of cases we are seeing is much higher, and what drives our decision-making is no longer highly dependent on PPE, but on bed space in the hospital and the availability of key personnel who are contracting the virus through community spread.

Our best-case scenario is we weather this as well as we did in the spring, without slowing down screening practices and maintaining timely operative interventions. Our worst-case scenario is that our hospitals enter a scenario where we do not have enough bed space to allow our cancer care to proceed according to national guidelines.

This time will be different—in the spring, the state and the country stopped, and it allowed us to catch our breath, so to speak. We will not have that this time, and it will pose very different challenges moving forward.

> “Our best-case scenario is we weather this as well as we did in the spring, without slowing down screening practices and maintaining timely operative interventions.”
>
> *– Hannah Hazard-Jenkins*

The lessons of the spring are global—how the disease is spread, what precautions are necessary, maintaining adequate PPE and increasing capacity for testing. We developed mechanisms to mitigate potential exposures such as using telemedicine and we developed algorithms for identifying priorities for operative cases with cancer being highest in schema.

All of these are being implemented again, but with a different bend. We aren't making decisions based on availability of PPE and testing; we are making them based on bed space from high

community spread. Those decisions look a little different, but we have a solid frame of reference based on our spring experience.

There were some definite moves we (and the nation) made in the spring we will try not to repeat and ultimately learn from. We learned the impact of not screening as we are seeing patients present with more advanced disease and the hope is to maintain screening during this surge.

We learned we could do telemedicine but I think more importantly, we learned everyone is not capable of getting care this way. There are portions of our catchment area that do not have broadband at their homes and a portion of our older population are not technologically savvy enough, even if they did have broadband.

So, we learned we need other ways to deliver care and that telemedicine is not quite as successful in some areas of the country. Aside from the above "technical" components of our learning curve, what I was struck with most in the spring was the grace and humility of our cancer community.

Patients acknowledged and accepted deviations of care to keep themselves and others safe. Our staff showed up to work every single day, putting the unknown and fear of catching a deadly virus second to their dedication to their patients. Never once did I hear opposition to any task set before them because they knew the lives of our patients are that important.

Our volume shift in the spring varied on type of treatment received. Our clinic volume certainly dipped, and we moved patients to telephone or telemedicine when possible. As with most of the country, our screening volume went to nothing, and we are seeing the consequences of that now. However, our infusion volume varied, at most, by 15% and most of that was for the non-chemotherapy infusions.

Additionally, our radiation oncology practice maintained and at times exceeded the expected volume. We will provide cancer serves during this surge as we did through the last. My hope is that with this surge, we will not have to halt our screening practices and we will be a little more discriminatory on which patients can do telemedicine and which patients can and need an in-person visit. My plan is our clinical and screening patient volumes will not drop as it did in the spring.

We all must be smart in our choices. In the spring it was easy—the world basically stopped, and everyone abided/adhered to the recommendations of social distancing and masking due to fear and lack of knowledge. It has been a long eight months for our country and the frustrations of isolation and lack of a treatment will become more apparent as we are denied the ability to congregate in large groups. My recommendation is to maintain the bubble established over the last 8 months.

This year, for me, what I am thankful for is different than years past; I am thankful for the ability to celebrate, even though it is different, and I am thankful for the dedication and selfishlessness of every single healthcare worker and hospital/outpatient personnel that has shown up to work since the beginning of the pandemic.

Paul J. Hesketh
Director, Lahey Health Cancer Institute; Director, Sophia Gordon Cancer Center and Thoracic Oncology, Lahey Hospital and Medical Center

I am more optimistic than I was when the initial surge occurred in the spring. At that time the complete lack of knowledge about COVID-19, its natural history, most appropriate management strategies and the rapid increase in number of infected patients requiring hospitalization, often with admission to ICUs strained many health systems to the near-breaking point.

We are now much better prepared to deal with a new surge of cases given expanded testing capabilities, adequate PPE supplies, more effective therapeutic capabilities and the development of organizational and administrative structures totally focused on responding to any new challenge.

During the first surge, most non-cancer-related elective surgical and diagnostic procedures were canceled. Cancer surgeries, for the most part, with the exception of some patients with prostate and breast cancer, continued. Cancer screening procedures, such as mammography, CT-lung screening and colonoscopies were shut down.

The potentially negative impact of delayed screening remains to be seen, but is a major concern. We did not experience a major reduction in our cancer infusion volumes, because, again, for most patients, therapy could not be safely postponed. Radiation therapy volumes did go down somewhat, espe-

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cially for some early stage breast and prostate patients.

The negative emotional and physical toll on our cancer providers cannot be forgotten as we had to re-deploy both physicians, advanced practitioners and nurses from our cancer clinics to the ICU's and inpatient floors to care for the overwhelming number of COVID-19 patients. In addition, our research mission was negatively affected as we had to temporarily close a number of clinical trials to accrual and postpone the initiation of several new trials.

My best-case scenario is that our ability to deliver timely and effective cancer therapeutic services will be minimally disrupted by the currently developing surge in COVID-19 cases. Best practice measures to create a safe environment for patients and staff (pre therapy COVID-19 testing, pre-visit and on-site patient screening, mandatory mask, hand washing and social distancing measures, expanded telehealth) will allow us to continue to function without major disruption.

We also have plans to continue critical radiographic screening procedures. At Lahey Hospital and Medical Center we have one of the largest CT lung cancer screening programs in the US and we are committed to minimizing the impact of COVID-19 on this life-saving program.

We have been provided greater flexibility by both governmental and commercial regulatory authorities to incorporate telehealth and remote monitoring options into our clinical trials which should allow our essential clinical investigation program to maintain momentum.

My worst-case scenario, which I think is much less likely, is that there will be a rapid increase in the number of COVID-19 cases requiring hospitalization, similar to the volumes noted in the spring which could prove overwhelming. Although better prepared, our hospitals will again be challenged to maintain all essential services for non COVID-19 patients.

This would have the potential to divert resources away from cancer services to care for this critically ill population. So far, although numbers of COVID-19 hospitalized patients are increasing in our Beth Israel Lahey Health system hospitals, lower proportions are requiring ICU admission than during the spring surge. The long-term negative financial impact on our institutions could also prove to be a less immediately visible but ultimately greater threat to our ability to fulfill our clinical and research cancer missions.

> "The important thing to keep in mind is that current progress in the development of effective therapeutics and especially vaccines makes it very likely that our holiday season one year from now will be markedly different."
>
> *– Paul J. Hesketh*

We have learned a number of key points during our initial experience with the COVID-19 pandemic which should prove invaluable as we start to deal with a second surge in cases.

These include:

- The rate of COVID-19 positivity in asymptomatic cancer patients presenting for treatment in our infusion, radiation therapy and diagnostic centers has been very low
- The likelihood of staff members practicing appropriate precautions acquiring COVID-19 infection from patients has also been very low
- Treatment with chemotherapy and checkpoint inhibitors could be safely delivered during the peak of the first wave without leading to an apparent increase in morbidity or mortality
- Additional tools:
  - Markedly expanded telehealth capabilities with an increasing proportion of video as compared to telephone only visits
  - Much more robust capabilities for COVID-19 testing

Unless there is an overwhelming second surge, I am confident that essential cancer services will continue to be delivered in a safe and timely manner. Patient volumes for those on active treatment should not significantly diminish given the protocols that are now in place to insure patient and provider safety. Please see additional comments made in response to question one.

Clearly it will be a dramatically different year for all of us as we plan our holiday celebrations. My advice includes maintaining strict adherence to good hygiene (mask use, hand washing and social distancing, especially as most activities shift indoors) postponing typical in-person social gatherings, minimizing non-essential travel, and limiting family get-togethers to small numbers of individuals who, for the most part, have all been living in the same household.

The important thing to keep in mind is that current progress in the development of effective therapeutics, and

especially vaccines, makes it very likely that our holiday season one year from now will be markedly different.

