TCL
THE CANCER LETTER

Inside information on cancer research and drug development

Vol. 46 No. 25

JUNE 19, 2020

www.cancerletter.com

## SHARPLESS: COVID-19 EXPECTED TO INCREASE MORTALITY BY AT LEAST 10,000 DEATHS FROM BREAST AND COLORECTAL CANCERS OVER 10 YEARS

The COVID-19 pandemic will likely cause at least 10,000 excess deaths from breast cancer and colorectal cancer over the next 10 years in the United States.

→ PAGE 5

ACS FACES PRECIPITOUS DROP IN FUNDRAISING—UNCERTAINTY SURROUNDS FALL ROUND OF GRANTS

→ PAGE 11

**GUEST EDITORIAL**
CONQUEST OF COVID-19: PUBLISH IT TO DEATH?

→ PAGE 15

**IN BRIEF**
SITEMAN CANCER CENTER EARNS HIGHEST NCI RATING

→ PAGE 24

**TRIALS & TRIBULATIONS**
MOBILE PHARMACIES—DRIVING DOWN RURAL CANCER CARE DISPARITIES

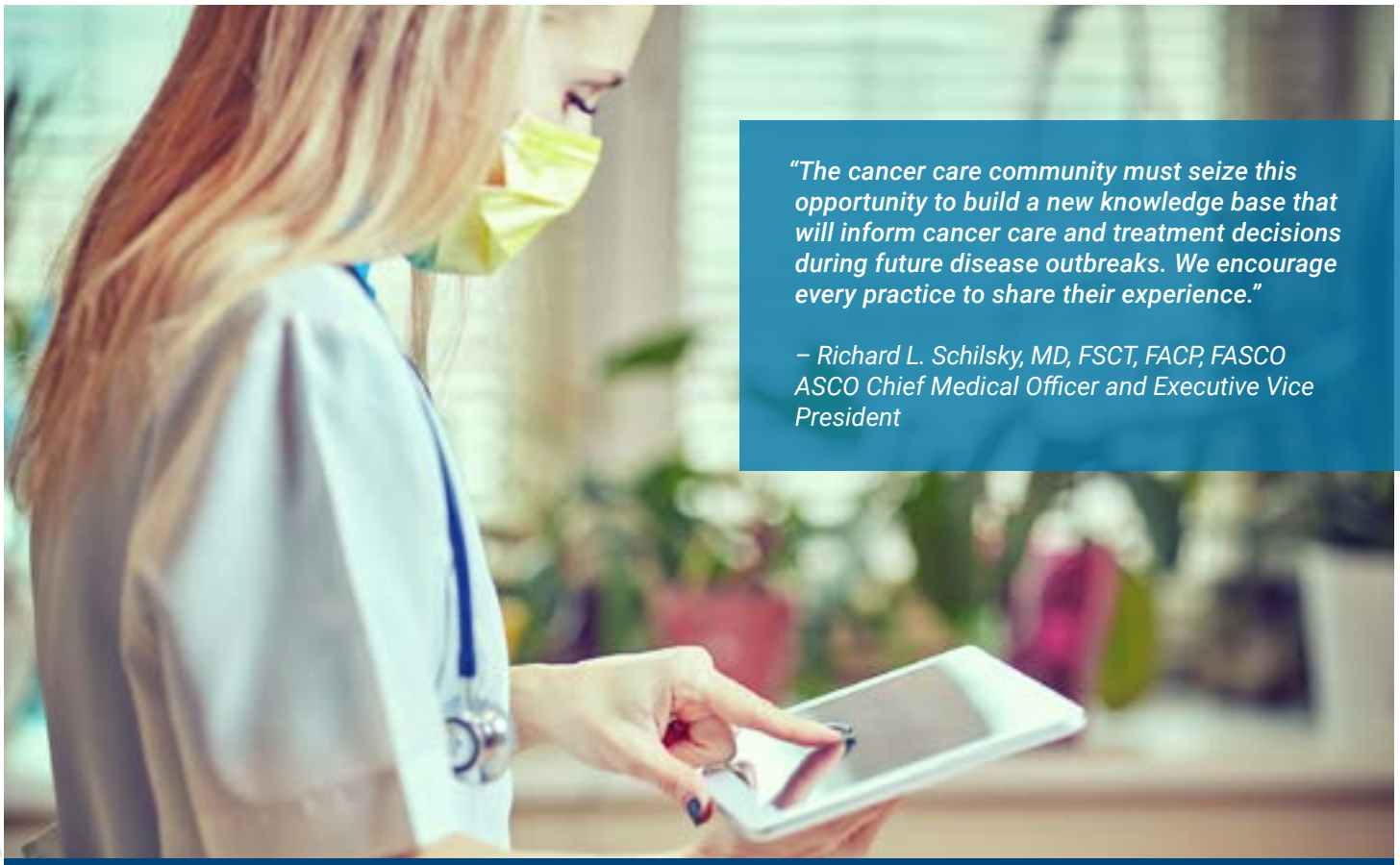
→ PAGE 28

# Help close the coronavirus data gap. Enroll in the ASCO COVID-19 Registry today.

To address the coronavirus data gap, ASCO established the ***American Society of Clinical Oncology Survey on COVID-19 in Oncology Registry***. The ASCO Registry will help the cancer community learn more about the treatment and outcomes of cancer patients with COVID-19, and how COVID-19 is impacting the delivery of cancer care.

**ASCO COVID-19 Registry Highlights:**

- Collects baseline and follow-up data on COVID-19 impact
- Delivers periodic reports with key findings
- Provides insight to inform treatment now and in the future
- Qualifies as an accepted clinical trial registry for improvement activities under the Merit-Based Incentive Payment System (MIPS)



*"The cancer care community must seize this opportunity to build a new knowledge base that will inform cancer care and treatment decisions during future disease outbreaks. We encourage every practice to share their experience."*

*– Richard L. Schilsky, MD, FSCT, FACP, FASCO*
*ASCO Chief Medical Officer and Executive Vice President*

**SIGN UP TODAY: asco.org/asco-coronavirus-information/coronavirus-registry.**

ASCO® Registry

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

# In this issue

**Editor & Publisher**
Paul Goldberg

**Associate Editor**
Matthew Bin Han Ong

**Reporter**
Alexandria Carolan

**Designer**
Jacqueline Ong

**Illustrator & Operations Manager**
Katie Goldberg

**Web Developer**
David Koh

**Editorial, Subscriptions and Customer Service**
PO Box 9905 -
Washington, DC 20016

**T** 202-362-1809
**F** 202-379-1787
**W** www.cancerletter.com

Individual subscriptions $555 per year worldwide. Group subscriptions required for institutional distribution. To subscribe, click here.

ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd.

©Copyright 2020.
The Cancer Letter Inc.
All rights reserved.

®The Cancer Letter is a registered trademark.

**COVER STORY (NCI DIRECTOR'S REPORT)**

**4** Sharpless: COVID-19 expected to increase mortality by at least 10,000 deaths from breast and colorectal cancers over 10 years

**10** ACS faces precipitous drop in fundraising—Uncertainty surrounds fall round of grants

**GUEST EDITORIAL**

**15** Conquest of COVID-19: Publish it to death?

**COVID-19 UPDATES**

**19** FDA joins Reagan-Udall, Friends of Cancer Research to form COVID-19 Diagnostics Evidence Accelerator

**19** Research!America seeks $26 billion boost to NIH, CDC, FDA funding in FY21

**20** Algorithm helps select breast cancer patients for urgent surgery or chemotherapy during pandemic

**21** FDA issues warning letters to companies marketing antibody tests

**21** TERAVOLT registry tracks outcomes of treatments among thoracic cancer patients with COVID-19

**22** Immunotherapy clinical trial for COVID-19 open at Mount Sinai

**IN BRIEF**

**23** Siteman Cancer Center earns highest NCI rating

**23** MSK's Charles L. Sawyers named AACR Academy president-elect

**24** Postow, Merea, named to new positions at MSK

**24** Kunle Odunsi named SITC board member

**24** Glenn D. Steele Jr. named chair of City of Hope board of directors

**25** David Cortez named associate director of basic science research at VICC

**25** Jessica Karen Wong joins Fox Chase

**26** OSUCCC – James Cancer Diagnostic Center speeds up diagnosis, treatment

**26** Roswell Park dermatology expert Oscar Colegio dies at 47

**REACH PEOPLE WHO MATTER IN ONCOLOGY**

Advertise your meetings and recruitments in The Cancer Letter and The Clinical Cancer Letter

Find more information

**HERE**

or visit: http://cancerletter.com/advertise/

**INSTITUTIONAL PLANS**

Allow everyone in your organization to read The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans

**HERE**

or visit: http://cancerletter.com/subscribe/

THE CLINICAL CANCER LETTER

**TRIALS & TRIBULATIONS**

27 Mobile pharmacies—driving down rural cancer care disparities

**CLINICAL ROUNDUP**

29 LLS, NCI and Children's Oncology Group collaborate on global master clinical trial for acute leukemia

29 Research and framework for genetic testing in prostate cancer supports broader use of panels, testing in early stage disease

30 Berzosertib shows promise in first clinical trial

31 Tecentriq improves response rate in early TNBC

31 ACE-CL-001, ASCEND trials demonstrate long-term efficacy and tolerability of Calquence in CLL

31 Blood test to monitor cancer is up to 10 times more sensitive than current methods

**DRUGS & TARGETS**

33 Keytruda receives second biomarker-based indication from FDA, regardless of tumor type

34 FoundationOne CDx receives FDA approval as companion diagnostic with Keytruda

34 Lurbinectedin receives accelerated approval by FDA for metastatic SCLC

34 Gemtuzumab ozogamicin receives extended indication for CD33-positive AML in pediatric patients

34 City of Hope signs licensing agreement with Scopus BioPharma to develop novel, targeted IO gene therapy

35 Royal Philips and MD Anderson to facilitate personalized oncology treatments and clinical trial matching based on genomic markers

35 Isoray, University of Cincinnati physicians company sign research agreement to study head and neck cancers

NCI DIRECTOR'S REPORT

# Sharpless: COVID-19 expected to increase mortality by at least 10,000 deaths from breast and colorectal cancers over 10 years

*By Matthew Bin Han Ong*

The COVID-19 pandemic will likely cause at least 10,000 excess deaths from breast cancer and colorectal cancer over the next 10 years in the United States.

Scenarios run by NCI and affiliated modeling groups predict that delays in screening for and diagnosis of breast and colorectal cancers will lead to a 1% increase in deaths through 2030. This translates into 10,000 additional deaths, on top of the expected one million deaths resulting from these two cancers.

"For both these cancer types, we believe the pandemic will influence cancer deaths for at least a decade," NCI Director Ned Sharpless said in a virtual joint meeting of the Board of Scientific Advisors and the National Cancer Advisory Board June 15. "I find this worrisome as cancer mortality is common. Even a 1% increase every decade is a lot of cancer suffering.

"And this analysis, frankly, is pretty conservative. We do not consider cancers other than those of breast and colon, but there is every reason to believe the pandemic will affect other types of cancer, too. We did not account for the additional non-lethal morbidity from upstaging, but this could also be significant and burdensome."

An editorial by Sharpless on this subject appears in the journal *Science*.

The early analyses, conducted by the institute's Cancer Intervention and Surveillance Modeling Network, focused on breast and colorectal cancers, because these are common, with relatively high screening rates.

CISNET modelers created four scenarios to assess long-term increases in cancer mortality rates for these two diseases:

1. The pandemic has no effect on cancer mortality
2. Delayed screening—with 75% reduction in mammography and, colorectal screening and adenoma surveillance for six months
3. Delayed diagnosis—with one-third of people delaying follow-up after a positive screening or diagnostic mammogram, positive FIT or clinical symptoms for six months during a six-month period

## 4 Combination of scenarios two and three

Treatment scenarios after diagnosis were not included in the model. These would be: delays in treatment, cancellation of treatment, or modified treatment.

"What we did is show the impact of the number of excess deaths per year for 10 years for each year starting in 2020 for scenario four versus scenario one," Eric "Rocky" Feuer, chief of the NCI's Statistical Research and Applications Branch in the Surveillance Research Program, said to *The Cancer Letter.*

Feuer is the overall project scientist for CISNET, a collaborative group of investigators who use simulation modeling to guide public health research and priorities.

"The results for breast cancer were somewhat larger than for colorectal," Feuer said. "And that's because breast cancer has a longer preclinical natural history relative to colorectal cancer."

Modelers in oncology are creating a global modeling consortium, COVID-19 and Cancer Taskforce, to "support decision-making in cancer control both during and after the crisis." The consortium is supported by the Union for International Cancer Control, The International Agency for Research on Cancer, The International Cancer Screening Network, the Canadian Partnership Against Cancer, and Cancer Council NSW, Australia.

A spike in cancer mortality rates threatens to reverse or slow down—at least in the medium term—the steady trend of reduction of cancer deaths. On Jan. 8, the American Cancer Society published its annual estimates of new cancer cases and deaths, declaring that the latest data—from 2016 to 2017—show the "largest ever single-year drop in overall cancer mortality of 2.2%." Experts say that innovation in lung cancer treatment and the success of smoking cessation programs are driving the sharp decrease (*The Cancer Letter*, Feb. 7, 2020).

The pandemic is expected to have broader impact, including increases in mortality rates for other cancer types. Also, variations in severity of COVID-19 in different regions in the U.S. will influence mortality metrics.

"There's some other cancers that might have delays in screening—for example cervical, prostate, and lung cancer, although lung cancer screening rates are still quite low and prostate cancer screening should only be conducted on those who determine that the benefits outweigh the harms," Feuer said. "So, those are the major screening cancers, but impacts of delays in treatment, canceling treatment or alternative treatments—could impact a larger range of cancer sites.

"This model assumes a moderate disruption which resolves after six months, and doesn't consider non-lethal morbidities associated with the delay. One thing I think probably is occurring is regional variation in these impacts," Feuer said. "If you're living in New York City where things were ground zero for some of the worst impact early on, probably delays were larger than other areas of the country. But now, as we're seeing upticks in other areas of the country, there may be in impact in these areas as well"

How can health care providers mitigate some of these harms? For example, for people who delayed screening and diagnosis, are providers able to perform triage, so that those at highest risk are prioritized?

"From a strictly cancer control point of view, let's get those people who delayed screening, or followup to a positive test, or treatment back on schedule as soon as possible," Feuer said. "But it's not a simple calculus, because in every situation, we have to weigh the harms and benefits. As we come out of the pandemic, it tips more and more to, 'Let's get back to business with respect to cancer control.'

