How is our isolated existence different from a month ago? In many ways... we know a lot more about COVID-19; much still to learn, but lessons are emerging:

- Predictions about social distancing flattening the incidence curve have proven correct. The case load has been attenuated, and along with it, the death rate. Across the US, the will of the majority has been exercised with rare unity of purpose. Now we know that it may have protected especially the weakest, the oldest members of society.

- Global awareness increased as lessons were gleaned from the preparations and responses across the world. The immediate interventions in Korea, where we have several EA members, were rewarded with a return to normalcy after low mortality as we write. However, we have much to learn regarding how, with similarly excellent health systems, high mortality was experienced through Italy, France, Spain and Portugal.

- On the principle that “bad news travels fast,” it seems reasonable to conclude that cancer patients seem no more susceptible to coronavirus infection, nor, when infected, is their outcome much worse. And, though the limited literature is conflicting, there seems no deleterious interaction between checkpoint inhibitors and viral infection. We hope that the many studies ongoing will be able to quickly reassure patients and physicians.

- Finally, perhaps as a result of an enforced contemplative existence, we are in general more accepting of social distancing, a practice that may need to continue for a long time. We are reminded that the flu epidemic at the end of World War I continued, with peaks and valleys, for three years. We will be thoughtful about our interactions through a similar period of time.

But our greatest change from ten weeks ago, when normalcy, security, and the economy simply dissolved before us, is a growing confidence that this condition can be managed, both at a societal level (who knew that epidemiologists would be rock stars?), and for the most part at a patient level. Introspection yields to the demands of the quotidian. Welcome back, EA members who have re-opened clinical research activities. Welcome back, research nurses and data coordinators who relish re-engaging with their patients and studies. Welcome back, laboratory colleagues, whose work underpins our protocols (and powers local economies). As we all hit the “restart” button, let’s appreciate being able to exercise our chosen profession in however much of the pre-COVID environment we can reconstruct. We have work to do!

In this issue, we call attention to a timely initiative led by our colleagues at the NCI: a clinical study of people with cancer who have COVID-19. NCI will provide full reimbursement for each patient enrolled on this study, called COVID-19 in Cancer Patients Study (NNCAPS). With sorrow, we remember Valerie Guild, founder and president of AIM at Melanoma and a patient advocate on our Melanoma Committee for more than a decade. We also share emotional support resources that may prove helpful as we navigate the demands of providing health care in the era of COVID-19. And, this month we highlight the Indiana University Melvin and Bren Simon Comprehensive Cancer Center. Led by Kathy Miller, MD, Indiana University has been a leader in ECOG-ACRIN since they joined in 1986.
Now Enrolling: FEATURE (EA1183) – FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer

The FEATURE study is an imaging trial for patients with bone dominant (BD) metastatic breast cancer (MBC). Co-led by Dr. Jennifer Specht (Fred Hutch/University of Washington, pictured here, left) and Dr. Heather Jacene (Dana-Farber, pictured here, right), FEATURE is evaluating whether FDG-PET/CT imaging can be used to serially measure and classify the response of bone metastases from breast cancer to systemic therapy. The study team will assess if the categories of metabolic response measured by FDG-PET/CT are predictive of key clinical endpoints: progression free survival (PFS), time to skeletal related events (SRE), and overall survival (OS).

Importantly, successful completion of FEATURE will allow for patients with BD MBC – who are often excluded from clinical trials – to participate in multicenter studies, resulting in improved outcomes and survival for patients with breast cancer. Additionally, accurate response criteria will permit discontinuation of ineffective therapies at an earlier time point, which may result in less toxicity, cost, and improved outcomes for patients who switch to more effective therapies.

Patients with BD MBC who are beginning new systemic therapy are eligible for this trial. FDG-PET/CT will be obtained at baseline, after which patients will then start new systemic therapy at the discretion of their local physician/investigator. Patients will be followed with standard of care (SOC) imaging at 12-week intervals for 4 intervals then every 24 weeks until unequivocal disease progression, up to three years after registration. FDG-PET/CT will be obtained at baseline (study-funded if completed after registration), 12 weeks after the start of systemic therapy (study-funded), and again at the time of unequivocal progression (SOC).

