TCL
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Inside information on cancer research and drug development

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COVID-19 AND COMMUNITY CANCER CARE – A PANORAMA OF A CATASTROPHE

The COVID-19 pandemic has been catastrophic to health care in the US.

→PAGE 6

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- Brain cancer
- Colorectal cancer
- Esophageal cancer
- Head and neck cancer
- Immunotherapy
- Liver cancer
- Mesothelioma
- Metastatic cancers
- Neuroblastoma
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https://cdmrp.army.mil/funding/pdf/20prcrpreftable.pdf

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In this issue

IN BRIEF

CLINICAL ROUNDUP

DRUGS & TARGETS

NCI TRIALS

GUEST EDITORIAL

COVID-19 and community cancer care

A PANORAMA OF A CATASTROPHE

The COVID-19 pandemic has been catastrophic to health care in the US.

By Debra Patt, MD, MPH, MBA
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By Michael Kolodziej, MD, FACP
Senior advisor, ADVI Health

Much has been written about the impact on hospitals and on the health care professionals enduring horrific stress to support the acutely ill. These providers are heroes, and we are all indebted to them. But less attention has been paid to the indirect effects of the pandemic on health care, particularly the care delivered to those with chronic medical illnesses.

What has happened to cancer patients? Although we will be able to trace the course of the acute infectious elements of COVID, which play out over weeks and perhaps a couple of months, the impact on cancer care will likely play out over many months and even years.

These effects are important to address from several perspectives, including those of the patient, the provider, the payers, and the research enterprise. Potential lasting effects, both good and

bad, need to be considered. What does cancer care look like now? And how will it be changed forever?

The patient perspective

Absent screening and neglected symptoms

There is never a good time to get cancer. COVID has made it infinitely more complicated.

Depending on where the patient is on the cancer journey, the disruption has been either inconvenient or even life-threatening. Let's start at the beginning. Although statistics are not readily available, people aren't getting mammograms or colonoscopies. Cancer surgeries are also way down, even though one could debate as to whether these surgeries are really elective.

There is little doubt that patients are experiencing a delay in cancer diagnosis; to what degree this will impact outcomes is unclear.

We do know that when patients don't undergo cancer screening, they present with later-stage cancers and are more likely to die of their disease. At this time, how long it will take to get past these delays in screening is also unclear.

Given the backlog, even if you want to get screened, the line may extend for quite some time. Skipping screening this year could be a really bad decision. In addition to patients forgoing or delaying screening during the pandemic, symptoms that are often a harbinger of cancer that would normally precipitate a visit to the doctor have been tolerated or ignored because of anxiety to leave home and a desire to comply with social distancing.

What will happen to the woman who feels a lump in her breast and decides the risk of seeking medical attention is too great? The natural consequence of patients presenting with neglected symptoms of cancer is an unfavorable outcome.

Active treatment, immunocompromise, and increased risk

Patients undergoing active treatment encounter an entirely different set of challenges. Almost all patients undergoing active therapy, and especially those receiving chemotherapy, are taught that they are immunosuppressed and at risk of infection.

This is often linked to the white count and periods of neutropenia and its associated risk. But the truth is that the immunosuppression in cancer patients is multi-factorial, being both treatment-related as well as disease-related. This is particularly true in hematological malignancies.

> “What is clear is that the very limited data that exists does suggest that this immunosuppression is potentially life-threatening when it comes to COVID, with a much higher risk of infection, a complicated clinical course and even death.”

What is clear is that the very limited data that exists does suggest that this immunosuppression is potentially life-threatening when it comes to COVID, with a much higher risk of infection, a complicated clinical course and even death.

Patients who need therapy face a Hobson's choice. Should they leave their relatively safe shelters, be exposed to other immunosuppressed patients in their doctor's office, be exposed to the health care providers who are likewise multiply exposed, and face serious consequences? Will delaying therapy risk a poor cancer outcome?

Most authorities have favored moving ahead cautiously when the therapy is potentially curative or might result in significant clinical benefit. How often patients (or their providers) are delaying is not clear. Anecdotally, clinics have been maintaining their treatment volumes.

But there are certainly some therapies that are, for the most part, on hold, such as bone marrow transplant. And most bone marrow transplants are not elective procedures.

Support and management

Patients who have completed therapy or are receiving therapy (like hormonal therapy for breast cancer) that do not require close follow-up face yet another set of challenges.

Patients generally like seeing their oncologists at these visits. These visits are important for many reasons. They provide follow-up of the underlying malignancy as well as the ongoing or late toxicities of treatment. But they also provide an opportunity to reinforce health maintenance, like smoking cessation. And they reinforce an important personal bond between the care team and the patient.

They are reassuring and life-affirming. If there are problems, they offer an opportunity to intervene.

These visits have been the first to be eliminated during COVID. To some extent, they have been replaced by telehealth visits (more on telehealth later). But you cannot do a thorough breast exam or palpate lymph nodes on telehealth. You cannot check a CBC. And you cannot hold someone's hand.

It will literally be impossible to measure the impact that cancelling these visits will have.

Perhaps the impact on cancer survival will be negligible, but it will matter to patients. Some practices have been under the illusion that they would just bring these patients in when this is all over, but if the pandemic lasts a lot longer, they just won't have the capacity.

These direct consequences are easy to articulate. There are many others. The impact on mental health, especially depression, which is always a risk in cancer patients, will be profound. There are likely to be issues with substance abuse, including opioids and alcohol.

People will lose employer-sponsored health insurance as a consequence of losing their jobs, making access to care even more of a problem. The consequences of financial toxicity will be magnified.

There is little doubt that the COVID pandemic will increase mortality for cancer patients, even among those never infected with the virus.

The provider perspective

Taking care of cancer patients is a hard job. COVID has made it much harder.

Many of the clinical challenges patients experience are also experienced by the oncologist. Making decisions about whom to treat and whom to delay are incredibly difficult. The impact of these decisions on patient outcomes is totally unknown and may well remain unknown for some time.

But for oncologists, particularly community oncologists, practical matters regarding keeping their practices safe and solvent are especially challenging.

Altering clinic PPE rations

A safe environment for patients and the care team has been taken as a given. Even complex issues like safe chemotherapy handling are executed in an almost matter-of-fact way by most practices.

But COVID is different. The risk of infecting patients and staff has mandated adoption of infection control procedures completely foreign to most practices.

From telephone screening of patients immediately prior to their visits, through triage at clinic entrances, to immediate quarantine and testing of suspected cases, to providing PPE/safe distancing/strict handwashing practices to safeguard staff, there is no such thing as business as usual.

Practices have consolidated sites of service. Visitors are excluded from the office. CDC guidance changes frequently and staffing, masking, and contact protocols are constantly changing. Rescheduling clinic patients and evolving staff working from home models cause recurring challenges clinically and administratively.

Testing availability is limited, and testing efficacy is suboptimal.

Practices are burdened with insufficient supplies of masks and other PPE, and the normal supply chain has been altered when production or competing need present obstacles to standard operating procedures.

The oncology office of today is nothing like the oncology office of yesterday. And the staff is feeling the stress, both of the risk of infection as well as the risk of losing their jobs.

Telemedicine

For many patients, this has meant not coming to the office at all. To provide clinical services, practices have turned to telemedicine as an alternative.

Contrary to popular perception, this has not been a smooth transition. To start with, most physicians (especially older ones) are not particularly tech savvy. The mechanics of a telemedicine visit are different.

And patients are equally challenged. Data suggests as many as 40% of cancer patients do not have a smart phone or access to a computer at home. And there are clear limitations to a telehealth visit, including the inability to have a meaningful physical exam or check routine labs.

Patients do value interacting with their doctors, but whether a telehealth follow-up visit is as valuable as a clinic visit is purely speculative.

Medicare has helped a lot. Reimbursement for telehealth is at parity with office visits and HIPAA restrictions have been lessened. This provides significant and much needed revenue to practices. Telehealth is a life preserver in these challenging times, but its future after COVID remains uncertain.

To be certain, after COVID, the vetting of the various telemedicine solutions (which has not taken place in the typical fashion due to the crisis) will occur, as well as an analysis of the both the clin-

ical as well as economic implications of managing specific patient subsets with this technology.

Practice support

Foot traffic in most oncology offices is decreased substantially. Although there is regional variation, practices in hot spots have seen a 60 percent drop in visits.

Treatment visits are down as well, but to a lesser extent. New patient referrals have plummeted, which means patient volume will remain low even after shelter in place restrictions are lifted. Medical oncology is the subspecialty of medicine with the highest ratio of overhead to revenue, largely as a consequence of the cost of chemotherapy.

But labor costs in oncology practices are very high due to the number of oncology nurses as well as other support staff needed to support every oncologist. Jobs are in jeopardy.

Oncologists have access to at least three sources of revenue from the government. First, they can apply for the small business loans that provide payroll support. These loans are forgiven if staff is retained. They provide about ten weeks of payroll support.

Many oncology practices have applied for these loans. But the application process has been onerous. Further, as of this writing, the initial appropriation has been depleted.

Second, the practices are eligible for a grant via the Cares Act. These grants provide an award based on last year's Medicare billing. There are conditions the practice must attest to in order to qualify, including agreeing to take care of COVID patients.

Unfortunately, it is almost impossible to figure out how much money each practice is entitled to. CMS has provided a rough calculation, but it is impossible to figure out how CMS arrived at the number.

Finally, practices can request accelerated and advance payments from Medicare. This allows practices to request prepayment for services they expect to provide over the next three months; any invoices submitted for services actually rendered will be reconciled against the prepayment.

If this sounds confusing, it is. Practices, frankly, have enough on their plates without trying to manage this ledger, although it is possible that hospitals might be interested.

Hospitals

Hospitals face even greater challenges.

The demands on hospitals to transform their existing organizations into massive emergency rooms and ICUs has been challenging and expensive. COVID patients, especially Medicare patients, consume a lot of health care resources that are not adequately reimbursed.

And the most lucrative patients, especially those undergoing elective surgical procedures, have disappeared.

The staff that serviced these elective surgical patients are expensive to employ, and they are idle. The balance sheet is not pretty. Hospitals are hemorrhaging money.

The Cares Act gets hospitals money from Medicare. But even with this grant, hospitals have been forced to furlough staff, or significantly reduce their compensation in the non-ER and non-ICU space. Given the incredible stress that hospital staff is already experiencing, this adds insult to injury.

The point of this long discourse is that practices are financially strapped and have significant staff commitments. The government is genuinely trying to help, but this money in no way can offset loss of revenue from care administered to commercial health plan patients.

Like many other businesses in America, they are endangered.

The payer perspective

The effect of the COVID pandemic on payers has been difficult to evaluate.

Patients hospitalized with severe COVID-related illness are very expensive. Medicare is shielded from these costs, because they pay the DRG that is billed (which does not even come close to the cost of care, a burden borne by the hospitals).

Some commercial payers pay hospitals on a DRG basis, but many more pay a percent of billed charges. As a consequence, each COVID patient represents a million-dollar expenditure. However, for any given payer, the number of these patients is relatively small.

But health plans are protected by stop-loss insurance. And these costs are more than offset by the dramatically reduced numbers of patients undergoing elective procedures.

Recently, some payers have released first-quarter earnings, and this offset has preserved their profit margin.

Not everything is rosy. Employees are losing employer-sponsored health insurance, and as a consequence, the payer is losing the premium dollars. Some payers have extended the grace

period for premium payments for 30-60 days, but some employers will go out of business and others won't be able to afford the health care premiums for their workers.

It is to be expected that as the country recovers, the demand for these elective procedures will increase, but it won't happen overnight. There is precedent. During the recession in 2008, health care expenditures dropped substantially, and the upward trend resumed as soon as the financial crisis resolved.

But it took time.

More importantly, from an oncology perspective, the inertia that had built up behind alternative payment models in oncology has been halted. Although CMMI has not publicly announced a delay in the transition from the Oncology Care Model to the Oncology Care First Model, it is impossible to imagine them moving forward.

In fact, it seems obvious that they will need to somehow adjust the two-sided risk requirement of the Oncology Care Model due to the potentially catastrophic impact of the cost of a COVID patient attributed to any practice in the OCM. Commercial payers, likewise, have been forced to put programs on the back burner.

Practices are simply too engaged in responding to COVID to consider the effort required to succeed.

Finally, discussions regarding trying to control the costs of prescription drugs have gone totally silent.

In fact, the national sentiment that an anti-viral or a vaccine, which almost certainly be the product of intense R&D activity in the life sciences sector makes it difficult to envision a time when resurrecting this debate will be politically possible.

The research perspective

COVID has been devastating to clinical trials.

This disruption has included a delay in opening new trials, a suspension of new accruals for ongoing trials, and challenges with continuing therapies on patients in the middle of the trial.

There is also a question about diversion of funds earmarked for cancer R&D to COVID-related projects.

Why is this a problem? Most oncologists believe that in many cases, enrollment on a clinical trial offers the best treatment option; this is particularly so if the trial is examining an exciting novel therapy in a disease in which conventional treatment options are poor.

Further, trials (particularly registration trials) are the path to access post regulatory action. In many cases, these novel therapies represent a significant improvement over standard of care. And if the pipeline is shut off at the source (due to reallocation of resources), the outcome cannot be good, though it may be impossible to measure.

The biggest problem, however, will be faced by those drugs that have ongoing registration trials. How will we be able to analyze efficacy and toxicity when doses are skipped and evaluations are missed? How will the FDA mange this aberration in trial performance?

Again, the indirect damage of interrupting what has been a tremendously successful research enterprise on the downstream beneficiaries, i.e. cancer patients, cannot be good

Cancer care post-COVID

Surely, the vast majority of cancer patients and cancer doctors would love to wake up tomorrow and find COVID was just a bad dream. We dare say most oncologists would jump at the chance to have things the way they used to be. Are there any silver linings in these clouds?

There are at least two:

Paradigm shifts

We will rethink routine care.

Although we may pretend that oncology is scientific and evidence-based, much of what we do is more related to habit.

For example, how often is it appropriate to see a woman receiving adjuvant hormonal therapy for early-stage breast cancer? How often should an oncologist see a woman receiving trastuzumab for a year? How about a CML patient on imatinib?

The answer to these questions is that there is no answer. Practice is arbitrary and often transactional. And there is some evidence, particularly for patients with serious cancer receiving therapy, these interactions do not really happen when patients need them, because of toxicity or symptom burden.

The emergence of telehealth as well as remote patient monitoring may change this. Prior to COVID, there was some interest in moving these forward, with new billing codes and an emergence of technology.

But COVID has accelerated this. There is tremendous potential to use these technologies to dramatically change how we engage our patients. It is easy to see how this might improve care. This will not replace the office visit; it will supplement it.

There will still be a need for the physical exam and the lab monitoring and the personal touch. How far this might go is a little tough to predict.

Recently, CMS allowed home infusion of intravenous cancer therapies. Of course, the rule is complicated and full of restrictions. It requires an accredited home care agency. It requires tele-monitoring during the infusion. It requires a complicated financial relationship between the physician and the home care agency providing the infusion.

The overwhelming majority of infusion therapies for cancer require direct physician supervision. Adverse events, like allergy or clinical decompensation, occur frequently in an infusion room and require physician intervention.

> “Cancer care has been collateral damage. Irrespective of the public health wisdom of opening America, we need to be able to resume caring appropriately for cancer patients.”

But the patient receiving the trastuzumab for a year, or one receiving denosumab for bone health, or leuprolide for prostate cancer could easily be managed at home. They key to the realization of this remote monitoring and therapy is the payers.

What will CMS do after COVID?

Can we get commercial payers on the same page?

Telemedicine

While one can argue that telehealth cannot replace an in-person visit, it will find its niche. Telemedicine can offer acute care, follow-up, advanced care planning, survivorship, genetic screening, supportive care, and palliative care.

If supportive telehealth policies continue after the pandemic, telemedicine can serve patients by providing more comprehensive services without patients having to travel. It makes comprehensive cancer care easier.

Many have opined that clinical trials need an overhaul and COVID has proven that. Clinical trials do not meet the patient where they are. They are designed for the convenience of the physician investigator and the study sponsor.

It is insensitive to patient challenges. A lot of this can be done at home, and it should be.

Again, telehealth can perform as the primary modality for many study visits. The ability to simplify the process of participating in a trial will help accrual markedly and speed completion of trials. COVID should lead to intense reflection on the potential benefits of clinical trial evolution using telehealth.

COVID has been devastating to health care.

Cancer care has been collateral damage. Irrespective of the public health wisdom of opening America, we need to be able to resume caring appropriately for cancer patients. We need to build on the enhanced patient engagement we have seen during COVID.

The oncology community has very high expectations for the quality of care delivered. Until we emerge from this dark time, we need to be nimble and evolve to serve our most vulnerable patient population.

THE CANCER LETTER | MAY 8, 2020 | VOL 46 | ISSUE 19

NCI receives $306 million in new money for COVID-19 serology test research; Details to follow at BSA meeting May 12

By Paul Goldberg

NCI has received additional $306 million under a COVID-19 aid package "to develop, validate, improve, and implement serological testing and associated technologies applicable to COVID-19."

The measure was signed by President Donald Trump April 24.

"The emergency appropriation will allow NCI to continue to work with the Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases, and other government agencies to apply our expertise and advanced research capabilities to respond to this pandemic, including efforts to rigorously characterize the performance of serology assays," NCI said in a statement in response to questions from *The Cancer Letter.*

"Additionally, NCI will leverage the experience, expertise, and breadth of the extramural research community to grow the national serologic testing capacity, develop novel assays and gain a deeper understanding of the viral infection and immune response to coronavirus, particularly among cancer patients and other vulnerable populations," the statement reads. "We plan to outline funding opportunities at an upcoming meeting of the Board of Scientific Advisors May 12."

Last month, at an emergency virtual meeting of the NCI Board of Scientific Advisors and the National Cancer Advisory Board, Douglas Lowy, NCI principal deputy director, described the institute's initiatives focused on SARS-CoV-2 (*The Cancer Letter,* April 17, 2020).

Lowy listed three projects underway at the NCI's Frederick National Laboratory for Cancer Research:

- Testing and validating serologic assays for SARS-CoV-2 in the Serology laboratory of the Vaccine, Immunity, and Cancer Program,
- Identifying genetic determinants of SARS-CoV-2 susceptibility and outcomes at the Cancer Genomics Research Laboratory, and
- High-throughput screening for small molecule inhibitors of SARS-CoV-2 proteins, with technology developed by the RAS Initiative.

On May 6, FDA released the first test report and published data from an independent validation study performed to assess the sensitivity and specificity of 12 serology tests.

The assessment was performed at FNLCR.

According fo FDA, the results come from a collaboration between the regulatory agency, NIH, Centers for Disease Control and Prevention, and Biomedical Advanced Research and Development Authority to evaluate certain serological tests.

"While the [Emergency Use Authorization] request was not granted solely based on the validation data, the data were leveraged to inform FDA's decision-making," FDA said. "The NCI FNL-CR test report provides new details on the testing that is being performed by NCI. Essential samples and materials used in the evaluation were provided by the NIH National Institute of Allergy and Infectious Diseases, the Mount Sinai Health System, the Icahn School of Medicine at Mount Sinai, including members of the Departments of Microbiology and Pathology, and the Vitalant Research Institute."

Altogether, 12 tests have been given EUAs, the agency said in a recent blog post describing evolution of it criteria for authorization of serology tests for SARS-CoV-2.