Roy A. Jensen
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

Thus far, the new COVID-19 surge has not limited our ability to provide comprehensive cancer care. We continue to operate at full capacity in our treatment and research functions with no plans to limit access to needed services. In order to do so, extra efforts are needed to protect the health and emotional well-being of patients, families, medical providers and staff.

We are expanding all possible resources, improving and streamlining communications, and extending cancer care services to meet patient needs. Examples of this include telehealth and home infusion services, and keeping our staff healthy. In addition, there is added emphasis on educating our community on COVID-19 prevention and safety through our patient advocates.

The best-case scenario is that the safety measures and protocols we have in place continue to be enough to provide uninterrupted patient care. We hope to have enough protective measures such as PPE, and a vaccine for at-risk populations, including cancer patients and medical providers.

The worst-case scenario is that we see a continuance or acceleration of the current curves for new cases and deaths. Limited staffing or bed availability could create a need to triage care based on a series of predetermined algorithms around need and severity.

The oncology workforce could be compromised by staff COVID-19 infections and quarantine requirements, and we could experience PPE and resource shortages, which in turn could then lead to further staffing issues. If cancer care services are limited, this could delay or stop life-saving surgeries, radiation and medical treatments—eventually leading to more cancer deaths due to COVID-19 and cancer.

Transmission and infection of COVID-19 is preventable if people wear face masks and appropriate protective equipment, social distance and wash hands regularly. In the spring/summer we implemented rigorous safety procedures and protocols. We learned how to consent and take care of cancer patients remotely, and with a limited crew physically on-site.

COVID-19 testing is now available to almost everyone who needs to be tested. In March, we were one of the first centers to test patients for COVID-19 before starting chemotherapy—preceding any standard of care guidelines around asymptomatic testing.

We did this via an investigator-initiated trial, which we developed and launched in just nine business days. Our decision to screen patients pre-chemotherapy was based on early reports indicating their increased susceptibility to complications from the virus.

We have adequate PPE and telehealth tools providing the ability for some procedures to be completed close to home, saving the patient a trip and limiting both patient and staff exposure. Since March 29, 2020, a total of 16,813 telehealth appointments have been conducted, representing roughly 13.3% of all appointments with a physician/APP. Most importantly, KU Cancer Center's health professionals and administrators are united, and we are optimistic we will have effective COVID-19 treatments and a vaccine in the near future.

Yes, KU Cancer Center's proactive safety measures for both patients and staff have been a tremendous success. We have provided a safe environment for our patients and continue to demonstrate to our patients the extra steps we have taken including physical distancing and cleaning protocols, temperature and symptom screening, limiting access and people in certain high-risk areas, as well as staff and patient COVID testing.

Our multidisciplinary care setting has helped us greatly during this time. Rather than a patient having to go to several offices with different rules, precautions, etc., our approach to care as well as our interdisciplinary communications helps us provide consistent, stable care. Experiencing cancer is stressful enough, we want to make it as easy as possible for our patients.

There are several leadership and taskforce committees looking at education, prevention, research, communication and cancer center resources. We have numerous options for both patients and staff to be tested for COVID-19 for their safety and our cancer center community. During the last two weeks of March, while the above measures were implemented, we had a mild decrease of patients in clinic and treatment but since then we have been fully operational.

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The COVID-19 infection rate among staff providing oncology patient care is ~1%.

We know we must remain nimble in the ever-changing situation. Our multidisciplinary approach to care, with our solid research infrastructure, allows us to look at challenges from all angles and move forward quickly with solutions.

Local, state and federal guidelines could impact us, however KU Cancer Center is prepared and we do not anticipate decreased patient volumes. We continue to communicate to our patients that KU Cancer Center is doing everything possible to keep them safe and that cancer care should continue during the pandemic.

We all want to be with friends and family for the holidays, however we need to protect each other, our community and our patients. Transmission of the disease is relatively easy to prevent: mask up, practice physical distancing and wash your hands. Look for alternative ways to be with friends and family such as virtual dinners and activities.

Consider stopping by to see family, but stay 6+ feet apart for a limited time to show your love during this special time. The safer we can be now to limit the spread of COVID-19, the sooner we can resume normal activities. We may have to make sacrifices this holiday season, but this will make future get-togethers all the more meaningful and special.

Mia Levy
Director, Cancer Center at Rush University Medical Center;
Associate professor, Department of Internal Medicine,
Division of Hematology, Oncology and Cell Therapy,
Rush University;
The Sheba Foundation Director, Rush University Cancer Center;
System vice president of cancer services, Rush System for Health

This second surge in COVID-19 cases does require us to implement changes to the delivery of cancer care, but our hope is that it will not disrupt our ability to provide all cancer care services.

In the best case scenario we will be able to continue to provide all cancer related services, leveraging the lessons learned from the first wave in the spring including the principles of social distancing, use of personal protective equipment, and COVID testing for patients and staff.

With respect to social distancing, we have implemented several strategies to decrease the total number of people in the medical center to enable social distancing in clinic waiting rooms and common areas where staff congregate. In particular, we have resumed visitor policies that limit the number of people entering the medical center and cancer clinics.

Likewise, we have resumed work-from-home approaches for all employees whose job functions can be performed remotely. All meetings including tumor boards continue to be held virtually.

Furthermore, we have continued to offer virtual visits to our patients as an alternative to in-person visits. We deployed this extensively at the beginning of the pandemic in the spring with upwards of 35% of our clinical encounters converted to virtual visits.

Throughout the summer we maintained approximately 10% of all ambulatory clinical encounters as scheduled virtual visits. Now with the fall surge, we are seeing an increasing interest in patients requesting scheduled virtual visits. Virtual visits help achieve social distancing goals by decreasing the number of patients in the medical center and enable family members to participate in appointments when we have limited visitor policies.

> We fully expect to be able to continue to provide cancer services throughout this second wave. We do not expect patient volumes to be as low as they were in the spring.
>
> *– Mia Levy*

In the worst case scenario, we would need to modify our services due to limits in hospital bed capacity. In particular, limits to hospital bed and ventilator capacity impact elective surgery services. As an institution, however, we will continue to prioritize life saving and palliative cancer surgeries with the goal of not disrupting cancer services to the greatest extent possible.

Ambulatory clinical services could also be impacted if a high enough number of staff are out on sick leave due to active

COVID infection or symptoms awaiting testing results. While we don't anticipate that this would decrease capacity for ambulatory cancer services to the levels experienced in the spring, it could have an impact.

In the spring and summer, we learned how to continue to deliver cancer care to patients with active COVID infection and those in the immediate six weeks post-infection. We implemented PPE and COVID testing strategies that allow us to continue to deliver infusion and radiation therapy to cancer patients with recent COVID infections. We have developed these workflow processes for safe delivery of care in this setting and anticipate we will be able to continue to do so during this fall surge.

Furthermore, new COVID treatments and treatment protocols are improving clinical outcomes for patients with cancer and we are already seeing the impact with decreased length of stay in the hospital and decreased in ICU admissions and intubation.

We fully expect to be able to continue to provide cancer services throughout this second wave. We do not expect patient volumes to be as low as they were in the spring.

In accordance with the CDC guidelines, we are recommending that both patients and faculty/staff participate in in-person holiday celebrations limited to the members of their immediate household and otherwise participate in virtual holiday celebrations with those family and friends outside of their household.

Michael A. Thompson
Medical director, Early Phase Cancer Research Program,
Co-director, Oncology Precision Medicine Program,
Advocate Aurora Health

In the spring, cancer center responses were often dependent on local regulations and case rates. There were peaks at different sites over time, but now clearly there are high rates all over the U.S. We know that this has decreased clinical trial accrual from the spring through fall. Accrual was starting to improve and will predictably drop again as hospitals tighten up and more research staff work from home amongst other factors.