Learn more about EA1183 on ECOG-ACRIN.org, the CTSU website, or ClinicalTrials.gov.

NCI’s Natural History Study of COVID-19 in Cancer

This month, the National Cancer Institute (NCI) launched a large clinical cohort study of people with cancer who have COVID-19. The NCI COVID-19 in Cancer Patients Study (NCCAPS) will involve all of the NCI’s clinical trial programs (NCTN, NCORP, ECTCTN) and NCI-designated Cancer Centers. Sites that participate in NCCAPS can expect full reimbursement for each patient enrolled.

The purpose of the trial is to better understand the virus’s effect on people with cancer. NCCAPS is currently open to adults who are undergoing testing for SARS-CoV-2 or already have COVID-19 and are receiving cancer treatment at a health care facility. The trial will expand to include children with cancer and COVID-19 at a later date.

NCCAPS is collecting documentation from more than 2,000 patients across over 1,000 sites, and following those patients for an extended period. Eligibility criteria includes:

**Step 0**
- Age ≥ 18 years old
- Patient must have a prior or current cancer diagnosis (e.g. solid tumor or hematologic malignancy)
- Patient must be undergoing or have undergone testing for SARS CoV-2
- HIV-infected patients are eligible
- Patients with brain metastases are eligible
- Co-enrollment on other clinical trials (for cancer or for COVID-19) is allowed

**Step 1**
- Positive SARS CoV-2 test within the 14 days prior to enrollment to Step 1

Please consider participating in this important effort that will help guide future treatment for cancer patients who develop COVID-19. Sign up to receive updates about NCCAPS and learn more on the CTSU website.
Remembering Valerie Guild, a Tireless Advocate for Patients with Melanoma

Valerie Guild (pictured right), Founder and President of the non-profit organization AIM at Melanoma, died on May 21, 2020 of complications from cancer. She served as a patient advocate on ECOG-ACRIN’s Melanoma Committee for over ten years, helping to ensure the patient experience was represented throughout the research process. Those familiar with her note her loss will be felt deeply—and not just at ECOG-ACRIN.

“This is a huge loss for melanoma advocacy on a global scale,” said John M. Kirkwood, MD, former Chair of the EA Melanoma Committee and current Co-Chair of the Prevention, Screening and Surveillance Committee. “Val and AIM at Melanoma knitted together the international melanoma community for 15 years.”

Val founded AIM at Melanoma after losing her 26-year-old daughter to the disease. Va’s numerous accomplishments include: creating the first and only international think tank in melanoma, the International Melanoma Working Group; launching the AIM at Melanoma website to bring vital information and education to patients, caregivers, and families; opening the first collaborative fresh-frozen primary tissue bank for melanoma; obtaining the first Department of Defense grant for melanoma and skin cancer research; and working with lawmakers in nearly every state to attempt to ban indoor tanning for minors.

“This is a significant loss in so many ways,” said Jedd D. Wolchok, MD, PhD, current chair of the Melanoma Committee. “Val was indeed the heart and soul of many advocacy efforts.”

AIM at Melanoma plans to continue its work in Val’s memory with her daughter, Samantha Guild, assuming the role of President.

Novel Virus, Novel Stressors: Emotional Support Resources for Physicians and Health Care Providers

Lynne I. Wagner, PhD
Co-Director, Cancer Control and Outcomes Program

Anxiety is a normal, emotional response to a threat, and COVID-19 has threatened each and every one of us to our core. COVID-19 has added unique challenges and uncertainty to an already overwhelmed health care system populated by a health care workforce teetering on professional burnout. COVID-19 has significantly increased work demands by elevating the medical complexity of caring for patients with cancer. Social distancing requirements have led to changes in workflow, the need to learn new processes and technologies to deliver telemedicine, and physical disconnection from our patients and colleagues. Unknowns related to the course of the pandemic contribute to our demands by requiring constant adjustments to a shifting landscape.