The $306 million in new funds given to NCI are larger initiative to fund development of diagnostic, serologic, antigen, and other tests by federal agencies:

- That of the amount appropriated under this paragraph in this Act, not less than $306,000,000 shall be transferred to the "National Institutes of Health—National Cancer Institute" to develop, validate, improve, and implement serological testing and associated technologies for the purposes specified under this paragraph in this Act.
- That of the amount appropriated under this paragraph in this Act, not less than $500,000,000 shall be transferred to the "National Institutes of Health—National Institute of Biomedical Imaging and Bioengineering" to accelerate research, development, and implementation of point of care and other rapid testing related to coronavirus.
- That of the amount appropriated under this paragraph in this Act, not less than $1,000,000,000 shall be transferred to the "National Institutes of Health—Office of the Director" to develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and for partnerships with governmental and non-governmental entities to research, develop, and implement the activities outlined in this proviso.
- That of the amount appropriated under this paragraph in this Act, not less than $1,000,000,000 shall be available to the Biomedical Advanced Research and Development Authority for necessary expenses of advanced research, development, manufacturing, production, and purchase of diagnostic, serologic, or other COVID–19 tests or related supplies, and other activities related to COVID–19 testing at the discretion of the Secretary.
- That of the amount appropriated under this paragraph in this Act, $22,000,000, shall be transferred to the "Department of Health and Human Services—Food and Drug Administration—Salaries and Expenses" to support activities associated with diagnostic, serological, antigen, and other tests, and related administrative activities.

> "NCI will leverage the experience, expertise, and breadth of the extramural research community to grow the national serologic testing capacity, develop novel assays and gain a deeper understanding of the viral infection and immune response to coronavirus, particularly among cancer patients and other vulnerable populations."
>
> *– NCI*

THE CANCER LETTER | MAY 8, 2020 | VOL 46 | ISSUE 19

Fox Chase will not be sold to Jefferson after all

Deal becomes a "casualty of COVID-19"

By Paul Goldberg

The deal is off: Fox Chase Cancer Center will not be sold to Thomas Jefferson University.

After 15 months of due diligence and a "binding definitive agreement" announced in December 2019, Jefferson and Temple University, which owns Fox Chase, have ended negotiations of the acquisition, citing financial pressures from the COVID-19 pandemic.

On May 5, Jefferson and Temple issued a brief joint press release, declining to answer further questions.

"This transaction is the latest casualty of COVID-19," Stephen K. Klasko, president of Thomas Jefferson University and CEO of Jefferson Health, said in the joint statement. "Because of the tremendous impact that the virus has had on our operations, Jefferson must focus entirely on providing patient care and safety, student education and safety, and for the well-being of our dedicated employees."

The sale would have been the first of its kind. No cancer center carrying an NCI designation has ever been sold on the open market (*The Cancer Letter*, Jan 18, Dec. 20, 2019).

Fox Chase has a Comprehensive Cancer Center designation from NCI. Jefferson has a Cancer Center designation. Fox

Chase is also one of the 11 "dedicated cancer centers," a group of freestanding institutions that treat cancer and no other disease. These centers are exempt from being reimbursed based on DRGs, or Diagnosis-Related Groups, under the Prospective Payment System.

As a unit of Temple, Fox Chase doesn't file separate tax documents. However, the venerable cancer center's at-a-glance table posted on its website as part of the annual report shows that the center was operating in the black through 2019. It's unclear how these data are separated from Temple's financials and it's not publicly known what the Fox Chase balance sheet looked like in the first quarter of 2020.

Announcing the termination of the deal, Temple President Richard M. Englert also cited the coronavirus: "There is no question that but for the catastrophic economic impact of the virus, both institutions were prepared to move forward to complete this transaction. We fully understand and accept this reality, and we look forward to identifying new ways for our institutions to work together in the future to better serve our community."

The announcement is all the more surprising, because late last year the two parties announced a "binding definitive agreement" for Jefferson's acquisition of Fox Chase Cancer Center, Temple's Bone Marrow Transplant Program and transition of Temple's membership interest in Health Partners Plans, a Philadelphia-based managed care program, to Jefferson.

The announcement mentioned that the deal was contingent on "closing conditions," but didn't include a closing date for the transition. Presumably, this back-door clause has been used to end the deal.

Financials

2019 By the Numbers

640
Scientific Publications

120,087
Outpatient Visits

8,637
New Patients

26
New Faculty Members

294
Actively Enrolling Clinical Research Studies

98
Investigator Initiated Clinical Research Studies

Numbers represent Fiscal Year 2019

Philanthropy Snapshot

$14,832,857
Total Philanthropic Support

$1,200,000
Raised at *In Vino Vita*

11,466
Total Donors

3,826
Total New Donors

451
Current Donors Who Have Given 30+ Years

$461,731
Board of Associates Total Gifts

Volunteer Snapshot

531
Volunteers

88,319
Total Volunteer Hours

$280,094
Volunteer Department Budget

$2,245,952
Value of Hours*

$1,965,858
Net Value Added to Fox Chase

*Based upon the independent sector value of $25.43/h

Source: Fox Chase Cancer Center

Last December's agreement opened the door for the leadership of Fox Chase and Jefferson's Sidney Kimmel Cancer Center to discuss integration of the two NCI-designated cancer centers.

Outside observers wondered about the logistics:

- What will be the name of the integrated entity?
- Will PIs from both institutions with similar federal grants be able to retain their funding?
- How would the acquisition of Fox Chase alter Jefferson's catchment and service areas?
- Will there be changes in staffing? Are employee benefits going to change?

Clinical Snapshot (In Thousands)

	FY19
REVENUES — CLINICAL ACTIVITY	
Patient Care Revenue — Hospital	$410,402
Patient Care Revenue — Physicians	$34,629
Philanthropy, Outreach & Other	$11,710
Clinical Revenue	**$456,741**
OPERATING EXPENSES — CLINICAL ACTIVITY	
Direct Patient Care	$335,001
Support Services	$19,008
Administrative & General	$50,169
Capital Related Costs	$8,265
Maintenance & Plant Operations	$12,056
Clinical Expenses	**$424,499**
KEY PATIENT CARE STATISTICS	
New Patients	8,637
Hospital Admissions	3,814
Chemotherapy Infusions & Related Procedures	64,692
Radiation Therapy Treatments	27,411
Surgical Procedures	5,054

Research Snapshot

ACTIVE FUNDED PROJECTS

Funding Source	Number of Projects	Direct Costs	Total Costs
PEER-REVIEWED			
NCI	81	$12,407,245	$20,284,919
Other NIH	57	$12,249,984	$18,358,208
Other	34	$4,991,888	$6,884,943
Subtotal of peer-reviewed	**172**	**$29,649,117**	**$45,528,070**
NON PEER-REVIEWED			
Industry	80	$5,690,731	$7,319,709
Other non peer-reviewed	31	$2,245,986	$2,541,620
Subtotal of non peer-reviewed	**111**	**$7,936,717**	**$9,861,329**
GRAND TOTAL	**283**	**$37,585,834**	**$55,389,399**

Source: Fox Chase Cancer Center

Temple and Jefferson focused on each other as merger partners following discussion with other parties. Now that the deal is off, it's unclear whether these negotiations will resume in the midst of the pandemic that has diminished the resources of potential suitors.

Fox Chase is a multi-site NCI-designated comprehensive cancer center that employs over 2,312 people. In fiscal year 2019, it reported having 8,637 new patients and had clinical revenues of $456.7 million and clinical expenses of $424.5 million. There were 283 research projects with total costs of $55.3 million, and philanthropy brought in $14.8 million. The number of indexed patients—those whose tumors are in the registry—was 3,947 in fiscal 2019.

Fox Chase was sold to Temple in 2012 for $84 million. The cancer center was in financial distress at that time, and this was more of a rescue than a sale. Multiple bids were not formally sought at that time.

The announcement of the end of negotiations over Fox Chase makes no mention of the sale of Temple's interest in Health Partners Plans.

The focus of Health Partners is a great deal broader than cancer. Tax documents show that in 2017, the most recent year for which financials are available, the health plan had about $1.89 billion in revenues, nearly five-fold the revenues posted by Fox Chase. Revenues minus expenses were at $11 million. Most of this is a pass-through of federal and state funds.

Until recently, Health Partners was owned by three health systems: Aria, Einstein and Temple. Aria and Einstein have been acquired by the Jefferson system, which leaves only Temple's stake outside Jefferson's control.

The Health Partners acquisition would plunge Jefferson into a tough business. Health insurance insiders say that administering Medicare Advantage programs—which now enroll a bit more than a third of Medicare recipients nationwide—can make for a solid commercial endeavor.

This is because people who sign up for Advantage plans stay for at least six years, which makes it possible to improve their health, thereby taming expenses. State-run Medicaid—which, according to the Health Partner tax filings, represents the vast majority of the plan's enrollees—presents a bigger challenge.

Medicaid patients tend to stay in such plans for a short time—often less than a year. There is a lot of mental illness within the Medicaid population, and the opportunities to realize savings by improving health are much lower than in the Medicare Advantage populations.

COVID-19 slams into the nation's capital region; Here is the damage assessment at six institutions

By Matthew Bin Han Ong

In the first effort of its sort, *The Cancer Letter* has compiled a damage assessment, gauging the severity of the COVID-19 outbreak in the District of Columbia, Maryland and Virginia, gathering information on populations that were struck hardest, and quantifying impact on academic cancer centers and large hospital systems.

In interviews with *The Cancer Letter*, leaders at Johns Hopkins University, Georgetown University, The George Washington University, Inova Health System, The University of Virginia, and Virginia Commonwealth University described their institutions' strategies for managing workflows and resources as the region prepares to reopen.

Conversations with the leaders of cancer centers at these institutions appear on page 23.

The questionnaire included the following:

- Have you had to take austerity measures?
- How has cancer care and clinical trials changed in your institution?
- How is COVID-19 affecting underserved communities and populations in your catchment area?
- Is there a need for a more robust system for managing public health crises at the federal level?

At this writing, there are over 30,000 confirmed cases and 1,500 deaths in Maryland. In D.C., there are over 5,600 cases and nearly 300 deaths. The number of cases in Virginia has exceeded 22,000, with a death toll of over 800. The epidemic curve continues to trend upward in the region.

"Looking back, the high transmissibility of SARS-CoV-2, particularly during asymptomatic phases of COVID-19 illness, the propensity of the virus to cause serious life-threatening illness, and the degree to which COVID-19 cases seeded throughout several regions of the country, were generally underestimated," William Nelson, director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, said to *The Cancer Letter*.

Large hospital systems and matrix academic cancer centers in the DMV area have had to implement cost-saving measures to limit operating shortfalls caused by the COVID-19 pandemic:

- Inova has eliminated 500 nonclinical positions, and implemented pay cuts for leadership and employees who are not serving on the front lines,
- UVA has furloughed many of its staff members, and applied a 20% salary reduction to faculty, senior staff, leadership, and administrators through the summer,
- Johns Hopkins has reduced leadership salary, limited hiring, eliminated merit increases and suspended employer retirement contributions for the coming year, and furloughed some employees, and
- GW has not laid off employees or made pay cuts, but hiring is on hold.

"There are going to be health systems that don't survive this," John Deeken, president of Inova Schar Cancer Institute and medical director for the Inova Schar Head and Neck Cancer Program, said to *The Cancer Letter*. "There'll be practices that don't survive this.

"So, there's definitely going to be a forced efficiency that we've already seen, and that, I assume, is only going to continue, because it's not like payers are going to say, 'Let's go back to the banner days of 2019,' or whatever the framework is."

Basic and translational research, as well as clinical trials, have largely seen a setback, said Louis Weiner, director of the Georgetown Lombardi Comprehensive Cancer Center, director of the MedStar Georgetown Cancer Institute, and chair of the Department of Oncology at the Georgetown University School of Medicine.

"It is difficult to maintain momentum in the face of this pandemic," Weiner said to *The Cancer Letter*. "We have numerous video meetings to assure we can sustain our research momentum, though actual wet bench experimentation is largely inactive at this point. After a brief contraction, we are ramping up our clinical trials efforts, even as a large proportion of our patients are being seen through the MedStar telehealth platform."

As the federal response faltered, the DMV-area institutions moved quickly to comply with state and local guidelines.

While resources are dwindling and frontline personnel endure stress as waves of COVID-19 patients arrive at their facilities, none of these institutions have experienced a surge that exceeded their inpatient capacities—avoiding worst-case scenarios and patient overflows seen in New York City, Spain, Italy, and Wuhan (*The Cancer Letter*, May 1, April 9, April 3, March 20, March 11, 2020).

"We were clearly, as a society, not truly prepared for this," Mitchell Smith, associate center director for clinical investigations and director of the Division of Hematology and Oncology at The GW Cancer Center, said to *The Cancer Letter*. "And we can argue, without getting into politics, about whose fault it was, but clearly, we were not prepared.

"Regionally, with individual institutions, my hope would be that we would get together public and private institutions, even the VA, and have a plan among ourselves, so that we're not competing for the limited resources, and that we move patients and staff around as necessary—so that we have sort of a local-regional pandemic disaster plan, whether it's for a pandemic or an acute natural disaster."

While patient volumes and treatment visits for cancer patients aren't necessarily down across the board for these institutions, the financial impact of the pandemic on university health systems and larger networks appears to mirror the challenges faced by community oncology practices.

Early data compiled by Flatiron Health and made available exclusively to *The Cancer Letter* show that weekly visits to community practices dropped by nearly 40%, while cancellations and no-shows have nearly doubled (*The Cancer Letter*, May 1, 2020).

Some conservative media outlets interpreted these data as a sign that the economy needs to reopen swiftly, due to unintended sequelae of public health measures designed to slow the spread—delayed treatments for cancer patients and financial hardships for health care providers.

"We know that patients may not be getting the screenings and early diagnoses that are crucial for better outcomes, and that community oncology practices are hurting financially," Bobby Green, chief medical officer at Flatiron Health, said to *The Cancer Letter*. "But reopening the economy while ensuring the health and safety of the public is an incredibly difficult and complex balance to strike—people's lives and their livelihoods depend on it.

"We must make informed decisions that are based on science and data, and listen to the public health experts who have outlined parameters for reopening the economy."

SARS-CoV-2 has tipped the scale of benefits and risks in medicine on the side of potential harms, said Len Lichtenfeld, deputy chief medical officer of the American Cancer Society.

"There are areas of the country where there are virtually no cases of COVID-19, and it's one thing to consider what you do in that circumstance, but something else entirely when you're in a community that still has evidence of coronavirus infections, and particularly in communities where those infections are rising in number," Lichtenfeld said to *The Cancer Letter*.

"So, finances, we can recover from. Death, we cannot. It's a false choice and it's a false premise to compare the two," Lichtenfeld said. "Life and safety come first; finances come second, we can resolve those issues. We must never forget our core principles and to whom we have the greatest responsibility—and it's not to our pocketbooks."

More than half of ACS grantees report that their cancer research has been halted as a result of the COVID-19 pandemic, according to survey results released by the organization May 8.

"It is abundantly clear that the COVID-19 pandemic is having a major impact on cancer research," William Phelps, ACS senior vice president of extramural research, said in a statement. "In some labs queried for our survey, all non-essential research had been halted, with research on COVID-19 being the only type of research being encouraged.

"In addition to the deceleration in progress against cancer, these laboratories and institutions will face significant additional costs associated with restarting the cancer research enterprise in the coming months."

Upward trend in cases as DMV looks to reopen

The DMV region, which was expected to be the next major COVID-19 hotspot after New York, thus far appears to have succeeded in flattening the epidemic curve, with coordinated stay-at-home orders, which resulted in relatively high compliance.

"I think social distancing has really worked. It did what it was supposed to do, which was smooth out the curve, so we didn't see the surge that New York had," GW's Smith said. "I can certainly see how that could have happened. But we haven't seen a downtrend.

"The trade-off is that I think we're going to be at this for a while. I don't think it's going to magically be, 'Oh, because we tamped down the curve, it'll still be over in two more weeks.' I think we're going to be at this level for a long period.

"It's going to be an ongoing learning experience. This is not, 'It's gone away and we're done.'"

The situation can change quickly, as businesses reopen and social activities resume.

"As was apparent in Germany and Singapore, reopening does come at the risk of increasing the number of newly infected COVID-19 patients," Robert Winn, director of the VCU Massey Cancer Center and a professor in the Division of Pulmonary Disease and Critical Care Medicine, said to *The Cancer Letter*. "It appears that we have gotten past the first peak. I am however, very concerned about the fall and winter."

The number of active COVID-19 cases at institutions in the DMV region range from as low as 20 at UVA, in Central Virginia, to over 300 across a network, as is the case at Inova in high-density Northern Virginia, as well as at Georgetown and across its affiliated MedStar health system, which has many hospitals throughout the region.

"We've certainly been impacted less than most centers thus far. We had more lead time than some of the major cities, especially in the Northeast," Michael Williams, the Byrd S. Leavell Professor of Medicine and associate director of clinical affairs at the UVA Cancer Center, said to *The Cancer Letter*.

"Depending on which models you look at, the peaks come at variable times.

"It's expected that as Virginia starts to loosen statewide restrictions on usual activities, that we may see a bump in cases. We hope not to see a major surge at this point, unless something changes dramatically," said Williams, who is also chief of the Division of Hematology and Oncology and physician lead of the Cancer Service Line at UVA. "We do anticipate that over the coming six to 12 months, before we have an effective vaccine, we're going to see peaks and valleys of cases.

"As people get newly active, new populations get exposed and develop the infections that we're going to see more of those, off and on. We're looking ahead, right now, to understand what it's going to look like as we get into the next influenza season and we start having overlap of patients, with flu and with COVID in the mix as well."

The pandemic has catalyzed rapid uptake of telehealth and telemedicine across all health systems, which experts anticipate will become a mainstay of U.S. health care.

"For cancer care, tactics like telemedicine, pre-visit phone calls, drive-thru injection clinics, home care, and many other approaches have been rapidly deployed, and progressively perfected," Hopkins's Nelson said. "The patient response has been overwhelmingly positive.

"Three years from now, we will still be using many of these approaches to make cancer care, and cancer clinical trials participation, more accessible and convenient, decreasing the time spent in waiting rooms and increasing the time spent at home with loved ones."

Racial disparities apparent in COVID-19 deaths

The overall patterns of disparities among COVID-19 patients in the DMV mimic those seen elsewhere throughout U.S. metropolitan areas.

"Unfortunately, in Richmond, 13 of the 14 COVID-19 deaths were African American," VCU's Winn said. "Of the 321 people who tested positive in Richmond, 61 of those were hospitalized, and of the 14 deaths, 13 of those were African Americans.

"The most important health care policy lesson is that we must stop studying our most vulnerable populations, and actually get up off our butts and address the issues in these communities with information and approaches that we already know work," Winn said. "It has not been the lack of knowledge, but the lack of political and social will that continues to plague this communities.

"We already know that good housing, having a great education, and having access to excellent health care will improve the health of these communities. The real question is, will we really address these issues in a post-COVID-19 world?

"The second thing that this crisis has actually taught me is that you can be wealthy or poor, but if we don't all take care of one another the COVID virus will continue to win. So, this is the one time where we all are in the same boat, literally."

People of color are especially at risk for significant complications from the SARS-CoV-2 infection, Inova's Deeken said.

"Since we don't have widespread screening, we don't know what the actual rate of infection is, unfortunately," Deeken said. "But in terms of the patients seeking care, being diagnosed, needing testing, and therefore being diagnosed, there seems to be a high prevalence in those populations."

In D.C., 80% of those who died from COVID-19 and whose deaths are listed on the D.C. Department of Health website were African American.

"Clearly, there's a disparity in mortality, likely reflecting comorbidities and other health problems, but also socioeconomics," GW's Smith said. "So, yes, we do see disparities in who ends up in the ICU. That's a big concern."

Minority populations, the poor and the uninsured are especially vulnerable to poor outcomes, because of comorbid conditions—an existing public health crisis that requires federal attention.

"This system should finally tackle the underlying public health challenge of obesity, high blood pressure, cigarette smoking, and diabetes, especially in poor and underserved populations, as if it were a crisis," Hopkins's Nelson said.