In response, in the spring, many patient visits shifted to telemedicine. However, cancer screenings, including colonoscopy, mammography, etc. slowed or stopped. We can expect stage migration from the decrease in cancer screenings.

In the best case we will extend things that worked—work from home for some workers, telemedicine/telehealth visits, changes in chemotherapy schedules, and triage and prioritization changes. We need the ability to tele-consent for research and reimbursement for time and intellectual effort involving clinical care and research.

Clinically, we restrict visitors, screen for symptoms (questions in person and/or app) and temperature at the door and ensure masking. Cleaning protocols and physical separation in waiting areas has changed. Ten percent or more visits are virtual using an embedded EMR app. Patient care is individualized and might include greater spacing between visits if doing well, chemo breaks, or oral instead of parenteral dosing.

We have more data. There are multiple COVID19 registries and meetings that have helped evaluate risks in various populations. I was involved in the crowdsourced formation of the COVID-19 and Cancer Consortium (CCC19, CCC19.org)

A series of publications (in *The Lancet*, ASCO 2020 annual meeting abstract, *Cancer Discovery*) have provided more information, including an ASH 2020 abstract looking specifically at the hematologic malignancy population. Additionally, the NCI COVID19 registry will evaluate patients with cancer that are COVID-19 positive with sequential laboratory testing and outcome tracking.

We should have multiple COVID-19 vaccines by spring 2021, although we don't have data on the utility in cancer patients yet—we will still suggest vaccination. In a limited study, we do see antibody response despite Ig level in multiple myeloma. Additionally, more data may emerge showing that COVID-19 convalescent plasma may benefit patients when given early.

My gestalt is that treating patients in the time of COVID-19 is a risk/benefit analysis. Patients that don't need to be seen should be seen virtually or spread out appointments. Patients that are newly diagnosed or progressing need treatment.

We did and will continue to optimize the patient experience to deliver care as best we can. We need assistance from government entities and the community to decrease the risk to our immunocompromised and at other at risk patients. I suspect we will not drop to the low volume we did in the spring for multiple reasons noted previously including learning how to handle clinics in this new environment.

> There is a light at the end of this long and dark tunnel. Celebrate with your local (same home) family. Vaccines will help, but may take until next winter to decrease risk substantially. Please, individualize your treatment strategy which may include telemedicine visits with your physician and oncology team.
>
> *– Michael A. Thompson*

There is a light at the end of this long and dark tunnel. Celebrate with your local (same home) family. Don't travel or meet in groups outside of your immediate family. Vaccines will help, but may take until next winter to decrease risk substantially. Please, individualize your treatment strategy which may include telemedicine visits with your physician and oncology team.

Michael J. Zinner
Chief executive officer,
Executive medical director,
Miami Cancer Institute

We are extremely worried about the surge that is coming between Thanksgiving and January, because if it mirrors what happened in March and April, and then again in July, we will see a decrease in the numbers of patients screened—and a decrease in the numbers of patients we'll be able to see.

The best-case scenario would be that things won't get any worse than they are right now, but I don't think that is realistic. The worst-case is that a COVID-19 spike hits us hard, affecting patients, staff and the community at a higher rate.

We learned to scale up on testing. We have a multi-step COVID-19 screening process with rapid patient and employee testing. Our surveillance testing is mandatory, much like how the flu vaccination is mandatory for our staff.

Our COVID Command Center has been refined and expanded. Information from our detailed screening is entered into a Miami Cancer Institute-designed database and through a sophisticated program, we have intense observations and contact tracing and we follow patients at home. In addition, Miami Cancer Institute has been involved in many of the COVID-19 clinical trials. Everything we learn from those helps us as we move forward in developing better treatments for the infection.

We never stopped providing cancer care during the pandemic, and we will continue to provide care. We do realize, however, that when we have a COVID-19-positive patient, for example, who is already undergoing radiation therapy treatment for a solid tumor, things will be different.

We bring those patients in through a different entrance, we move them to the end of the day, we take them out through a separate exit and we enhance our already extreme cleaning methods. At the height of the pandemic's first wave, we were seeing about 60% of our medical oncology follow-ups virtually through telemedicine.

We are down to about 30% now, but, if this wave continues to increase, I expect we'll go back up. As far as patient volume, I think we'll stay at about 80% of our normal volume. I would like to stress, though, that anyone experiencing symptoms of any disease should not ignore symptoms and should not be afraid to seek care at a hospital because of COVID-19. Going to a hospital is safer than a trip to the grocery store or a restaurant. We are taking extreme precautions so that our environment is safe.

Patients should be very careful about gatherings this holiday—period. For the past 27 years, I would bring my entire family together in Miami or Massachusetts, all 20 or 25 of them, for a holiday event. This is the first time in 27 years we are canceling. We are doing a Zoom celebration instead. Social distance. Wear masks. Wash your hands. Do not gather in groups.

NEWS ANALYSIS

Trump et al. are wrong: Biden Cancer Initiative is not to be confused with the Beau Biden Cancer Moonshot

By Matthew Bin Han Ong

On Nov. 15, shortly after midnight, President Donald J. Trump tweeted a link to a *New York Post* headline:

> "Tax filings reveal Biden cancer charity spent millions on salaries, zero on research"

Photo courtesy of Pix_Arena / Shutterstock.com

Waking up later that morning, Fox News host Laura Ingraham and former Trump campaign manager Corey Lewandowski, gleefully lent their voices to the now-familiar cacophony of disinformation. A day later, Fox News host Sean Hannity joined their chorus.

For those just tuning in, the president was retweeting a story about the Biden Cancer Initiative, a small organization that is not to be confused with the Beau Biden Cancer Moonshot, a bipartisan effort to increase funding for cancer research.

The Moonshot demonstrates President-elect Joe Biden's deep understanding of cancer and defines Biden's legacy in the Obama administration (*The Cancer Letter*, Nov. 13, 2020). The *Post* story and the subsequent brouhaha are noteworthy because of their failure to recognize the fact that Biden had already obtained $1.8 billion for cancer research via the 2016 Moonshot—and their failure to distinguish between the Moonshot and a small nonprofit that was never intended to fund research. Creating confusion—conflating—seems to be the point.

Let's untangle this knot:

- The Beau Biden Cancer Moonshot is a government program resulting from an unprecedented bipartisan effort to double the rate of progress in cancer research. In 2016, then Vice President Biden's leadership and steadfast congressional support for biomedical research culminated in the Moonshot legislation, which authorized $1.8 billion over seven years for cancer research (*The Cancer Letter*, Dec. 16, 2016).
- The Biden Cancer Initiative, the object of coverage here, was a short-lived cancer nonprofit that was launched in New York on June 26, 2017, in the afterglow of the Beau Biden Cancer Moonshot of 2016 (*The Cancer Letter*, June 30, 2017). The organization ran for two years, suspending operations during the Biden presidential run.

The *New York Post* is factually correct on one point: The Biden Cancer Initiative funded no research. That's because, again, it was never intended to.

The anatomy of disinformation

After *The Cancer Letter* published this news analysis Nov. 13, the *New York Post* and the *Daily Mail* ran stories lambasting the Biden Cancer Initiative for spending "ZERO" dollars on cancer research.

The two articles stirred the Trumpian Twitterverse into a frenzy, as tenths of thousands of consumers of alternative media retweeted the alleged scandal, screaming "CROOKED BIDEN!" and "LOCK THEM UP!"

The *New York Post* story was written by Isabel Vincent, a Canadian. The *Daily Mail* story had no byline. The *Post* is owned by Rupert Murdoch, and the *Daily Mail* is a London-based tabloid.

The stories demonstrate zero understanding of either the Beau Biden Cancer Moonshot or the Biden Cancer Initiative:

- "A cancer charity started by Joe Biden gave out no money to research, and spent most of its contributions on staff salaries, federal filings show," Vincent wrote.
- "President-elect Joe Biden's cancer charity spent the majority of its money on staff payroll and gave none to research, it has been revealed," an anonymous "DailyMail.com Reporter" wrote.