This novel virus introduces novel stressors. Changes in our work and personal lives are occurring in tandem with diminishing resources in the workplace, including reduced access to equipment intended to keep us safe and reduced staffing due to illness. In very simple terms, stress occurs when demands exceed our resources. Therefore, when demands are on the rise as they currently are due to COVID, a good strategy to recalibrate the stress equation is to bolster one’s resources. This can be most effectively accomplished when the strategies employed address the controllable and the uncontrollable aspects of the stressor.

There are many aspects of this pandemic that are out of our control, including its course and the behavior of this novel virus. Many people get stuck when they dwell on uncontrollable aspects, which can lead to worry and rumination. First, focus your attention on using problem-focused coping strategies to address controllable aspects of current stressors.
**Novel Virus, Novel Stressors: Emotional Support Resources for Physicians and Health Care Providers (cont’d)**

Advances in technology have led to the rapid expansion in web-based programs and apps to promote health and self-management. I strongly recommend the web-based program available for free at Virusanxiety.com. The site provides comprehensive education on health-related anxiety and a range of techniques and interactive exercises to promote adaptive coping skills.

**Headspace** is a wonderful app to teach mindful meditation. Mindfulness is a very effective strategy to provide relief from anxiety about the future by focusing on the present. Headspace has added content titled “Weathering the Storm” which is tailored to managing COVID-related stress and is available to health care providers free of charge. The **Calm app** provides dozens of mindful meditation exercises as well as sleep stories which offer an effective distraction from the worrisome thoughts that keep us up at night. Calm also provides diaphragmatic breathing exercises; diaphragmatic breathing is deceptively simple in effectively engaging the parasympathetic branch of the autonomic nervous system to reverse the negative physiological effects of stress. Mentalhealthapps.org provides access to eHealth interventions that have been publicly funded and are now available for free. Last, the **Cancer Support Community** is a wonderful resource for patients and their caregivers. In response to COVID, the Cancer Support Community has expanded the hours for its toll-free support line: 888-793-9355.
A key goal for researchers at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center (IUSCCC) (pictured right) is to address the cancer disparities in Indiana and beyond.

My IUSCCC colleague Bryan Schneider, MD is currently leading EAZ171, a trial that hopes to improve outcomes for black women with breast cancer. Black women are 41 percent more likely to die from breast cancer than white women. Recent research shows that patients of African ancestry who take certain chemotherapy drugs have a higher risk for neuropathy.

This study aims to determine which women are most at risk for neuropathy based on their DNA, and to determine which chemotherapy treatment—docetaxel or paclitaxel—will result in less of a side effect of peripheral neuropathy for black women with breast cancer. Schneider’s trial is accruing patients across the United States and parts of Africa.

Last year, Schneider and colleague Milan Radovich, PhD discovered how to predict whether triple negative breast cancer will recur, and which women are likely to remain disease-free. They found that women whose plasma contained circulating tumor DNA (ctDNA) had only a 56 percent chance of being cancer-free two years following chemotherapy and surgery. Patients who did not have ctDNA in their plasma had an 81 percent chance that the cancer would not return after the same amount of time.

It’s research like this that led the National Cancer Institute to award its prestigious Comprehensive Cancer Center designation to the cancer center in August 2019. The comprehensive status recognizes the center’s excellence in basic, clinical, and population research as well as its outstanding educational activities and effective community outreach program across the state. It is Indiana’s only NCI-designated comprehensive cancer center.

The center works with partner organizations around the state to improve the health of all Hoosiers. The collaborative work focuses on reducing the number of new cancer cases and the number of deaths caused by the disease, especially among underrepresented populations. This includes initiatives to increase HPV vaccination rates, as well as developing, testing, and disseminating interventions to increase breast, cervical, and colorectal cancer screening in racially diverse and rural populations in Indiana.