"Telemedicine doesn't completely substitute for seeing patients in person, but at least people could get the advice they need, and then are triaged through their health care providers to indicate if they really should prioritize coming in. That helps the individual and the health care provider weigh the harms and benefits, and try to strategize about what's best for any individual."

If the pandemic continues to disrupt routine care, cancer-related mortality rates would rise beyond the predictions in this model.

"I think this analysis begins to help us understand the costs with regard to cancer outcomes of the pandemic," Sharpless said. "Let's all agree we will do everything in our power to minimize these adverse effects, to protect our patients from cancer suffering."

*Sharpless's remarks at the June 15 NCAB-BSA virtual meeting follow:*

> We are delighted to welcome four new full members to the NCAB today. Dr. Anna Barker, former deputy director of NCI, now at USC. Dr. Howard Fingert, a medical oncologist with significant translational expertise who's had a long experience advising the NCI and FDA. Dr. Andrea Hayes-Jordan, surgeon-in-chief at the University of North Carolina Children's Hospital, and Dr. Susan Vadaparampil, vice chair of Health Outcomes and Behavior, the department at the Moffitt Cancer Center. Thank you.
>
> It seems that, lately, each time that we meet, our circumstances have

changed in ways that we did not foresee. In early April, we held an extra joint board meeting to focus on the pandemic and NCI's response. At that point, NCI and many of your institutions had just moved to the mostly telework environment for COVID-related care and research, and we were just three to four weeks into that new way of working at that time. Convening a meeting virtually entirely was still new and the cancer research community was frankly reeling, making urgent decisions with limited evidence on how to proceed forward.

Many of you remember that Dafna [Bar-Sagi] gave us a glimpse into the pandemic's epicenter at NYU. I reflected at that time on a quote from Hamlet that I like. "When sorrows come, they come not as single spies, but as battalions." And sadly, that sentiment is still with us today. On May 12, the BSA gathered for a regular meeting, a marathon virtual meeting that reviewed 13 concepts. I know I for one found it reassuring to focus on our bread-and-butter cancer research, identifying and incentivizing this insanely great cancer research that is the business of the NCI.

And now today, just four weeks later, it seems everything once again has been scrambled and changed. The news is now filled with images that are shocking and unforgettable, but also that defy easy explanation. No longer now of crowded ERs and ICUs and ambulances, but instead of police brutality, marches and protests. While we each wrestle with the stark realities of racial injustice that recent events have laid bare, we also have to confront these issues at institutions as a profession, as people who've devoted our careers to alleviating suffering.

I'm grateful to the many leaders within our cancer research community who were speaking out on these topics. Something in particular I really admired were two pieces in the recent June 5 issue of *The Cancer Letter* from Rob Winn, a cancer center director at VCU, and our own Otis Brawley, who's with us today. For those of you who have not read these pieces, I highly recommend them. And Otis, thank you for your comments on this topic and your lifetime of leadership on these issues.

“While we each wrestle with the stark realities of racial injustice that recent events have laid bare, we also have to confront these issues at institutions as a profession, as people who've devoted our careers to alleviating suffering.”

I anticipate that in future board meetings, we will formally seek the counsel of the NCAB and the BSA on how NCI can enhance our current programs to address cancer disparities and workforce diversity. We also have some new things in the works in this vein that we will want to discuss soon when they're ready for talking about. In the meantime, as always, we are here to listen.

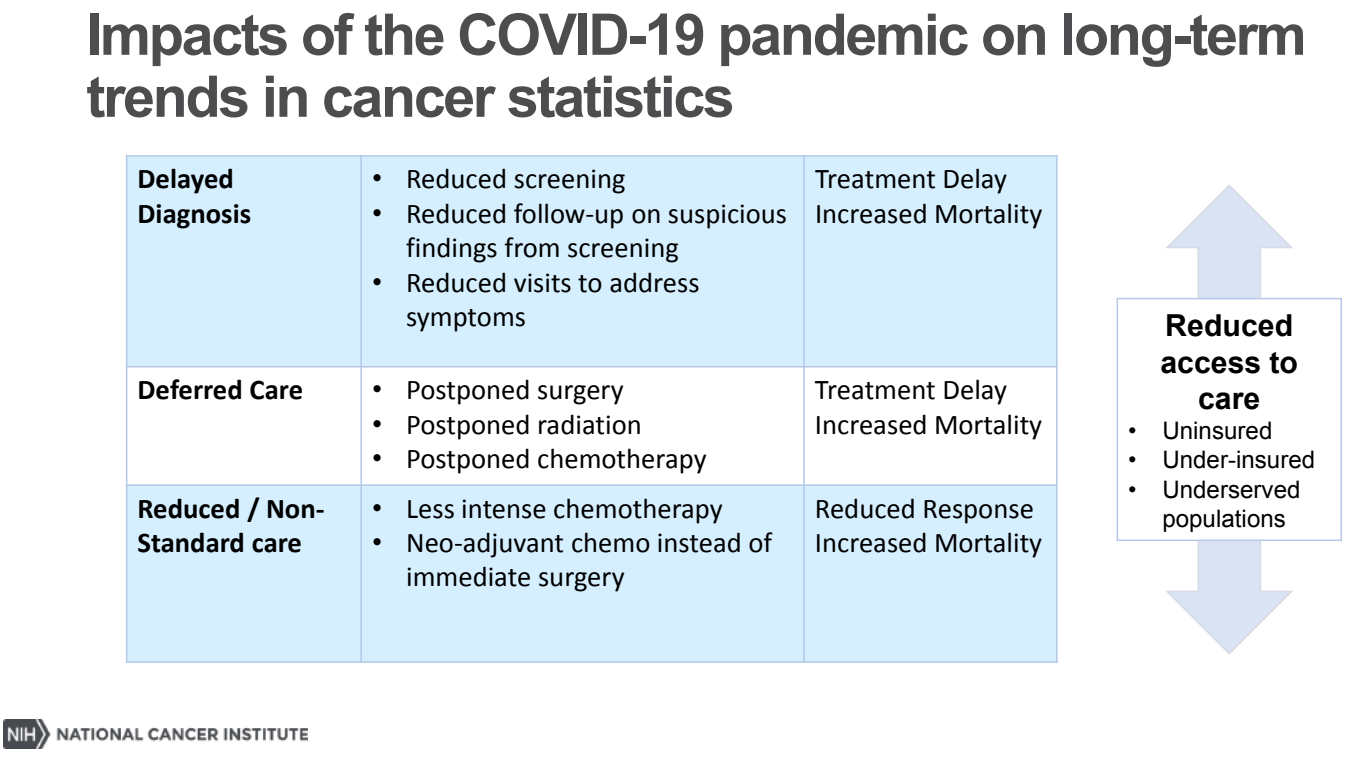
As a little bit of usual business, I thought I would show a traditional slide that I always show at this meeting, where we are in the budgeting process. Obviously this year's appropriation process is quite strange and different from prior years. Congress, in addition to working on the 2021 budget, is also hard at work still on a fifth supplement to the 2020 budget. There's a lot in play on this topic. It's complicated, and I will leave this to M.K. Holohan to talk about later on this morning. It's very interesting. A lot going on.

Our primary concern is, of course, the health and safety of people with cancer, healthcare providers and NCI grantees and staff, and we are fortunate and proud to be able to continue to contribute our expertise and infrastructure to the critical research on COVID-19.

We discussed a lot of this at prior meetings so I won't go into too much detail today, and Doug will be talking about serology a bit more. I will highlight the bottom here on the clinical trials of immunomodulatory agents. That's a new trial that is opened for tocilizumab and compassionate use, as well as based on a recent paper from Lou Staudt and Wyndham Wilson on acalabrutinib as a potential therapy for severe COVID-19. And even though we've had recent presentations on many of these items, I will update you on a few areas of progress very briefly.

## Serology and related technologies

So, as many of you are aware, Congress has provided the National Cancer Institute with a large supplemental appropriation for research of COVID-19 serology and related technologies. The history of this is that, in early March, during the early days of the pandemic response, we pivoted our top-notch serology lab at Frederick National Lab, which does regulatory-grade work for HPV, and we've moved that lab to work on coronavirus.




We collected a lot of samples of reagents and working with CDC and NIAID, we quickly developed a high quality ELISA assay. In particular, I personally sent about 30 emails to various cancer center leaders and other academics requesting their help, and their response to that was wonderful, with many institutions really helping the NCI with expertise in samples.

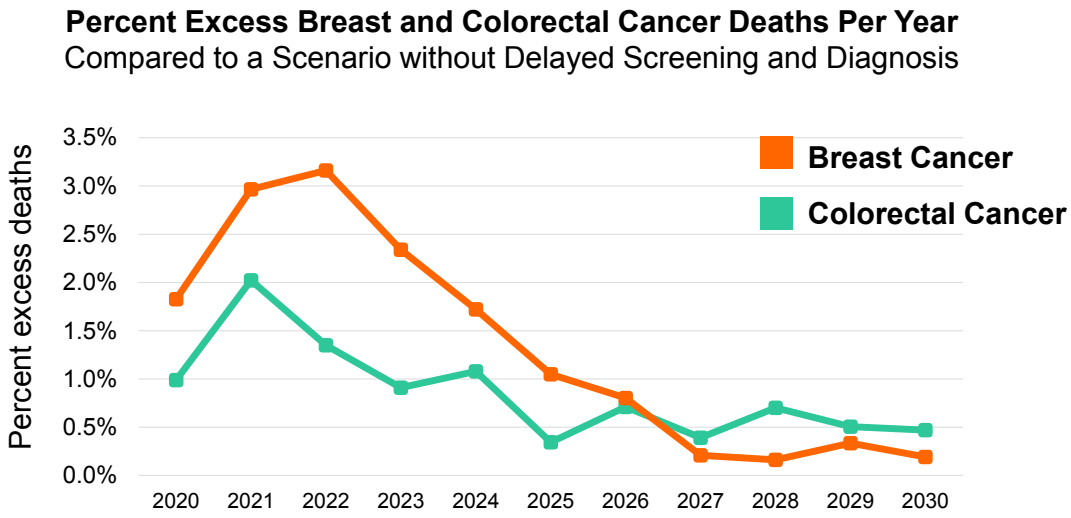
While developing reagents, we were approached by the device center at FDA who asked for our help with performance testing.This led to a really exciting and gratifying inter-agency collaboration to test the usability of these devices in real world settings. Serology work at Frederick National Lab and other parts of the NCI continues today at a furious pace with collaborators at FDA, CDC, BARDA, and NIAID.

I should also mention, regarding serology, at the May meeting Dinah Singer shared with the BSA plans for Serological Sciences Network, which we're now calling SeroNet. It was said then, but bears repeating, really, hats off to Dinah and her team, who mobilized NCI staff incredibly quickly to craft this program. We recently published two new funding announcements (RFA-CA-20-038, RFA-CA-20-039) that will create SeroNet. To meet the urgent need associated with the pandemic, these open RFAs were developed in record time at close on July 22.

We recognize that expertise in these areas is well beyond the researchers usually at NCI's pool, so we're reaching out through a number of organizations and channels that are not our traditional stakeholders. I also explained at the meeting how this NCI-NIAID-administered network is not solely cancer-focused, although we fully hope and expect many of the basic science studies to be supported by this network. For example, examine the links between cellular and humoral immunity or studies about antibody structure and function. So, we hope and expect that these sorts of studies will be highly valuable to cancer research as well.

Jim Doroshow shared plans for this study with all of you in April. This is our clinical trial studying COVID-19 natural history in cancer patients, and things on this front have progressed marvelously. You recall this is not a registry, but a trial with informed consent that allows longitudinal collection of samples and data from patients, including imaging results. There will be a robust analysis of serum biomarkers in order to identify predictors of outcome in these patients, as well as analysis of germline genetics. This trial, we're now calling NCCAPS, launched on May 21 and already has nearly 450 sites activated with plans to enroll 10,000 patients.

# Modeling Potential Effects of the Pandemic on Cancer Mortality




NIH NATIONAL CANCER INSTITUTE

*Courtesy of Dr. Eric Feuer, NCI & CISNET.* 7

## Modeling an increase in cancer mortality

At the BSA meeting in May, I spoke briefly about the impact of the pandemic on cancer outcomes, I think something that many of us are becoming more concerned about. We've seen decades of great progress with regard to national cancer mortality statistics, and no one wants to see that progress undermined. This slide shows what we should be worried about, the ways in which the global pandemic could disrupt cancer progress.

There's the issue of delayed diagnosis, because patients are less likely to see doctors for a new symptom or for routine screening during the pandemic. There's the issue of deferred care, because hospitals and clinics have stopped certain "elective procedures." Elective, like resection of tumors and elective chemotherapy. And they've stopped these elective procedures to preserve hospital capacity during the pandemic. And then, there's the issue of reduced and nonstandard care during the pandemic.

For example, some centers have been using neoadjuvant therapy to delay surgery for some diagnosed cancers, which is not a standard practice necessarily in those diseases. It's unclear how these nonstandard regimens will affect outcome. To be clear, we think these hospital closures and pauses were appropriate at the time, but we are also now very much interested in understanding how we get our patients back in the clinic and get care resumed for their benefit.

To get an idea of an estimate of what we think the impact of these changes will be, I asked Rocky Feuer at NCI CISNET, as well as our extramural fundees in this area to help figure this out. I think most of you are familiar with the CISNET network, which does state-of-the-art and cutting edge cancer modeling. I asked them to try and understand the effects of delayed and deferred care on cancer outcomes.

We chose to do this for breast and colon cancer, since these are common cancers with relatively high screening rates. And CISNET investigators had developed sophisticated and validated simulation models that had provided a link between complex evidence and actionable public health strategies for those diseases. We made reasonable assumptions about the effects of COVID-19 on cancer screening and treatment, and modeled the effects on mortality for these two cancers over the next decade.

This analysis, as shown here with the excess mortality plotted by year, it suggests that we will see roughly 10,000 excess breast and colorectal

cancer deaths over the next 10 years, which represents a roughly 1% excess in deaths from these two tumor types over that period. For both these cancer types, we believe the pandemic will influence cancer deaths for at least a decade.

