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ISSUES

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November | December 2020

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Paving the Way for APPs in Clinical Research

A Q&A With Christa Braun-Inglis The first advanced oncology certified nurse practitioner in the state of Hawaii, today Braun-Inglis splits her time between her clinical work with breast cancer patients and her part-time faculty member responsibilities supporting clinical research. She is committed to educating others about the importance of non-physician investigators, and to mentoring and training her fellow APPs to actively participate in clinical research opportunities at their own clinics. by Barbara A. Gabriel



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ONCOLOGY ISSUES

The Official Journal of the Association of Community Cancer Centers

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FROM THE EDITOR A Fond Farewell

BY JENNIE R. CREWS, MD, MMM, FACP



column as Editor-in-Chief of *Oncology Issues*, and it has been a privilege to serve in this inaugural role. As I reflect over the past three years and the

his is my last

topics covered in previous columns, I am amazed by the challenges that oncology has weathered and the changes we have navigated.

Together, we have tackled payment reform with the introduction of the Oncology Care Model, wider adoption of value-based care, and continued focus on price transparency. We continue to face issues of drug pricing and financial toxicity that threaten the sustainability of cancer care. We have witnessed the explosion of information, big data, and precision medicine and contemplated ways to harness technology to better serve our patients and practices. Incorporating predictive analytics has allowed us to identify high-risk patients and deploy tactics to optimize resource utilization. We have seen immunotherapy become standard across many tumor types and have redefined what it means to be a cancer survivor due to the success of this therapy. We have struggled to increase access to clinical trials to bring life-saving care to more patients, particularly underrepresented minorities and those in rural areas.

This past year has brought previously unseen challenges with the onset of the COVID-19 pandemic. We responded with major re-engineering of clinical care, including screening measures and routine use of personal protective equipment. We expanded use of telemedicine to service patients safely and are envisioning its continued use in this COVID-19 era. Many of us experienced financial hardship and are still struggling with recovery and the uncertainty of how COVID will play out over the coming year. Our specialty is bracing for the possibility of patients presenting with more advanced stages of disease due to delayed screenings and postponed evaluation of symptoms. (For practical strategies to help you prepare for what many are forecasting to a surge in patient volume, turn to page 56 and read "After the Outbreak: Preparing for the Return of Cancer Cases.")

Though our present and future challenges are daunting, I am reminded of the theme of my very first column-collaboration. ACCC is unique in its diversity of oncology specialties represented: providers, pharmacists, nurses, social workers, medical nutritionists, and more. ACCC membership includes the spectrum of practice models from small private practices to large academic institutions. This diversity brings a variety of perspectives and sometimes differences of opinion. However, our diverse membership also offers opportunity to join forces in developing creative solutions for our patients and programs. With the challenges and changes we have faced and the ones yet to come, we truly are better together.

Now, please join me in welcoming my successor, Sibel Blau, MD. Oncology Issues' incoming Editor-in-Chief is an oncologist and medical director at Northwest Medical Specialties, Tacoma, Wash. Dr. Blau is immediate-past president of the Washington State Medical Oncology Society and one of the founding members of the Quality Cancer Care Alliance, a clinically integrated network of seven oncology practices across the country. She is also a friend, a colleague, and an innovator who exemplifies the value of women leaders in our field. Welcome, Dr. Blau. I know our members will benefit from your expertise and insights. ACCC PRESIDENT'S MESSAGE The Importance of Connectivity

BY RANDALL A. OYER, MD



reetings from ACCC. With so many challenges occupying our minds, our time, and our activities, I'd like to pause and reflect on the importance of connectivity. During times of extreme

stress (what some might call 2020) connectivity is even more critical. Connection, of course, comes from many sources. Some connections are personal; others are professional. Connection is two neighbors stopping to talk while walking their dogs. Connection is also an entire country mobilizing around critical issues like equity and voting.

Finding connection today is challenging. Many of us are feeling its oppositeisolation-which only compounds our stress and deprives us of life-supporting connection. If you didn't hear the opening keynote at the ACCC 37th [Virtual] National Oncology Conference, it's available on demand, and I urge you to take a listen at courses.accccancer.org/p/ACCCNOC. Leadership guru Greg Heibert does a wonderful job sharing how to turn difficult experiences into positive learning and growth for yourself and others. Greg suggests that the term "social distancing" is the wrong messaging and that what we are really being asked to do is better called "physical distancing." Remember, though Zoom and Microsoft Teams are great tools to keep you connected, at a physical distance of 6 feet or more, you can still enjoy making safe in-person connections.

I wanted to mention here the connections that have been important to me at a professional level, chief among them my ACCC connections, especially with all of you, my fellow ACCC members. Whether you know it or not, I value each of you and your organizations, because I know that we are connected in something that is meaningful and essential to our nation: the continued provision of high-quality and compassionate cancer care for all. During this extraordinary and difficult time, ACCC members have connected across the United States, with ACCC as our convener and connector. I urge you to leverage this shared connection, and here are a few ideas to get you started.

- Join the conversation. ACCC hosts a COVID-19 Discussion Group in its ACCCeXchange online community. If you have an account, you can log in with the email address and password you used previously to access ACCCeXchange and the ACCC eLearning portal. If you don't have an account (or don't know if you have an account), go to accc.force.com/login, click "Reset Password," and use your work email address to create an account. From the "My Profile" page, view and update your contact information. Click on "Groups" at the top of the screen to get to the ACCCeXchange home page. Then click on the "COVID-19 Discussion" link.
- Share your successes. In September, eight of your colleagues shared their innovations at the ACCC 37th [Virtual] National Oncology Conference. More than 700 people registered to hear their presentations! The 2021 ACCC Innovator Awards open in December. Look for an email, share it with your team, and apply and be recognized on a national platform for all of the great work you do on behalf of your patients.
- Subscribe and listen to the ACCC podcast. CANCER BUZZ is on Apple Podcasts, Spotify, or wherever you else get your podcasts. Hear your colleagues share insights on timely topics such as closing the gender gap in oncology. If you are short on time, try one of ACCC's minipodcasts to hear topics like how surgical oncology has been impacted by the coronavirus pandemic and how programs are adapting to fluctuations in staff availability.