Experts: Failure of federal leadership

As the White House failed to provide consistent leadership, DMV institutions looked to state and local authorities:

"At the local, regional, and at the state levels, I've been impressed with the quality of response," UVA's Williams said. "At the federal level, my opinion is that the coordination has been less organized and effective and less measured in terms of emergency management and in setting priorities."

VCU's Winn agreed: "There has been a complete failure of leadership from the very top. I also have to give credit to the various health systems in Virginia that decided to work together for the greater good. It was tough, and probably strange, for many of these systems to have to work together in the manner in which they did.

"I think that there should have been more clarity and thoughtfulness, and

consistency from the highest office of the land, it would have helped out a lot."

Federal officials have missed many opportunities to mitigate the crisis over the last few months, Inova's Deeken said. "I think we've all seen the challenges with not having a robust public health system and rapid response from the federal level, and states being left to do many initiatives on their own," he said.

Public health systems in the U.S. aren't as robust as they are in many other developed countries.

"Frankly, when you look at our CDC response, compared to other countries, it fell short," GW's Smith said. "Our testing, even now, is not where we would like it to be. Hopefully, this is a true wake-up call and we will be ready next time. One can only hope, but it has to be at the federal level."

The U.S. needs rapid, better-coordinated early responses to emerging pandemics, Georgetown's Weiner said.

"These responses are needed to accelerate drug development, expand distribution networks and develop/implement testing for active and prior infections," Weiner said. "Had we done this with COVID-19, it would have blunted the devastating impact of this virus."

Balancing the scales

As restrictions are eased, keeping the public healthy while ensuring that businesses remain viable is a precarious balancing act—even as hospitals and practices bear the brunt of responding to a surge of COVID-19 patients and deal with the deficits that come with movement control orders and economic recession.

"Cancer centers are having difficulty, just like hospitals and medical practices—and particularly primary care medical practices—when it comes to financial issues," ACS's Lichtenfeld said. "They've been caring for patients as best they can, but certainly not at the level of activity that they have in the past.

"However, we're getting ourselves into a false choice—by opening full-throttle, versus paying attention to the virus, versus considering the economic factors," Lichtenfeld said. "We're talking about human lives, and first and foremost, medical organizations and medical practitioners have an absolute, absolute ethical responsibility to preserve life and keep people safe."

Pandemic or not, patients with cancer require high-quality care in a timely fashion, said Richard Schilsky, chief medical officer and executive vice president of the American Society of Clinical Oncology.

"While the pandemic has clearly disrupted many aspects of cancer care, our job still is to deliver the best care as safely and sensibly as possible in the face of this or any public health crisis," Schilsky said to *The Cancer Letter*. "ASCO recognizes that cancer care delivery teams are doing their best to protect the safety of their patients and providers, to maintain adequate staff, and to be available to patients whenever necessary. We remain committed to doing all that we can to help our members and the entire cancer community serve their patients during this difficult time."

Safeguarding patients with cancer from the coronavirus poses unique challenges for screening and treatment interventions, said Otis Brawley, the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University.

"We definitely need to have a balance," Brawley said to *The Cancer Letter*. "That balance must take into account the true advantages of each of our interventions and the risk of exposure to SARS-CoV-2.

"Treatment of certain faster-growing tumors needs to continue with very limited delay. Pancreatic surgery, some lung cancer treatments, therapy for many of the faster growing leukemias and lymphomas need to continue and should not take much of a holiday for COVID. These patients do need to be extremely careful not to catch the disease."

For patients who would normally receive adjuvant therapy—for instance, after breast, colon, and lung cancer surgery—the benefit of chemotherapy may not outweigh the increased risk of getting the virus and having a bad outcome from COVID, Brawley said.

"Unfortunately, we have to use 'may' as no one can fully quantify this. We can quantify half," Brawley said. "We know how to calculate the benefit in terms of preventing tumor relapse, but not the risk of getting COVID or dying from it.

"Some of those who are concerned about the decreased amount of screening right now believe screening contributes more to the decline in mortality than the data would suggest. They also tend to think weeks, or months, matter more than screening data would suggest.

"The studies do not suggest a great difference in women in yearly programs of mammography screening vs. every two years. The most important, in breast, colon and likely lung screening, is a regular program of screening, not one screen that might be delayed by a few months. That being said, I would not want to have a prolonged greater than a four-to-six month delay in most screening.

"I worry that a substantial number of Americans do not get optimal cancer therapy in normal times. Those people are more likely to get less-than-optimal therapy now."

Q & A

Six experts spoke with Matthew Ong, associate editor of The Cancer Letter.

CONVERSATION WITH THE CANCER LETTER

Lessons from COVID-19:

Leaders of six cancer centers in the DMV area tell us about caseloads, the outlook—and impact

William G. Nelson, MD, PhD

Director, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins;
Professor of Oncology

Mitchell R. Smith, MD, PhD

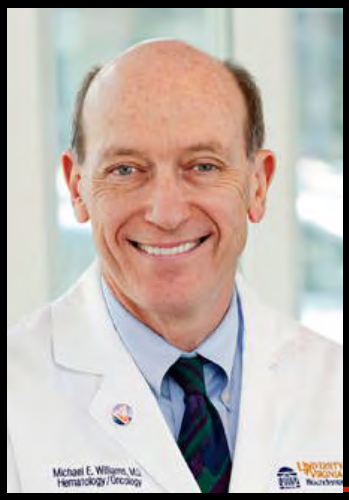
Associate center director, clinical investigations,
Director, Division of Hematology and Oncology,
George Washington University Cancer Center

Louis M. Weiner, MD

Director, Georgetown Lombardi Comprehensive Cancer Center;
Director, MedStar Georgetown Cancer Institute;
Chair, Department of Oncology, Georgetown University School of Medicine

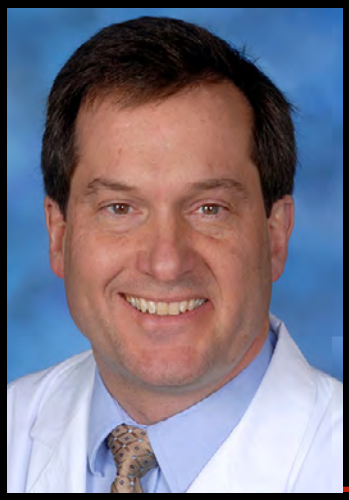
Robert A. Winn, MD

Director, Virginia Commonwealth University Massey Cancer Center;
Professor, Division of Pulmonary Disease and Critical Care Medicine



Michael E. Williams, MD, ScM

Byrd S. Leavell Professor of Medicine, Chief, Division of Hematology and Oncology,
Physician lead, Cancer Service Line,
Associate director, clinical affairs,
University of Virginia Cancer Center



John F. Deeken, MD

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

As the District of Columbia, Maryland, and Virginia prepare to loosen pandemic restrictions and reopen economies, hospital networks and academic cancer centers brace for a potential uptick in SARS-CoV-2 infections.

While the region has avoided a cataclysmic surge of confirmed cases and deaths, because of social distancing measures, overall, the epidemic curve has neither plateaued nor taken a downward trend.

In six interviews, leaders of major cancer centers in the DMV describe cost-saving measures at their institutions, what it will take to manage the pandemic in the coming months, and how they are ramping up their clinical and research enterprises.

Matthew Ong, associate editor of *The Cancer Letter,* asked all six experts the same 14 questions.

Matthew Ong: If I called you three years from now, which aspect of the COVID-19 pandemic would you say left the most lasting impression?

Nelson, Hopkins: The medical response to the deluge of COVID-19 cases presenting for healthcare has been astonishing.

Of course, at hospitals throughout the country, specialized acute care and intensive care units have been created to serve the needs of COVID-19 patients while protecting medical care teams and other hospitalized patients against SARS-CoV-2 transmission.

This was just the beginning. For cancer care, tactics like telemedicine, pre-visit phone calls, drive-thru injection clinics, home care, and many other approaches have been rapidly deployed, and progressively perfected.

The patient response has been overwhelmingly positive. Three years from now, we will still be using many of these approaches to make cancer care, and cancer clinical trials participation, more accessible and convenient, decreasing the time spent in waiting rooms and increasing the time spent at home with loved ones.

Smith, GW: We don't know where we're going to be. If it's totally gone in three years and it was a blip in the past, we're going to have one story. But if this was lingering, as it might, as a new disease that's in the system and that has changed the way we live, I think then the answer's going to be a little bit different.

I think the lesson will be adaptability, that people have been incredibly adaptable in the face of this challenge. Sometimes with the help of systems, but often having to fight entrenched systems, but people are adaptable and make things work to take care of patients. It's quite remarkable.

Weiner, Georgetown: First, we have learned how quickly we can act when it is necessary. I suspect that regulations regarding clinical trials, for example, may change. I also think that all manner of meetings will be conducted in the zoomiverse, or whatever replaces that technology.

Winn, VCU: I think the most lasting impression from the COVID-19 crisis will be the astounding acts of courage and self sacrifice shown by the medical community, the grocery workers, the postal workers, and our urban underserved, rural, suburban communities throughout Virginia.

It was really impressive how our communities came together to consistently do the right thing, for example adhering to the social distancing as best they could. That's what I'll remember most.

Williams, UVA: As a leader of cancer services and programs at UVA, the thing that impressed me the most has been the collaboration and coordination across the health system, which in turn reaches well into the university itself.

As with all academic centers, we've had to do a great deal of preparation for what was going to be an unknown number of COVID patients and what that might mean for the ongoing care of our already very busy clinical and research programs.

I think back a few weeks to the challenges of whether there was going to be enough PPE, and how we were going to staff units that may be missing personnel. This was a huge lift, as it was for any center, and it could not work without people just being willing to step up and do everything that they could, and then some.

Deeken, Inova: I say this as a physician and a father: I think the biggest impact is actually going to be psychological, especially on young people. Certainly, our patients, our healthcare providers who've been on the front line—in terms of prolonged psychological impact, post-traumatic stress, and all the other psychological manifestations—I think we're going to have to contend with this for some time.

Obviously, there's going to be all the kids who had to be out of school who will see a lag in terms of their getting back up to grade level. But that's a societal question. In terms of health care, I think the biggest impact is the jumpstart we've had to telemedicine and using technology for clinic evaluations that may not be in person.

I think there's going to be a streamlining and financial cutbacks. There are going to be health systems that don't survive

this. There'll be practices that don't survive this. So, there's definitely going to be a forced efficiency that we've already seen, and that, I assume, is only going to continue, because it's not like payers are going to say, "Let's go back to the banner days of 2019," or whatever the framework is.

So, I think you're going to see a lot of forced efficiencies and downsizing that will persist, a heavy reliance on telemedicine and other technology. But otherwise, hopefully, in three years, after a vaccine has been developed and works, we'll be back to more of something that looks like what we have been doing and need to do for cancer patients.

How many patients with COVID-19 are in your hospital right now? What's the most you've had, and what's your capacity?

Nelson, Hopkins: As of the first week of May, the state of Maryland has some 1,700 people hospitalized for COVID-19.

The Johns Hopkins Health System operates five hospitals in the region and can distribute COVID-19 patients throughout these sites to ensure all who need acute care or intensive care can receive treatment in a setting configured for COVID-19 care and staffed with dedicated COVID-19 expertise.

In addition, in collaboration with the University of Maryland Medical System and the Maryland Department of Health, Johns Hopkins operates the Baltimore Convention Center Field Hospital, a 250-bed facility accepting COVID-19 patients from all Baltimore City Hospitals.

Smith, GW: We've been running 50 to 60. It's been pretty steady for the last three weeks, and the admission rates have been pretty steady. The patients stay for several weeks. It's pretty intense because these are labor intensive patients.

But we haven't seen a downtrend. I think social distancing has really worked. It did what it was supposed to do, which was smooth out the curve, so we didn't see the surge that New York had. I can certainly see how that could have happened.

Credit goes to people and institutions managing to lower the curve. The tradeoff is that I think we're going to be at this for a while. I don't think it's going to magically be, "Oh, because we tamped down the curve, it'll still be over in two more weeks." I think we're going to be at this level for a long period.

We were prepared for more. We had plans for converting all sorts of beds. We certainly made some wards COVID wards, so it's definitely expanded, but we haven't seen a situation like New York, making ICU's in the cafeteria and those sorts of stories. So, we've been able to manage the numbers.

The physicians and staff are pretty stressed, because it's intense. We have taken a few physicians out of their comfort zone to help take care of patients in ICU or backfill into the wards. We had multilevel plans for staffing, but we've only had to dip our toe into that plan so far. Hopefully that will continue and not see the big surge.

Not as many go into the ICU, and actually not all of them are vented. That's a tribute to information dissemination rapidly adopted by our ICU, pulmonary and infectious disease colleagues. There's been a steep learning curve.

The usual triggers for ventilation aren't necessarily applicable in this disease, so that we can let people get more hypoxic as long as they're not in distress. I think we're allowing people to test the limits and only intubating them if we really need to. Proning helps.

So, I think that the intubation rate is actually on the order of closer to 10% to 20% of admissions of COVID patients.

Weiner, Georgetown: All of our hospitals have significant numbers of COVID-19 patients—but the numbers are frequently changing.

Winn, VCU: As of a week ago, I believe the Richmond area had a total of 321 cases, 61 of those where hospitalized and 14 deaths total. In the state, we have had 21,570 cases, 2,955 hospitalizations, and 769 COVID-19 deaths.

We at VCU Massey were certainly preparing for the worst. The initial surge number of cases for Virginia as calculated by the IHME were quite concerning at the beginning of the crisis. We had about 50 ICU COVID-19 cases at our peak. We are all very relieved that we were able to avoid the cataclysmic numbers that were first predicted for the Richmond area.

I think that there were two things that help us avoid a disaster. The first, was Governor [Ralph] Northam's quick and decisive action to adopt social distancing practices early, and the willingness of communities all over Virginia to adhere to the social distancing measures. I also certainly think it helped that our governor was a physician. These actions together really helped us to avoid many more deaths.

Williams, UVA: We've certainly been impacted less than most centers thus far. We had more lead time than some of the major cities, especially in the Northeast. As of now we have 20 to 25 COVID-positive inpatients with about a third in the ICU.

A couple of weeks ago, we were running in the 30 to 35 range, but it seems to be

leveling out. And the expectation is that we're going to have a very protracted level of COVID admissions, with periodic bumps from localized outbreaks.

We serve a very large geographic area, including much of Virginia and a good bit of West Virginia. As COVID infections reach into rural areas, especially given that rural hospitals don't necessarily have the capacity and the staffing, especially ICU-level care, we're ready, if needed, to take patients in transfer from those areas.

The capacity that we have overall is excellent, as we were just about to open a new hospital tower. There was a great deal of effort that brought two of those floors online this past month. It's allowed us to create COVID acute care units in those new rooms.

This adds to our existing capacity in the main hospital tower ICUs and acute floors. So, if we had to go up in response to a surge, we would be able to handle upwards of 125 ICU patients and about 250 acute care patients with COVID.

Deeken, Inova: Inova, as a system, started preparing for this more than eight weeks ago. We've had sufficient capacity to take care of inpatients. Our ICUs have not become overloaded. We've had plenty of ventilators. We have more ventilators than are currently being used right now, as the care has moved towards not ventilating if at all possible. We've been successful.

I think we have had over 800 patients discharged to home. At our main hospital, we play a song over the loudspeaker every time a COVID patient goes home. So, we're still seeing the numbers go up. We're in the upper 300s right now, in terms of inpatients across the system, which continues to go up by the day. And I think that reflects both the new diagnoses who need to come in, and then also discharges.

So, the net numbers are slowly increasing, because I think the volumes in our catchment area are going up. We're getting people discharged, but more than those are coming in on the front end. So we're still seeing trend lines going up, in terms of diagnosed patients who need inpatient hospitalization.

Fortunately, we've got plenty of capacity to take care of that. Much of the PPE issues have been resolved, not that it's completely resolved. Testing is still incredibly in short supply, and our staffing, our ICU physicians, nursing, respiratory tech staffing have definitely been pushed to the limit.

They are truly heroes, the ones on the front lines here, and that's a continuing concern, I think, as we continue to see increasing cases in our area, and increasing hospitalizations from those patients.

Did you know what to expect? Has anything in your career prepared you for this?

Nelson, Hopkins: Looking back, the high transmissibility of SARS-CoV-2, particularly during asymptomatic phases of COVID-19 illness, the propensity of the virus to cause serious life-threatening illness, and the degree to which COVID-19 cases seeded throughout several regions of the country, were generally underestimated.

For cancer care, previous experience with the influenza A virus subtype H1N1 epidemic in 2009 provided us with some operational preparation. Then, like now, we created screening tents at hospital and ambulatory clinic entry points, performed nasal swab testing, and adopted clinical care workflows to isolate infected patients in order to protect other patients and staff against virus transmission.

Smith, GW: No. The simple answer is no. I was training back in the AIDS day and everyone you'll hear will talk about, "HIV, it was scary because we didn't understand it, and we didn't know how it spread." In New York at the time where I trained, it was scary, but we didn't get the sense that the entire system was stressed to the point of breaking and being overwhelmed.

And so, this is more like a natural disaster, but not just for one day. A natural disaster that just keeps going and going and going. And that, I don't think anyone has really seen.

Weiner, Georgetown: I can't say we were surprised. We saw what happened in China, Italy and Spain, and then in New York City. While it certainly is an extraordinary time, we remain ever-ready to handle emergency situations like this given the hospital's preparations for SARS, MERS, and anthrax among others.

Winn, VCU: No. Nothing from my training as a Pulmonary Critical Care physician prepared me for this COVID-19 crisis. I honestly don't think that any of us could be prepared.

My disaster training included things like preparing for natural disasters—tornadoes, gun violence, etc., but I was not prepared for a pandemic. Nothing in my previous training prepared me for this COVID-19 crisis.

The stress from the COVID-19 crisis has been tremendous. Many of you probably have heard or read about one of our outstanding ER physicians who unfortunately took her own life.

There has not been a lot on the frontline to help our healthcare providers deal with their own mental health. I

lived through the HIV period in the 80's and 90's. While this current crisis has some similarities to the HIV crisis, there have also been a number of important differences.

Williams, UVA: Nothing on this scale, of course. We already had plans in place to deal with previous influenza outbreaks, the SARS preparation that was done a few years back, and more recently the Ebola outbreak. The work had identified how those patients would enter the system, where they would be isolated, how they would be managed. And so we had a template that we were able to build upon.

Deeken, Inova: Being in D.C., and I'm sure in the other hospitals you talked to, D.C. has had its fair share of events, whether it be 9/11, the anthrax attack—I was an intern in the ICU here at Fairfax Hospital when the anthrax patients came in early 2002—and then we had the H1N1 epidemic, and then we had Ebola. So, just being in the D.C. area, and the risk of bio-terrorism, I think the D.C. hospitals have had to be on the higher end of being prepared for mass events like this.

I think we've been very well prepared across the geography in D.C., because of our potential targets, and because we've had things to contend with. Inova as a health system, from supply chain to emergency room surging capabilities, to ICU capabilities, we've been incredibly well-prepared for this kind of thing.

We have had to face these events in the past, and each time succeeded, because we didn't face worst case scenarios, and fortunately, so far, we haven't had with COVID. Hopefully that will continue to be the case, with all the precautions in place.

So, I think D.C., like New York City, has uniquely seen a number of events in most people's careers, over the last 10 to 20 years. While this is worse than any of those, they made us develop capabilities and processes and team approaches to contending with these things when they did happen, so that we could take care of the patients of our community when it did.

What is your outlook for your city or the DMV region for the next month, this summer, and later in 2020? Do you think we've peaked, or is there more to come?

Nelson, Hopkins: As you know, there are several mathematical models for SARS-CoV-2 transmission, medical resource utilization, COVID-19 mortality, etc., in the Maryland, District of Columbia, and Virginia region.