I find this worrisome as cancer mortality is common. Even a 1% increase every decade is a lot of cancer suffering. And this analysis, frankly, is pretty conservative. We do not consider cancers other than those of breast and colon, but there is every reason to believe the pandemic will affect other types of cancer, too. We did not account for the additional non-lethal morbidity from upstaging, but this could also be significant and burdensome.

Perhaps most crucially, this analysis assumes only a moderate disruption in screening and care that completely resolves after six months. Obviously, if the pandemic disrupts routine cancer care to a greater degree or for a longer period, the effect on current cancer mortality could be even worse. I think this analysis begins to help us understand the costs with regard to cancer outcomes of the pandemic. Let's all agree we will do everything in our power to minimize these adverse effects, to protect our patients from cancer suffering.

## Notable research

I'd like to briefly show some science from the intramural program. This is a really handsome paper from Tim Greten and colleagues from CCR published last week in Cell. NCI investigators studied biomarkers for liver cancer. This is the largest study to date analyzing serological samples using a high-throughput viral technology in patients with the hepatocellular carcinoma.

Parenthetically, before, I mentioned that NCI has some great serology and biology researchers, as evidenced here. This study shows that viral exposure signatures hold promise for being developed as cancer biomarkers for the early onset of hepatocellular carcinoma. After initial training analysis, the researchers tested their signature on blood samples from 173 people with chronic liver disease who were part of a 20-year study. During that time, 44 of the participants developed hepatoma.

Using blood samples taken when the cancer was diagnosed, the signature correctly identified those who developed HCC with an area under the curve of 0.98. And importantly, the signature also worked when the researchers used blood samples taken at the beginning of the study, up to 10 years before diagnosis, with an AUC of 0.91. These are very promising developments for a cancer where there's not been a lot of good news and it is of growing importance, both in the United States and internationally.

Here's another effort of something we were just getting started with that we've been working on a long time and to address another very difficult GI malignancy, pancreatic cancer, where there has not been sufficient progress. As many of you know, new-onset diabetics over the age of 50 are at much higher risk of being diagnosed with pancreatic cancer within three years of their diabetes diagnosis. NCI, in partnership with PanCAN as well as NIDDK, has developed a new-onset diabetes study to examine this high-risk population. This will prospectively collect a cohort to follow individuals for the development of pancreatic adenocarcinoma.

The study will establish a biobank of clinically annotated biospecimens. It will facilitate validation of emerging tests for identifying NOD subjects at high risk for having pancreatic cancer using the clinically annotated biospecimen reference set. And it will provide a platform for the future development of an early detection protocol for sporadic pancreatic cancer in new-onset diabetes subjects that incorporates novel imaging as well as other clinical parameters.

## Leadership updates

As many of you are aware, we will soon welcome Dr. Phil Castle, I'm told, in early July, as director of the Division of Cancer Prevention. We are extremely grateful to Debbie Winn for her superb work holding down that job in the acting capacity for the past, more than a year.

I am also pleased to announce that Emily Tonorezos will also be joining the NCI as director of the Office of Cancer Survivorship. Dr. Tonorezos is currently at Memorial Sloan Kettering and has specialized in long-term follow up of adult cancer survivors. She's been selected for the appointment, pending clearance. And I would like to thank our old friend Deb Mayer of UNC, who has been instrumental in supporting the Office of Cancer Survivorship since the retirement of Julia Rowland.

Final word, I'd like to remind you of our Bottom Line blog. We've continued to post articles of particular interest to the NCI about concepts, about cancer research in COVID-19 era, about cancer training during the pandemic. I think the response to these posts has been really great, and I hope you found it useful and you'll continue to spread the word and point others to this as well, where it contains a lot of information for our grantees and other interested stakeholders.

# ACS faces precipitous drop in fundraising

## Uncertainty surrounds fall round of grants

*By Paul Goldberg*

The American Cancer Society has raised $160 million so far this year, an astonishingly low number for an organization that historically has booked about half of its funds from walks, runs, and relays that take place in the spring and early summer.

These walks, runs, and relays, have, alas, been cancelled amid the COVID-19 pandemic.

According to information widely shared with the staff, ACS, the largest nonprofit focused on all cancers, is hoping to raise $512 million this year. This target represents the best-case scenario for the charity, which is believed to have raised around $700 million last year. The 2019 numbers have not been reported.

Responding to questions from *The Cancer Letter,* ACS said its overall goal for the year is realistic. "Our fundraising goal for the year is $512 million, and while the economic climate continues to be very volatile, we believe we will meet that goal, based on our revenue projection," the society said in a statement.

"COVID-19 upended many of ACS' key fundraising events, including Relay for Life, and we, like many others, were forced to quickly find digital and virtual ways this year to continue," ACS said. "We had virtual events throughout the spring, and will continue with those through the summer and fall. We'll reach [the fundraising goal] the way ACS has always raised money: we'll engage volunteers and partners, both online and offline, to share the urgency of continuing our lifesaving work."

The $512 million target represents an eerie landmark for the charity—nearly a 50% drop from the $1.039 billion in total public support it reported in 2007, its best year ever. The society's financial performance has been eroding since then, amid attempts at fundamental reorganizations, experiments with fundraising strategies, and struggles to tame discord among top leaders.

While gross receipts have been eroding steadily, the latest downturn is much steeper than anything seen since the bad stretch set in.

ACS is acknowledging the possibility that for the first time in its history it may not be able to fully fund approved grants this fall. Altogether, ACS has given out $4.9 billion in research funding since 1946.

The society has said publicly that in 2018 it spent $147 million on funding cancer research. Research funding remained at the same level in 2019, sources say. That year, about $98 million was paid out in grants, an estimated $12 million was spent on grants administration, and the remainder—about $37 million—funded ACS intramural research.

So far in 2020, ACS has awarded an estimated $36.165 million in 79 extramu-

ral research and training grants during the spring round of funding. The grant starting date was moved from July 1 to Sept. 1, to accommodate institutions that are partially shut down because of COVID-19.

The ACS Council for Extramural Research also approved 73 grant applications for funding, totaling $38,988,850 that could not be funded due to budgetary constraints.

If the fall round of grants, which usually occurs in September, is skipped, this would mean that researchers would not get roughly $60 million in grants, compared to last year.

"If current revenue trends continue, we could be forced to cut new research funding this year by 50%," ACS said in a statement. "We continue to meet the commitments made for multi-year grants, sending millions of dollars every month to institutions across the country.

"At this point, we are exploring options around new allocations, but we will not make final decisions until we have a clearer fiscal picture. As the largest private, not-for-profit funder of cancer research in the United States, reducing our research spend by any amount is an action we want to avoid.

"Researchers across the country need us, and importantly, cancer patients depend on the discoveries our research yields. In addition, we are doing everything possible to protect funding for other mission priorities, including prevention and early detection (lung, HPV, colorectal, breast, tobacco), health equity, patient care and services, clinical partnerships, and survivorship and palliative care."

Sources said that the ACS grant review team was drastically reduced in the most recent round of staff cuts.

It's not publicly known how other cancer charities have been affected by the COVID-19 pandemic.

While publicly traded companies have to release quarterly reports and announce developments that affect their financial performance, non-profits have no such obligations. Even their annual tax filings become publicly available about a year after the year's end.

Thus, in 2018, the most recent year for which tax filings are available, ACS reported having the net assets of $1.092 billion. It's not publicly known how much of that amount was available and whether any of it has been drawn down in 2019.

Last week, the society said it has eliminated 1,000 positions across the U.S., as part of an effort to reduce its overall budget by approximately 30%. The staff cuts mean that the society would now have a workforce of about 3,000.

"We are expecting a minimum of a $200 million shortfall in 2020," ACS said in response to questions from *The Cancer Letter*. "Essentially, ACS has gone from a $700 million operating budget to $500 million operating budget. As a result, ACS had to reduce its overall budget by approximately 30%, with cuts to both non-personnel and personnel expenses.

"Our $500 million operating budget was done carefully, based on forecasting that takes the country's current climate and giving trends into account. Layoffs are our last resort, and we believe that the painful staff downsizing done this spring is in line with our projections and will be sufficient. We will continue to monitor the external environment closely and look for additional opportunities to streamline our operations so that we are able to best respond and continue advancing our mission."

The society's long decline cannot be blamed on the financial crisis on 2007. Indeed, while its fundraising sputtered, ACS was surpassed by St. Jude Children's Research Hospital and the American Lebanese Syrian Associated Charities Inc., a group that raises money for the Memphis-based pediatric hospital. According to their tax filings for 2017, St. Jude raised $981 million in 2017 and ASLAC raised $1.65 billion that year. On top of that, the two organizations have billions in assets.

> "COVID-19 upended many of ACS' key fundraising events, including Relay for Life, and we, like many others, were forced to quickly find digital and virtual ways this year to continue."
>
> *– American Cancer Society*

Meanwhile, ACS has been reorganizing its structure, eliminating divisions, cutting out events believed to produce insufficient revenues, shedding real estate that once housed local operations, courting corporate relationships that sometimes backfired, dabbling in venture capital—and reducing staff.

As it happened, ACS top leadership was in transition when COVID struck (*The Cancer Letter*, Feb. 7, 2020).

In February, after months of turmoil among top-tier warlords, CEO Gary Reedy stepped away from the society's day-to-day operations, and Kris Kim, ex-

ecutive vice president for the Northeast Region, stepped in as an acting COO.

"I recognize the need for me to focus my efforts externally, which requires different leadership to oversee day-to-day operations," Reedy said in an email dated Feb. 5 and addressed to the ACS staff. At the time, Reedy wrote that the "changes to the senior staff… will better position the American Cancer Society to deliver on the three-year enterprise strategic plan so that we may meet the challenge goal to reduce cancer mortality by 40 percent by 2035."

> Essentially, ACS has gone from a $700 million operating budget to $500 million operating budget. As a result, ACS had to reduce its overall budget by approximately 30%, with cuts to both non-personnel and personnel expenses.
>
> *– American Cancer Society*

Knowledgeable sources at the time said that conflicts among members of the society's "senior leadership team" have on several occasions reached the board level. At least two SLT members have been known to take their grievances directly to the board, sources said.

In an emailed response to questions from this reporter in February, Reedy wrote that the society's "financial profile has stabilized, and we are on solid ground. In fact, the financial stability that we've worked so hard to achieve over the past few years is in large part what now positions us to undertake our Strategic Plan, with this new leadership structure to support it."

Over the past year, ACS has gone through three CFOs: Catherine E. Mickle was replaced by Robert M. King, who lasted roughly six months and resigned to go to become CFO of Goodwill of North Georgia, after which Mickle returned to the old job, which is now relinquishing for Kael Reicin, a CFO at Geller & Co., a firm that provides custom strategic financial advice and wealth management for businesses, individuals, families and not-for-profit organizations.

Sources said that in preceding months ACS experienced difficulties while implementing a customer relationship management system by Salesforce, a software developer.

"Over the past few years, the American Cancer Society has undertaken the challenging process of replacing very old back office systems that were creating inefficiencies and operational risk," Reedy said in response to questions from *The Cancer Letter* at the time. "It has been a complex process, and hiccups were expected. Our transition to Salesforce is now complete, and while we certainly expect to tweak the systems as we go, we are now positioned to leverage technology for greater efficiency and impact."

When he spoke with this reporter in 2018, Reedy, formerly a Johnson & Johnson executive, said his initial employment contract was signed in April 2015 was renewed for another three years in 2018, giving him through April 2021 (*The Cancer Letter*, Jan 26, 2018).

To control costs, Reedy presided over three earlier reductions in staff between 2015 and 2018. Insiders say the savings are making ACS more self-sufficient in the long term. Reedy also said that at the time of his arrival, the society's No. 1 fundraising event, the Relay for Life, wasn't producing money.

"Part of the strategic plan, Paul, was looking at everything we're doing across the board, and looking at it from efficiency and an effectiveness standpoint, and where it's having impact in the communities, where people are engaged, then we are continuing to do that and will continue to, and will also continue to make it more customized," he said.

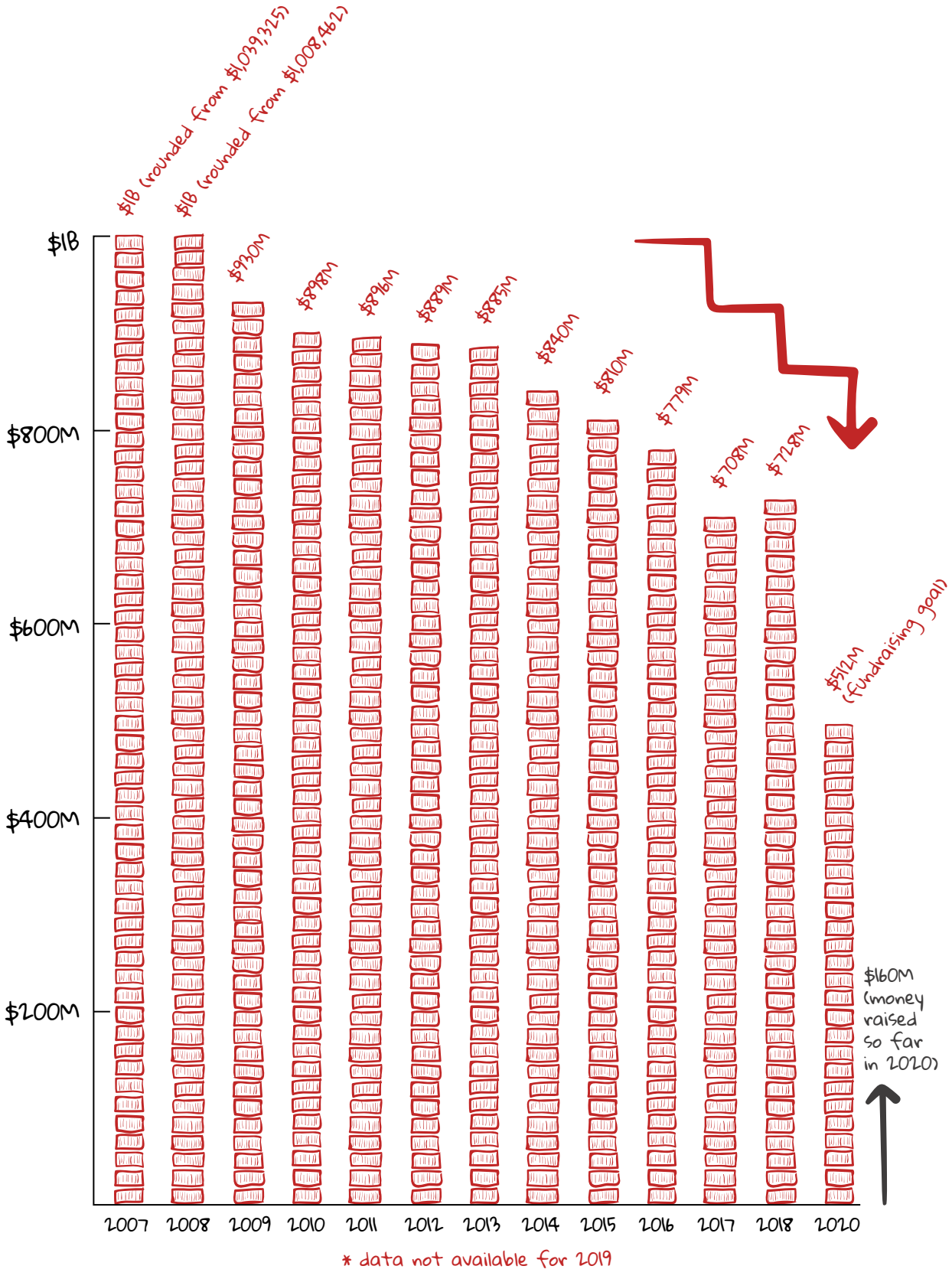
"But in areas where we were doing Relay events or whatever, there was very little engagement and we were putting a lot of time and resources into it, and from a revenue standpoint, we're actually losing revenue. We cut those out. We knew going into '17 that our revenue more than likely was going to be a little bit less than 2016, and it is, but for 2018 going forward, I'm expecting to have revenue increases every year from here on out."