Concerned citizens of Twitter responded to this disinformation by countering with a link to the Nov. 13 story published in *The Cancer Letter*. Soon enough, *The Cancer Letter* received a barrage of emails accusing its reporters of supporting a "corrupt politician," committing "fiction," playing a "bad joke," etc.

Contemporaneous coverage by this reporter demonstrates that from the outset, the Biden Cancer Initiative was not designed to be a grant-giving organization.

It was created to allow Biden to continue playing the role of convener, and to maintain momentum generated by the Beau Biden Cancer Moonshot, which at that time had already slated $1.8 billion for NCI over seven years and $500 million over a decade for FDA.

Shortly after Congress overwhelmingly approved the Beau Biden Cancer Moonshot—and months before the Biden Cancer Initiative was formed—Biden said the nonprofit's primary purpose was not philanthropy (*The Cancer Letter*, Dec. 22, 2016).

"It's not so much about raising money or philanthropy—though there will be some of that—but it's more about keeping these guys cooperating and changing the culture," Biden said Jan. 3, 2017 to a woman who came up to greet him after a ceremonial swearing in of Sen. Kamala Harris (D-CA). "I'm going to be based out of Penn for foreign policy. I'm deliberately not associating with any one medical center."

At the 2017 annual meeting of the American Association for Cancer Research in Washington, D.C., Biden laid out his mission plan for the Biden Cancer Initiative:

"The initiative will focus on improving data standards, and giving patients some mechanism to share their data so they can help many other patients going through the same fight, so researchers can use data to find new patterns and new answers, working with community care organizations help improve access to quality care so outcomes aren't wholly dictated by the patient's ZIP code, convening a national conversation with the pharmaceutical companies, insurers, biotech companies and others to ensure patients can actually access the treatments that become available and as are needed," Biden said at the time (*The Cancer Letter*, April 7, 2017).

> The Post story and the subsequent brouhaha are noteworthy because of their failure to recognize the fact that Biden had already obtained $1.8 billion for cancer research via the 2016 Moonshot.

On July, 15, 2019, the Biden Cancer Institute announced that it has suspended operations, three months after the former vice president and Jill Biden stepped down as co-chairs to refocus their efforts on Biden's 2020 presidential campaign (*The Cancer Letter*, July 19, 2019).

The nonprofit's 990s from fiscal years 2017 and 2018 show that it received a total of $4,809,619 in "gifts, grants, contributions, and membership fees," which includes $2,886,167 in "public support." These filings can be downloaded here.

Of the over $4.8 million, $3,070,301—or 63.8%—was spent on payroll over two years. Other large expenses include a total of $799,671 over two years for conferences, conventions, and meetings.

According to the *New York Post*, then-BCI president Gregory Simon "raked in $429,850 in fiscal 2018 (July 1, 2018, to June 30, 2019), according to the charity's most recent federal tax filings."

Those filings show that Simon received a total of $654,389, or $327,194 each year when averaged over the two years.

"The president's salary is determined by the board of directors using comparative data," the filings state. "Staff salaries are determined by the president with consultation of the board of directors and within the structure determined by the board approved annual operating budget. The last salary review took place in July 2018."

It's not uncommon for large nonprofits to pay their CEOs and presidents millions of dollars every year. For instance, the American Heart Association pays its CEO nearly $2.4 million, while the Prostate Cancer Foundation pays its president over $1.3 million, according to Charity Watch. The CEO of the National Rifle Association, Wayne LaPierre, made over $2.2 million in 2018.

990 filings for smaller nonprofits in health care and oncology that are more comparable to the Biden Cancer Initiative show that the top executives receive similar compensation packages:

- $348,609 for the president/CEO of The Livestrong Foundation in 2018
- $352,567 for the president of Prevent Cancer Foundation in 2018
- $580,713 for the executive VP of American Institute for Cancer Research in 2017
- $617,217 for the president/CEO of The Multiple Myeloma Research Foundation in 2018
- $655,137 for the CEO of The Milken Institute in 2017

Trump is in no position to gloat on the subject of charities, including those dealing with cancer.

In November 2019, a New York state judge ordered Trump to pay a $2 million judgment for improperly using his Trump Foundation charity to further his 2016 presidential campaign.

In a controversy involving donations for pediatric cancer, Forbes published a report in 2017 stating that, based on filings from the Eric Trump Foundation and other charities, more than $1.2 million "has no documented recipients past the Trump Organization."

The Cancer Letter is taking a Thanksgiving break. We will return on Dec. 4.

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LETTER TO THE EDITOR

AACI: President-elect Biden has proven his unyielding commitment to defeating cancer

Karen E. Knudsen, MBA, PhD
President, Association of American Cancer Institutes
Enterprise director, Sidney Kimmel Cancer Center at Jefferson

In a year of monumental health care and operational challenges for cancer centers, the Association of American Cancer Institutes marks with enthusiasm the electoral victory of a presidential candidate who has proven his unyielding commitment to defeating cancer.

AACI stands ready to work with President-elect Joe Biden, Vice President-elect Kamala Harris, the new administration, and Congress to continue our collective efforts against both cancer and the coronavirus pandemic.

Representing the 102 major cancer centers of North America, and dedicated to accelerating progress against cancer, AACI formed a strong bond with President-elect Biden during his leadership of President Barack Obama's Cancer Moonshot initiative, launched in 2016.

On the first stop of a tour following a Cancer Moonshot Summit, in Washington, D.C., Biden, then vice president, visited Case Comprehensive Cancer Center, in Cleveland, meeting with the center's director, Dr. Stan Gerson, who was AACI's president-elect at the time. Overall, 40 AACI cancer centers hosted regional Cancer Moonshot summits in 25 states.

Following the Cleveland meeting, AACI submitted a white paper to the Moonshot office, signaling the AACI cancer centers' readiness to deliver high-quality care across networks and improve the availability of carepaths, innovation, proper referrals, and clinical trials to a larger population of patients. The document was signed by all cancer center directors at the national summit and marked the first step in Dr. Gerson's network care AACI Presidential Initiative.

At the request of the Moonshot Task Force, cancer centers submitted development projects for consideration as part of a Cancer Moonshot investment portfolio. A total of 224 proposals from 55 AACI cancer centers were shared with Greg Simon, executive director for both the Biden Cancer Initiative and the Cancer Moonshot Task Force. Mr. Simon was later a featured speaker at the 2016 AACI/CCAF Annual Meeting.

AACI looks forward to extending its key role in contributing to the federal government's accelerated effort to eradicate cancer. As a consistent advocate for increased federal funding for cancer research, AACI this year asked Congress to ensure that additional funds be made available through the 21st Century Cures Act for the Beau Biden Cancer Moonshot.

AACI also looks forward to working with the new administration in the current AACI Presidential Initiative to leverage the strength of the AACI cancer centers to understand and mitigate cancer disparities [*The Cancer Letter*, Oct. 16, 2020].

Finally, we applaud president-elect Biden's selection of Kamala Harris as the nation's first woman and person of color to be vice president. Her rise to the highest level of government sets an example for cancer centers seeking diversity and inclusion in both institutional leadership and the wider oncology workforce [*The Cancer Letter*, Oct. 9, 2020].

IN BRIEF

Hannah Hazard-Jenkins named director of WVU Cancer Institute

Hannah Hazard-Jenkins, associate chair of surgery for cancer services, was named the permanent director of the WVU Cancer Institute after having served in the position on an interim basis since January.

"I have been and will always be committed to ensuring that everyone who seeks us out for care has access to the latest advancements in treatment, procedures, and clinical trials regardless of where they come into our system—whether it's at our flagship campus in Morgantown or one of our regional sites," Hazard-Jenkins said in a statement.