Some of the best have come from Johns Hopkins. The projections of each of these predictive tools varies substantially with the effectiveness of mitigation tactics like social distancing.

I believe that if SARS-CoV-2 transmission can be suppressed in a sustained way, even after re-animating the economy of the region, then the medical systems in the region will be able to meet any challenges to come.

Smith, GW: I am concerned that what we see right now is pretty much what we're going to be at for weeks and probably several months. I don't think it's magically going to go away when the summer heat comes.

People say, "Oh, New York, 25% of the people have antibodies," but that means 75% don't. And here it's probably lower. So, I think we're going to see this rumbling along of similar numbers. And if there was a sense that it was going to go down a little, that's going to be balanced by more people being out and more transmissibility. So, I think we're going to be sitting at this level for some time, barring some effective antiviral medicine.

As for a vaccine, vaccines are not 100% effective. Even if you had a vaccine that tested well, the logistics of gearing up to make it, distribute it, and get it to the people who need it, and then it's not 100% effective. So I think people are placing their bets on a vaccine, and I think in the long run, that's where we want to be, but I don't see that coming anytime in the near future.

I would put more hope in an antiviral, because what really made HIV manageable is effective antiretroviral medicines, which I think are more likely to come more quickly than a vaccine.

Weiner, Georgetown: It's still hard to know, as we don't know what our long-term discipline will be regarding physical distancing in D.C., and whether effective testing for active infection, prior infection, antivirals or vaccines will emerge, and when. My sense is that we will experience a continuing burden of new cases, and we will gradually ramp up activities as we learn which physical distancing approaches are most effective.

Winn, VCU: I am cautiously optimistic that we will reopen without a huge negative impact on our communities. As was apparent in Germany and Singapore, reopening does come at the risk of increasing the number of newly infected COVID-19 patients. It appears that we have gotten past the first peak. I am however, very concerned about the fall and winter.

Williams, UVA: Depending on which models you look at, the peaks come at variable times. It's expected that as Virginia starts to loosen statewide restrictions on usual activities, that we

may see a bump in cases. We hope not to see a major surge at this point, unless something changes dramatically.

We do anticipate that, over the coming six to 12 months, before we have an effective vaccine, we're going to see peaks and valleys of cases. As people get newly active, new populations get exposed and develop the infections that we're going to see more of those, off and on. We're looking ahead, right now, to understand what it's going to look like as we get into the next influenza season and we start having overlap of patients, with flu and with COVID in the mix as well.

Deeken, Inova: While you'll have daily fluctuations that go up or down, from what I see, the curve still looks like it's going up, and that's the same in Maryland and D.C. as well. I think we flattened the curve, but we haven't plateaued.

The curve has less of a slope, fortunately, and therefore, we're not getting the overwhelming numbers that New York had to suffer through. And social distancing and all the things we've gone through have succeeded, but I don't think we've seen the peak.

I don't think we've seen a plateau in terms of the DMV area, if you look at just the publicly available numbers from CDC and Hopkins, and the people who are gathering these data. If you look at those trend lines, they're continuing to go up. We haven't plateaued.

We certainly haven't come back on the other side of the curve, which is concerning for plans of opening things up. I think all of us who are on the front lines of this are concerned, depending on how we open up and how rapidly, we could get ourselves back into trouble that we successfully avoided over the last six to eight weeks by all the precautions and stay at home orders that have been in place.

What's happening at your basic research labs?

Nelson, Hopkins: In accordance with Governor [Larry] Hogan's order on March 23 to close all "non-essential" businesses in the state of Maryland, laboratory research, including cancer research, has been ramped down substantially.

The exceptions have been laboratory work on SARS-CoV-2/COVID-19 aimed at improving detection, diagnosis, prevention, and treatment of the disease.

The results have been stunning. In early March, clinical microbiologists Karen Carroll, MD, and Heba Mostafa, MBBCh, PhD, developed one of the first SARS-CoV-2 tests able to secured an Emergency Use Authorization from the FDA to allow its introduction into clinical care.

Shortly thereafter, Mario Caturegli, MD, PhD, created a serologic test for antibodies to SARS-CoV-2 now also available for use in the clinic. The Good Manufacturing Practices (GMP) facility in the Cancer Center, used to produce anti-cancer vaccines and other novel treatments for cancer clinical trials, was converted to a COVID-19 testing kit factory, now well on its way to producing tens of thousands of such kits.

Currently, in addition to writing grant proposals and authoring scientific papers, our laboratory researcher leaders are working to build plans for deploying social distancing maneuvers throughout all of the laboratory facilities to ensure maximal safety for workers and for the community-at-large.

These plans will be ready for implementation when Governor Hogan permits reopening of the laboratories and return-to-work.

Smith, GW: The cancer center here is a matrix cancer center, so we're under the university. And the university has basically said, "All buildings are shut down. All research labs, only essential people keeping essential experiments going, cell lines, etc." It's put a little bit of a damper on the ability to pivot to COVID research., though we're in the process of doing that. There are some seed grants to stimulate that, but the initial reaction was really, "Shut down the university, follow the D.C. guidelines."

We've done that, and now we're slowly saying, "Okay, these are critical investigations just ramping up." We didn't quite turn everyone directly to COVID research, which, in retrospect, might've been a little bit better plan, but we're starting to ramp up those efforts now.

We have strengths, for instance, in cell therapy. So, can we target T cells to virally infected cells? Thinking a little outside the box from drugs and vaccines. Those are the kinds of things that we're starting to open up.

Weiner, Georgetown: All non-COVID-19 research remains on hold, with the exception of necessary maintenance of critical cell lines and mouse colonies.

Winn, VCU: The COVID-19 crisis has been devastating for our basic scientists. Despite the crisis, there are a number of unsung heroes that have been critical to keeping the laboratories going, even if many of our labs are only on life support.

Those people who have taken care of our animal models and various cell lines deserve special recognition for their efforts. The sad reality is many of us are trying to simply be able to keep our bench research projects alive.

Reopening the laboratories will not be trivial. How do we do that safely? Who will be the first phase of lab workers to

go back? How will we maintain the appropriate social distancing measures?

Williams, UVA: Much of the wet lab experimental work has been on hold. That's been true across the university. But a lot of the cancer center investigators have been working remotely. They're doing data analysis. They're writing new grant proposals. They're getting manuscripts finished up.

School of Medicine research leaders are planning now to start to phase back in the research lab onsite work.

We're in our 34th year as an NCI center, with a CCSG renewal that goes in a little less than a year from now. That work is continuing under Dr. Tom Loughran, the UVA Cancer Center director. All the program leaders within the NCI grant continue to have regular virtual meetings and reviews, and build research priorities and productivity in each of our programs.

Deeken, Inova: We have more translational labs than basic science, because we're not a university. But most of those have shut down their work while we survive this. We're one of the sites for the Moonshot proteomics program, which is APOLLO.

We have some other translational lab research. Most of that has been shut down as best as possible just to keep the lab people safe, and to get them home. With our lab researchers, staff, as with our clinic staff, people that can work at home and stay at home and work remotely, we've done that across the board, including in those areas of research.

Obviously, clinical lab staff are fully on board, because we're fully busy and fully open. But our research staff that can work remotely, clinical research and translational research, we've gotten them home while we ride this out.

How have cancer care and clinical trials changed in your institution? Which of these changes are here to stay and will be carried forward as best practice?

Nelson, Hopkins: For cancer care, I believe that there will be increased use of telemedicine, home care, and other services that improve patient access and convenience.

Clinical cancer research will exploit some of these same tools. Basic cancer research, and cancer training and education, will benefit from increased use of videoconference interactions.

Smith, GW: Clinical trials, we basically had to shut down. Any extra visits would have exposed patients to extra risk. We have difficulty in scheduling procedures or CAT scans. There would be deviations. So, we're still planning trials, hopefully to open them in the next few months.

For active trials, patients on trial were monitored as needed. We tried to convert, as we did cancer care, to telemedicine visits, getting labs locally, rather than coming all the way to the main campus, if that was possible. We've tried to limit patients' exposure with extra visits, make sure that they're taken care of safely. If they were on treatment, clearly we keep that treatment going. We didn't stop any treatments, but ancillary visits, we tried to minimize.

That's similar to what we did in cancer care. We had a little bit of a lead time warning , and we're carefully screening patients coming to the clinic with questionnaires, and, more recently, testing. We limited visits to the clinic. We have patients get their labs closer to home. We've gone quite quickly into telemedicine. A vast majority of our patients, if they're not on treatment, are not coming in for visits, they're being visited electronically. We've had pretty good uptake from our providers and our patients for that, which is interesting.

We've made changes in our infusion room. We've taken out some chairs so that we have more space between patients. We then expanded hours to compensate for that, because the treatments are still ongoing.

We made staffing changes, rotated staff, so that not everyone is in every day, so that if someone did get sick, we have backups at home who aren't sick or exposed who can come in. We did that with physicians, nurses and staff, rotating teams.

We've been pretty fortunate actually; so far, our health care workers have not been hit hard. I think that's a testimony to people's caution, and screening patients and wearing PPE. But we've made significant changes to reduce exposure of patients and staff to potential infection.

Fortunately, we've been able to make these changes work. All of these things, until there's really a clear treatment for the virus, I think are here to stay. The idea of people sitting in a waiting room, a crowded waiting room, is just not going to happen in the foreseeable future.

I think there will be some real changes to clinical trials. European trials often beat the U.S. They simplify their trials, perhaps not getting all the lab correlatives that we would want, maybe not every endpoint we would like, but we have to go back and say, "Do our trials have to be so complex? Do we have to get every visit, every endpoint? How can we do this? Can we monitor people at home instead of a visit? What can we do locally? What can we do on the phone or telemedicine?"

There are lessons we could learn from this to simplify our trials to make them more patient-friendly, user-friendly. Some of the barriers to clinical trials are the complexity, the time and effort it takes for a patient to come for an extra visit, to arrange child care or get off work.

We can learn to simplify trials, try to make trials easier and more accessible to the broad range of patients. There are some opportunities here.

Weiner, Georgetown: This is truly a moving target. We are exercising necessary fiscal discipline, but it's too soon to know what changes will be temporary, as opposed to durable.

Winn, VCU: At least for VCU Massey, there has been a silver lining. I'd like to say that the institution, as a whole, from our frontline staff to our nurses to even our community, have come to really appreciate the value of why we do clinical trials, beyond COVID-19.

There has been a particular renewed interest in ramping up our clinical cancer trials. The crisis has forced us all to work better together and to reduce the amount of red tape that had previously served as obstacles, preventing many high impact clinical trials.

Williams, UVA: For active therapeutic clinical trials we have worked out a mechanism for clinical research staff to work remotely, with a rotating schedule for some to come in to see patients who need to be consented for a clinical trial, or to help with onsite monitoring.

We're part of the national ORIEN network, and have put in a process to do remote consenting. As a result, we're able to obtain tissue and other biologic samples for banking and correlative research.

Deeken, Inova: For good or ill, as we keep telling ourselves, cancer doesn't stop for COVID. So, we've seen, across the board, our volume stayed the same, as busy as it was. We've moved to using telemedicine for about half of our patient visits.

But otherwise, our infusion units, our radiation facilities are fully being utilized, and we haven't seen any drop. We saw a little bit of drop in breast surgery clinic visits, because mammograms are being held off. But even those are starting to come back.

So, we haven't seen any drop in outpatient care. And we made a conscious effort, since we were open for business and taking care of patients, including new patients, that we kept open our clinical research program fully as well. We're doing a lot of e-consenting and a lot of video meetings of patients to discuss clinical trials.

We're fully open for business, and we haven't seen a big impact in our volumes. We already were heading towards things like e-consenting and things like that. Our clinical research staff has done a lot of work remotely via video for patients who have identified an interest in a clinical trial.

The sort of trials where we're just getting bio samples and just biobanking samples, we've pulled back from that, just because we don't want to expose additional risk to our patients and to the staff collecting samples. So, pure biobanking studies, we've put on hold, but clinical research studies are fully open here, phase I to phase III.

What have you learned about any deficiencies in your existing systems in a crisis model?

Nelson, Hopkins: The response of our cancer center to the COVID-19 crisis has revealed far more strengths amongst our personnel than weaknesses in systems.

The innovative approaches to how cancer care and cancer clinical trials had to change quickly—and will need to change for longer term—which have been proffered by our folks, have been remarkable.

Smith, GW: We are not as nimble as we would've liked to be, or thought we were, in terms of opening trials. Switching our trials effort to COVID focus, outpatient trials versus hospital trials as COVID trials are largely in the hospital, which has been a barrier. Getting trials opened quickly has been a barrier.

We have to rethink our systems. I understand how much is in place because of safety and prior abuses, but the system has become very cumbersome, and we have to learn to streamline clinical trials both in terms of opening and managing them, and also designing them.

That's a lesson I hope we will be able to learn: Streamline the number of steps, the number of committees and the number of hands in the pot that slow down getting trials open.

Weiner, Georgetown: I have been simply awed by the coordinated and highly effective response across our partner health care system to this existential challenge. This pandemic has actually brought together clinicians from multiple disciplines in conducting research, organizing patient care and standing side by side in the trenches. It has been genuinely inspiring.

Winn, VCU: The COVID-19 crisis has shown all of us deficiencies exist in every system, ours was no exception. Many of our regulatory and compliance units have come to recognize that they were inadvertently preventing getting patients on trials. The crisis also showed us the need for better and more effective communications between units.

The crisis has forced us all to become less siloed.

Williams, UVA: I can't say I've found any particular deficiencies. We benefit from having really excellent facilities for our clinics and infusion, and just opened a new and much expanded infusion area this past December that complements our regional cancer center clinics and infusion facilities. So, the density of patients being treated and seen in the clinics has been kept at an appropriate level.

Testing for COVID, of course, has been a real challenge nationally. Under the leadership of our infectious disease experts, Dr. Amy Mathers and her team in UVA clinical labs brought online one of the first COVID tests available at any institution nationally. That's been a huge benefit for our institution and the testing is now to a point that other centers in Virginia are now using UVA clinical labs for COVID testing.

Deeken, Inova: At our individual institution, we certainly had to learn how to build and fly the plane at the same time. We rapidly set up working groups to look at different components of our care operation in terms of patient testing, and employee testing, and work processes to get patients tested who needed to be tested, and do that safely on the outpatient side with rapid testing.

So, we've had to develop processes that are new and unique to COVID, and working groups that have worked on those processes. And that's been incredibly successful. We've gotten a lot of support from Inova as a health system, knowing that we were different in cancer care, since we are dealing with immunocompromised patients who had to get treatment.

When we first got the rapid Abbott testing machines, cancer got one as well as our ERs on the first pass, because we needed that to keep going in terms of taking care of patients on a day-to-day basis. So, we've had incredible support from Inova as a system.

The challenges that we faced in cancer are the same that the system faces, which are the same that the country faced—initially, shortages of PPE, and then still persistent shortages of testing capabilities and testing kits. So, that's not unique to us. It's nationwide.

In cancer in general, if you look at our societies, I think there's been a learning curve for our societies, whether it be the American College of Surgeons, American Society of Breast Surgeons, ASCO, ASTRO—I think they've been trying to be helpful, in terms of issuing guidelines in how to manage patients during this.

I would say, sometimes, it's been a little delayed, and maybe not as specific as they needed to be. Again, but we're also learning about this at the same time that we're trying to develop care guidelines.

This is a brand new and unique illness, whether it's the stroke risk or everything we're seeing.

I think a lesson learned when we come out of this is that our medical societies, ASTRO, ASCO, ACS, and ASBS will, hopefully, in the future be a little more nimble to issue guidelines, so that we're all not trying to do this and figure it out on our own—use that collective crowdsourcing of information and recommendations to come up with guidelines that are meaningful to physicians and oncology nurses on the front lines, to know what we should do and how we should do it.

How have you been managing your resources and optimizing workflows with the ICU surges?

Nelson, Hopkins: The matching of intensive care unit capacity with intensive care unit need for both COVID-19 cases and non-COVID-19 cases has been managed by the Johns Hopkins Hospital Incident Command Center, which coordinates a considerable array of resources, including Hospital Epidemiology and Infection Control, facilities, supply chain/procurement, and Command Center functions in the cancer center and in other departments.

Smith, GW: It's not a tidal wave. It's a big wave, but not a tidal wave. We had a couple of weeks lead time looking at Europe and then New York, and I think one of the things we did well was a lot of active planning, having and then changing plans on the fly, thinking through the workflows. What's our nursing staff? What's our medical staff? How are we going to rotate people in and out?

A lot of thought went into that, and I'm sure we will, after the fact, go back and think of the things we could have done better. But I do think that we had pretty effective plans for using our resources.

Would we have liked to have a better amount and use of PPE? Absolutely. That's a big deficit that's not just us, but the things we could really manage in terms of our staff resources, I think we've done well, and largely because we didn't see that surge, though we prepared for it.

So, getting a big wave, instead of a tidal wave, has allowed us to manage it with the plans we put in place pretty well. There are certainly stresses to the system, emergency and hospital-based docs, such as hospitalists and intensivists are stressed. But I think we were able to manage it, and I think the learning is that you can plan pretty quickly if everyone's on board.

Weiner, Georgetown: This has been a coordinated effort led by teams based out of our emergency medicine, infec-

tious disease and pulmonology divisions. But, everyone has played a role.

Winn, VCU: The issue with getting adequate PPE at the beginning of the COVID-19 crisis was a struggle.

I think we have all learned an important lesson that running a cancer hospital system too lean and too mean, in the long run may not be the best approach for the overall health of our communities. In Virginia, even with our surge, we were prepared in the context of the number of ventilators.

However, our VCU partners were very creative in developing 3D-printed ventilators, in case we needed more last resort type ventilators. From a ventilator perspective, I think we did well as a health system. From a PPE perspective, we struggled and continue to struggle.

Williams, UVA: We've activated effective telemedicine capabilities for many patients who are routine follow ups, most not on parenteral anticancer treatment or treatment for a blood disorder. This spares them the travel to Charlottesville or our regional sites unless essential.

For patients who need to be here for assessment of acute symptoms, of course, or for their treatment, we've been able to do so in as safe an environment as we can provide.

Deeken, Inova: Early on, we literally set up a central COVID command unit that would be taking care of policy issues, as well as resource allocation issues. That was a system-wide effort. We really, I think, excelled in terms of that coordination. We're five hospitals with multiple ambulatory settings, and our vision of Inova is that we're a unified system.

That came to be the fact, actually—I'm not just saying that because I work for Inova—but it really was system solutions and centralized command, where there were rapid decisions on key aspects that had to be agreed to as a system. If one hospital was running short on ventilators early on, we deployed ventilators between hospitals, and even deployed staff.

If there was a surge at one of the hospitals, a mini-surge over a day or two, we could surge up to what was needed across the system. And that was all done by great leadership at the helm and at the center who have managed all of those issues along the way.

We've had issues pop up here and there, but there's rapidly been system-wide responses and support, no matter who needed what at what point.

Have you had to take austerity measures in oncology? Has compensation for physicians and other healthcare professionals in your hospitals been affected by the expected decrease in patient visits and delay of interventions, especially surgical procedures?

Nelson, Hopkins: Johns Hopkins Medicine has its eye on ensuring financial stability to support its mission of clinical care, research, and teaching.

To reduce some of its costs, it announced leadership salary reductions, no merit increases for coming year, new hiring for critical positions only, limited/targeted furloughs to minimize staff reductions, suspension of employer retirement contributions for the next fiscal year, non-personnel expense reductions, suspension of capital projects and equipment purchases, and improvements in information technology infrastructure.

In addition, Johns Hopkins Medicine created a special COVID-19 workforce relief fund to provide grants-in-aid for its lowest-resourced employees.