Some of the society's efforts to get sponsorships led to entanglements that appear to be inconsistent with the society's public health mission. To wit, The New York Times reported the society's campaign that amounted to sanctioning Long John Silver's marketing of deep-fried Twinkies. Also, ACS has allowed its iconic shield to be displayed by a sports bar chain called Tilted Kilt as well as the dietary supplements marketer Herbalife (*The Cancer Letter*, Nov. 9, 2018).

The campaigns also reportedly led to departure of Otis Brawley, the society's chief medical officer, who is now the Bloomberg Distinguished Professor of Oncology and Epidemiology at the Johns Hopkins University (*The Cancer Letter*, Nov. 9, 2018).

THE CANCER LETTER | JUNE 19, 2020 | VOL 46 | ISSUE 25

## AMERICAN CANCER SOCIETY TOTAL PUBLIC SUPPORT




*Source: American Cancer Society*


GUEST EDITORIAL

# Conquest of COVID-19: Publish it to death?

Early in the War Against Cancer, when huge amounts of federal funds were suddenly funneled into cancer research, many scientists and clinicians working in other fields suddenly found it convenient—if not essential—to incorporate cancer into the title of their grant applications.

**Robert Peter Gale MD, PhD, DSc(hc), FACP, FRCP, FRCPI(hon), FRSM**
*Visiting Professor of Haematology,*
*Imperial College London*

The hope was the application would be directed to a National Cancer Institute review panel, instead of a less-funded institute. The situation became so acute, some cynics commented more people were living from than dying from cancer. Fortunately, some of these re-directed research efforts were productive in unpredictable ways and helped us make substantial progress against cancer, even if total victory is not yet ours.

Sadly, some diseases can be cured by medical interventions, others not. When not, are there other approaches to control or cure? One possibility is to try to publish a disease to death, a therapy strategy first proposed by my late colleague Prof. David Golde from UCLA. Here I consider whether this strategy is working in the fight against severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) pandemic and the associated coronavirus infectious disease-2019 (COVID-19).

To test this hypothesis I queried PubMed on May 16, 2020 for citations using the search terms SARS-CoV-2 and/or COVID-19. There were 12,959 hits since January 2020—or roughly 162 citations per day. I confirmed this by comparing this number with a similar PubMed search I did on May 14, 2020. The difference of 484 citations is consistent with a recent publication rate of 220 per day.

This is one publication for every four daily deaths from COVID-19 in the U.S. on June 8, 2020. And this is only for citations covered by PubMed. I also found 3915 publications on medRxiv and 925 on bioRxiv [1]. The figures from the World Health Organization,

which tracks every manuscript on the virus and its disease submitted in their journals irrespective of publication, would be much greater.

How to explain this burst of publications? Can many high-quality studies be done so quickly? Unlikely. In fact, of 1,556 studies of COVID-19 listed in ClinicalTrials.gov, only 249 (16%) were phase III trials, and fewer than 100 included more than 100 subjects [2]. Given the baseline estimate, 85% of clinical research is not useful or wrong—we may be pushing this estimate to 90 or 95% this year [3,4].

One explanation of this publications deluge is the opportunity the pandemic offers authors and journals. Some journals (but not *BJH*) have lowered their criteria for acceptance. Publications of series of two or five subjects are appearing in high impact factor journals which would otherwise have appeared, if at all, in the *Lesotho Journal of Plant Biology*.

Although this change may be motivated by the goal to rapidly disseminate information about SARS-CoV-2 and COVID-19, it is also possible some journals and authors are jumping on the SARS-CoV-2 and COVID-19 bandwagon. (I am also guilty publishing several typescripts on this subject; εκπειραζοντες αυτον οι ιερεις ινα εχωσιν κατηγοριαν αυτου—the saints have been accused of this accusation) My mentor, Prof. Martin Cline, cautioned: No data is better than bad data [5].

Other forces may be operating. Submissions to scientific and medical journals increase dramatically over the Christmas and New Year holidays and on weekends [6]. Most scientists' laboratories are closed and clinicians not directly involved in treating persons with COVID-19 have reduced clinical responsibilities and work from home via telemedicine. Their options: help with online schooling, cook dinner, vacuum (Dyson V7 highly recommended) or hide in your (newly designated) home office and complete a long-delayed typescript. The choice between publish or perish has never been starker.

Another issue I considered was that many, if not most, of this surge of publications are from Chinese authors. Figure 1 shows data on numbers of publication by geographic region and country [7]. Although China surpassed the U.S. in 2015, they trailed the EU in 2016. This is likely to change in 2020.

Another growth industry is the publication of management guidelines for SARS-CoV-2 and/or COVID-19. A PubMed search on May 16, 2020 found 599 SARS-CoV-2 and/or COVID-19 guidelines. For the *BJH*, I list only guidelines directed towards persons with hematological disorders, including hematopoietic cell transplant recipients and recipients of cell therapies such as chimeric antigen receptor (CAR) T-cells including one from the U.K. National Institute for Health and Care Excellence (NICE) [8]; one from an international expert panel [9]; one from the European Bone Marrow Transplant Group (EBMT) [10]; and one from the American Society for Transplantation and Cellular Therapy (ASTCT) [11].

There were 52 authors of the international expert panel guidelines—making me suspicious so many physicians could agree on anything, save authorship on a publication. I contacted six co-authors I know, none of whom had cared for someone with COVID-19. Furthermore, none of these four guidelines is listed in the National Guidelines Clearinghouse [12].

My next step was to evaluate the quality of these guidelines using criteria of the Infectious Diseases Society of America (Figure 2; [13]). Readers will not be surprised the four guidelines received a C for Strength of Recommendation (Poor evidence) and a III for Quality of Evidence (Evidence from opinions of

respected authorities… without clinical trials data).

Nevertheless, recommendations in these guidelines, although not evidence-based, seem sensible and may be useful. The risk is that they will be awarded the imprimatur of delivering quality health care absent anything better. Wiser people than me have commented on the value of consensus in decision making. For example, Abba Eban, an ex-Israel Foreign Minister noted: Consensus means that lots of people say collectively what nobody believes individually.

Michael Crichton, physician and author commented: Historically, the claim of consensus has been the first refuge of scoundrels; it is a way to avoid debate by claiming that the matter is already settled. Whenever you hear the consensus of scientists agrees on something or other, reach for your wallet, because you're being had.

Limitations of consensus guidelines and their detrimental effect on critical thinking are discussed by others, by Profs. Gianni Barosi and me, and by Shaun McCann (who also evaluates guidelines on wine making) [14-19].

What proof have I that my criticism of these guidelines is valid? Might I be biased? As a test I performed a series of controlled experiments in mice. Animals were divided into 2 cohorts, one was fed shredded versions of the 4 guidelines, and the other cohort, shredded blank paper (placebo). After a week I combined mice in each cohort and placed them in a large cage into which I put a block of cheese labeled Conquer COVID-19 with a marker pen (Sounds like The Patchwork Mouse? [20]).

My initial experiments failed for 2 reasons: (1) the first cheese I tried was Époisses de Bourgogne—because it has a soft rind, the Conquer COVID-19 quickly became invisible; and (2) even without the writing, the mice were quickly asphyxiated (think Stinking Bishop, Pont L'Evequ or Petit Muenster). To appreciate this danger, be advised it is illegal in France to open an Époisses de Bourgogne on a public transport.

My second attempt using Shropshire Blue was more successful, even though it was challenging to read Conquer COVID-19 between the veins. The bottom line, however, is there was no statistically significant difference in the time it took the mice in either cohort to consume the Shropshire Blue, whether they were fed shredded guidelines or placebo.

Other innovative strategies to conquer SARS-CoV-2 and COVID-19 have also been tried, such as having interminable meetings, perhaps a way of talking a disease to death. A bonus of these frequently remote audio-only meetings during the SARS-CoV-2 pandemic, is one can, in your sleeping costume, finish breakfast, check emails, and complete typescripts on SARS-CoV-2 and COVID-19 to submit (see above). Unfortunately, it seems the talking cure will not cure COVID-19 [21]. (Apologies to Josef Brueur and Anna O.)

Coming back to the strategy of publishing a disease to death, we have been there before with hairy cell leukemia. In the 1970s, many people with this disease were referred to Profs. Golde and me at UCLA, or Prof. Harvey Golumb at the University of Chicago. We were in a vigorous academic competition but the only intervention we had was splenectomy, effective in some people but not a cure in most.

What to do? Golde suggested: If we can't cure hairy cell leukemia, perhaps we can publish it to death. Can it work?

Who knows? Fortunately, for hairy cell leukaemia we now have cladribine, pentostatin, rituximab and interferon amongst others. For SARS-CoV-2 and COVID-19 we await a safe and effective vaccine, and safe and effective therapies.

Lastly, we may never know if the strategy of publishing COVID-19 to death worked, because the SARS-CoV-2 pandemic may subside during or soon after this deluge of publications. Was this merely an association or cause-and-effect? Many associations, regardless of how strong, are not cause-and-effect. Take, for example, the correlation between per capita cheese consumption (not only Époisses de Bourgogne) and likelihood of dying by becoming tangled in one's bedsheets [22].

Causal inference is tricky. Perhaps, when the dust settles, we will have time for a rigorous evaluation of what is effective (and, perhaps more importantly, what is not) and we can be better prepared for the next coronavirus pandemic.

**Acknowledgements**

1. *RPG acknowledges support from the National Institute of Health Research (NIHR) Biomedical Research Centre funding scheme.*
2. *This article was modified from a typescript published June 1 in the British Journal of Haematology.*

**Conflict of Interest:** I have no fiscal interest in makers of Époisses de Bourgogne, Stinking Bishop, Pont L'Evequn nor Petit Muenster. However, during the lockdown, shipments of these would be greatly appreciated and can be sent to 11693 San Vincente Blvd, Los Angeles, CA USA 90049-1533.

**References**

1. *https://connect.medrxiv.org/relate/content/181*
2. *https://clinicaltrials.gov/ct2/results?cond=covid&term=&cntry=&state=&city=&dist*
3. *Glasziou PP, Sanders S, Hoffman T. Waste in Covid-19 research. BMJ.2020;369:m1847.*
4. *Ioannis J. Why most clinical research is not useful. PLoS Med. 2016;13:e1002049.*
5. *(https://www.financialpolicycouncil.org/blog/garbage-in-garbage-out-why-bad-data-is-worse-than-no-data/).*
6. *Barnett A, Newburn I, Schroter S. Working 9 to 5, not the way to make an academic living: observational analysis of manuscript and peer review submission over time. BMJ 2019;367:l6460.*
7. *https://www.nsf.gov/statistics/2018/nsb20181/assets/1387/overview.pdf*
8. *https://www.nice.org.uk/guidance/ng164)*
9. *Zeidan AM, Boddu PC, Patnaik MM. Special considerations in the management of adult patients with acute leukaemias and myeloid neoplasms in the COVID-19 Era: Recommendations by an International Expert Panel. Lancet Haematol.2020;in press.*
10. *https://www.ebmt.org/ebmt/news/coronavirus-disease-covid-19-ebmt-recommendations-update-march-23-2020*
11. *https://higherlogicdownload.s3.amazonaws.com/ASBMT/a1e2ac9a-36d2-4e23-945c-45118b667268/UploadedImages/COVID-19_Interim_Patient_Guidelines_4_20_20.pdf)*
12. *https://health.gov/node/160*
13. *Khan AR, Khan S, Zimmerman V, Baddour LM, Tleyjeh IM. Quality and strength of evidence of the Infectious Diseases Society of America clinical practice guidelines. Clin Infect Dis. 2010;51:1147-56.*
14. *Shekelle PG, Ortiz E, Rhodes S, Morton SC, Eccles MP, Grimshaw JM, Woolf SH. Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA. 200;286:1461-7.*
15. *Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS.Evidence based medicine: what it is and what it isn't. 1996. Clin Orthop Relat Res. 2007;455:3-5.*
16. *Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schünemann HJ; GRADE Working Group. What is "quality of evidence" and why is it important to clinicians? BMJ. 2008;336:995-8.*
17. *Metlay JP, Armstrong KA. Annals Clinical Decision Making: Weighing Evidence to Inform Clinical Decisions. Ann Intern Med. 2020;172:599-603.*
18. *Barosi G, Gale RP. Is there expert consensus on expert consensus?Bone Marrow Transplant. 2018;53:1055-60.*
19. *McCann SR. COVID-19, HCT and wine. Bone Marrow Transplant. 2020; doi: 10.1038/s41409-020-0932-3. [Epub ahead of print].*
20. *Hixson J. The Patchwork Mouse. 1976; Anchor Press, New York, NY, USA.*
21. *http://commentary-gonzalo86.blogspot.com/2020/04/interminable-meetings-found-ineffective.html))*
22. *Zheng C, Dai R, Gale RP, Zhang MJ. Causal interference in randomized clinical trials. Bone Marrow Transplant. 2020;55:4-8.*

# The First International Summit on Interventional Pharmacoeconomics

Finding Solutions to High Drug Costs

Learn More!