As the director of clinical services for the WVU Cancer Institute's Mary Babb Randolph Cancer Center, Hazard-Jenkins helped manage clinical affairs and programmatic development, as well as the institute's statewide network of cancer care. She also serves as the director of the institute's Comprehensive Breast Cancer Program and as chief of staff at WVU Medicine J.W. Ruby Memorial Hospital.

Edward S. Kim named physician-in-chief of City of Hope Orange County

Edward S. Kim was named senior vice president and vice physician-in-chief at City of Hope, and physician-in-chief at City of Hope Orange County.

As City of Hope Orange County's chief physician, he will be responsible for driving innovation in cancer care and delivery for the Orange County network of care and the planned Irvine campus.

He is an expert in molecular prognostication for lung, head and neck cancers.

Kim is a former chair of Solid Tumor Oncology and Investigational Therapeutics, the Donald S. Kim Distinguished Chair for Cancer Research, and medical director of the Clinical Trials Office at the Levine Cancer Institute, Atrium Health. Kim was also a professor of medicine at the University of North Carolina, Chapel Hill.

Prior to the Levine Cancer Institute, he held many leadership positions including associate tenured professor in the Department of Thoracic/Head and Neck Medical Oncology at Texas MD Anderson Cancer Center. Kim has recently completed his Masters in Business Administration at the University of North Carolina Kenan-Flagler School of Business.

Julia H. Rowland and Tom Smith receive NCCS Ellen L. Stovall Award

Julia H. Rowland, member of the National Coalition for Cancer Survivorship Board of Directors and former director of NCI's Office of Cancer Survivorship, and Thomas J. Smith, director of palliative medicine for Johns Hopkins Medicine, received the 2020 Ellen L. Stovall Award for Innovation in Patient-Centered Cancer Care, presented by The National Coalition for Cancer Survivorship.

Rowland and Smith received the award Nov. 18 at the NCCS virtual awards reception.

The award is named for former NCCS CEO Ellen Stovall, who died in 2016 due to long-term complications from three bouts of cancer.

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Rowland is a long-time clinician, researcher, and teacher in the area of psychosocial aspects of cancer. She has worked with and conducted competitively funded research among both pediatric and adult cancer survivors and published broadly in psycho-oncology.

She was recruited to NCI to become the first, full-time director of the Office of Cancer Survivorship. After 18 years in this role, Rowland retired from service at the NCI in September 2017 and assumed the role of senior strategic advisor at Smith Center for Healing and the Arts, a small non-profit organization that provides integrative support services to cancer patients and their families.

Smith is a professor of oncology at the Johns Hopkins University School of Medicine and the Harry J. Duffey Family Professor of Palliative Care.

He is a medical oncologist and a palliative care specialist with a lifelong interest in better symptom management, communication, and improving access to high quality affordable care.

Smith began Johns Hopkins' hospital-wide palliative care consult service as well as an inpatient unit. He is also a prostate cancer survivor, experiencing first-hand surgery, recurrence, salvage radiation therapy and androgen deprivation therapy with many significant side effects.

Delegate Eleanor Holmes Norton (D-DC) presented the award to her constituent, Julia H. Rowland, and Sen. Chris Van Hollen (D-MD) presented the award to his constituent, Thomas J. Smith.

Ingo Mellinghoff named chair of MSK's Department of Neurology

Neuro-oncologist Ingo K. Mellinghoff was named chair of the Department of Neurology at Memorial Sloan Kettering Cancer Center.

Mellinghoff holds the Evnin Family Chair in Neuro-Oncology and runs a research lab in the Human Oncology and Pathogenesis Program. He is also professor of neurology and neuroscience in the Feil Family Brain and Mind Research Institute at Weill Cornell Medicine.

Mellinghoff previously served as chief of the MSK Brain Tumor Service and vice chair of research in MSK's Department of Neurology.

Jedd Wolchok receives Hearst Foundation Grant

Jedd Wolchok received a $1 million grant over a three-year period from The William Randolph Hearst Foundation to establish a new immuno-oncology research fellowship at Memorial Sloan Kettering Cancer Center, and support postdoctoral students who are conducting exceptional research in the field of immune-oncology and immunotherapy.

Wolchok is the Lloyd J. Old/Virginia and Daniel K. Ludwig Chair in Clinical Investigation, chief of the Immuno-Oncology

Service, director of the Parker Institute for Cancer Immunotherapy, and associate director of the Ludwig Center for Cancer Immunotherapy at Memorial Sloan Kettering Cancer Center.

The fellowship program will be a part of the Human Oncology and Pathogenesis Program's Immuno-Oncology service, led by Wolchok.

CPRIT awards $26 million in new recruitment grants

The Cancer Prevention and Research Institute of Texas awarded nine new academic research grants totaling $26 million to recruit cancer researchers to Texas.

"Applications to recruit distinguished cancer researchers from across the country and abroad continue to increase even during the pandemic because Texas is now a magnet for world-class cancer research," CPRIT CEO Wayne Roberts, said in a statement.

The nine potential recruits will join 218 CPRIT Scholars working at 21 institutions across Texas. Two Established Investigator awards will allow MD Anderson Cancer Center to bring researchers from two cancer research institutions in the United Kingdom. CPRIT's Oversight Committee also approved seven First-Time, Tenure-Track Faculty Member recruitment awards for promising young researchers from California, Massachusetts and Switzerland.

In addition to MD Anderson, the institutions receiving grants today include Baylor College of Medicine, The University of Texas Health Science Center at San Antonio, The University of Texas Medical Branch at Galveston, and The University of Texas Southwestern Medical Center.

The grants awarded and their recipients follow:

Recruitment of Established Investigators Awards*—Two grants totaling $12 million

- Bissan Al-Lazikani, Recruitment to MD Anderson Cancer Center from the Institute of Cancer Research - $6 million
- Peter Van Loo, Recruitment to MD Anderson Cancer Center from The Francis Crick Institute - $6 million

Recruitment of First-Time, Tenure-Track Faculty Members Awards* - Seven grants totaling $14 million

- Furqan Fazal, Recruitment to Baylor College of Medicine from Stanford University School of Medicine - $2 million
- Guy Nir, Recruitment to The University of Texas Medical Branch at Galveston from Harvard Medical School - $2 million
- Jihan Osborne, Recruitment to The University of Texas Southwestern Medical Center from Boston Children's Hospital, Harvard Medical School - $2 million
- Xiaoli Sun, Recruitment to The University of Texas Health Science Center at San Antonio from University of California San Diego - $2 million
- Jeanine Van Nostrand, Recruitment to Baylor College of Medicine from The Salk Institute for Biological Studies - $2 million
- Pavan Bachireddy, Recruitment to The University of Texas MD Anderson Cancer Center from the Dana Farber Cancer Institute - $2 million
- Mauro Di Pilato, Recruitment to The University of Texas MD Anderson Cancer Center from the Institute for Research in Biomedicine - $2 million

CPRIT awards three types of recruitment grants: Established Investigators for senior research faculty with distinguished professional careers and established cancer research programs; Rising Stars for early-stage investigators who have demonstrated promising continued and enhanced contributions to the field; and First-Time, Tenure-Track Faculty awards for emerging investigators pursuing their first faculty appointment, and who are expected to make outstanding contributions in cancer research. Recruits receive the "CPRIT Scholar" designation.

New AMA policy recognizes racism as a public health threat

New policy adopted by physicians at the American Medical Association's Special Meeting of its House of Delegates recognizes racism as a public health threat and commits to actively work on dismantling racist policies and practices across all of health care.

In June 2020, the AMA Board of Trustees acknowledged the health consequences of violent police interactions and denounced racism as an urgent threat to public health, pledging action to confront systemic racism, racial injustice and police brutality.