Smith, GW: Obviously, this is a drain on the economics of the system, and a number of places have furloughed people, cut salaries, etc. That's above my pay grade, but we've not done that yet.

I don't think we're out of the woods. It wouldn't shock me if the realities get to the point where we have to do it. We've really focused on outpatient practice telemedicine, which has eased things a little.

Our chemotherapy revenues have continued, because we need to keep treatments going. Our radiation oncology group has done a good job, actually publishing their planning model. Their volumes are down also, but so far we've managed without true financial austerity measures, though every dollar is looked at.

We're not hiring anyone, we're not expanding. People are doing extra jobs. There is some natural attrition—we had jobs that would have been filled that we're not filling, so people are having to fill those positions with extra work.

Fortunately people who were on staff have not suffered any decrease. But as I said, I think that's a day-by-day, week-by-week decision.

Weiner, Georgetown: It's a bit early to know what will happen. It is simply too soon to know exactly how hiring, furloughs, compensation changes and the like will shake out, as we are still in the fog of war.

Winn, VCU: I'm super proud of the folks here at VCU Massey. We did have to scale back on our clinical trials. We limited our trials to the tier one trials that as a cancer center believed would have the highest and most favorable impact.

Our associate director for clinical research, Harry Bear, and with others throughout the hospital, were able to keep open a number of important clinical trials. It was not easy. We had to change the culture in which we were seeing patients.

Telehealth has become incredibly important to our clinical trials and to our care for most of our patients. In fact, we're able to keep up our number of visits.

A big change that was difficult for us to implement, was the rule to not have family members in the examining room with our patients. This was tough, but necessary to keep everyone safe.

Williams, UVA: Of course, COVID has had a major adverse financial impact on the university as a whole and on the health system in particular. Just in the last two weeks, financial mitigation measures have been put in place, including temporary salary reductions for faculty and senior staff.

There's also a mechanism for staff members who are not taking a salary reduction to be furloughed for two to four weeks. It's an additional and significant challenge in a very difficult time. However, those who are furloughed will continue to have their health and dental insurance.

Deeken, Inova: We definitely had to take some, across Inova as a system, which is over 17,000 people. We eliminated almost 500 nonclinical positions, as a means of cost savings. Our leadership, a number of lawyers have taken pay cuts for this year, the highest pay cut was done by our CEO.

For physicians, especially the frontline physicians, we haven't had to take any cuts in their base salary or anything like that, which has been respectful, I think, of their contribution to this.

But we have had some personnel position eliminations and some base salary reductions, again on the leadership and administrative side of the house.

How is COVID-19 affecting underserved communities and populations in your catchment area? How does your institution cope, and what can be done?

Nelson, Hopkins: The state of Maryland has both rural and urban underserved populations.

A significant worry is that during this COVID-19 epidemic, minority populations, the poor, and the uninsured may be especially vulnerable to poor outcomes because of obesity, high blood pressure, cigarette smoking, and diabetes—all conditions that could be prevented or treated.

These same risk factors propel increased risks for cancer as well. As such, in addition to improving access to high-quality cancer care for all Marylanders, much of the community engagement of the cancer center has targeted these chronic disease risk factors.

Over the past few years, a community-anchored clinical trial of weight loss among cancer survivors in Baltimore City was completed with the help of support from the State of Maryland Cigarette Restitution Fund.

Further clinical studies of such interventions are planned or underway throughout the state.

Smith, GW: We are a nascent cancer center, planning to apply for NCI designation, so we do assess our catchment area. Our patient population matches the D.C. area, which is between 40 and 45% African American, and we have a significant Hispanic population as well.

The difference is, and we see this, in the mortality among African Americans in D.C. Eighty percent of the deaths listed on the D.C. Department of Health website are African American, with over 40% of the cases.

Clearly, there's a disparity in mortality, likely reflecting comorbidities and other health problems, but also socioeconomics. So, yes, we do see disparities in who ends up in the ICU. That's a big concern.

Given our catchment area, we focus on community outreach in normal times. Just announced earlier this week was the new hospital in collaboration with GW in the East Side Ward 7 and 8 areas.

In the long term, we're here to stay in that catchment area. In the short term, it's taking care of the patients that we have and understanding that they have special needs. Our social workers have gotten Zoom accounts, just as our physicians, and they are doing telemedicine support groups to reach out. So, we're doing what we can to reach out to the community. As this rolls on, we're going to make additional efforts to get out into that area.

Weiner, Georgetown: Underserved communities have felt the brunt of this pandemic in our region, just as elsewhere. MedStar Washington Hospital Center has emerged as a leading site of care for such patients, but the burden is shared across the MedStar health system.

Winn, VCU: Unfortunately, in Richmond, 13 of the 14 COVID-19 deaths were African American. Of the 321 people who tested positive in Richmond, 61 of those were hospitalized, and of the 14 deaths, 13 of those were African Americans.

During this crisis, people have been more afraid to visit our hospital and

clinics. But the lack of testing, the lack of early intervention, the lack of effective communication in these communities have contributed greatly to the poor outcomes in Richmond and the U.S.

Since the African American church remains an anchor institution for most black and underserved communities, we have started a Facts, Faith, Friday roundtable partnership with VCU Massey and the Faith leaders of Richmond to get better information to our faith leaders.

These leaders have served as a trusted and reliable source of data for these communities. We have been working with this group along with city and state leaders to help them get through this COVID-19 crisis.

> The lack of testing, the lack of early intervention, the lack of effective communication in these communities have contributed greatly to the poor outcomes in Richmond and the U.S.
>
> *– Robert Winn*

Williams, UVA: I don't have specifics as to our local COVID population aside from the state health department releases, which are updated every day.

Deeken, Inova: I don't have the breakdown in terms of our system numbers. What I do know is Virginia numbers, and the thing that is impressive are the number of patients coming from nursing homes, assisted living, and long-term care facilities. That's sort of well-known.

In Virginia, I think what's also interesting is the number that have come from the Hispanic community. I think I heard on the news this morning that up to half the patients in Virginia have been of Hispanic origin.

That definitely comports, I think, to what we've seen in terms of our inpatient census, that it does seem to be a high predilection to people of color, both Hispanics and African Americans. And that's something that I could probably confirm anecdotally here in our cancer center.

We've done a significant number of COVID testing in our cancer center, patients who meet CDC requirements, or ASH guidelines. So, we've tested a large number of cancer patients, and some of them have certainly tested positive. We've had a few that have died, unfortunately, of COVID.

Our numbers are consistent with the percentage that you're seeing nationally. It's not the 40 to 50% that they initially saw in Wuhan, but it's probably closer to 10% that we've seen in some of the reports so far in the U.S. of COVID-positive patients who also have cancer, or a recent treatment for cancer, in terms of their mortality risk.

But in terms of the Virginia demographics, it seems like people of color are especially at risk for the significant complications from the infection. Since we don't have widespread screening, we don't know what the actual rate of infection is, unfortunately.

But in terms of the patients seeking care, being diagnosed, needing testing, and therefore being diagnosed, there seems to be a high prevalence in those populations.

Has the pandemic affected your ability to carry out your mission that comes with having an NCI designation, or your plans to seek NCI designation?

Nelson, Hopkins: Our Cancer Center Support Grant competitive renewal submission is due in May of 2021.

Clearly, for the calendar year 2020, we expect to have fewer clinical trials completed than we had planned, and there has been a government-ordered gap in laboratory research activity.

Nonetheless, the output of high-impact publications that change clinical practice, lead to new paradigms, and drive policy decisions has continued at nearly full speed.

Smith, GW: Certainly things have been delayed. Our external advisory board was due late June, we've put that back a couple of months. As for investment in new programs, it wouldn't surprise me if that's delayed somewhat.

It'll be interesting to see how the NCI and NIH react to these things, as you put in grants that might've required institutional support, as that institutional support may not be as strong as it would have been pre-pandemic, I think it'll be interesting to see how the agencies deal with that.

Yes, we want to be a cancer center, yes we have institutional commitment, but they may not have the resources that they used to have to support that. How do we deal with that in a larger

NCI-designating programmatic way? I think that's an open question.

I think we will get some financial support from [new CARES Act funds for NCI] and that will be helpful, but I think what the institute is realistically going to be able to say is not, "We're giving you $100 million to support your cancer center."

They might say, "You know what? We can't commit to that because we don't know what finances we have." What does that do to your grant application? Hopefully, the reviewers will take that into consideration.

Weiner, Georgetown: It is difficult to maintain momentum in the face of this pandemic. We have numerous video meetings to assure we can sustain our research momentum, though actual wet bench experimentation is largely inactive at this point. After a brief contraction we are ramping up our clinical trials efforts, even as a large proportion of our patients are being seen through the MedStar telehealth platform.

Winn, VCU: Absolutely. Having an NCI designation has helped tremendously in our ability to have a positive impact on our communities. The resources available to our center has gone a long way to bring groups of scientists together and has really served to benefit our community outreach and engagement efforts.

Williams, UVA: I would say no in terms of our research operations, and in terms of getting patients in and getting them seen. If we get a call from an outside facility or provider, we get those patients transferred in as soon as need be.

Deeken, Inova: We're not NCI-designated nor seeking that designation at this time, but we are a major regional cancer center. At our main cancer center, which is across the street from Fairfax Hospital, we have over 400 patients coming in a day to get treatment. And that, again, that really hasn't changed.

We've put in a whole lot of procedures in place at our center, and did so early on, from masking patients, allowing only one visitor, having visitors masked, having all people coming in the buildings temperature-wanded, all staff have masks, all staff have temperature checked every day.

We pre-screen patients a day before they come to see if they've had any symptoms. And we've been expanding that list of questions they're asked as we learned more about the epidemic. Early on it was, "Have you traveled to China?" Now it's, "Have you been in contact with," and really not those geographic questions that we had early on.

So, our screening of patients the day before, the screening at our entrance doors, and our protections in terms of masking and temperature checking have slowed things a little bit, but not significantly.

Again, we have moved to probably about half of our patients being seen, little over half being seen via telemedicine, mainly video. So that's impacted our care delivery. But in terms of active treatments, radiation, surgery, and chemotherapy, it actually hasn't been impacted at all.

Is there a need for a more robust system for managing public health crises at the federal level?

Nelson, Hopkins: Yes. And this system should finally tackle the underlying public health challenge of obesity, high blood pressure, cigarette smoking, and diabetes, especially in poor and underserved populations, as if it were a crisis.

Smith, GW: Yes. The clear answer to that is, yes. We were clearly, as a society, not truly prepared for this. And we can argue, without getting into politics, about whose fault it was, but clearly, we were not prepared. And frankly, when you look at our CDC response compared to other countries, it fell short. Our testing, even now, is not where we would like it to be.

So, there's no question that we need better planning and facilities. And as people have pointed out, this is not sexy stuff. When things are going well and you don't have a pandemic, no one wants to invest in some of these basic planning-for-disaster scenarios.

And we got away with SARS and MERS, which we sort of escaped. And it wasn't the wake-up call, it was like, "Oh, we got away with that. I guess we don't need to worry about it anymore."

Hopefully, this is a true wake-up call and we will be ready next time. One can only hope, but it has to be at the federal level.

Meanwhile, regionally, with individual institutions, my hope would be that we would get together public and private institutions, even the VA, and have a plan among ourselves, so that we're not competing for the limited resources, and that we move patients and staff around as necessary—so that we have sort of a local-regional pandemic disaster plan, whether it's for a pandemic or an acute natural disaster.

I think the lesson is that we can rely on the federal government, and that's fine, but maybe we should be doing more ourselves to plan to be independent of that, as a backup.

Weiner, Georgetown: Yes. Our country needs more rapid and better coordinated early responses to emerging pandemics. These responses are needed to accelerate drug development, expand distribution networks and develop/implement testing for active and prior infections.

Had we done this with COVID-19, it would have blunted the devastating impact of this virus.

Winn, VCU: Oh my God, yes. There has been a complete failure of leadership from the very top. However, I thank the high heavens for our governor and state and local leaders. They have served Virginia well.

I also must thank Drs. Fauci and Birx for their courage to lead under extraordinary circumstances. Their ability to tell the truth about the crisis, and to give us honest advice, despite being pressured, has been remarkable. They have set the example for all to emulate.

I also have to give credit to the various health systems in Virginia that decided to work together for the greater good. It was tough, and probably strange, for many of these systems to have to work together in the manner in which they did.

I think that there should have been more clarity and thoughtfulness, and consistency from the highest office of the land—it would have helped out a lot.

Williams, UVA: At the local, regional, and at the state levels, I've been impressed with the quality of response.

At the federal level, my opinion is that the coordination has been less organized and effective and less measured in terms of emergency management and in setting priorities.

Deeken, Inova: Yes. I think we've all seen the challenges with not having a robust public health system and rapid response from the federal level, and states being left to do many initiatives on their own.

I think we've all seen the opportunities that maybe have been missed over the last couple of months. Hopefully, those will be lessons that we learn and keep in mind in the years ahead, if any kind of thing like this ever happens again.

Is funding for infectious disease epidemiology and pandemic preparedness—including the stimulus from the CARES Act—sufficient? Has it been helpful to your institution?

Nelson, Hopkins: Support for public health and pandemics is not enough. Significant funding will be needed through the National Institutes of Health to fuel the broader biomedical research enterprise.

The final conquest of SARS-CoV-2, and future pandemic threats, will almost certainly include contributions from researchers otherwise focused on cancers, immunity, cardiovascular diseases, basic molecular biology, etc.

Smith, GW: I'm not sure, in the broader term. I think in the real world, at our level, we haven't seen it. I think when you read about small businesses, etc., that some of the dollars are out there, but there's lots of confusion as to how it's going to be distributed and what you can use it for and not use it for.

My hope is that over the next couple of months that will be clear, and some of the big deficits we appear to be running will be less severe, as some of this money comes in to fill those spots. But I think honestly, right now, it's too early to know how beneficial that's going to be at different levels.

Weiner, Georgetown: Funding to support the work we are doing is important. It is difficult to say if it is enough.

Winn, VCU: We certainly appreciate the CARES Act, but the CARES Act, in and of itself, is not enough to sustain most health systems. However, it certainly has been appreciated and a welcome relief. At this point, every little bit will help.

I think from a preparedness perspective, we have learned a ton about being prepared for the next COVID-19 wave. It turns out that the dismantling of the pandemic preparedness team that President Obama assembled was likely a mistake. I think that if we have learned one post-pandemic lesson, it is that we must reestablish the principle that effective public health matters.

Williams, UVA: The CARES Act has provided much needed support to UVA Health, although I don't have the dollar amounts.

There's a well-recognized need for COVID testing. If we want to start opening things up more, socially and economically, we need to know who's infected, do tracing of cases, and have sharper instruments to decide who needs to be staying home and quarantining. I'm hopeful that federal funding will be able to catalyze these technologies and strategies.

Deeken, Inova: I think there's a fair question about that, and hopefully, the after-action reports that Congress will do will tell us whether the investment was sufficient enough, and what we might need in terms of pandemic preparations and public health and epidemiology. I think in terms of the CARES Act, I think it was very generous from the federal government.

Inova and some of our private practice partners in the community have benefited from a part of that support, and helped to partially offset the losses that we've all seen. The emphasis there is on partial, and I think we're all still struggling operationally, but also financially, and we're all hoping that we'll come through this intact.

Certainly, Inova came in financially very strong, so we're not worried about our long-term soundness as a health system. Other systems in the state or in the country certainly might be at risk, but the CARES Act, so far, has provided some help for us, which we're grateful for.

Do you have any other health care policy lessons that you'd like to impart?

Nelson, Hopkins: Older people, particularly those with comorbid conditions or frailty, have proven extraordinarily susceptible to serious consequence SARS-CoV-2 infection. The aging also bears a significant burden of cancer and other chronic diseases. New approaches to caring for older populations and new research on the basic biology of aging should be explored.

Smith, GW: I was not a boy scout, but boy, be prepared. I think the health policy lesson really is that we can't really operate on the edge, where we have no fluff in the system, which is the way we've been doing it. On the other hand, you can't afford to have excess capacity.

So, we have to be creative, I think, to figure out what we did in an emergent situation. Okay, we want to maximize efficiency day to day, but how do we build in expansion capacity? Not that it's sitting there unused all the time, but how can we have expansion capacity for such an event like this, so we're not scrambling quite the way we were? How do we be prepared, but in a cost-effective way? I think that's the question.

I just can't imagine what people in New York were facing. The ethical, moral questions, the pain of the stories of those people, even staff who were exposed and died, or staff who can't go home to see their kids, because they're afraid of infecting them.

The horror stories that come out of there, we are just very thankful we have not seen here. It's been stressful, but I just sympathize and empathize with the people in Italy, the people in New York. I just can't imagine what they've gone through.

Winn, VCU: I think the most important health care policy lesson is that we must stop studying our most vulnerable populations, and actually get up off our butts and address the issues in these communities with information and approaches that we already know work.

It has not been the lack of knowledge, but the lack of political and social will that continues to plague these communities. We already know that good housing, having a great education, and having access to excellent health care will improve the health of these communities. The real question is, will we really address these issues in a post-COVID-19 world?

The second thing that this crisis has actually taught me is that you can be wealthy or poor, but if we don't all take care of one another, the COVID virus will continue to win. So, this is the one time where we all are in the same boat, literally.

Williams, UVA: From the local level, I think we've done the best we can, and are fortunate to have very committed and dedicated staff at every facet of the organization. Hopefully, we've got enough of a handle on the crisis that, at least for our own part of the world, we'll be able to manage it and minimize the impact on our patients and our local and regional populations.

Deeken, Inova: I think the move that CMS made rapidly to allow telemedicine visits, allow reimbursement for those visits, and even the decision, either earlier this week or last week to reimburse telemedicine, even telephonic visits, at the same rates as in-person visits are fantastic. And again, it will jumpstart this telemedicine revolution that's probably going to start now.

So, those policies and the technology for video connections, hopefully will stay in place and continue even after this. CMS has been, I think, incredible on the forefront of allowing those innovations.

Did we miss anything?

Smith, GW: I think the lesson is, we're not out of the woods. And people think, "Oh yeah, we're going to open up over the next few weeks and everything's going to be fine." I think we have to do that, and we have to be smart and we have to do social distancing, but we recognize what we do know, and listen to that.

We have to know what we don't know and recognize that we're going to get a second wave and a third wave. We can't let down our guard. Life has to go on, but we have to do it and we have to be very alert to, if we make a change and two weeks later, we see a big bump in infections and people in the ICU, we're going to have to go back and say, "That wasn't such a good idea. Let's figure out another way to do this."