***ZOOM Web Conference June 29 – July 1, 8am-1pm ET daily***

## SESSION TOPICS

PROOF OF CONCEPT

HIGH- VALUE OPPORTUNITIES

CLINICAL TRIAL DESIGN: STATISTICAL OPTIONS/CHALLENGES

BIOSIMILARS AND PATENT ISSUES

CREATING THE INFRASTRUCTURE FOR INTERVENTIONAL PHARMACOECONOMIC TRIALS

OPPORTUNITIES TO OPTIMIZE CANCER DRUG POLICIES

THE INTERVENTIONAL PHARMACOECONOMIC TOOLBOX

FOCUS ON OPTIMAL DOSING OF IBRUTINIB

## WELCOME ADDRESS

**Allen Lichter**
Value in Cancer Care Consortium

## KEYNOTE SPEAKER

**Cliff Hudis**
American Society of Clinical Oncology

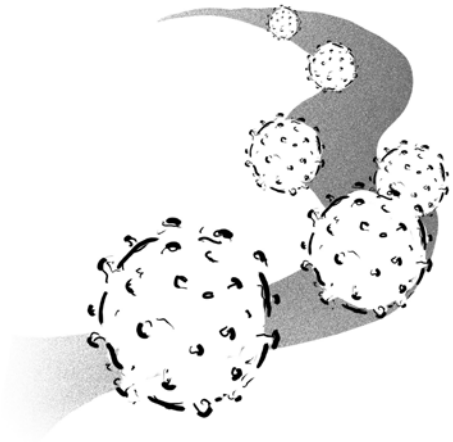
## Web Conference Organizers

Daniel Goldstein, MD – Davidoff Center, Rabin Medical Center, Israel
Mark J Ratain, MD – The University of Chicago

## Hosted by:

The University of Chicago, Value in Cancer Care Consortium (Vi3C), Clalit Health Services

COVID-19 UPDATES



# FDA joins Reagan-Udall, Friends of Cancer Research to form COVID-19 Diagnostics Evidence Accelerator

FDA is participating in the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder collaborative project to advance the development of diagnostics. The accelerator is organized by the Reagan-Udall Foundation for FDA in collaboration with Friends of Cancer Research.

"While there are current studies of viral diagnostic and antibody tests using traditional assessment methods, the Diagnostics Evidence Accelerator will allow the community to analyze both diagnostic and clinical data in real time, which has the potential to contribute to the scientific evaluation of diagnostic tools and medical interventions for COVID-19," Amy Abernethy, FDA principal deputy commissioner, said in a statement. "FDA's participation in the Diagnostics Evidence Accelerator is another example of how we are working with a broad set of experts in healthcare data and analytics to understand the performance of SARS-CoV-2 tests and to inform clinical and public health decision-making."

The Diagnostics Evidence Accelerator is the companion project to the previously announced Therapeutic Evidence Accelerator, which brings together leading experts in health data aggregation and analytics in a unified, collaborative effort to share insights, compare results and answer key questions to inform the collective COVID-19 response.

"This collaboration with the FDA, scientists and data experts is meeting the urgency of the moment to speed the pace of diagnostic testing," Ellen V. Sigal, chair of both the Reagan-Udall Foundation and Friends of Cancer Research, said in a statement. "We all share the goal of deepening our understanding of COVID-19 on every front to ensure that patients receive the best care as quickly and safely as possible."

Research questions that will be examined through the Diagnostics Evidence Accelerator include evaluating the real-world performance of SARS-CoV-2 diagnostic tests and antibody tests, how they are best used to tailor testing strategies to specific populations, and what test results and data may reveal about the prevalence of disease, chains of transmission, and individual and population-level immunity.

The effort will focus on how real-world data can help understand whether the presence of antibodies can indicate future immunity and if so, which specific antibodies and epitopes contribute to some level of protection against future infection.

Using real-world data can also provide actionable information about the prevalence of SARS-CoV-2 in specific populations and highlight individual risk factors for patients, helping to improve our understanding of the disease, tailor public health interventions and strategies to mitigate risks for individuals and communities, and help stop the spread of SARS-CoV-2. The evidence generated through the Diagnostics Accelerator is intended to be complementary to other studies that have been conducted or are underway as well as to address questions not yet answered.

"We recognize that questions related to the accuracy of diagnostic tests require different data elements that are not as widely available as those in the therapeutic space. They also require a different approach to data integration and analysis," Jeff Shuren, director of FDA's Center for Devices and Radiological Health. "The aim of the accelerator is to propose questions, refine them, evaluate the feasibility of different approaches, and bring together groups that have the data to answer the questions and develop lasting solutions. Ultimately, we hope that real-world data can provide a more generalizable and rapid read-out of results than traditional clinical trials."

The Diagnostics Evidence Accelerator represents the type of data-focused effort that has the potential to inform our future emergency efforts. In an emergency setting, the FDA may issue emergency use authorizations (EUAs) which are evaluated using a different standard than is required for approval or clearance in non-emergency situations. Gaining a better understanding of the real-world performance characteristics of diagnostic tests and antibody tests can help inform future EUAs.

# Research!America seeks $26 billion boost to NIH, CDC, FDA funding in FY21

In a letter to House and Senate leaders, Research!America has asked for a

massive boost in federal spending to address the damage the U.S. research organizations have sustained as a result of the COVID-19 pandemic.

"Funding of $26 billion is the minimum needed to re-seed the U.S. R&D continuum across all federal research funding, and to address gaps in voluntary health organization and philanthropic research funding resulting from the pandemic," Mary Woolley, president and CEO of Research!America, writes in the letter. "NIH Director Francis Collins has indicated that NIH alone needs $10 billion to address erosion in grant dollars."

The text of the letter follows:

Dear Leader McConnell, Speaker Pelosi, Minority Leader Schumer, and Minority Leader McCarthy:

We greatly appreciate your continued bipartisan commitment to responding resolutely and responsibly to the COVID-19 pandemic. Among the extreme impacts of COVID-19 is the destabilizing and stultifying effect on progress against the plethora of other deadly and debilitating diseases that threaten Americans and populations across the globe. We are writing to urge you to coalesce around two actions to empower desperately needed, lifesaving progress.

First, we ask that you provide the funding needed to restart research stalled or reprogrammed as a result of the pandemic. NIH Director Francis Collins has indicated that NIH alone needs $10 billion to address erosion in grant dollars. Funding of $26 billion is the minimum needed to re-seed the U.S. R&D continuum across all federal research funding, and to address gaps in voluntary health organization and philanthropic research funding resulting from the pandemic.

Second, we ask that you craft Fiscal Year 2021 appropriations in a way that accommodates unanticipated, but critically important, pandemic and VA funding needs while continuing to advance other top American priorities. The current budget caps were established before COVID-19 altered virtually every facet of American life. The pandemic did not, however, alter the importance of such enduring priorities as meeting the needs of our nation's veterans and speeding progress against cancer, Alzheimer's, and other destructive health threats. We ask that you exempt funding for the VA MISSION Act and pandemic-related spending from the budget caps to enable robust growth in the annual budgets of NIH, CDC, FDA, AHRQ and other research agencies critical to medical and public health progress.

We appreciate your consideration of these two pivotally important actions. Thank you, and please express our gratitude to your respective staff members, for your exceptionally hard work on behalf of the American people.

## Algorithm helps select breast cancer patients for urgent surgery or chemotherapy during pandemic

Researchers in the U.K, Germany and the United States have developed an algorithm to better select breast cancer patients in need of urgent surgery or chemotherapy during the COVID-19 pandemic.

The algorithm, using data from multiple international trials, can identify postmenopausal patients with primary ER+HER2- breast cancer who have either less endocrine-sensitive tumors and who should be prioritized for early surgery or neoadjuvant chemotherapy, or an endocrine-sensitive tumor that can be treated for up to 6 months with an endocrine drug with a safe surgical delay.

While patients diagnosed with triple negative breast and HER2-positive cancer have still been going forward for urgent surgery or chemotherapy, it is safe for a large group of patients to defer these treatments and treat with neoadjuvant endocrine therapy instead. Researchers have identified this method to reduce the stimulation of the disease by estrogen without the surgical removal of the breast tumour as the best course of treatment.

Matthew Ellis, professor and director of the Lester and Sue Breast Center at Baylor College of Medicine, was a key collaborator on the study published in *NPJ Breast Cancer*. The work highlighted that while 85% of patients can defer surgery and are safe to remain on NeoET treatment for up to 6 months, 15% of patients are resistant to this treatment and risk disease spread and tumor progression with delayed surgery. Ellis led the Alliance for Clinical Trials in Oncology Z1031 study that provided key data.

"NeoET jumped from being an esoteric, occasionally used option to the predominant standard of care within one month of the COVID-19 epidemic curtailing surgical access," Ellis, a McNair Scholar and Susan G. Komen Scholar at Baylor, said in a statement. "We wanted to be sure that those unfamiliar with the approach could have a data-driven algorithm to apply so this useful approach could be used wisely."

"By accessing unpublished results from clinical trials involving thousands of patients, we have developed a new way of directing patient treatment in this global crisis," Mitch Dowsett, professor and head of the Ralph Lauren Centre

for Breast Cancer Research at the Royal Marsden in London, and corresponding author of the study, said in a statement. "Using the data on tumor estrogen receptor, progesterone receptor and proliferation status in newly diagnosed patients, our simple calculator can be used by fellow clinicians worldwide to immediately identify the best course of treatment for about 80% of their patients."

Researchers also found that they could identify women who were at risk for loss of disease control by measuring Ki67, a protein that measures the number of cells dividing in the tumor, a few weeks after the start of NeoET. Those women, about 20% of the patients, were recommended surgery or neoadjuvant chemotherapy.

## FDA issues warning letters to companies marketing antibody tests

FDA has issued warning letters to three companies for marketing adulterated and misbranded COVID-19 antibody tests.

Generally, antibody tests, also called serological tests, detect antibodies to SARS-CoV-2, which can help identify individuals who have developed an adaptive immune response to the virus, as part of either an active infection or a prior infection. These tests may be important in the fight against this pandemic, as they may provide information on disease prevalence and the frequency of asymptomatic infection. Today's warning letters are the first set of letters the agency has issued for marketing adulterated or misbranded COVID-19 test kits.

"Providing regulatory flexibility during this public health emergency never meant we would allow fraud," Jeff Shuren, director of FDA's Center for Devices and Radiological Health, said in a statement. "When tests are marketed inappropriately, with inaccurate or misleading claims – such as the ability to perform the test completely at home, or that the test is authorized, cleared, or approved when it is not – they put the health of Americans at risk. Such conduct will not be tolerated by the FDA, and we will continue to monitor tests marketed in the U.S., taking appropriate action as warranted."

Warning letters were issued to: Medakit Ltd. of Sheung Wan, Hong Kong; Antibodiescheck.com and Yama Group; and Dr. Jason Korkus, DDS and Sonrisa Family Dental d/b/a My COVID19 Club of Chicago, Illinois. Violations outlined in the warning letters include: offering test kits for sale in the United States directly to consumers for at-home use without marketing approval, clearance, or authorization from the FDA; misbranding products with labeling that falsely claims products are "FDA approved"; and labeling that bears the FDA logo, which is only for the official use by the FDA and not for use on private sector materials.

There are no diagnostic or antibody COVID-19 test kits that are authorized, cleared or approved to be used completely at home. Testing in the home can present unique and potentially serious public health risks, including whether a lay user has the ability to collect their specimen, run the test, and interpret their results accurately. However, the FDA has authorized several diagnostic COVID-19 tests for use with at-home collection of samples—such as from the nose or saliva—that can then be sent to a lab for processing and test reporting. However, there are not any serology tests that are authorized for use with at-home collection of samples.

The FDA has requested that the companies take immediate steps to correct violations, such as ceasing the sale of the products or preventing future sales. Failure to immediately correct the violations cited in the warning letters may result in legal action, including possible seizure and injunction.

The FDA reminds consumers to be cautious of websites and stores selling products, including test kits, that claim to prevent, mitigate, treat, diagnose or cure COVID-19. Fraudulent COVID-19 products defraud consumers of money and can place consumers at risk for serious harm. Using these products may lead to delays in getting proper diagnosis and treatment of COVID-19 and other potentially serious diseases and conditions.

The FDA encourages health care professionals and consumers to report adverse events or quality problems experienced with the use of COVID-19 products to the FDA's MedWatch Adverse Event Reporting program.

## TERAVOLT registry tracks outcomes of treatments among thoracic cancer patients with COVID-19

New data from TERAVOLT, a global consortium that tracks outcomes of people with thoracic cancers affected by COVID-19, could demonstrate why thoracic cancer patients experienced a high death rate of 33% when COVID-19 swept across Europe.

While the majority of those who died were hospitalized, only 9% were admitted to intensive care units, according to a study published June 12 in *The Lancet Oncology*. Most died from complications of COVID-19, not the progression of cancer.

"Just having a lung cancer diagnosis in and of itself shouldn't exclude patients

from care," senior author Leora Horn, Ingram Associate Professor of Cancer Research at Vanderbilt-Ingram Cancer Center and TERAVOLT consortium steering committee member, said in a statement.

The study is based on the first 200 patients for whom TERAVOLT received outcomes data. Of the 152 hospitalized patients, 134, or 88%, met the criteria for ICU admission, but only 13 of those patients were admitted to an ICU. Only five were mechanically ventilated.

Most of the patients were hospitalized in Italy, France and Spain. The study's lead author, Marina Garassino, of the National Cancer Institute of Milan, initiated the idea for the registry, which led to the TERAVOLT consortium (Thoracic cancERs InterAtional coVid 19 cOLlobaraTion).

"We tried to capture the reasons for the lack of ICU admission," the authors noted in the study. "Difficult decisions were made limiting ICU admissions to cancer patients and others with terminal illness due to equipment and personnel shortages. However, we are aware that behind these choices there may also be patients' decisions, cultural and institutional choices that our work is unable to properly capture."

"Not all lung cancer patients are at risk for hospitalization," Horn said.

Initial data indicated that patients on tyrosine kinase inhibitors appeared to be at decreased risk for hospital admission. This remained true when Horn presented updated data from the TERAVOLT registry last month at the virtual annual meeting of the American Society of Clinical Oncology. The data presented at the ASCO meeting were based on those first 200 patients in *The Lancet Oncology study*, plus an additional 200, including many from the United States.