The new policy approved by the AMA, representing physicians and medical students from every state and medical specialty, opposes all forms of racism as a threat to public health and calls on AMA to take prescribed steps to combat racism, including:

1. acknowledging the harm caused by racism and unconscious bias within medical research and health care;

2. identifying tactics to counter racism and mitigate its health effects;
3. encouraging medical education curricula to promote a greater understanding of the topic;
4. supporting external policy development and funding for researching racism's health risks and damages; and
5. working to prevent influences of racism and bias in health technology innovation.

"The AMA recognizes that racism negatively impacts and exacerbates health inequities among historically marginalized communities. Without systemic and structural-level change, health inequities will continue to exist, and the overall health of the nation will suffer," AMA Board Member Willarda V. Edwards said in a statement. "As physicians and leaders in medicine, we are committed to optimal health for all, and are working to ensure all people and communities reach their full health potential. Declaring racism as an urgent public health threat is a step in the right direction toward advancing equity in medicine and public health, while creating pathways for truth, healing, and reconciliation."

Though previous AMA policies and principles have emphasized the need to eliminate health disparities and called on physicians to prevent violence of all kinds, the new policy explicitly acknowledges racism's role in perpetuating health inequities and inciting harm against historically marginalized communities and society as a whole.

Specifically, the new policy recognizes racism in its systemic, cultural, interpersonal, and other forms as a serious threat to public health, to the advancement of health equity, and a barrier to appropriate medical care. It makes clear that a proactive approach to prevent, or identify and eliminate, racism is crucial—particularly considering that studies show historically marginalized populations in the U.S. have shorter lifespans, greater physical and mental illness burden, earlier onset and aggressive progression of disease, higher maternal and infant mortality, and less access to health care.

The policy describes the various forms of racism as follows:

- Systemic racism: structural and legalized system that results in differential access to goods and services, including health care services.
- Cultural racism: negative and harmful racial stereotypes portrayed in culturally shared media and experiences.
- Interpersonal racism: implicit and explicit racial prejudice, including explicitly expressed racist beliefs and implicitly held racist attitudes and actions based upon or resulting from these prejudices.
- In addition, the new policy requests AMA to identify a set of best practices for health care institutions, physician practices, and academic medical centers to address and mitigate the effects of racism on patients, providers, international medical graduates, and populations. It also guides the AMA's position on developing and implementing medical education programs that generate a deeper understanding of the causes, influences and effects of all forms of racism—and how to prevent and improve the health effects of racism.

The policy asks that AMA support the creation of external policy to combat racism and its effects and encourage federal agencies and other organizations to expand research funding into the epidemiology of risks and damages related to racism. Additionally, the policy asserts that the AMA will work to prevent, and protect against the influences of racism and bias in innovative health technologies.

ASTRO: Radiation oncologists urge Congress to advance bills that protect patient access to cancer care during the pandemic

Radiation oncologists across the country met virtually with members of Congress this week to urge lawmakers to pass legislation that will safeguard access to high-quality, value-based health care for people with cancer.

The doctors met with congressional leaders and staff as part of the American Society for Radiation Oncology virtual Advocacy Day Nov. 19-20.

Radiation oncologists emphasized four legislative priorities in their meetings with lawmakers:

- Prevent pending cuts to Medicare reimbursement for radiation therapy and provide temporary relief for physicians who continue to provide care during a pandemic.
- Engage with the Centers for Medicare and Medicaid Services to fix the recently released Radiation Oncology Model and protect patient access to cancer care.
- Reform a broken prior authorization system that, according to new data, has grown worse during the pandemic and unnec-

essarily delays patient access to lifesaving cancer treatments.

- Increase investments in cancer research at the NIH and NCI.

Under the 2021 Medicare Physician Fee Schedule, CMS plans to move forward with changes to evaluation and management codes that will result in an overall reimbursement cut of 6% for radiation therapy services covered by Medicare. Many key services, including weekly management of patients currently undergoing treatment, will be cut by 10% or more.

"The proposed Medicare payment policy, set to start on Jan. 1, 2021, would cause significant additional financial challenges for radiation oncology practices as they enter the new year. Despite many practices already experiencing revenue declines of 20-30% due to the COVID-19 pandemic, CMS is still pushing ahead with large additional cuts for radiation oncology and other specialties," Thomas J. Eichler, chair of the ASTRO board of directors, said in a statement.

ASTRO and a broad coalition of health care provider organizations are urging both Congress and CMS to waive or suspend the budget neutrality requirement, which would trigger the cuts. More than 200 bipartisan members of the House of Representatives also co-signed a letter last month urging Congress to pursue changes to the 2021 MPFS to avoid the excessively steep cuts.

Radiation oncologists are asking lawmakers to join the bipartisan cosponsors of the Holding Providers Harmless from Medicare Cuts During COVID-19 Act of 2020 (H.R. 8702), which would stabilize Medicare payment levels for the next two years and provide temporary relief from the threat of additional cuts for radiation oncology and other medical specialties.

Since CMS introduced the Radiation Oncology Model (RO Model) as a proposed advanced alternative payment model, ASTRO has said it expressed concerns with the model's mandatory and excessive reimbursement cuts for radiation therapy providers.

While these concerns were echoed by bipartisan senators and representatives in oversight letters to CMS that requested changes to the model, they were not addressed in the agency's final rule, ASTRO said.. Radiation oncologists are now asking Congress to intervene and protect patient access to radiation therapy treatments.

The RO Model in its current form would be a significant burden for the 950 practices required to participate, particularly as most are already experiencing revenue declines due to COVID-19, ASTRO said. ASTRO surveys of practices from the spring and summer of 2020 indicated that patient volume dropped at nearly 9 in 10 radiation oncology practices due to the pandemic, with an average decline of 31%. Half of the practices also had to reduce staff due to declining patient volume.

"The cuts to providers in the Radiation Oncology Model substantially exceed those in other models and, astoundingly, became more severe between the proposed and the final iterations from CMS," said Eichler. "We are concerned that these mandatory cuts will financially jeopardize practices' ability to deliver optimal care during the five-year demonstration period, especially as we continue to face a public health emergency. Unfortunately, CMS' failure to listen to our recommendations has turned a model with great potential to improve patient care into one that we're seriously worried will undermine patient care."

ASTRO said radiation oncologists are asking specifically for the RO Model's discount factors to be more consistent with other specialty models and more in line with the intent of value-based health care reform as outlined by the Medicare Access and CHIP Reauthorization Act of 2015.

Additionally, while an ASTRO-led effort recently secured a delay in the model's start date from January 1 to July 1, 2021, physicians say that without significant changes, the delay only represents a stay of execution from the massive cuts. Reps. Brian Higgins (D-NY) and Rep. Mike Kelly (R-PA) are leading a joint letter to CMS asking for essential reforms to the RO Model before its implementation, ASTRO said.

While prior authorization was a major challenge for radiation oncology before the COVID-19 public health emergency, the burden has grown more difficult during the pandemic and physicians say they increasingly are constrained from exercising their clinical judgment in the best interest of their patients, according to ASTRO.

ASTRO is also asking lawmakers to join the bipartisan cosponsors of the Improving Seniors' Timely Access to Care Act of 2019 (H.R. 3107), which would increase transparency in the prior authorization process and help curb delays for patients covered by Medicare Advantage plans.

ASTRO, in collaboration with cancer-focused organizations including ACS, is asking Congress to increase funding for cancer research at the NIH and NCI and provide emergency supplemental funding for projects that were stalled during the COVID-19 pandemic.

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THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

In vitro fertilization does not increase the risk of ovarian cancer

A new paper published in *JNCI: Journal of the National Cancer Institute* indicates that receiving assisted reproductive technology does not increase the risk women have for developing ovarian cancer.

Previous research indicated that women who use assisted reproductive technology in order to have a successful pregnancy could potentially be at risk for ovarian cancer and non-malignant borderline ovarian tumors due to excess stimulation of the ovaries.