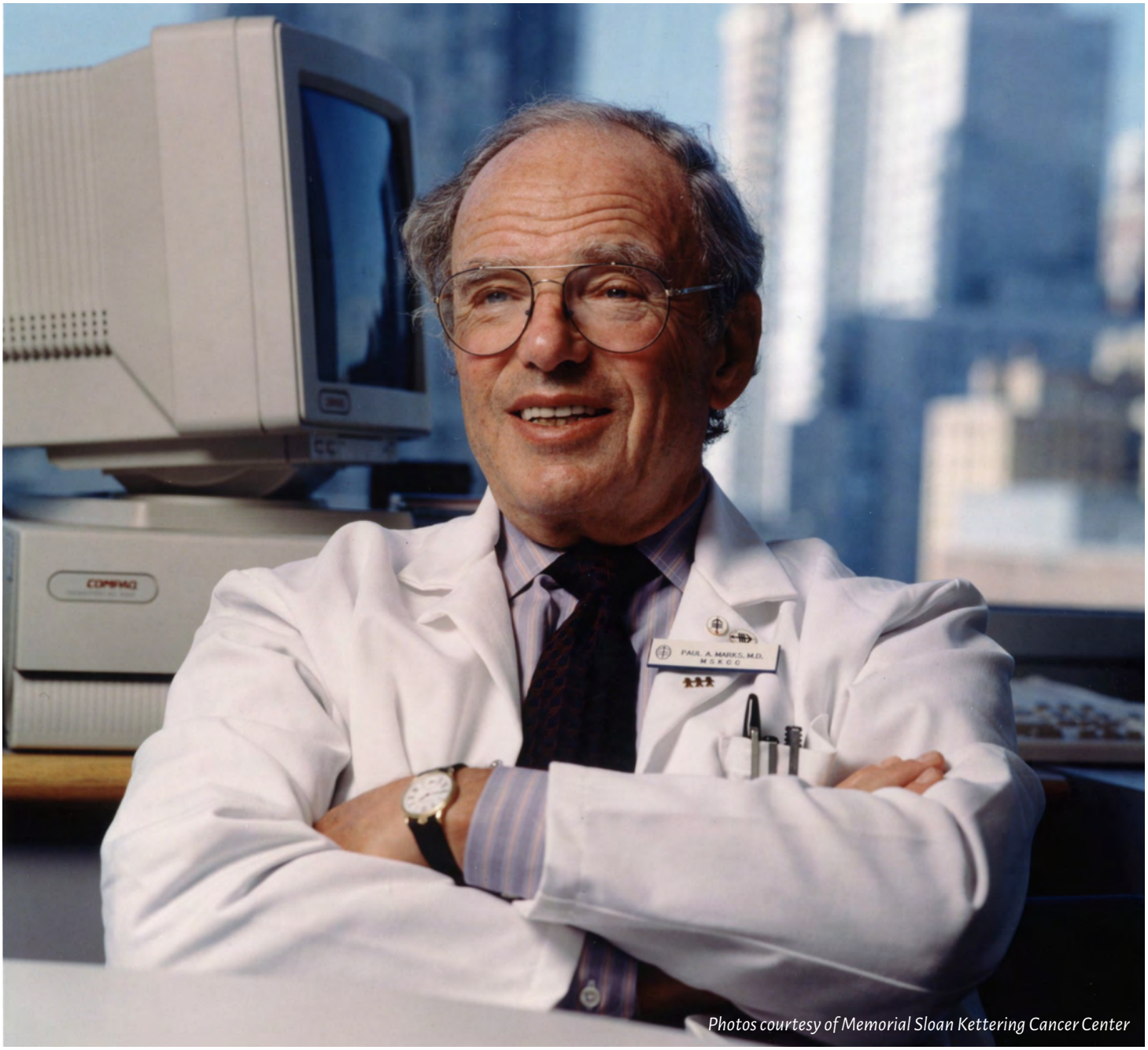
It's going to be an ongoing learning experience. This is not, "It's gone away and we're done." It's going to be a constant learning experience, and we have to adapt to that and we have to use it to learn, and hopefully have research that teaches us, so that we're not just using anecdotes. We actually need to learn from our experience.

Weiner, Georgetown: Our physicians and nurses on the front lines are true heroes. Scientists who have repurposed their work to attack coronavirus should inspire us all.

AN APPRECIATION

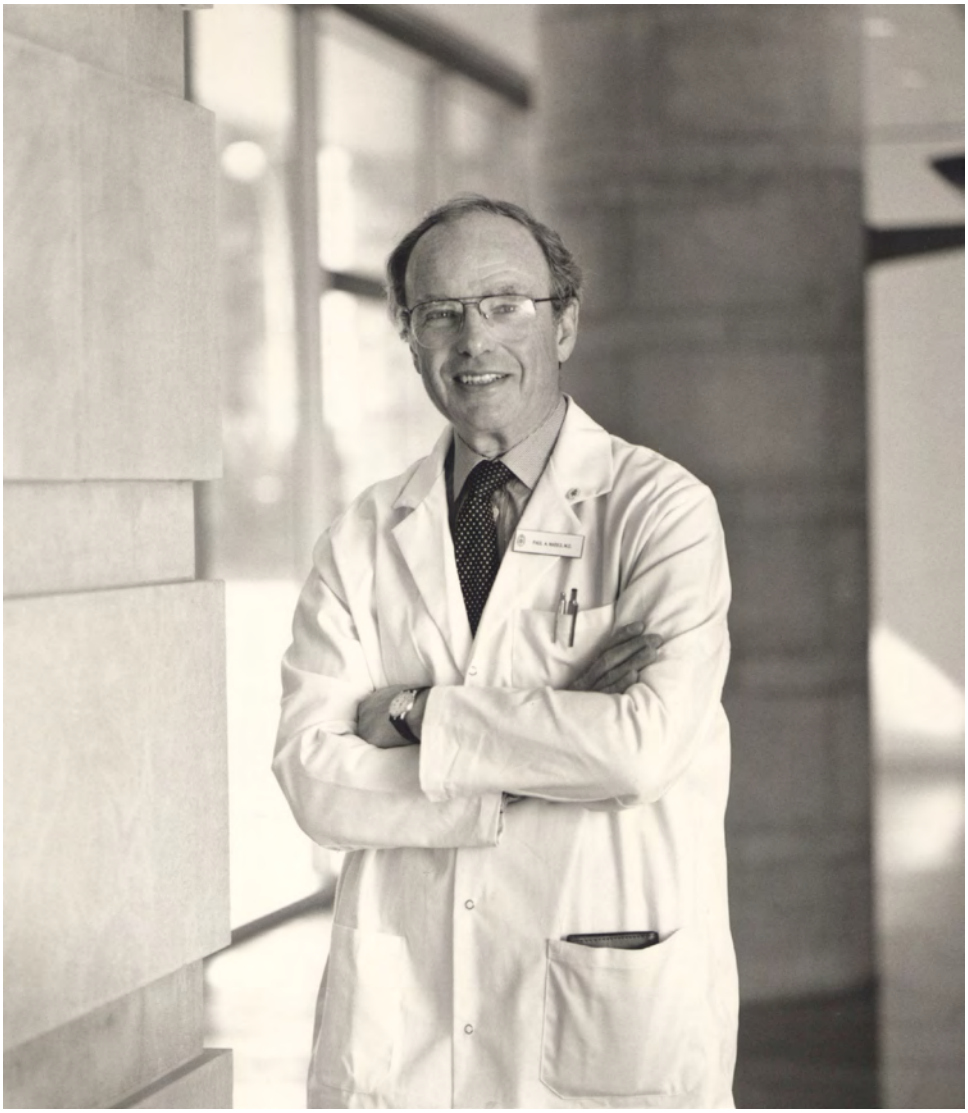
Paul A. Marks, architect of modern academic oncology who led MSK for two decades, dies at 93

By Larry Norton, MD



Photos courtesy of Memorial Sloan Kettering Cancer Center

On rare occasion, an innovator makes such a profound impact on the world that people thereafter cannot imagine what life was like before that transformation. Paradoxically, for those not witness to such an achievement, this phenomenon may have, in terms of legacy, a blunting effect.



For example, those of us who work in modern cancer centers, especially those who grew up professionally in such environments, might assume automatically that these organizations always existed in something like their present form. But this is not the case. Indeed, cancer centers as they now are, melding high-quality care with superb clinical and laboratory investigations, owe much of their invention to the vision, energy, and pugnacious perseverance of Paul A. Marks.

We lost Paul on April 28, at age 93, when he died of pulmonary fibrosis complicated, at the end, by lung cancer. His professional accomplishments and long list of accolades and awards is well known to the entire oncology community.

He was born in rural Pennsylvania, but spent formative years in Brooklyn, where his prodigious intelligence and legendary work ethic earned him a full scholarship to Columbia University. This led to his medical training at Columbia's College of Physicians and Surgeons.

After productive sojourns at the NIH and the Pasteur Institute he returned to Columbia to assume increasingly responsible roles: professor, dean, VP for medical science and cancer center director.

He joined Memorial Sloan Kettering Cancer Center (MSK) in 1980, serving as president and CEO for almost twenty years. Along the way, he not only made major scientific contributions—the mutational bases for some hemolytic anemias and thalassemia and the invention, with colleagues, of differentiation therapy of cancer among them—but garnered an impressive array of honors including membership in three national academies and the Presidential National Medal of Freedom (1991).

For most academic physician-scientists, this would be more than achievement enough. But what I assert will stand the true test of history is the revolution he produced at MSK in his two decades of leadership.

My first contact with Paul was well before that, when, as a medical student at Columbia in the late 1960s, he lectured my class in hematopathology. In describing him then, formidable is much too weak a word. Large and powerful in body, brilliant and demanding in intellect, with a piercing visage, he had no tolerance for laziness or imprecision in thought or communication. Frankly, he was terrifying… but a great teacher.

And he was obviously a leader among his peers, commanding and receiving admiration and respect. It was for these reasons that I was surprised as well as gratified when at a ceremony

in which he awarded honors to medical students I realized how genuinely happy he was to recognize the talents in that young crew. There was honest joy in every handshake and congratulatory comment.

I suspected then that his (sometimes) irascible demeanor was a means to an end, a ploy to motivate people to strive toward the best of their abilities, for their good as well as for the good of our noble professions.

Fast forward to 1988, the year I joined the faculty at MSK, eight years after the start of his tenure there. By then, he had wrought a miraculous change. To understand the magnitude of this, one needs to appreciate what oncology looked like to organized Medicine in the 1970s, before the impact of the National Cancer Act.

Cancer physicians other than surgeons, usually general surgeons in those days, were widely denigrated and even vilified by those who knew that radiation was strictly palliative and that medicines could never have any real efficacy except in rare circumstances.

Cancer patients with metastases were rapidly transferred out of major general hospitals to special facilities like Delafield Hospital, several blocks away from Presbyterian Hospital, as if they were lepers before the advent of antibiotics. Laboratory-based cancer research was considered second-rate at best and generally unworthy of "real" scientists studying basic, as opposed to applied, biology.

Paul saw something different. He recognized that the dawn of molecular medicine was also the beginning of a new approach to cancer, one in which fundamental discovery could translate into major advances, even cures and prevention strategies. And he realized that this would take two significant changes.

The first would be to attract the very best scientists to the field of cancer research. He was confident (one of his cardinal traits) that we needed people who could create new ideas as competently as the best minds in any other area of science and could conduct research with the same level of rigor and technical sophistication.

The second would be to bring these scientists into close communication with the best clinicians of all disciplines, both to generate relevant questions and to design clinical trials to test new answers in the setting of actual human disease.

To accomplish these tasks, he tackled MSK at a difficult moment in its history. It was just emerging from a major scandal of scientific misconduct. It housed outstanding clinicians, but clinical oncology then was largely removed from the then rapid progress in DNA science and cell biology.

While much has been written about his methods and style during this period, the fact stands out that by his simple act of melding MSK's hospital with its research arm, the Sloan Kettering Institute, the two being separate at that time, he brought the two worlds together under effective, focused direction.

Moreover, his skill at recruitment of top talent—scientific, clinical, administrative, and board membership—and his ability to gather the financial resources necessary to allow them to do their jobs had already by 1988 made MSK a powerhouse in the field. For Paul, it was all about excellence and the fostering of dynamic, imaginative, fruitful interactions.

It is interesting in that regard that another of Paul's passions—visual art—is also all about excellence and adventurous creativity. He would sometimes escape in the middle of a particularly stressful day to the comforting European painting sections of the Metropolitan Museum of Art. (There, I amusingly ran into him once while I was playing hooky, if the truth be told.)

I remember a meeting in Paris where he and Joan skipped a festive meal, another of his passions, to see an exhibit of Giacometti sculptures. He was also quite adventurous athletically. I remember a particularly harrowing ski run down icy Les Diablerets, where we only discovered we were in forbidden off-trail territory when we found ourselves by the side of an obscure road at the bottom.

It was therefore consistent with his principles and his personality that he championed the building of the Evelyn H. Lauder Breast Center at MSK, the institution's first off-site facility, which opened in 1992.

Bringing together all disciplines and services in a setting conducive simultaneously to compassionate and comprehensive care and inventive clinical investigation seems in retrospect to be natural. However, it was a novelty at its time, an adventurous experiment, now proven successful—as is the modern cancer center in its entirety and now ubiquity.

So, beyond his own considerable scientific achievements, his leadership of national and international efforts, and his mentorship to many generations of clinicians and scientists, his legacy lives on in the very structure of how academic oncology now operates and thrives.

We owe him much and deeply mourn his passing.

The author is senior vice president, in the Office of the President, medical director of the Evelyn H. Lauder Breast Center, and the Norna S. Sarofim Chair in Clinical Oncology at Memorial Sloan Kettering Cancer Center.

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GUEST EDITORIAL

Embracing the increasing value of eHealth in patient-centered cancer care during the COVID-19 pandemic and beyond

In the past decade, there has been a growing interest in capitalizing on advances in information technology to provide quality and patient-centered care to cancer patients and survivors outside a hospital or clinic setting.

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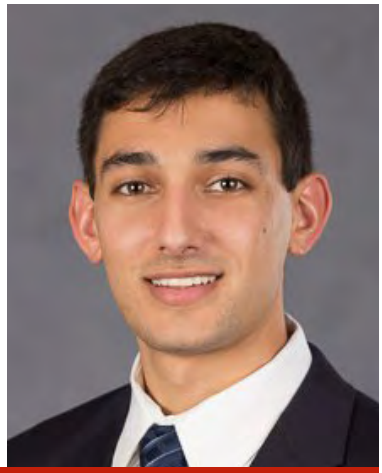

By Joshua Kronenfeld, MD
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Telehealth is not a recent innovation, but it continues to evolve with advances in communication and information technologies. eHealth involves the broad use of health information and communication technologies also referred to as telehealth, telemedicine or mHealth delivered via internet-based platforms or mobile applications.

eHealth during the COVID-19 pandemic

With the widespread use of computers, tablets and smartphones, delivery of cancer care via eHealth platforms continues to expand. This trend has accelerated dramatically this spring, as the COVID-19 pandemic has changed the landscape of clinical care in the U.S. and around the world.

The importance of the internet and web-based information during this pandemic was recently highlighted in a PEW Research Center article that reported that up to 87% of Americans report that the internet has been an "essential" or "important" source of information during the COVID-19 outbreak.

eHealth applications provide opportunities to deliver healthcare via mobile health, web-based portals and other telehealth and telemedicine platforms. Although initially conceptualized as a tool to connect health care providers and patients who are not in physical proximity, eHealth is now more of a necessity than an option to foster patient engagement, promote communication and facilitate ongoing patient care.

A silver lining in the challenges we face today in cancer care due to COVID-19 is that advances in eHealth have provided an unimaginable yet necessary route to maintain continuity of care while promoting the safety of patients and health care professionals alike.

As the pandemic has presented health systems with major and extraordinary challenges regarding patient and employee safety due to the risk of COVID-19 infection, many routine cancer care and follow-up appointments have been moved to telehealth sessions.

Whether comprehensive cancer care be effectively delivered via telehealth platforms during this pandemic is a key concern for the oncology community. Drawing from programs that have evaluated the utility of eHealth in assessing and managing patient symptoms and toxicities and improving psychosocial functioning and health-related quality of life, eHealth has the potential to effectively deliver and even enhance patient care.

eHealth programs in oncology patients

Studies suggests that up to 70% of cancer patients seek medical information via the web, while over 30% seek support programs to help them address the unique and complex challenges of a cancer diagnosis and treatment.

As access and use of the internet to obtain health information and support has become vastly widespread, much effort has been devoted to the development and evaluation of eHealth-based educational and support programs specifically targeting oncology patients.

Research conducted over the past decade suggests that eHealth applications can be effectively implemented to monitor and manage symptoms and deliver psychosocial and supportive care to cancer patients and survivors. Numerous studies have documented the feasibility and acceptability of the use of eHealth programs during and after active cancer treatment.

Most programs are self-directed, asynchronous and provide self-management and psychoeducational tools with a growing trend to embed these tools and patient experiences into electronic health records. Although most eHealth programs have been deployed in the context of controlled trials targeting psychosocial challenges and assessment and management of symptom burden with efforts to improve health-related quality of life, work to date is promising and supports the feasibility and acceptability of eHealth in oncology care.

Generally, eHealth programs have been shown to favorably and significantly impact fatigue, depression, anxiety and health-related quality of life. Recent studies also show positive results of eHealth interventions designed to help cancer patients and survivors manage pain, psychosocial distress and other symptoms, with good retention and engagement rates.

eHealth programs have also shown preliminary efficacy in various other specific outcomes, including reduced lymphedema-related chronic pain, improved sexual function in female survivors, and improved health-related quality of life. The eHealth programs involved a mix of tools that included texting support, chat functionality with peer support, therapist led structured online groups, and/or tailored feedback on PROs by health care providers.

Benefits of implementation of eHealth-based care

The implementation and expansion of eHealth to routine patient care affords a cancer center, and its patients, many potential benefits.

For patients who live far from a healthcare facility, such as those in rural areas or patients who wish to see a physician at a distant location, physicians can be accessed by utilizing voice or video com-

munications. The ability to provide care to patients at a distance greatly extends the geographic footprint of a healthcare system.

Patients also enjoy benefits of telemedicine encounters as waiting time in the office is often reduced and time spent traveling to and from appointments is eliminated. For patients caring for children or other persons, they can be evaluated by a provider from the comfort of their homes without worrying about abandoning these responsibilities or endangering others by bringing them to the provider visits.

eHealth also has the potential to improve patient-provider communications, improve symptom monitoring and management, and enhance patient engagement across the cancer care continuum. More and more, tools available via eHealth can be integrated into the patient record thus facilitating information exchange across providers regarding symptoms, toxicities, and other clinically relevant information.

Also, as capabilities of mobile devices and apps continue to expand, valuable lifestyle and clinical information, such as physical activity, body temperature and other data can be easily obtained and integrated to promote patient care.

The benefits of eHealth approaches surpass clinical care. With the onset of the COVID-19 pandemic, the eHealth delivery of cancer support services has increased dramatically. Many cancer centers now offer supportive programs, such as yoga, exercise, meditation, music, eBeauty, art, and other topics via a videoconferencing application.

Although pre-pandemic eHealth-based supportive services have been in place for some time, the fact that these programs are now only available via eHealth options will not only foster greater use of eHealth platforms but perhaps also lead to greater acceptability of remote delivery of these services.

Furthermore, in many cases patients cannot physically access these programs due to multiple barriers, such as transportation, scheduling conflicts and caregiving commitments. Therefore, the forced remote delivery of supportive care services in the presence of COVID-19 may have the unintended benefit of extending the reach of these programs and helping patients at need who otherwise would not be able to attend these supportive oncology programs in person.

Arguably, despite these benefits, there is a quality to the in-person encounter that eHealth cannot replace. The proximity or closeness of being with a patient and a caregiver, behavioral cues and obviously, the physical exam are irreplaceable.

Not surprisingly, and rightfully so, eHealth has been promoted and accepted as an ancillary approach that can facilitate and enhance, but not replace, in-person care or reach patients that otherwise would not be able to physically attend a visit with a care provider.

Suddenly, with not much warning, eHealth-based care has become an only option for many. Although time will tell as research studies report on the quality of cancer care delivery via telehealth, we are likely witnessing a cultural shift among many in their appreciation of technological advances that have facilitated, albeit not without many challenges, the provision of routine oncology care due to COVID-19.

The technological divide

Technological advances in eHealth have great potential to expand and improve patient care. Ironically, these advances do not necessarily reach those patients who may benefit the most.

Most studies lack substantial inclusion of racial and ethnic minorities, rural and financially disenfranchised communities, and older patients.

These communities may have the most to gain from eHealth services, but also continue to face considerable barriers to adequately accessing eHealth programs. Patients who are financially disenfranchised are likely to have limited access to high-speed networks or be geographically located in communities with limited high-speed access.

Similarly, rural communities that face limited access to optimal cancer care can have limited broadband thus limiting the reach and potential benefits of eHealth programs. More eHealth research that includes larger and diverse samples, randomized trial designs, long-term follow-up, and evaluation of clinical outcomes are needed to establish the efficacy of these programs across promoting optimal outcome and providing patient care.