That data revealed that patients treated with chemotherapy within three months of a COVID-19 diagnosis had a significantly increased risk—64%—of dying from the coronavirus. Patients treated with anticoagulants to prevent blood clots and corticosteroids to reduce inflammation also had a greater mortality risk. Patients treated with immunotherapies had no increased risk of mortality.

It remains unclear if intubation and more aggressive care could improve survival for people with thoracic cancers sickened by COVID-19. Patients preferences could provide guidance for clinicians.

The TERAVOLT registry is an ongoing longitudinal study. Data collected from consortium participants across the globe are entered on a REDCap database hosted by Vanderbilt. The registry recently received $95,000 in funding support from the International Association for the Study of Lung Cancer on behalf of the Lung Ambition Alliance.

## Immunotherapy clinical trial for COVID-19 open at Mount Sinai

Mount Sinai Health System is beginning the first clinical trial in the New York metropolitan region of an immune-boosting therapy in COVID-19 patients.

The phase II randomized trial is expected to recruit 66 patients to study peginterferon lambda in hospitalized patients receiving supplemental oxygen. Peginterferon lambda is injected under the skin as a single, one-time dose, and scientists believe it can help the immune system control the virus infection, decreasing the duration and severity of COVID-19.

"There is significant evidence from laboratory studies done here at Mount Sinai and abroad that patients' own immune systems are making inadequate amounts of interferon lambda—an alert signal the lungs normally send out to the immune system that a virus is present—when patients are infected with the coronavirus causing COVID-19," principal investigator Thomas Marron, assistant director of Early Phase and Immunotherapy Clinical Trials at The Tisch Cancer Institute at Mount Sinai, said in a statement. "As naturally occurring interferon lambda is the first line of defense against COVID-19, we have designed a clinical trial that will quickly determine whether treatment with peginterferon lambda will decrease the severity of COVID-19."

Scientists at Mount Sinai knew about peginterferon lambda from phase III trials for viral hepatitis and felt its antiviral properties would be beneficial to COVID-19 patients based on studies in mouse models. Scott Friedman, dean for Therapeutic Discovery at the Icahn School of Medicine at Mount Sinai, sought out the maker of the therapy, Eiger Biopharmaceuticals.

Together with Eiger, Friedman also sought funding from the COVID-19 Early Treatment Fund started by Silicon Valley entrepreneur and philanthropist Steve Kirsch, who in turn found matching funds from donors that include Corrigan Walla Foundation and David Baszucki, the founder and CEO of Roblox Corporation, and his wife, author Jan Ellison Baszucki. The total monetary donation was $500,000, and Eiger Biopharmaceuticals donated the drug for the trial.

Other sites are testing peginterferon lambda's effectiveness prophylactically and in outpatients with mild COVID-19 cases. Mount Sinai's Human Immune Monitoring Center, led by Miriam Merad, director of the Precision Immunology Institute at the Icahn School of Medicine at Mount Sinai, will perform extensive analysis of patients' blood to characterize the response to the peginterferon lambda, and help determine if it is effective in activating the immune system to attack the coronavirus.

IN BRIEF


## Siteman Cancer Center earns highest NCI rating

Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine in St. Louis received an "exceptional" rating from NCI during its site visit for 2020.

The evaluation resulted in a nearly perfect score from NCI.

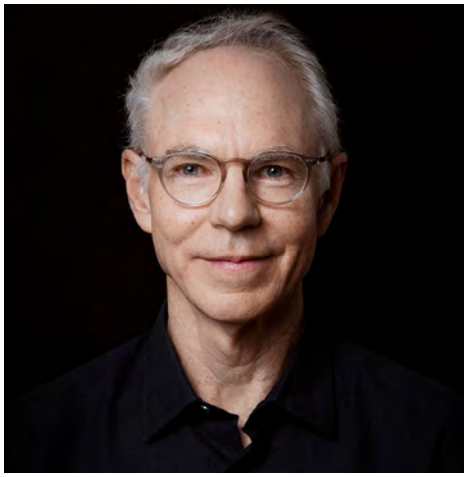
Siteman earned its latest exceptional rating based on a January site visit by 22 researchers and administrators from academic cancer centers across the U.S. During the visit, Washington University researchers and physicians presented research programs that included:

- Siteman's portfolio of more than 600 clinical studies and the cancer center's enrollment of more than 12,000 patients in clinical studies per year.
- Genomic research to identify personalized targets and create personalized vaccines.
- The use of ultrasound and photoacoustic imaging, which relies on light and sound rather than tissue samples, to diagnose ovarian cancer.
- Community-based research to understand and reduce cancer disparities and lessen the burden of cancer in our entire region.
- Improvements in colorectal cancer screening in urban and rural areas.
- The use of cellular therapies and CAR-T cell therapy to treat blood and bone marrow cancers.
- The development of novel immunotherapies for the prevention and treatment of cancer.
- Community outreach and education, and enhanced access to cancer care.
- The range of educational opportunities available at Siteman, from mentorships for high school and college students to advanced training for medical students and junior faculty.

Siteman was named Missouri's only NCI-designated Cancer Center in 2001 and the state's only Comprehensive Cancer Center in 2005. Today, Siteman treats more than 75,000 unique patients, including 12,000 newly diagnosed patients, every year.

## MSK's Charles L. Sawyers named AACR Academy president-elect

Charles L. Sawyers, chair of the Human Oncology and Pathogenesis Program at Memorial Sloan Kettering Cancer Center, was elected president-elect by the fellows of the American Association for Cancer Research for 2020-2021.



Sawyers will assume the presidency during the 2021 AACR annual meeting.

As the AACR Academy president-elect, Sawyers will work with the other members of AACR Academy's Steering Committee and other elected fellows of the AACR Academy to provide advice and counsel to the AACR leadership.

Sawyers investigates the signaling pathways that drive the growth and drug resistance of cancer cells. He played a critical role in developing the molecularly targeted cancer drug imatinib (Gleevec) for the treatment of chronic myeloid leukemia.

Sawyers' research into treatments for cancer that becomes resistant to established therapies led to the development of dasatinib (Sprycel) for patients with imatinib-resistant chronic myeloid leukemia and enzalutamide (Xtandi) for metastatic prostate cancer that has become resistant to docetaxel.

In addition to serving as chair of HOPP at MSK, Sawyers holds the Marie-Josée and Henry R. Kravis Chair in Human Oncology and Pathogenesis and is an internist and hematologic oncologist.

Sawyers, an AACR member since 1997, was elected as a fellow of the AACR Academy in 2014. He served as the president of the AACR from 2013-2014 and

as a member of the board of directors from 2003-2006.

Sawyers conceptualized AACR Project GENIE and has served as chair of the AACR Project GENIE Steering Committee since its inception in 2015. He received the AACR-Princess Takamatsu Memorial Lectureship (2019); the AACR Team Science Award (2015); the Dorothy Landon-AACR Prize for Translational Medicine (2009); and the AACR-Richard and Hinda Rosenthal Award (2005).

Sawyers was associate editor for the AACR scientific journals *Cancer Research* (2000-2004) and *Clinical Cancer Research* (2002-2006). Sawyers served as scientific editor for the AACR's journal *Cancer Discovery*.

## Postow, Merea, named to new positions at MSK

Michael Postow was named chief of the Melanoma Service in the Division of Solid Tumor Oncology, and Valeria Silva Merea was named director of the Speech and Hearing Center at Memorial Hospital and the David H. Koch Center for Cancer Care at Memorial Sloan Kettering Cancer Center.

Postow assumed his new role May 24. As chief of the Melanoma Service, he will oversee the ongoing strategic goals of the Melanoma Service to expand the clinical and research programs and activities in melanoma.

Valeria Silva Merea, a surgeon who specializes in caring for people with early laryngeal cancer, and voice, airway, and swallowing disorders, assumed her role in January 2020. She will expand clinical services and MSK's research program for patients with the full spectrum of speech, voice, airway, swallowing, and hearing disorders.

## Kunle Odunsi named SITC board member

Kunle Odunsi, deputy director of Roswell Park Comprehensive Cancer Center, was named an at-large director of the Society for Immunotherapy of Cancer Board of Directors.

The organization's members voted for Odunsi during their election in May. He will begin his three-year term in January 2021.

Odunsi is also the Robert, Anne & Lew Wallace Endowed Chair in Cancer Immunotherapy, executive director of the Center for Immunotherapy and M. Steven Piver Endowed Professor and chair of the Department of Gynecologic Oncology at Roswell Park.

A fellow of both the Royal College of Obstetricians and Gynaecologists in the United Kingdom and the American College of Obstetricians and Gynecologists, he holds lifetime membership in the National Academy of Medicine.

## Glenn D. Steele Jr. named chair of City of Hope board of directors

Glenn D. Steele Jr. was elected board chair of City of Hope, effective June 1.

Steele joined the City of Hope Board of Directors in January 2016. Prior to becoming chair, he was chair of the Ex-

ecutive Compensation and Governance Committee from 2018-2020.

Selwyn Isakow, founder and chief executive officer of The Oxford Investment Group, is the immediate past chair.

His investigations have focused on the cell biology of gastrointestinal cancer and pre-cancer and, most recently, on innovations in health care delivery and financing.

Steele serves as chairman of GSteele Health Solutions, an independently-operated venture launched to help health care organizations create value and improve quality. He is the former chairman of xG Health Solutions and former president and chief executive officer of Geisinger Health System, an integrated health services organization recognized for its innovative use of the electronic health record and the development and implementation of care models.

Steele is past chairman of the American Board of Surgery, and serves on for-profit and not-for-profit boards and national committees, including vice chair of Health Transformation Alliance, Bucknell University Board of Trustees as an emeritus trustee, Stanford Board of Fellows, Peterson Center on Healthcare Advisory Board, and serves as an adviser on the private equity firms of General Atlantic and LRVHealth.

Steele is a member of the National Academy of Medicine and has served as the dean of the Biological Sciences Division and the Pritzker School of Medicine and vice president for medical affairs at University of Chicago, as well as the Richard T. Crane Professor in the Department of Surgery. Prior to that, he was the William V. McDermott Professor of Surgery at Harvard Medical School.

## David Cortez named associate director of basic science research at VICC

David Cortez was named associate director for Basic Science Research at Vanderbilt-Ingram Cancer Center.

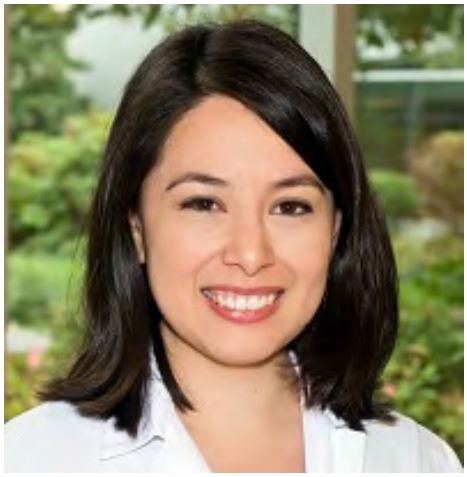
Cortez, the Richard Armstrong Professor of Biochemistry, joined Vanderbilt University in 2002. He is an expert in the field of DNA damage response and repair and made seminal discoveries about the mechanisms that maintain genome integrity.

Cortez is a member of the editorial boards for *Cell Reports* and *Molecular and Cellular Biology*. Cortez has been a co-leader of the Genome Maintenance Research Program since its inception in 2007 at VICC, and served as director of Graduate Studies in the Department of Biochemistry at Vanderbilt University for eight years.

Cortez replaces Scott Hiebert, professor of biochemistry and Hortense B. Ingram Professor of Cancer Research, who has served in the role since 2008. Hiebert is a member of the National Cancer Advisory Board.

Hiebert will continue in his role as associate director for shared resources and another interim leadership role to be announced soon. He will continue to focus on the molecular mechanisms of acute leukemia and the action of tumor suppressors in his own research program.

## Jessica Karen Wong joins Fox Chase



Jessica Karen Wong will join Fox Chase Cancer Center July 1 as assistant professor in the academic clinical track in the Department of Radiation Oncology.

Wong will join the staff upon completion of her radiation oncology residency program at Fox Chase, where she served as chief resident last year and won the RSNA Roentgen Resident/Fellow Research Award.

Before attending medical school, Wong earned her masters of engineering in biomedical engineering from the Harvard-MIT Division of Health Sciences and Technology. She received her medical degree from the University of Tennessee College of Medicine on multiple scholarships.

## OSUCCC – James Cancer Diagnostic Center speeds up diagnosis, treatment

A new center at The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute gives patients direct, expedited access to diagnostic testing for cancer.

The center's goal is to provide immediate community-wide patient access to cancer providers for anyone with a suspected cancer, especially in communities where access to healthcare is limited and has become more challenging during the COVID-19 pandemic.

The James Cancer Diagnostic Center offers a platform for expert evaluation and access to the appropriate diagnostic testing so that a cancer diagnosis can be made in a timely and precise manner, in a low-risk environment. Center visits can be virtual or in-person based on the patient's preference.

Launched on June 15, the Cancer Diagnostic Center is open daily and staffed by a team of advanced practice professionals and nurses who have expertise in oncology. The team is overseen by physicians with oncology experience and expertise.

The center is available for both self- or physician-referral. Center staff first identify and prioritize patient needs and concerns and then coordinate appropriate testing and evaluation on behalf of the patient at facilities within The James and the Ohio State Wexner Medical Center. Follow-up care is also coordinated with a specialized, multidisciplinary team at The James if a cancer diagnosis is made.

## Roswell Park dermatology expert Oscar Colegio dies at 47

Oscar Colegio, the Lawrence P. & Joan Castellani Family Endowed Chair in Dermatology at Roswell Park Comprehensive Cancer Center, died unexpectedly last weekend at a family residence in Connecticut. He was 47.

Colegio relocated to Buffalo when he was recruited to head Roswell Park's dermatology program in 2018. He had previously served as associate professor of dermatology, pathology and surgery at Yale University.

"Our hearts are with Dr. Colegio's family," Roswell Park President and CEO Candace S. Johnson, said in a statement. "In only two years' time, he became a dear friend, trusted physician and valued colleague to so many. He embraced his adoptive home of Buffalo and the Elmwood Village with warmth and friendship. Given who Oscar was personally and professionally, all that he accomplished and the passion with which he pursued his work, this loss leaves an enormous hole."