Since the introduction of assisted reproductive technology—including in vitro fertilization, intracytoplasmic sperm injection, and cryopreservation of embryos—four decades ago, some researchers have raised concerns that such technology might increase the risk of ovarian tumors. Researchers have proposed that this could potentially be due to large increases of sex hormone levels and multiple punctures disrupting ovarian tissue.

Because of the worldwide increase in the use of fertility treatments and the poor prognosis of ovarian cancer, it is important to examine the association between fertility treatments and long-term risk of ovarian tumors.

Several epidemiological studies have investigated the association between such treatments and risk of ovarian tumors, with inconsistent results. In 2013, two meta-analyses were published showing that women who received fertility treatments were more likely to develop ovarian cancer compared with the general population. But it remained unclear if fertility treatments caused women to develop ovarian cancer or if the association could be due to other factors, such as infertility itself.

Researchers here were able to link a database on use of assisted reproductive technology treatment procedures in the Netherlands with national cancer registries to see if an excess risk of ovarian tumors resulted.

This nationwide cohort study included 30,625 women who received ovarian stimulation for ART between 1983 and 2001 and 9,988 infertile women who did not receive such treatment. Incident invasive and borderline ovarian tumors were ascertained through linkage with the Netherlands Cancer Registry and the Dutch Pathology Registry. The researchers investigated risks of ovarian tumors in infertile women who received ovarian stimulation for assisted reproductive technology compared with the risks in the general population and with infertile women who received no such treatment.

After a median follow-up of 24 years, researchers observed 158 invasive cancers and 100 borderline ovarian tumors. No increased risk of ovarian cancer was found in women who received assisted reproductive technology treatment compared with infertile women who did not receive the treatment. Even after more than 20 years the risk of ovarian cancer was not increased. Compared with women in the general Dutch population, women who received assisted reproductive technology did have a higher risk of ovarian cancer, but this appeared to be mainly caused by the higher proportion of women who received assisted reproductive technology who remained childless. Childlessness has been shown to be a strong risk factor for ovarian cancer. Among assisted reproductive technology-treated women in the study, ovarian cancer risk decreased with a larger number of successful for assisted reproductive technology cycles (resulting in childbirth).

Women who received such treatment appear to have an almost two-fold increased risk of borderline ovarian tumors, both when compared with the general population and with infertile women not receiving the treatment. However, risks of borderline ovarian tumors did not increase after more treatment cycles or after longer follow-up. This suggests that the increased risks observed for borderline ovarian tumors might be due to underlying

patient characteristics rather than the treatment itself. Borderline tumors are rare in the general population and are generally easy to treat.

"Reassuringly, women who received ovarian stimulation for assisted reproductive technology do not have an increased risk of malignant ovarian cancer, not even in the long run," lead author Flora E. van Leeuwen said in a statement. "However, it is important to realize that even with the long follow-up in our study, the median age of the women at end of follow-up was only 56 years. As the incidence of ovarian cancer in the population increases at older ages, it is important to follow assisted reproductive technology-treated women even longer."

UCLA researchers find patients with lung cancer most likely to respond to immunotherapy

Researchers at the UCLA Jonsson Comprehensive Cancer Center found patients with a particular type of human leukocyte antigen (HLA), a protein scaffold involved in presenting pieces of proteins described as peptides to the immune system, were particularly likely to benefit from immunotherapy.

This research explained a surprising finding seen among patients in the clinic.

The data, published in *Nature Cancer*, focused on a type of HLA called B44, which is present in approximately half of people. In melanoma, patients with HLA-B44 tend to do well with immunotherapy, but in non-small cell lung cancer, the most common type of lung cancer, most people with HLA-B44 did not do as well as people without HLA-B44. In the study, authors figured out that the different responses were driven by the different types of mutations that are common in each of the cancer subtypes.

"Finding out that immunotherapy in HLA-B44 patients performed differently in non-small cell lung cancer than melanoma really set us off on this journey to dive down into how HLA-B44 works," lead author Amy Cummings, clinical instructor of hematology/oncology at the David Geffen School of Medicine at UCLA and member of the Jonsson Cancer Center, said in a statement. "Usually you would think that for two types of cancers that generally respond well to immunotherapy, there would be similar principles in terms of characteristics of patients who benefit, but that's not the case in this instance."

To investigate the role of HLA in immunotherapy response, UCLA researchers performed whole-exome sequencing on melanoma and non-small cell lung cancer tumors and blood samples. Whole-exome sequencing looks at the protein-making genes and the mutations that may be present in the cancer.

Mutations in protein-making genes often lead to a peptide that the immune system can recognize as abnormal, called a neoepitope. The team predicted the neoepitopes generated by patients' mutations to identify which would most effectively bind to HLA-B44 and be presented to immune cells. With this information, they analyzed treatment outcomes, including survival.

Through these tests, the researchers found that in HLA-B44 non-small cell lung cancer patients, only those who had neoepitopes similar to those commonly found in melanoma had good responses to immunotherapy. More importantly, those responses tended to be durable, meaning non-small cell lung cancer patients with HLA-B44 and melanoma-like neoepitopes had responses to immunotherapy that lasted for years, some longer than five years.

"This certainly has a lot of implications for how we run clinical trials and may be able to help us stratify patients much better in terms of their likelihood of response to immunotherapy," Cummings said.

"From the time that we discovered the contradictory outcomes in HLA-B44 patients with melanoma and non-small cell lung cancer, we became fascinated by the mechanism that could explain this," senior author Edward Garon, professor of hematology/oncology and director of the signal transduction and therapeutics program at the Jonsson Cancer Center, said in a statement. "While seeking this explanation, we gained important insight into how the immune system identifies tumors. We hope to eventually harness these findings to design therapies that can further enhance the immune response against tumors in specific patients."

AI can pick the best candidates for skin cancer treatment

Researchers at NYU Grossman School of Medicine and Perlmutter Cancer Center trained a computer to tell which skin cancer patients may benefit from drugs that keep tumors from shutting down the immune system's attack on them.

The study showed that an artificial intelligence tool can predict which patients with a specific type of skin cancer would respond well to such immunotherapies in four out of five cases. Specifically, the study examined patients with metastatic melanoma.

While the drug class studied, immune checkpoint inhibitors, has been more effective for many patients than tradi-

tional chemotherapies, half of patients do not respond to them. Researchers say the drugs may cause side effects in many of them, and are also expensive.

"Our findings reveal that artificial intelligence is a quick and easy method of predicting how well a melanoma patient will respond to immunotherapy," first author Paul Johannet, a postdoctoral fellow at NYU Langone Health and its Perlmutter Cancer Center, said in a statement.

The study, published in *Clinical Cancer Research*, is the first to explore artificial intelligence, or machine learning, to predict a melanoma patient's response to immune checkpoint inhibitors, the investigators said. The team designed their computer program to learn how to get better at a task but without being told exactly how. Such programs build mathematical models that enable decision-making based on data examples fed into them, with the program getting smarter as the amount of training data grows.

For the investigation, the researchers collected 302 images of tumor tissue samples from 121 men and women treated for metastatic melanoma with immune checkpoint inhibitors at NYU Langone hospitals. Then, they divided these slides into 1.2 million portions of pixels, the small bits of data that make up digital images. These were fed into the computer along with factors such as the severity of the disease, which kind of immunotherapy regimen was used, and whether a patient responded to the treatment.

The study investigators repeated this process with 40 slides from 30 similar patients at Vanderbilt University to determine whether the results held true from a separate hospital system that used different equipment and sampling techniques.

The researchers note that aside from the computer needed to run the program, all of the materials and information used in the Perlmutter technique are already a standard part of cancer management that most, if not all, clinics use.

"A key advantage of our artificial intelligence program over other approaches such as genetic or blood analysis is that it does not require any special equipment," co-author Aristotelis Tsirigos, director of applied bioinformatics laboratories and clinical informatics at the Molecular Pathology Lab at NYU Langone, said in a statement.