As most cancers occur in people 65 years of age or older, it cannot go unnoticed that a significant technological gap exists for many seniors in the U.S. Seniors continue to lag in technology adoption, particularly in access to broadband high-speed services, cell phone ownership and use of the internet relative to all American adults 18 years or older.

PEW estimates indicate that over 70% of the elderly population goes online every day or almost every day with 82% accessing the web three to five times per week. But this elderly population is also more likely to face functional limitations and greater symptom burden due to cancer treatments and comorbid conditions that add complexity to their care.

Another point to consider is that most of the available programs are self-administered and intended to provide self-management skills or psychoeducation.

Therefore, while patient acceptability has been high, one must consider that these programs were not intended to provide or replace routine care as it has been necessary during this pandemic.

Whether patients will accept eHealth as a viable option during routine cancer care independent of a crisis such as we are facing remains to be determined.

One should also not lose sight of the impact eHealth on the provider experience. Human factors research that has evaluated clinician user interfaces for telemedicine services point to multiple challenges including, but not limited to, poor or disrupted video imaging and sound quality, real-time information processing via video conferencing, connectivity issues, and poor integration into existing clinical workflows.

> We are now witnessing technological developments that will transform models of cancer care delivery. We are at a pivotal point in this transformation.

Additionally, privacy remains a major concern, and secure and Health Insurance Portability and Accountability Act compliant services needed to be employed. These services included platforms such as Facetime, Zoom, or other similar tools allowing audio and video communication between providers and patients.

In addition to establishing an avenue for delivery of care, there needed to be the ability for providers to receive payment for these virtual encounters. The Centers for Medicare and Medicaid Services responded to this need by expanding reimbursement for telemedicine encounters to allow for adequate compensation for healthcare providers and healthcare systems.

Establishing the infrastructure for healthcare providers and systems, however, overcomes only some of the barriers to providing adequate healthcare remotely.

Looking ahead

Advances in eHealth technology offer a timely opportunity to optimize research on cancer care delivery and address the multiple challenges faced by patients, their families, and care partners. Today, eHealth applications support the delivery of valuable psychosocial services and monitoring of symptoms and toxicities among patients and survivors.

As we face the COVID-19 pandemic, eHealth can present an opportunity to sustain valuable patient care under challenging circumstances. Telemedicine, although not a recent innovation, has become the primary mechanism of care delivery for patients during the COVID-19 crisis. While obstacles are present for hospitals and providers to establish these services, many barriers exist with patient access to these services.

Appropriate follow-up should be provided for those with chronic medical illnesses and malignancies, helping to prevent the deterioration of these conditions during the COVID-19 crisis.

We are now witnessing technological developments that will transform models of cancer care delivery. We are at a pivotal point in this transformation.

Deploying eHealth services can enable better management of both patients and cancer survivors. In addition to improving patient outcomes, implementation of eHealth programs and patient can also ultimately improve systems-level outcomes, such as a reduction in visits to emergency departments, hospital readmissions and other high-cost services.

We are amid a transformative experience that has necessitated the use of real-time, dynamic, and technology-assisted assessments, interventions and cancer care delivery via telehealth. eHealth has the potential to improve the delivery of cancer care through enhanced patient–provider communication, improved symptom and toxicity assessment and management, and optimized patient engagement across the cancer care continuum.

Finally, when considering eHealth programs, a critical consideration is to ensure equity for all patients seeking to access health services. Patients of lower socioeconomic status, racial/ethnic minorities, and older adults may require additional assistance in connecting with providers, and it is our duty to help solve these issues.

Telemedicine can connect patients and providers during this time of crisis, but hopefully, this will serve as a model for continued use after the global pandemic has abated.

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GUEST EDITORIAL

With the COVID-19 pandemic, the cancer clinical trials—they are a-changing

Prior to the COVID-19 pandemic, NCI estimated that about 3% to 5% of adult cancer patients participated in clinical trials.

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Lung cancer specialist, Helen F. Graham Cancer Center and Research Institute, Christiana Care;
Associate professor, Thomas Jefferson University Medical School

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The reasons for this low accrual rate have been discussed and debated ad nauseam, with a lot of energy and resources devoted to improving adult clinical trial participation. Efforts to increase accrual have included more lenient entry criteria, a more robust support staff to identify eligible patients, and resources for physicians and caregivers to set aside time needed to make these studies available to their patients.

Patients enrolled on clinical trials often receive equivalent or better care, perhaps due to the standardization of care and close monitoring, even on standard arms of these studies.

Programs such as the NCI Clinical Oncology Research Program, or NCORP, provide resources to support the time and effort needed to enroll patients on clinical cancer trials.

But the current coronavirus pandemic has interrupted this program, too. In addition to the tragic toll this disease is taking on the general population, it had also led to a 44% decline in cooperative group trial accrual as of early April, according to an NCI communication.

At the Helen F. Graham Cancer Center & Research Institute, various programs and policies have been implemented to support accrual to NCORP trials, and strong institutional support has allowed our accrual rate to rise over the last 15 years to 20% or more—prior to the pandemic.

But what can we do now with new barriers to enrollment imposed by the COVID-19 pandemic?

Patients express fear of coming in for evaluation, tests and treatments due to the risk of infection. They have heard the message: stay home if you want to stay safe.

But for cancer patients embarking on a treacherous path back to health, these lost visits can mean fewer opportunities to understand their options to participate in trials, to get the needed testing to become eligible, and to receive the therapeutic interventions they need.

Recent data from the Alliance for Clinical Trials in Oncology suggests that clinical trial enrollment may be down 40% to 60% across the country due to these new, unique challenges. Patients are often seen by telemedicine, and that may make it more difficult to fully explain the clinical trial and its implications, and to give patients fully informed consent.

“Clinicians at our institution are burdened with new guidelines and distractions as well as the increased stress of dealing with personal and family health issues and concerns. This may take their attention away from the extra effort often required to enroll patients on a clinical trial.”

Many of our patients cannot or will not come to the office, and it is therefore more difficult to identify appropriate clinical trials for that population.

Clinicians at our institution are burdened with new guidelines and distractions as well as the increased stress of dealing with personal and family health issues and concerns. This may take their attention away from the extra effort often required to enroll patients on a clinical trial.

One complicating factor is many of our nurses are working from home, leading to a decrease in personnel power available at the point of care. We all have some component of excess anxiety, fear, and even complaints of burnout with these new stresses during the pandemic.

We also have to deal with the concern about patient safety if they enroll on a clinical trial and may need additional visits, scans, labs, thereby increasing potential exposure to COVID-19 infection.

Fewer patients are being seen due to a decrease in screening testing, surgical biopsies, and patients going to their primary care physicians to follow-up on routine complaints.

There may be delays in the required testing to enroll in a clinical trial including labs, scans and molecular testing results. This can make it more challenging to get all the required criteria completed for clinical trial eligibility.

At the Helen F. Graham Cancer Center & Research Institute, we focus on a collaborative approach to identify appropriate patients for clinical trials, and a systematic process to encourage enrollment when appropriate.

This has led to a team effort amongst the three disciplines, including surgery, radiation and medical /hematologic on-

cology, with multidisciplinary disease site teams that include research trial nurses. With this approach, along with continuing to activate new trials and supporting our affiliate institutions, we have noticed a favorable trend to maintaining our high accrual in the last two months during the COVID-19 pandemic.

> While some institutions have placed clinical trials on hold, at our institution there remains strong support for enrollment. Maybe we see this as a collective challenge to beat this invisible foe.

While some institutions have placed clinical trials on hold, at our institution there remains strong support for enrollment. Maybe we see this as a collective challenge to beat this invisible foe. Our research nurses are actively assessing eligibility, helping to identify new patients. The current pandemic offers an opportunity to face these challenges head-on and continue to improve an imperfect system.

We can work to identify the blockades to optimal patient care, including barriers to enrolling patients on clinical trials at our institutions, and move forward with improved ways to screen for eligible patients, and identify the most appropriate treatment approaches, especially as part of a clinical trial.

With fewer patients coming into the office, we may be able to spend more time explaining the value of clinical trials for their situation, and how their participation is good for them and others in their community. We have found that many patients want to know how they can contribute—and participating in a clinical trial is one such opportunity.

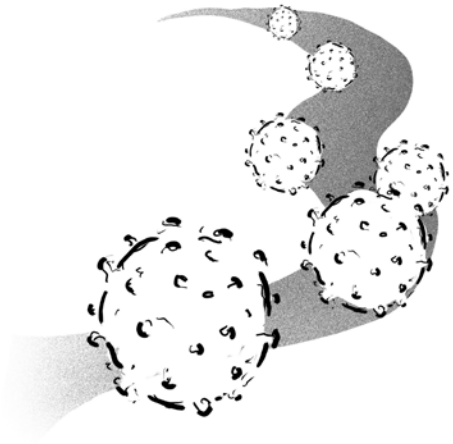
With the option of telemedicine, we may be able to divide information sessions into visits with shorter encounters that may not be as overwhelming to patients. Several discrete conversations may increase the chance to fully explain the value of clinical trial participation. We can harness our collective wisdom and experience to take advantage of the crisis, and rethink how to make the system better.

Yes, there are devastating losses with this international health crisis, but let us not miss a chance to serve our patients, and use clinical trials to move medicine forward for our current and future patients.

At our cancer center, we did not stop clinical research, but saw a challenge that has led to a favorable trend to a sustained high clinical trial accrual. We now talk about eventually getting back to a new normal.

From what we have learned from COVID-19, that new normal should lead all of us to reducing barriers to clinical trial participation and increasing clinical trial accrual.

COVID-19 UPDATES



Democratic senators call for $26B in next COVID-19 relief package to support research workforce

Senators Edward J. Markey (D-MA) and Thom Tillis (R-NC) and 31 of their Senate colleagues are calling for protections for the U.S. scientific research community during the coronavirus pandemic.

Although novel coronavirus-related research is a current federal government priority, most other research has slowed or stopped due to closures of campuses and laboratories. The people who comprise the research workforce—graduate students, postdocs, principal investigators, and technical support staff—face financial and other hardships from the disruption of their research activities.

The senators are calling for $26 billion in emergency relief funding for the research community in the next coronavirus relief package.

"Research universities, academic medical centers, and national labs are major employers in all 50 states, and protecting the research workforce is critical to state economies," wrote the senators in their letter to Senate leadership. "Congress must act to preserve our current scientific workforce and ensure that the U.S. is prepared to continue our global scientific leadership once this crisis ends."

In their letter, the senators specifically call for funding in the next relief package to:

- Cover supplements for research grants and contracts caused by the pandemic, including additional salary support and/or research related ramp-up costs;
- Provide emergency relief to sustain research support personnel and base operating costs for core research facilities and user-funded research services until such time as facilities reopen and research activities return to pre-pandemic activity levels; and
- Fund additional graduate student and postdoc fellowships, traineeships, and research assistantships for up to two years. Graduate students who could not complete their degrees due to the pandemic should be given priority for graduate fellowships and other forms of support so they can complete their research and degrees.

This effort has been endorsed by the Association of American Universities, American Council on Education, Association of Public and Land-grant Universities, Association of American Medical Colleges, Union of Concerned Scientists, ACT for NIH, Alzheimer's Association, American Association for Cancer Research, American Cancer Society Cancer Action Network, American Geophysical Union, American Lung Association, American Mathematical Society, American Meteorological Society, American Chemical Society, American Physical Society, American Physiological Society, American Society for Cell Biology, American Society for Microbiology, Association of Independent Research Institutes, Autism Speaks, Coalition for the Life Sciences, EveryLife Foundation for Rare Diseases, Friends of Cancer Research, Geological Society of America , JDRF, Research!America, Society for Neuroscience, and other groups.

House members call for equal access to affordable oral chemotherapy prescription drugs amidst COVID-19 outbreak

Members of the House of Representatives are pushing for the next COVID-19 emergency package to include language giving cancer patients equal access to oral chemotherapy medications that can be taken at home.

Brian Higgins (D-NY), Brett Guthrie (R-KY), Doris Matsui (D-CA), and Gus Bilirakis (R-FL) sent a letter to House leadership urging inclusion of oral chemo parity in the next coronavirus emergency legislation.

"Because those with compromised immune systems are at a higher risk for contracting COVID19, people with cancer are particularly vulnerable at this time. It is more important than ever that cancer patients are able to access oral anti-cancer medications that they can take at home," the House members wrote.

Though oral chemotherapy is popular with both patients and oncologists, insurance coverage for cancer treatments has not kept up with some of the most promising oncology research. Consequently, some cancer patients lack access to potentially lifesaving oral therapies. While IV treatments are usually covered under a plan's medical benefit

component, orally administered cancer medications are covered under a plan's prescription drug component, which often requires a higher percentage of cost-sharing for the patient. Studies have consistently shown that, when faced with high co-pays for orally administered cancer drugs, some patients choose to simply not fill a prescription.

Over 50 cancer organizations also recently wrote to Congressional leadership listing oral chemo parity among their priorities for cancer patients during the coronavirus outbreak.

Because those with compromised immune systems are at a higher risk for contracting COVID-19, people with cancer are particularly vulnerable. Early estimates show that the mortality rate for cancer patients who contract the virus is around 6%, nearly seven times higher than that for patients with no underlying medical conditions.

On March 13, 2019, Higgins announced H.R. 1730, the Cancer Drug Parity Act, a bill that would require all insurance payers to offer oral cancer medications with the same cost-sharing as IV cancer treatments. The legislation has 129 cosponsors in the House and 17 cosponsors in the Senate.

IN BRIEF

Patton named CEO of OneOncology

Jeff Patton was named chief executive officer of OneOncology. Patton has been Acting CEO and president of Physician Services since February.

OneOncology includes five practices throughout the U.S., represents over 400 providers, and cares for approximately 250,000 patients annually at 160 sites of care. OneOncology partner practices deliver integrated oncology care services including screening and diagnosis, clinical trials, therapies, and survivorship or end-of-life care. A main responsibility of OneOncology is to help its partner practices expand services in cancer care.

"We formed OneOncology in 2018 with the idea that with physician leadership, common technology platforms, and access to capital, practices could have both the necessary scale and local decision-making authority needed to not only survive but thrive in today's marketplace," Patton said in a statement. "Today, as practices grapple with COVID-19 and plan for caring for patients post peak, the ideas that brought us together are exactly what will propel our future growth."

Patton will continue as the executive chairman of the board at Tennessee Oncology.

Blumenthal named VP of Global Oncology Regulatory Affairs at Merck

Gideon Blumenthal was named vice president for Global Oncology Regulatory Affairs at Merck.

He is a former deputy director of the FDA Oncology Center of Excellence.

Haura, Khushalani named clinical science research leaders at Moffitt

Eric B. Haura was named the associate center director of Clinical Science at Moffitt Cancer Center, and Nikhil Khushalani was named assistant center director of Clinical Research Review & Partnerships in a newly created role at Moffitt Cancer Center.

Haura will provide the strategic vision in developing physician-led laboratory science, as well as oversight of Moffitt's clinical research operations, which includes more than 600 active clinical interventional trials and over 100 observational studies, including Moffitt's Clinical Trials Office and Clinical Research Unit. Additionally, he will facilitate team science and clinical research opportunities with affiliate and consortium partners, and he provide guidance and mentorship to investigators at Moffitt.

Haura joined Moffitt in 2000 and has served in leadership roles in research, including director of the Lung Cancer Center of Excellence and co-leader of the Chemical Biology and Molecular Medicine Program. His research focuses on identifying new vulnerabilities and biomarkers in lung cancer, where his goal is to develop novel therapeutic strategies for his patients. His lab is also heavily involved in proteomics, the large-scale study of proteins, to identify new diagnostic tools for lung cancer. Haura treats patients as a senior member of the Department of Thoracic Oncology.

As assistant center director of Clinical Research Review & Partnerships, Khushalani will oversee Moffitt's clinical trial scientific review operations. He will also work closely with Jennifer I. Vidrine, assistant center director of Research Strategic Partnerships, to expand clinical research offerings to affiliates and partners, including a clinical research unit opening in collaboration with AdventHealth in Celebration, Florida. This position also reports to Haura.

Khushalani joined Moffitt in 2015 as an associate member of the Department of Cutaneous Oncology, and became the vice chair and a senior member of the department. His clinical and research interests are in the development of novel therapeutics for patients with melanoma and other skin cancers. He studies the economic impact of new skin cancer therapies on health care, with the goal of devising strategies to reduce costs for patients. Khushalani is the principal investigator on several skin cancer clinical trials at Moffitt.

Bona named director of Benign Hematology at Smilow Cancer Hospital

Robert Bona was named professor of medicine (hematology) and inaugural director of the Benign Hematology Program at Smilow Cancer Hospital. He will also join as Medical Director of the Hemophilia Treatment Center for the Pediatric Hematology & Oncology Program at Smilow Cancer Hospital.

Bona will begin in his roles July 1.

Bona has been serving as a part-time member of the hematology department at Yale Cancer Center for the last three years.

Bona joins Yale from Quinnipiac University where he is a founding faculty member and professor of medical sciences at the Frank H. Netter MD School of Medicine. Bona has led several research studies, clinical trials, and care innovations to advance the treatment of blood diseases.

Prebet, Zeidan named hematology leaders at Yale Cancer Center

Thomas Prebet was named leader of myeloid malignancies on the Disease Aligned Research Team, and Amer Zeidan was named director of the Hematology Early Therapeutics Program at Yale Cancer Center.

In these new roles, Prebet and Zeidan will work closely with Stephanie Halene, interim chief of hematology at YCC.

Prebet is an associate professor of medicine (hematology) and is focused on developing clinical trials for myeloid malignancies and translational advances for patients with acute myeloid leukemia and myelodysplastic syndromes. In his new role as DART leader for myeloid malignancies, he will oversee the clinical trial team for myeloid malignancies and work to develop a complete portfolio of trials for our patients.

Zeidan is an associate professor of medicine (hematology) and is the Yale principal investigator for multiple NCI-sponsored and clinical trials in myeloid malignancies. Zeidan is also chairing the steering committee for a large pharma-sponsored randomized trial of myelodysplastic syndromes. As director of the Hematology Early Therapeutics Program, Zeidan will partner closely with Patricia LoRusso, associate cancer center director for Experimental Therapeutics at YCC, to develop a comprehensive phase I clinical trial portfolio for patients with hematologic malignancies.

Hamilton, Danilov join City of Hope

Stanley Hamilton, formerly of MD Anderson Cancer Center, was named chair of the Department of Pathology at City of Hope, and Alexey Danilov was named associate director of City of Hope's Toni Stephenson Lymphoma Center.

Hamilton said his goal is to bring access to state-of-the-art specialized pathology to every patient at every City of Hope satellite center, as well as improving and enhancing the biomarker data used in clinical trials, and further integrating digital pathology into the overall informatics of the institution.

Danilov brought his independently-funded lab to City of Hope's Toni Stephenson Lymphoma Center. Danilov researches treatment of chronic lymphocytic leukemia and many forms of lymphoma.

Danilov is focused on identifying cell proteins—some that promote cancer growth, some that inhibit it—learning how they deteriorate, and finding drugs that can affect the process.

Tempera named associate professor in the Gene Expression & Regulation Program at Wistar

Italo Tempera was appointed associate professor in the Gene Expression & Regulation Program of The Wistar Institute Cancer Center.

Tempera is a molecular virologist with special expertise in the study of the Epstein Barr virus and how it regulates expression of its genes in the host cell during infection. Although EBV infection is very frequent and asymptomatic in most cases, in some individuals, especially those with a compromised immune system, it has a causative role in development of some types of cancer, including Burkitt's lymphoma, nasopharyngeal carcinoma, and Hodgkin's and non-Hodgkin's lymphomas.