A clinician and scientist with more than 20 years of experience, Colegio was president of the International Immunosuppression and Transplant Skin Cancer Collaborative, a professional society dedicated to understanding skin cancer in organ transplant recipients.

He specialized in cutaneous squamous cell carcinoma, basal cell carcinoma, melanoma, immunology, immunodeficiency-associated skin cancers and solid organ transplantation. Consistently named to the national Top Doctors list, he earned doctoral and medical degrees from Yale University in New Haven, Connecticut.

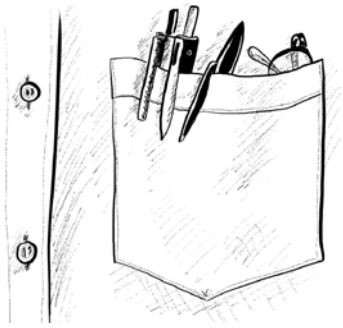
Colegio is survived by his wife, Brenda, and two sons, Otto and Austin. A fund will be established in his name to support research on cancers of the skin. A gift in his memory may be designated to the fund here.

**FOLLOW US ON LINKED-IN**

linkedin.com/company/The-Cancer-Letter

THE CANCER LETTER | JUNE 19, 2020 | VOL 46 | ISSUE 25

THE CLINICAL CANCER LETTER



TRIALS & TRIBULATIONS

# Mobile pharmacies—driving down rural cancer care disparities

**Justin Floyd DO, FACOI**
*Cancer Care Specialists of Illinois*

**James L. Wade III MD, FACP, FASCO**
*Cancer Care Specialists of Illinois*

**Allison Braden, PharmD**
*Cancer Care Specialists of Illinois*

People living in rural communities are often located far away from the major cancer centers that offer a full spectrum of treatments, including clinical trials.

This distance barrier makes cancer patients vulnerable to disparities in care. Delivering cancer care to patients in or near the rural communities in which they reside reduces barriers and improves access.

Unaddressed, these barriers ultimately may prevent patients from pursuing cancer care or perhaps even more significantly, keep them from participating in cancer research trials.

One strategy to address this disparity is the implementation of central hubs housing personnel and resources that can radiate towards rural communities. In practice and principal, this has been demonstrated to be an effective tactic to deliver state of the art care to cancer patients in their home communities.

However, in order to improve efficiency and benefit for patients, this strategy must be continously evolving. A recent step in the evolution of this model of care has resulted in the development and implementation of a mobile, USP 800 compliant, compounding pharmaceutical vehicle... a "mobile pharmacy."


Cancer Care Specialists of Illinois, a founding member of Heartland Cancer Research NCORP, has designed, developed, and launched a first of its kind mobile pharmacy. This vehicle resides in a rural hub where it is stocked and serviced daily by a ground crew, preparing it for daily travel to more remote rural clinics.

Upon arrival at a rural satellite clinic, the pharmacy allows a traveling oncologist to see patients and deliver anti-neoplastic agents to patients in their hometown, in real time.

Regulations around drug compounding continue to evolve to ensure safety to patients and health care providers. These new regulations are not easy to implement, are expensive, and may require special staff and equipment for compliance, none of which are necessarily readily available in rural communities.

Mobile pharmaceutical services allow these complex services to be rolled out in smaller communities without having to build infrastructure in a rural community that may only require such infrastructure one day a week.

Mobile pharmaceutical services reduce the waste of high cost medications. Wastage of such pharmaceutical agents results in a negative economic and environmental effect. Compounding high cost pharmaceutical products centrally and bringing the compounded product to the patient has proven to be effective.

However, issues including shelf life of the compounded product, patient compliance, and newly identified drug toxicity all add significant risk to a compounded agent being successfully delivered to the patient. Once compounded, if not administered, the cost of the drug must be paid without reimbursement. In addition, the environmental effects of the waste created will be realized without any benefit to the patient.

Mobile pharmaceutical services allow the drug to be delivered in the uncompounded state to the patient and compounded on-site once the patient has been evaluated and is deemed fit for therapy. This "real time" drug compounding is the process by which chemotherapy is typically compounded and administered in cancer centers.

Mobile pharmaceutical services assure that the same level of pharmacy care demanded by QOPI certification at the practice's main hubs are now available to patients in rural clinics. The pharmacy ordering and verification process is run through the EPIC EHR system, just like in a centralized cancer center. Vial tracking, labeling, coding, and billing are also performed in EPIC, assuring patients are receiving and being billed for the correct treatment.

Finally, mobile pharmaceutical services increase patient access to therapeutic clinical trials since investigational drugs can be compounded on site in a USP 800 compliant pharmacy. Although many patients in rural communities receive standard of care therapeutic agents for cancer, they may be required to travel to a central site to participate in a therapeutic treatment trial.

Mobile pharmaceutical service providers, working closely with the Heartland NCORP, allow for compounding of investigational agents, by trained research study pharmaceutical staff on-site for real-time delivery of investigational agents close to home.

This assures that NCI, FDA, and science base pharmacy tracking requirements are met, while improving access to cancer research. The mobile pharmacy program is one additional step in closing the divide between cancer outcomes in rural vs urban patients (1).

Providing excellent cancer care to patients close to home continues to be an integral part of oncology care. Innovation has and will continue to advance this initiative. Keep an eye out—you may see us roll into a community near you.

## References

1. *Unger, J, et al. JAMA Netw Open. 2018;1(4):e181235. doi:10.1001/jamanetworkopen.2018.1235*

CLINICAL ROUNDUP

## LLS, NCI and Children's Oncology Group collaborate on global master clinical trial for acute leukemia

NCI, The Leukemia & Lymphoma Society and the Children's Oncology Group plan to develop a global precision medicine clinical trial for children with acute leukemia.

The new study, called LLS PedAL (Pediatric Acute Leukemia), is a master clinical trial that will test simultaneously multiple targeted therapies for children who experience a relapse of their acute leukemia, experienced by approximately 40% of children with AML, and 20% of children with high-risk acute lymphoblastic leukemia.

The study will take place at more than 200 sites that are part of the NCI-supported COG network of children's hospitals, including those in the U.S., Australia, New Zealand, and Canada. The LLS PedAL team will also collaborate with other overseas partners in the UK and EU to implement the trial in those regions. Through these established clinical trial infrastructures, nearly every child in these regions who experiences a relapse of acute leukemia will have access to the trial.

LLS PedAL is a key component of The LLS Children's Initiative, the society's $100 million multi-year endeavor to attack pediatric blood cancer from every direction: research grants to advance novel treatments for children, enhanced free education and support services for children and their families, and new policy and advocacy efforts.

LLS led the Beat AML Master Clinical Trial, a precision medicine trial for adults with acute myeloid leukemia. The trial tested novel targeted therapies and identified disease subtypes based on specific biomarkers. Then, researchers matched them with treatments best suited for their diagnosis. A similar model will be used in the LLS PedAL trial, which will match children whose acute leukemia has returned with targeted therapies.

Before the LLS PedAL trial can launch, LLS must secure approval from FDA to begin testing therapies in patients. LLS will be responsible for regulatory submissions to the FDA and will be the Investigational New Drug holder. LLS plans to submit its IND application to the FDA later this year.

The NCI Pediatric Central Institutional Review Board will review all protocols for all of the sites in the COG network before the trial begins. The COG Data Safety Monitoring Committee will provide oversight once the trial is underway.

"Many targeted therapies have been approved to treat adults with acute leukemia over the past decade, but few have been sufficiently studied in children to demonstrate their benefit. This study will give us the opportunity to learn what new targeted therapies are effective for children with acute leukemias," E. Anders Kolb, Nemours Center for Cancer and Blood Disorders, chair of the COG Myeloid Disease Committee, and LLS Pedal co-chair, said in a statement.

The LLS PedAL trial will launch with three novel therapies to treat children with relapsed acute leukemia, with plans to add additional treatments as they become available. The study will ensure that every child with relapsed AML and many with ALL will be screened to identify their disease subtype and matched to the most appropriate treatment. Some of these patients will participate in LLS PedAL substudies, while others will be referred to other treatments, including other open clinical trials based on discussions with their physicians.

The LLS PedAL trial will include a technology platform to enable participating institutions to consolidate, share and analyze data about pediatric blood cancer patients using standardized terminology. The data will help doctors better understand how children will respond to novel therapies, and the underlying causes of resistance or relapse.

## Research and framework for genetic testing in prostate cancer supports broader use of panels, testing in early stage disease

New recommendations from a large, multidisciplinary consensus conference published this week in the *Journal of Clinical Oncology* suggest expanding use of genetic testing to guide treatment for men with prostate cancer, including the use of panel testing and testing patients with early stage disease.

The full consensus statement can be found in the *Journal of Clinical of Oncology*.

Taken together with research recently presented by Invitae, the publications underscore the utility of increased access to genetic testing for men with prostate cancer across all stages of disease.

Invitae was among the non-voting sponsors of the conference, which gathered more than 100 experts across a number of specialties with the goal of developing recommendations for how clinicians can use genetic testing to help patients benefit from precision medicine approaches to prostate cancer.

"This framework provides a very thoughtful approach to implementing genetic testing for prostate cancer treatment, screening and family testing," Sarah Nielsen, a medical affairs liaison at Invitae who previously participated in the conference, said in a statement.

"Importantly, the framework recognizes that changes in a number of different genes can increase prostate cancer risk and therefore encourages greater use of panel testing for men with metastatic disease," Nielsen said. "With new precision therapies linked to specific genetic changes, increased genetic testing can help identify patients who could benefit from these approaches."

Among the consensus conference recommendations:

- Larger panels are useful for patients with metastatic disease
- Large germline panels and somatic testing were recommended for patients with metastatic prostate cancer. Of the approximately 12-17% of men with metastatic prostate cancer who harbor germline variants, the majority are found in DNA damage repair genes such as BRCA1, BRCA2, ATM, CHEK2, PALB2, and the DNA mismatch repair genes. Large panels provided information across these and other genes of significance, information which is increasingly informing options for PARP inhibitors, immune checkpoint inhibitors, platinum chemotherapy, and clinical trials.
- Genetic information can support early diagnosis and inform disease surveillance
- Germline test results are increasingly important for early detection, as men with BRCA2 variants exhibit higher rates of prostate cancer, often with a younger age at diagnosis and more clinically significant disease. Among patients with early-stage disease, emerging data suggest that men with germline BRCA2 mutations and possibly ATM mutations have higher rates of upgrading of prostate biopsies while on active surveillance, suggesting the utility of genetic information in shaping surveillance strategies after diagnosis.
- Importance of using genetic information requires novel strategies to increase access to counseling resources
- The guidelines recommend broad access to genetic counseling support but shortages of genetic counselors and wait times for traditional genetic counseling workflows will require development of alternate models for timely and responsible delivery of genetic testing for men and their families. The consensus framework provides suggestions for clinicians on how to counsel and provide alternatives to traditional in-person appointments for patients across a number of issues related to testing, including using pretest education materials and the use of telehealth genetic counseling sessions.

A study presented at the American College of Medical Genetics and Genomics online annual meeting further underscored the frequency of actionable variants expanded testing can help uncover.

The study of 2,252 men who participated in Invitae's Detect Prostate Cancer program found an overall positive rate of 13% with no statistical differences in rates among stages of disease. Only half of patients with an actionable variant reported a family history suggestive of increased risk. Nearly three-quarters (71%) of positive patients were eligible for management guidelines and/or potentially eligible for approved precision therapies or clinical trials. These data suggest that broader testing criteria and greater access to testing leads to better informed care for patients and their families.

The consensus conference noted the need for additional research into the associations between genetics and prostate cancer in African-American men, who are 1.8 times more likely to be diagnosed with and 2.2 times more likely to die from prostate cancer. Importantly, this study included 16% participation among African-Americans, which is greater participation than previous similar studies, aligning to the consensus conference research priorities.

## Berzosertib shows promise in first clinical trial

In a phase II clinical trial, patients with high-grade serous ovarian cancer who were treated with berzosertib and chemotherapy lived substantially longer than did those treated with chemotherapy alone.

Researchers at Dana-Farber Cancer Institute are conducting the study. The findings were published in *The Lancet Oncology*.

"Our results in this phase II trial suggest that ATR inhibition in combination with chemotherapy has the potential to offer

significant benefit to patients with chemotherapy-resistant HGSOC and, potentially, other tumor types where ATR plays a key role," lead author Panagiotis Konstantinopoulos, director of translational research, Gynecologic Oncology, at Dana-Farber, said in a statement.

In the study, investigators at 11 cancer centers around the country enrolled 70 patients with HGSOC that was resistant to platinum-based chemotherapy. Half the participants were randomly assigned to receive the standard chemotherapy agent gemcitabine alone and half received gemcitabine in combination with berzosertib.

"The unbridled growth of cancer cells places enormous stress on the process of DNA replication," Konstantinopoulos said. "ATR helps them survive that stress: its job is to coordinate the halting of the cell cycle to check if the DNA is intact or needs repair. Drugs that inhibit ATR – that deprive tumor cells of such repair – have the potential to be particularly effective in some cancers."

The estimated median progression-free survival of patients receiving gemcitabine alone – the period in which their disease was in retreat or stable—was 14.7 weeks. For those receiving gemcitabine and berzosertib, it was 22.9 weeks. Among patients with the most platinum resistant tumors (i.e. those who had progressed within 3 months from prior platinum-based chemotherapy), the difference was even greater: 9 weeks for gemcitabine versus 27.7 weeks for gemcitabine and berzosertib.

## Tecentriq improves response rate in early TNBC

The phase III IMpassion031 study, evaluating Tecentriq (atezolizumab) in combination with chemotherapy (Abraxane [albumin-bound paclitaxel, nab-paclitaxel]; followed by doxorubicin and cyclophosphamide) in comparison to placebo plus chemotherapy (including Abraxane), met its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in pathological complete response for the treatment of people with early triple-negative breast cancer, regardless of PD-L1 expression.

Tecentriq is sponsored by Genentech, a member of the Roche Group.

In the study, fewer patients who received the Tecentriq combination as a neoadjuvant (before surgery) treatment had evidence of tumor tissue detectable at the time of surgery, regardless of PD-L1 expression, in comparison to the control arm.

Safety for the Tecentriq combination appeared to be consistent with the known safety profiles of the individual medicines and no new safety signals were identified.