"Even the smallest cancer center could potentially send the data off to a lab with this program for swift analysis," senior author Iman Osman, Rudolf L. Baer MD Professor of Dermatology at NYU Langone and its Perlmutter Cancer Center, said in a statement.

Osman is also director of the interdisciplinary melanoma program and associate dean for translational research support at NYU Langone.

The algorithm is not yet ready for clinical use until they can boost the accuracy rate from 80% to 90% and test the algorithm at more institutions, Osman said.

The research team next plans to collect more data to better train the computer. Even at its current accuracy, the AI tool can still be used as a screening method to determine which patients across populations would benefit from more in-depth tests before treatment, Osman said.

Phase III trial shows decrease of chemotherapy-induced neutropenia

Phase III trial data shows that a developmental drug, plinabulin, could help keep cancer patients on needed chemotherapy treatments.

Developers at BeyondSpring will now seek FDA approval—citing that the study reached primary endpoints and significant secondary endpoints including decreased rate of grade 4 neutropenia and shorter duration of severe and profound neutropenia.

Plinabulin is sponsored by BeyondSpring.

Plinabulin is a small molecule therapy that is administered through an IV. Data show it significantly decreased incidence of chemotherapy-induced neutropenia when used with standard of care, compared to patients receiving standard of care alone.

CIN is the primary cause of reductions in dose or duration of chemotherapy, which can ultimately lead to less effective cancer treatment. About 86% of oncologists consider CIN a priority among chemotherapy-related treatment decisions because reductions in chemo lead to decreased survival for patients. Plinabulin can potentially be used at any time throughout the chemo cycle.

In addition to seeking FDA approval, BeyondSpring is also expected to seek approval in China in early 2021.

Neratinib in HER2-positive HR-negative early stage breast cancer shows DFS benefit vs. placebo

Nerlynx (neratinib) demonstrates a 5.1% invasive disease-free survival benefit versus placebo in the phase III ExteNET

trial evaluating Nerlynx in HER2-positive, hormone receptor-positive early stage breast cancer.

Nerlynx is sponsored by Pierre Fabre. Results from the trial were published in *Clinical Breast Cancer*.

In the HR+ /< 1 yr patient population, the absolute 5-year invasive disease-free survival benefit versus placebo was 5.1% and absolute 8-year overall survival benefit was 2.1%. The 5-year cumulative incidence of Central Nervous System metastases was 0.7% in the neratinib arm and 2.1% in the placebo arm.

In the HR+/ <1 yr, subgroup of patients who did not achieve pCR upon neo-adjuvant treatment, and hence were at a high risk of disease recurrence, the absolute 5-year iDFS benefit in the neratinib arm versus placebo was 7.4% (HR=0.60; 95% CI 0.33???1.07) and the 8- year overall survival benefit was 9.1% (HR=0.47; 95% CI 0.23- 0.92).

The primary endpoint of the trial was invasive disease-free survival, with overall survival as a key secondary endpoint. Within the European Union, Nerlynx is approved in adult patients with HER2+/HR+ early breast cancer who initiated treatment within one year of completing an adjuvant trastuzumab based regimen.

ExteNET is a multicenter, randomized, double-blind, phase III trial of 2,840 HER2-positive eBC patients who received neratinib after neoadjuvant and/or adjuvant therapy with chemotherapy and trastuzumab.

Patients were stratified by hormone receptor, lymph node status and sequential vs concomitant chemotherapy administration, and randomly assigned to one year of treatment with either oral neratinib 240 mg/day or placebo.

DRUGS & TARGETS

Keytruda receives accelerated approval from FDA for locally recurrent, unresectable or metastatic TNBC

Keytruda (pembrolizumab) received accelerated approval from FDA in combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (CPS ≥10) as determined by an FDA approved test.

Keytruda is sponsored by Merck.

FDA also approved the PD-L1 IHC 22C3 pharmDx (sponsored by Dako North America Inc.) as a companion diagnostic for selecting patients with TNBC for pembrolizumab.

Approval was based on KEYNOTE-355 (NCT02819518), a multicenter, double-blind, randomized, placebo-controlled trial in patients with locally recurrent unresectable or metastatic TNBC, who had not been previously treated with chemotherapy in the metastatic setting. Patients were randomized (2:1) to receive pembrolizumab 200 mg on day one every every weeks or placebo in combination with different chemotherapy treatments (paclitaxel protein-bound, or paclitaxel, or gemcitabine plus carboplatin) via intravenous infusion.

The main efficacy outcome measure was progression-free survival as assessed by blinded independent review according to RECIST 1.1, tested in the subgroup of patients with CPS ≥10. Median PFS was 9.7 months (95% CI: 7.6, 11.3) in the pembrolizumab plus chemotherapy arm and 5.6 months (95% CI:5.3, 7.5) in the placebo arm (HR 0.65; 95% CI: 0.49, 0.86; one-sided p-value=0.0012).

FDA issues draft guidance to provide important considerations in cross labeling of oncology drugs

FDA has issued a Draft Guidance for comment describing the agency's proposed recommendations for including relevant information about oncology drug labels that have been approved for use in combination drug regimens.

Cross-labeling is the inclusion of information in product labeling of two or more oncology drugs approved in a combination regimen for a specific indication. The intent is to provide information in product labeling for the drugs used in a combination regimen that are complementary and consistent and not to include all of the same information in labeling for each drug in the combination regimen.

"Oncology drug applications to the FDA often add investigational drugs to current regimens to create new combination regimens with greater efficacy or safety. Sponsors have traditionally not requested cross-labeling—making changes to the labeling of a previously approved drug that describes how to use that drug in a new regimen," 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, recently we've seen an increase in the number of applications that have proposed cross-labeling for oncology drug combination regimens," he said.

The draft guidance includes procedures for cross-labeling application submissions and considerations for selected sections in the "Full Prescribing Information" part of the drug label.

"We are issuing today's draft guidance to serve as a starting point for discussions between the FDA and sponsors of oncology drugs, as well as the medical and academic communities, and the public on including relevant information in labeling for oncology drugs approved for use in a combination regimen," Pazdur said. "Cross-labeling can provide clear, consistent and accessible information to guide the safe and effective use of cross-labeled drugs in an oncology treatment regimen."

CDER and CBER to increase Emergency Use Authorization transparency

The Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research at FDA plan to take additional steps to increase transparency regarding CDER and CBER's review of the scientific information supporting the issuance of or revisions to an emergency use authorizations.

The goal is to be as transparent as possible under the law about the scientific basis for recommending that a drug or biological product be authorized for emergency use under the Federal Food, Drug and Cosmetic Act.

In the future, when a CDER-regulated or CBER-regulated product is authorized for emergency use, FDA intends to make public to the extent appropriate and permitted by law the center's review of the scientific data and information supporting our recommendation to issue, revise, or revoke the EUA.

When an EUA is revised, FDA also intends to make public to the extent permitted by law the center's reviews of the scientific data and information supporting our recommendations to revise the EUA.

Agendia and Paige collaborate on breast cancer research

Agendia Inc. and Paige, are collaborating to co-development treatment planning tools that integrate the cloud-based Paige Platform with genomic information from Agendia's proprietary MammaPrint and BluePrint diagnostic tests for patients with breast cancer.

These products aim to enable faster access to predictive and prognostic information, from diagnosis and early intervention to metastatic treatment planning.

"Our goal is to provide same-day turnaround in most cases, enable earlier intervention, preserve limited biopsy or surgical tissue specimens, and extend key benefits to physicians and their patients with access to testing in countries where tissue 'send out' is not allowed," Agendia Chief Executive Officer Mark Straley said in a statement.

The initial focus of the collaboration will be the development of digital tests for early treatment planning where genomic testing has played an essential role in determining recurrence risk and tumor biology as doctors and their patients make decisions about the path ahead.

Beyond early intervention, AI-derived biomarkers will be used to augment genomic testing in the metastatic setting, where therapeutic options can add to the complexity of treatment planning.