Research in the Tempera laboratory aims to disrupt the natural capacity of EBV to modulate its gene expression pattern as a new approach for treating EBV-associated cancers.

Tempera identified the main cellular factor that regulates the three-dimensional structure of the EBV genome and his laboratory focuses on the role of this factor, named CTCF, in the formation of loops in the virus DNA.

These loops allow distant segments of the genome to be in close proximity and regulate expression of EBV genes that are necessary for its life cycle within the cell. The team is also exploring how EBV chromatin loops are regulated by another cellular factor called PARP1. Given the role played by PARP1 in regulating cell metabolism after DNA damage, these studies could provide an exciting link between host cell metabolism and regulation of EBV chromatin structure.

The Tempera lab specializes in genomics techniques that allow them to study long-range interactions within chromatin, or the genetic material in which DNA and proteins are packed together to form chromosomes.

Tempera comes to Wistar from the Fels Institute for Cancer Research and Molecular Biology at the Lewis Katz School of Medicine of Temple University, where he established his lab in 2012 and was promoted to associate professor in 2017.

Bin Tian appointed professor, co-director of the Center for Systems & Computational Biology at Wistar

Bin Tian was appointed professor at the The Wistar Institute Cancer Center.

A molecular biologist by training, Tian focuses on RNA biology and understanding how gene expression is regulated at the post-transcriptional level. His research involves interdisciplinary approaches, including molecular biology, genomics and computational biology, to study RNA biogenesis and metabolism. His lab was among the first to characterize the functional genomics of alternative polyadenylation and has uncovered its role in many diverse cellular processes.

"Bin's research has led to groundbreaking advances understanding the role of alternative polyadenylation in development and cell differentiation as well as in the context of cancer and cellular stress," Dario C. Altieri, Wistar president and CEO, director of the Cancer Center, and the Robert and Penny Fox Distinguished Professor, said in a statement. "Bin's work strengthens our RNA biology research and brings expertise in complex computational and genomic methods that will synergize with the work of our scientists across our research programs."

Tian joins Wistar from Rutgers New Jersey Medical School, where he was a professor. In 2003, he established his research group at Rutgers New Jersey Medical School where he became a tenured professor in 2014.

Tsvi Gal named head of infrastructure at MSK

Tsvi Gal has been appointed Head of Infrastructure of MSK.

Gal will lead the hospital's technological and architectural development and make technical recommendations that align with MSK's institutional and digital priorities.

Reporting to MSK's Chief Information Officer, Atefeh Riazi, Gal will work with other leaders in Digital Informatics and Technology Solutions to develop a modernized infrastructure and data environment in support of MSK's digital strategy, set by MSK's Chief Digital Officer Claus Jensen.

Seattle Cancer Care Alliance opens Acute Clinical Evaluation Clinic

Seattle Cancer Care Alliance opened an Acute Clinical Evaluation clinic. The three bed ACE clinic at SCCA's South Lake Union campus serves individuals receiving cancer care at SCCA who experience cancer- and treatment-related pain and symptoms that surpass their ability to manage at home.

Originally planned for summer 2020, the ACE clinic opened ahead of schedule so that cancer patients would not have to visit an urgent care or emergency room for cancer-treatment related issues, especially important during the COVID-19 pandemic.

"We are committed to advancing the standard of cancer care, regionally and beyond, and the ACE clinic is a reflection of that commitment," said Nancy Davidson, president and executive director of SCCA. "At SCCA, we provide comprehensive care, and the ACE clinic provides our patients with access to care from our highly trained, compassionate staff, specifically for their treatment-related pain and other symptoms."

The ACE clinic is staffed by an oncology advanced practice provider and registered nurses specializing in cancer care. SCCA providers can refer patients to the clinic who need medical oncology care for pain and symptom management for issues including but not limited to gastrointestinal discomfort, fever/chills, dehydration, dizziness/lightheadedness, urinary tract infections, swallowing difficulties, swelling and skin conditions/rashes.

The ACE clinic does not provide emergency care and is limited to patients who are already receiving treatment from SCCA providers.

Robert Peter Gale receives ASJA award for "Chernobyl, the HBO miniseries: Fact and Fiction"

Robert Peter Gale has won an award in the opinion/op-ed category from the American Society of Journalists and Authors Inc. for his series "Chernobyl, the HBO miniseries: Fact and Fiction" (*The Cancer Letter*, May 17-June 21, 2019).

Gale is visiting professor of hematology at the Imperial College London, and executive director of clinical research in hematology and oncology at Celgene Corp.

"Gale's series is fortified by his firsthand experience with one of mankind's worst calamities," the ASJA judges wrote. "He provides unsparing detail, outstanding insight, and intense perspective as he sorts fact from fiction as presented by HBO's 2019 miniseries."

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

Cancer patients without insurance or Medicaid don't experience the same benefits of clinical trials

Cancer patients with no health insurance or those enrolled in Medicaid see smaller survival benefits from experimental therapies in clinical trials, according to a study published April 30 in *JAMA Network Open*.

The SWOG Cancer Research Network study is the first to examine whether treatment effects from randomized cancer clinical trials with positive findings apply to important demographic and insurance subgroups. The finding that cancer clinical trial patients with no or low insurance do not get the same benefits of experimental therapies as patients with private insurance—regardless of sex, age or race or ethnicity—supports efforts in Congress to expand insurance coverage.

These efforts include the Clinical Treatment Act, a bipartisan bill introduced in February in the House of Representatives that guarantees coverage of the routine care costs of clinical trial participation for Medicaid enrollees with a life-threatening condition. Nearly 20% of Americans receive health insurance through Medicaid.

The American Society of Clinical Oncology, the American Cancer Society, and the American Medical Association support the bill.

"A patient's insurance coverage seems to be related to the extent to which they benefit from new experimental treatments tested in trials," study lead Joseph Unger, a SWOG health services researcher and biostatistician based at Fred Hutchinson Cancer Research Center, said in a statement. "Our findings highlight the importance of policies that would provide more Americans insurance coverage, and underline the importance of improving that coverage."

Unger and his team examined data from 19 SWOG phase III randomized treatment trials that enrolled patients between 1984 and 2012 and followed those patients up to five years after their trial treatment. The 19 trials tested drugs for a number of cancers, including breast and lung.

The analysis included 10,804 patients. The team then assessed whether the overall survival rates, progression- or relapse-free survival rates, differed by age, sex, race and ethnicity, and insurance status.

Patients 65 or older, younger than 65, male, female, minority, non-minority, and with private insurance who received experimental trial drugs all, on average, lived longer compared to patients who received standard treatment. Uninsured patients or those enrolled in Medicaid did not have a strong survival benefit.

"People with fewer financial resources have access to fewer healthcare resources, which can have a persistent, negative influence on their health," Unger said. "Patients in trials having no or limited insurance may not have the financial means to pay for the extra supportive treatments or post-trial cancer treatments that help people live longer. This could be especially meaningful for understanding treatment benefits if experimental therapy requires more supportive care or is more difficult to adhere to than standard treatment."

The SWOG study was funded by the NIH through NCI grant awards CA189974, CA180888, CA180819. The Hope Foundation for Cancer Research also supported the study through a Dr. Charles A. Coltman Jr. Fellowship Award to Unger, as well as direct funding to the SWOG Statistics and Data Management Center based at Fred Hutch, funding which supports research infrastructure, trial design, and data analysis.

Along with Unger, the SWOG team includes Charles D. Blanke, of Oregon Health & Science University, the SWOG group chair; Michael LeBlan, of the SWOG Statistics and Data Manage-

ment Center and Fred Hutch, the SWOG group statistician; William Barlow, of the SWOG Statistics and Data Management Center and Fred Hutch; Riha Vaidya, of the SWOG Statistics and Data Management Center and Fred Hutch; Scott D. Ramsey, of Fred Hutch; and Dawn L. Hershman, of NewYork-Presbyterian/Columbia University Irving Medical Center, and the SWOG vice chair for NCORP research.

Libtayo shows clinically-meaningful and durable responses in second-line advanced basal cell carcinoma

Libtayo (cemiplimab) demonstrated clinically meaningful and durable responses in patients with advanced basal cell carcinoma who had progressed on or were intolerant to prior hedgehog pathway inhibitor therapy.

Libtayo is being jointly developed and commercialized by Regeneron and Sanofi under a global collaboration agreement. Regeneron and Sanofi said they plan regulatory submissions in 2020.

Approximately 20,000 U.S. patients have advanced BCC, and it is estimated that about 3,000 die each year. BCC marks the second non-melanoma skin cancer for which Libtayo has demonstrated first-in-class data and follows its initial U.S. approval in advanced cutaneous squamous cell carcinoma in 2018.

In the trial phase II, the objective response rate for patients (n=84) with locally advanced disease was 29% (95% CI: 19%-40%), with an estimated duration of response exceeding one year in 85% of responders. The durable disease control rate (DCR–response or stable disease lasting at least six months) was 60% (95% CI: 48%-70%). In a preliminary analysis of patients (n=28) with metastatic disease, the ORR was 21% (95% CI: 8%-41%), with an estimated DOR exceeding one year in 83% of responders. The durable DCR was 46% (95% CI 28%-66%). All data were assessed by an independent central review.

"These data in advanced BCC provide the third instance where Libtayo monotherapy has demonstrated robust and clinically meaningful outcomes in advanced cancer, and follows last week's announcement in advanced non-small cell lung cancer where the pivotal trial was stopped early for positive overall survival," Israel Lowy, senior vice president of Translational and Clinical Sciences, Oncology, Regeneron, said in a statement.

There were no new safety signals in this trial. Among the 132 patients assessed for safety (84 locally advanced and 48 metastatic), 95% experienced an adverse event (AE), 32% had a serious AE and 13% discontinued due to an AE. There were 10 deaths in the locally advanced group and nine deaths in the metastatic group; none of the deaths were considered treatment-related.

"While PD-1 inhibitors have transformed the outlook for many patients with melanoma, progress for patients with non-melanoma skin cancers has not been as rapid," said Peter C. Adamson, global head of Oncology Development at Sanofi. "We are continuing to address this unmet need by first bringing Libtayo to patients with advanced cutaneous squamous cell carcinoma, and now, with this second trial, as a potential therapy for patients with advanced basal cell carcinoma. These important new results further demonstrate Libtayo's potential in patients with difficult-to-treat, non-melanoma skin cancers."

In this ongoing, global phase II trial, patients received Libtayo 350 mg intravenously every three weeks for up to 93 weeks or until disease progression, unacceptable toxicity, withdrawal of consent or confirmed complete response. ORR is the primary endpoint and key secondary endpoints include overall survival, progression-free survival, duration of response, safety and quality of life.

New tumor sampling method significantly improves genetic testing for cancer treatment

A holistic tumor sampling method that more accurately detects genetic alterations in tumors has been developed by researchers from the Crick, Roche and The Royal Marsden NHS Foundation Trust. The study was published in *Cell Reports*.

Initially, the researchers tested improved sampling in lung and bladder cancers, where a simulation of improved sampling reduced misclassification rates in deciding whether a patient was suitable for immunotherapy from 20% to 2% and from 52% to 4% respectively, when compared to current methods.

Based on this finding, the researchers developed a technique called representative sequencing, which builds a more accurate picture of a tumor's DNA. This works by taking the majority of the tumor removed at surgery—tissue that is not currently sampled and is routinely discarded—and mixing it so that cells from different areas of the tumor are more evenly distributed. A sample is then taken from this mixture to be DNA sequenced.

The researchers tested the method in 12 patients with kidney, breast, colon, lung or skin cancer. Comparing new and current methods, they found that representative sequencing gave far more consistent results, as it avoids the bias of looking at just one small part of the tumor tissue. The new method captures information from a well-mixed representation of the whole tumor.

The method is being further tested in 500 tumors at The Royal Marsden in London to determine its feasibility and utility.

"By equipping clinicians with more accurate information about a tumor, we hope our method will lead to patients and treatments being significantly better matched. Additionally, there is an opportunity for critical biological insights to be made by increasing the search space within each tumor," Samra Turajlic, group leader at the Crick and consultant medical oncologist at The Royal Marsden, said in a statement.

Through extensive testing on a case of kidney cancer, the representative sampling method gave identical genetic results 95% of the time, compared to only 77% consistency with the current methods. Similarly, in a case of skin cancer, the new method correctly identified a highly complex and difficult to treat cancer from the outset, whereas the current method missed important genetic information.

"This method is more accurate, has more reproducible results and has the same sequencing cost as the current technique. In fact, by introducing an extra, simple purification step, it could become much cheaper than the existing process. It could be a gamechanger for tumor sampling in hospitals and in research," Kevin Litchfield, lead author and bioinformatician in the Translational Cancer Therapeutics Laboratory at the Crick, said in a statement.

DRUGS & TARGETS

FDA approves Tabrecta, first targeted therapy to treat metastatic NSCLC

FDA has granted accelerated approval to Tabrecta (capmatinib) for adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping as detected by an FDA-approved test.

Tabrecta is the first FDA-approved therapy to treat NSCLC with specific mutations (those that lead to mesenchymal-epithelial transition or MET exon 14 skipping).

Tabrecta is sponsored by Novartis.

FDA also approved the FoundationOne CDx assay (Foundation Medicine, Inc.) as a companion diagnostic for Tabrecta. Most patients had tumor samples that were tested for mutations that lead to MET exon 14 skipping using local tests and confirmed with the F1CDx, which is a next-generation sequencing based in vitro diagnostic device capable of detecting several mutations, including mutations that lead to MET exon 14 skipping.

"Lung cancer is increasingly being divided into multiple subsets of molecularly defined populations with drugs being developed to target these specific groups," Richard Pazdur, director of the FDA 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. "Tabrecta is the first approval specifically for the treatment of patients with non-small cell lung cancer whose tumors have mutations that lead to MET exon 14 skipping. This patient population now has an option for a targeted therapy, which they didn't have prior to today."

Efficacy was demonstrated in the GEOMETRY mono-1 trial (NCT02414139), a multicenter, non-randomized, open-label, multicohort study enrolling 97 patients with metastatic NSCLC with confirmed MET exon 14 skipping. Patients received Tabrecta 400 mg orally twice daily until disease progression or unacceptable toxicity.

The main efficacy outcome measures were overall response rate (ORR) determined by a blinded independent review committee using RECIST 1.1 and response duration. Among the 28 treatment-naïve patients, the ORR was 68% (95% CI: 48, 84) with a response duration of 12.6 months (95% CI: 5.5, 25.3). Among the 69 previously treated patients, the ORR was 41% (95% CI: 29, 53) with a response duration of 9.7 months (95% CI: 5.5, 13.0).

FDA approves daratumumab and hyaluronidase-fihj for multiple myeloma

FDA has approved daratumumab and hyaluronidase-fihj (Darzalex Faspro) for

adult patients with newly diagnosed or relapsed/refractory multiple myeloma. This new product allows for subcutaneous dosing of daratumumab.

Darzalex Faspro is sponsored by Janssen Biotech Inc.

Daratumumab and hyaluronidase-fihj is approved for the following indications that intravenous daratumumab had previously received:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant,
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy,
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy,
- as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Efficacy of daratumumab and hyaluronidase-fihji (monotherapy) was evaluated in COLUMBA (NCT03277105), an open-label non-inferiority trial randomizing 263 patients to daratumumab and hyaluronidase-fihj and 259 to intravenous daratumumab (daratumumab IV). The trial's co-primary endpoints were overall response rate and pharmacokinetic endpoint of the maximum Ctrough on cycle 3, day 1 pre-dose. Daratumumab and hyaluronidase-fihj was non-inferior to daratumumab IV in evaluating these two endpoints.

The ORR was 41.1% for daratumumab and hyaluronidase-fihj and 37.1% for daratumumab IV with a risk ratio of 1.11 (95% CI: 0.89, 1.37). The geometric mean ratio comparing daratumumab and hyaluronidase-fihj to daratumumab IV for maximum Ctrough was 108% (90% CI: 96,122).

Efficacy of daratumumab and hyaluronidase-fihj in combination with VMP (D-VMP) was evaluated in a single-arm cohort of PLEIADES (NCT03412565), a multi-cohort, open-label trial. Eligible patients were required to have newly diagnosed multiple myeloma and were ineligible for transplant. The major efficacy outcome measure, ORR, was 88.1% (95% CI: 77.8, 94.7).

Efficacy of daratumumab and hyaluronidase-fihj in combination with Rd (D-Rd) was evaluated in a single-arm cohort of this trial. Eligible patients had received at least one prior line of therapy. ORR was 90.8% (95% CI: 81.0, 96.5).

FDA accepts NDA for CC-486 in AML indication

FDA has accepted a New Drug Application for CC-486, an investigational oral hypomethylating agent, for the maintenance treatment of adult patients with acute myeloid leukemia who achieved complete remission, or CR with incomplete blood count recovery, following induction therapy with or without consolidation treatment, and who are not candidates for, or who choose not to proceed to, hematopoietic stem cell transplantation.

CC-486 is sponsored by Bristol Myers Squibb. FDA granted the application Priority Review and set a Prescription Drug User Fee Act goal date of Sept. 3, 2020.

The NDA submission was based on the efficacy and safety results of the phase III QUAZAR AML-001 study, which met the primary endpoint of improved overall survival for patients receiving AML maintenance treatment with CC-486 versus placebo.

"Often, newly diagnosed adult patients with AML achieve a complete response with induction therapy, however many patients will relapse and experience a poor outcome. Patients in remission are seeking treatment options that decrease the likelihood of relapse and extend overall survival," Noah Berkowitz, senior vice president of Global Clinical Development, Hematology, at Bristol Myers Squibb, said in a statement.

CC-486 is an investigational therapy that is not approved for any use in any country.

Caris Life Sciences submits two PMA applications to FDA for whole exome and whole transcriptome sequencing

Caris Life Sciences has submitted two Pre-Market Approval applications for MI Exome CDx and MI Transcriptome CDx to FDA.

MI Exome CDx, whole exome sequencing (DNA), and MI Transcriptome CDx, whole transcriptome sequencing (RNA), are precision medicine assays that include key companion diagnostic biomarkers with therapy claims, and detect all classes of alterations including genomic signatures for microsatellite instability, tumor mutation burden, and loss of heterozygosity.

MI Exome CDx is a next-generation sequencing-based test utilizing DNA isolated from formalin-fixed paraffin embedded tumor tissue specimens for the qualitative detection of genomic alterations. MI Exome CDx can identify genetic variants (single nucleotide variants, insertions and deletions), copy number alterations, MSI, TMB and LOH.

MI Transcriptome CDx is a next-generation sequencing-based test that utilizes RNA isolated from formalin-fixed paraffin embedded tumor tissue specimens for the qualitative detection of genomic and transcriptomic alterations. MI Transcriptome CDx is a broad, multi-gene panel utilized to identify gene fusions, transcript variants, genetic variants (single nucleotide variants, insertions and deletions), and gene expression changes. FDA granted MI Transcriptome CDx received Breakthrough Device designation in 2019.

NCI TRIALS

NCI Trials for May 2020

The National Cancer Institute Cancer Therapy Evaluation Program approved the following clinical research studies last month.

For further information, contact the principal investigator listed.

Phase II - A071702
A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent Glioblastoma

Alliance for Clinical Trials in Oncology
Dunn, Gavin Peter
(314) 747-6141

Phase II - EAQ191
Cancer Therapy Risk-Reduction with Intensive Systolic BP Management (CARISMA) - a Phase II Study

ECOG-ACRIN Cancer Research Group
Ky, Bonnie
(215) 573-6606

Phase II - S1905
A Phase II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) In Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)

SWOG
Advani, Anjali S.
(216) 445-9354

Phase III - EA5181
Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC

ECOG-ACRIN Cancer Research Group
Pennell, Nathan Adam
(216) 445-9282