Best known for developing the cure for testicular cancer, the IU Simon Comprehensive Cancer Center has benefitted countless patients around the globe by additionally altering or defining treatment standards for:

- breast cancer
- gastrointestinal cancer, including pancreatic and colon cancers
- genitourinary cancer, such as testis, bladder, and prostate cancers
- hematologic disorders, including multiple myeloma and leukemia
- thoracic cancer
- thymoma and thymic carcinoma
- tumors associated with neurofibromatosis type 1, primarily in children
- umbilical stem cell transplantation

As associate director of clinical research for the center, I see so many of my colleagues conducting impactful trials and research. Their work and our clinical trial participants are paving the way for improved outcomes for all patients.
News in Brief

Is something new or noteworthy happening at your institution? Send your updates to support@ecog-acrin.org.

ECOG-ACRIN Research at ASCO 2020

Researchers with the ECOG-ACRIN Cancer Research Group will present a wide range of research findings at the annual meeting of the American Society of Clinical Oncology (ASCO), occurring virtually May 29-31. The presentations include late-breaking data in two plenary sessions and several oral abstract presentations. Read the press release.

One of the oral abstract presentations will feature the results of E3311, a randomized phase two trial that showed transoral robotic surgery followed by low-dose radiation alone led to very good outcomes, similar to surgery with standard-dose radiation, in patients with HPV-positive throat cancer. Study chair Robert L Ferris, MD, PhD (UPMC Hillman Cancer Center) will share the findings as the first presentation in the Head and Neck Oral Abstract Session. Read the press release.

EA Members Receive FASCO Distinction

Several ECOG-ACRIN members are receiving the Fellow of the American Society of Clinical Oncology (FASCO) distinction in 2020. The award recognizes individuals for their extraordinary volunteer service, dedication, and commitment to ASCO. Recipients include:

- David Paul Carbone, MD, PhD, FASCO
  Ohio State University
- Anne C. Chiang, MD, PhD, FASCO
  Yale University
- Stuart M. Lichtman, MD, FASCO
  Memorial Sloan Kettering Commack
- Kathy Miller, MD, FASCO
  Indiana University
- Nathan A. Pennell, MD, PhD, FASCO
  Cleveland Clinic Foundation
- Brian I. Rini, FASCO, MD
  Vanderbilt University
- Mark E. Robson, MD, FASCO
  Memorial Sloan Kettering Cancer Center
- Gabrielle Betty Rocque, MD, MSPH, FASCO
  University of Alabama

- Vered Stearns, MD, FASCO
  Johns Hopkins University
- Jeremy Lyle Warner, MD, MS, FASCO
  Vanderbilt University

Travel to the Fall 2020 Group Meeting

At this time, ECOG-ACRIN still plans to host its in-person Fall 2020 Group Meeting in Fort Lauderdale, Florida from Wednesday, October 21 – Friday, October 23. However, due to the evolving and unpredictable nature of the COVID-19 pandemic, please be sure to choose the most flexible option when booking travel so that you may cancel, if needed, without penalty. Any changes to the status of the Fall Group Meeting will be relayed in a timely manner. Thank you for your understanding as we navigate this challenging situation.

EA Leaders on the Move

Rathan M. Subramaniam, MD, PhD, MPH, formerly of UT Southwestern Medical Center, became dean of the medical school at the University of Otago (New Zealand) in February. He retains his roles within EA as chair of the Quantitative Imaging Working Group and imaging chair of the Head and Neck Cancer Committee. Learn more.

Lale Kostakoglu Shields, MD, MPH left her position at Mount Sinai to become director of the Division of Nuclear Medicine at the University of Virginia. At EA, she serves as imaging chair of three committees: Leukemia, Lymphoma, and Myeloma.

Susanna I. Lee, MD, PhD of Massachusetts General Hospital has resigned as co-chair of the Gynecologic Cancer Working Group.


This report, typically created for the Group Meeting and featuring all of the studies in which ECOG-ACRIN participates, is now available to download from ECOG-ACRIN.org. Please contact support@ecog-acrin.org with any questions.