The IMpassion031 study is the second positive phase III study from Genentech demonstrating the benefit of Tecentriq in TNBC, and the first Tecentriq study to demonstrate benefit in early TNBC. Tecentriq in combination with nab-paclitaxel is approved in more than 70 countries, including the U.S. and across Europe, for the treatment of adults with unresectable locally advanced or metastatic TNBC in people whose tumors express PD-L1 (IC≥1%).

## ACE-CL-001, ASCEND trials demonstrate long-term efficacy and tolerability of Calquence in CLL

In the ACE-CL-001 trial, data showed 97% of previously untreated CLL patients continued to respond to treatment after more than four years with no new safety signals.

In the pivotal ASCEND trial, an estimated 82% of CLL patients with relapsed or refractory disease treated with Calquence remained progression free at 18 months vs. 48% for comparators. Overall, Calquence data delivered meaningful long-term clinical benefit with a favorable safety profile for patients with CLL, regardless of whether they're new to treatment or are managing relapsed or refractory disease.

A link to the ACE-CL-001 trial abstract can be found here, and the ASCEND trial abstract here.

## Blood test to monitor cancer is up to 10 times more sensitive than current methods

A method of analysing cancer patients' blood for evidence of the disease could be up to 10 times more sensitive than previous methods, according to research funded by Cancer Research UK and published in *Science Translational Medicine*.

The technique uses personalized genetic testing of a patient's tumour to search blood samples for hundreds of different genetic mutations in circulating tumour DNA. The researchers and their collaborators studied samples from 105 cancer patients, testing the method on small sets of patients with five different cancer types, with both early and late stage disease.

The method detected ctDNA at high sensitivity in patients with advanced breast and melanoma cancer, and in patients with glioblastoma, which is notoriously difficult to detect in blood. The test was also able to detect ctDNA in patients with earlier-stage disease,

where the level of ctDNA in the blood is much lower and difficult to find. This included patients with lung or breast cancer, as well as patients with early-stage melanoma who had already had surgery, which makes detection even more difficult.

In the coming years, this method and others based on this approach could lead to tests that more accurately determine if a patient is likely to relapse after having treatment, and could pave the way for the development of pinprick home blood tests to monitor patients.

Combined with new methods to analyze this data to remove background noise and enhance the signal, the team were able to reach a level of sensitivity that in some cases could find one mutant DNA molecule amongst a million pieces of DNA—approximately ten times more sensitive than previous methods.

"Personalised tests that can detect if cancer is still present, or find it early if it is returning, are now being tested in clinical trials," Nitzan Rosenfeld, senior group leader at the Cancer Research UK Cambridge Institute who led the team at the University of Cambridge that conducted this research, said in a statement.

"Whilst this may be several years away from clinical use, our research shows what is possible when we push such approaches to an extreme. It demonstrates that the levels of sensitivity we've come to accept in recent years in relation to testing for ctDNA can be dramatically improved. At present this is still experimental, but technology is advancing rapidly, and in the near future tests with such sensitivity could make a real difference to patients," Rosenfeld said.

Liquid biopsies to monitor cancer can become much more sensitive. Until recently, personalized liquid biopsies have searched for around 10-20 mutations in the blood and up to around 100 at most. In the material from a tube of blood, these would be able to detect ctDNA to levels on the range of 1 mutant molecule amongst 30,000 pieces of DNA.

This new technique looks for hundreds and sometimes thousands of mutations in each blood sample, routinely achieving a sensitivity of one mutant molecule per 100,000, and under optimal conditions can reach a level measured in parts per million.

In ongoing studies funded by Cancer Research UK, the team and their collaborators plan to use this method to measure ctDNA levels in individuals who are at high risk of developing cancer to help refine future tests for cancer early detection.

**FOLLOW US ON FACEBOOK**

facebook.com/TheCancerLetter

**FOLLOW US ON TWITTER**

@TheCancerLetter

**NEVER MISS AN ISSUE!**

Get e-mail alerts now.

CLICK HERE

or sign-up at: https://cancerletter.com/mailing-list/

DRUGS & TARGETS

# Keytruda receives second biomarker-based indication from FDA, regardless of tumor type

Keytruda was approved by FDA as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/ megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. The safety and effectiveness of Keytruda in pediatric patients with TMB-H central nervous system cancers have not been established.

FDA also approved the FoundationOne CDx test as the companion diagnostic to identify patients with solid tumors that are TMB-H (≥10 mutations/ megabase) who may benefit from immunotherapy treatment with KEYTRUDA monotherapy.

"These approvals stem from years of research into how TMB levels may influence a patient's response to immunotherapy," Brian Alexander, chief medical officer of Foundation Medicine said in a statement. "It's critical that healthcare professionals have access to a validated genomic test to measure TMB in clinical tumor assessments and pinpoint those who are more likely to respond. We're proud to be collaborating with Merck to help match appropriate patients to this important treatment."

The accelerated approval was based on data from a prospectively-planned retrospective analysis of 10 cohorts (A through J) of patients with various previously treated unresectable or metastatic solid tumors with TMB-H, who were enrolled in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label trial evaluating KEYTRUDA (200 mg every three weeks).

The trial excluded patients who previously received an anti-PD-1 or other immune-modulating monoclonal antibody, or who had an autoimmune disease, or a medical condition that required immunosuppression. TMB status was assessed using the FoundationOne CDx assay and pre-specified cutpoints of ≥10 and ≥13 mut/Mb, and testing was blinded with respect to clinical outcomes. Tumor response was assessed every nine weeks for the first 12 months and every 12 weeks thereafter. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR) in the patients who received at least one dose of KEYTRUDA as assessed by blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, modified to follow a maximum of 10 target lesions and a maximum of five target lesions per organ.

In KEYNOTE-158, 1,050 patients were included in the efficacy analysis population. TMB was analyzed in the subset of 790 patients with sufficient tissue for testing based on protocol-specified testing requirements. Of the 790 patients, 102 (13%) had tumors identified as TMB-H, defined as TMB ≥10 mut/Mb. The study population characteristics of these 102 patients were: median age of 61 years (range, 27 to 80); 34% age 65 or older; 34% male; 81% White; and 41% Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) of 0 and 58% ECOG PS of 1. Fifty-six percent of patients had at least two prior lines of therapy.

In the 102 patients whose tumors were TMB-H, KEYTRUDA demonstrated an ORR of 29% (95% CI, 21-39), with a complete response rate of 4% and a partial response rate of 25%. After a median follow-up time of 11.1 months, the median DOR had not been reached (range, 2.2+ to 34.8+ months). Among the 30 responding patients, 57% had ongoing responses of 12 months or longer, and 50% had ongoing responses of 24 months or longer.

In a pre-specified analysis of patients with TMB ≥13 mut/Mb (n=70), KEYTRUDA demonstrated an ORR of 37% (95% CI, 26-50), with a complete response rate of 3% and a partial response rate of 34%. After a median follow-up time of 11.1 months, the median DOR had not been reached (range, 2.2+ to 34.8+ months). Among the 26 responding patients, 58% had ongoing responses of 12 months or longer, and 50% had ongoing responses of 24 months or longer. In an exploratory analysis in 32 patients whose cancer had TMB ≥10 mut/Mb and <13 mut/Mb, the ORR was 13% (95% CI, 4-29), including two complete responses and two partial responses.

## FoundationOne CDx receives FDA approval as companion diagnostic with Keytruda

FoundationOne CDx has received FDA approval as a companion diagnostic for Keytruda (pembrolizumab), Merck's anti-PD-1 therapy.

FoundationOne CDx was also approved under accelerated approval for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

FoundationOne CDx is sponsored by Foundation Medicine.

FoundationOne CDx is the first and only FDA-approved companion diagnostic to measure TMB and help identify patients who may be appropriate for treatment with Keytruda, regardless of solid tumor type.

FoundationOne CDx, Foundation Medicine's comprehensive genomic profiling assay approved for all solid tumors, enables oncologists to identify TMB-H patients (≥ 10 mutations/megabase) with unresectable or metastatic solid tumors across all tumor types who could potentially benefit from Keytruda.

FoundationOne CDx is the first FDA-approved CGP test that is clinically and analytically validated for all solid tumors and incorporates multiple companion diagnostic claims. It is currently approved as the companion diagnostic test for more than 20 therapies across multiple cancer types.

## Lurbinectedin receives accelerated approval by FDA for metastatic SCLC

Lurbinectedin (Zepzelca) was granted accelerated approval by FDA for adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy.

Zepzelca is sponsored by Pharma Mar S.A.

Efficacy was demonstrated in the PM1183-B-005-14 trial (Study B-005; NCT02454972), a multicenter open-label, multi-cohort study enrolling 105 patients with metastatic SCLC who had disease progression on or after platinum-based chemotherapy. Patients received lurbinectedin 3.2 mg/m2 by intravenous infusion every 21 days until disease progression or unacceptable toxicity.

The main efficacy outcome measures were confirmed overall response rate, determined by investigator assessment using RECIST 1.1 and response duration. Among the 105 patients, the ORR was 35% (95% CI: 26%, 45%), with a median response duration of 5.3 months (95% CI: 4.1, 6.4). The ORR as per independent review committee was 30% (95% CI: 22%, 40%) with a median response duration of 5.1 months (95% CI: 4.9, 6.4).

## Gemtuzumab ozogamicin receives extended indication for CD33-positive AML in pediatric patients

Gemtuzumab ozogamicin (Mylotarg) was granted an extended indication by FDA for newly-diagnosed CD33-positive acute myeloid leukemia to include pediatric patients 1 month and older.

Mylotarg is sponsored by Wyeth Pharmaceuticals LLC.

Efficacy and safety in the pediatric population were supported by data from AAML0531 (NCT00372593), a multicenter randomized study of 1,063 patients with newly-diagnosed AML ages 0 to 29 years. Patients were randomized to five-cycle chemotherapy alone or with gemtuzumab ozogamicin (3 mg/m2) administered once on day 6 in Induction 1 and once on day 7 in Intensification 2.

The main efficacy outcome measure was event-free survival measured from the date of trial entry until induction failure, relapse, or death by any cause. The EFS hazard ratio was 0.84 (95% CI: 0.71-0.99). The estimated percentage of patients free of induction failure, relapse, or death at five years was 48% (95% CI: 43%-52%) in the gemtuzumab ozogamicin + chemotherapy arm versus 40% (95% CI: 36%-45%) in the chemotherapy alone arm. No difference between treatment arms in overall survival was demonstrated.

## City of Hope signs licensing agreement with Scopus BioPharma to develop novel, targeted IO gene therapy

City of Hope has signed an exclusive worldwide licensing agreement with Scopus BioPharma Inc. to develop and commercialize a City of Hope first-in-class, targeted immuno-oncology gene therapy.

A first in-human phase I clinical trial for B cell lymphoma patients that uses the

licensed gene therapy drug, CpG-STAT-3siRNA, a STAT3 inhibitor, is expected to commence at City of Hope in the second half of this year.

Growing evidence links B cell non-Hodgkin lymphomas to persistent activation of STAT3, a gene that drives tumor cell growth and anti-tumor immune suppression. The STAT3 inhibitor is a highly selective and targeted therapy that silences the activity of the STAT3 gene by way of RNA interference. It also stimulates the TLR9 receptors to activate the body's immune defense to recognize and kill cancer cells.

In preclinical testing at City of Hope, the STAT3 inhibitor has successfully reduced growth and metastasis of various preclinical tumor models, including melanoma, and colon and bladder cancers, as well as leukemia and lymphoma.

City of Hope's Hua Yu, Billy and Audrey L. Wilder Professor in Tumor Immunotherapy, associate chair/professor in the Department of Immuno-Oncology, and co-leader of the Cancer Immunotherapeutics Program, and Marcin Kortylewski, associate professor in the Department of Immuno-Oncology, who are both leading experts in the role of STAT3 in tumor angiogenesis and tumor immune evasion and in oligonucleotide-based cancer immunotherapies, developed the STAT3 inhibitor.

The strategy was developed based on seminal discoveries by Yu's team defining the key role of STAT3 in cancer cell survival and immune tolerance, combined with pioneering work by Kortylewski's team on STAT3 targeting using TLR9-targeted delivery of siRNA oligonucleotide therapeutics into immune cells.

"STAT3 is critical for the survival and metastasis of cancer cells, and for suppressing anti-tumor immune responses," Yu said in a statement.

"Our laboratories were the first to demonstrate that successful cancer immunotherapy needs to be two-step since TLR9 immunostimulation is only effective when STAT3 in the tumor microenvironment is no longer active," Kortylewski said in a statement. "It is exciting to see this technology approaching clinical application with a strong ally in biopharma."

## Royal Philips and MD Anderson to facilitate personalized oncology treatments and clinical trial matching based on genomic markers

The University of Texas MD Anderson Cancer Center and Royal Philips are providing oncologists with evidence-based therapy and clinical trial guidance through Philips' oncology informatics solutions and MD Anderson's Precision Oncology Decision Support system.

This collaboration will allow physicians around the world to personalize therapy based on the patient's genomic profile, with the aim of improving patient care.

MD Anderson developed the PODS system as an evidence-based tool to facilitate therapeutic decision-making at the point of care. The system provides actionable clinical information, including approved therapies and available clinical trials, based upon genetic alterations within the tumor. Through the Philips solutions, clinicians receive a unified view of therapies and clinical trials in the context of their patient's unique tumor, helping them make an evidence-based decision for their patient's treatment.

Philips and MD Anderson aim to help pathologists and oncologists serve their patients and provide them with therapeutic options and relevant clinical trials based on tumor markers.

## Isoray, University of Cincinnati physicians company sign research agreement to study head and neck cancers

Isoray Inc. has entered a research grant agreement with the University of Cincinnati Physicians Company for a study on treatment of recurrent head and neck cancers.

University of Cincinnati Physicians Company is the multispecialty practice group for University of Cincinnati College of Medicine and UC Health.

The planned trial will evaluate the safety and early effectiveness of the addition of Keytruda (pembrolizumab) to the regimen of Cesium-131 with surgical resection. A total of 50 patients whose head and neck cancers have recurred and who are eligible for surgical resection are planned to be enrolled.

The study, a trial combining Keytruda and Cesium-131 brachytherapy with salvage surgery in head and neck squamous cell carcinoma, will be carried out under the direction of principal investigators Shuchi Gulati and Chad Zender at the University of Cincinnati Medical Center. There is potential for other centers to participate in the study.

A previous multi-institutional study has provided evidence that the use of Cesium-131 with surgical resection is well-tolerated in the treatment of recurrent head and neck cancers.