Remember, the ACCC membership message is "Together We are Stronger." Those words have never been more true and more needed. Thank you for taking a few moments to read this column and thank you for staying connected to ACCC. Your membership and your engagement are everything. As always, we welcome your ideas for program and resource development. Tell us about your practice, your program, your community, and your needs. Let's stay connected.

Coming in Your 2020 ONCOLOGY ISSUES

- Avoidable and Unavoidable ER
 Utilization by Cancer Patients
 on Systemic Therapy
- Remote Work Program for Hospital-Based Cancer Registrars
- Use of Pharmacy Informatics to Standardize Pharmacist Review of Oral Oncolytic Medications for Hospitalized Patients
- Management of Hospital
 Admissions for Checkpoint
 Inhibitor Immune-Related
 Adverse Events at a Regional
 Cancer Center
- Medication Transitions in Hematologic Malignancy
 Patients at a Safety Net Hospital
- An Investigation of Self-Determined Work Motivation Among Young Adult Central Nervous System Cancer Survivors
- Bringing Phase I Trials to a Community Practice: Highland Oncology Group's Research Program
- Transportation: A Holistic Approach to a Systemic Problem
- Tailoring Distress Screening in Oncology Populations: Timing Distress Screening in Surgically Resectable Esophageal Cancer
- Leveraging a 3D Lung Nodule Educational Tool to Reduce Patient Distress
- Utilizing Technology to Identify Patient Co-morbidities and Reduce Hospital and ED Admissions
- Onboarding Experienced Nononcology Nurses to Address
 Staffing Shortages: Miami
 Cancer Institute's Oncology
 Training Academy

more online @ accc-cancer.org

ACCC Research Review

E-NEWS The September 2020 issue of the ACCC Research Review provides support, perspectives, and resources to make clinical trials more inclusive, diverse, accessible, and representative of patient populations. Topics include the importance of collaboration between community programs and academic institutions; highlights from an AACR panel on Racism and Racial Inequalities in Cancer Research; and more. accc-cancer. org/september-research-review.

🛜 | Closing the Gender Gap in Oncology

PODCAST CANCER BUZZ shares how Livestrong Cancer Institutes and Dell Medical School at the University of Texas at Austin are reaching out to young high-school women to generate interest in oncology. Through leadership training, meetings with program leaders, and a week-long research project, the Summer Healthcare Experience (SHE) lays the groundwork for female mentorship and support at an early age. accc-cancer.org/podcast-episode-20.

COVID-19 Discussion Group

NETWORK Part of the ACCCeXchange online community, this discussion group facilitates conversations, helps you engage with peers, and shares effective practices related to pandemic recovery efforts. Login with the email address and password you use to access ACCCeXchange and the ACCC eLearning portal. Or go to accc.force.com/login, click "Reset Password," and use your work email address to create an account. From the "My Profile" page, view and update your contact information. Click on "Groups" at the top of the screen to get to the ACCCeXchange home page. Then click on the "COVID-19 Discussion" link. Email membership@accc-cancer.org for questions or help.

Reframing Financial Navigation BLOGS During COVID-19

"Our team is talking to patients about cost estimates and out-of-pocket responsibilities for their treatment. Should we give patients any paperwork during these conversations?" "Is there a good benchmark ratio for the number of physicians to the number of financial navigators?" "How do you track copay reimbursement?" Experienced financial navigators answer these questions and more. accc-cancer.org/ financial-navigation-during-covid19.

Approaches to Shared WEBINAR Decision-Making

This six-part webinar series shares practical tips and guidance on topics such as Building a Culture of Patient Engagement; Treatment Goal-Setting with Patients with Metastatic Cancer; and Increasing Health Literacy to Improve Decision-Making. accc-cancer.org/SDM-Webinars.

Patients are gradually returning to hospitals and doctor's offices.

tast

According to the Commonwealth Fund, visits to physicians' offices, which declined **60%** from mid-March to mid-April, were about **20%** to **30%** below pre-pandemic levels by July.



Source. McGinley L. Patients are still delaying essential care out of fear of coronavirus. *Washington Post*. Available online at washingtonpost.com/health/wooing-patients-backis-tricky-business-as-coronavirus-spikes-in-many-states/2020/07/13/b86d676e-bbb1-11ea-8cf5-9c1b8d7f84c6_story.html.



Only 31% of hospitals and health systems are using capabilities within their EHR systems to conduct telehealth visits.

Source. Dress J. Less than one-third of hospitals are using EHR-embedded telehealth tools. *Becker's Hosp Rev.* Available online at beckershospitalreview.com/telehealth/less-than-onethird-of-hospitals-are-using-ehr-embedded-telehealth-tools.html.

facts

Advanced Breast Cancer Patients in the U.S. Cite Co-Payments as Main Financial Burden



- **87%** of respondents reported financial difficulties during their cancer treatment. Of that cohort, **57%** blamed their medical co-payments.
- High drug costs (38%) and added living and transportation costs (13%) were also cited.
- **25%** of surveyed patients delayed treatments or used less expensive or alternate medications due to high copayments.

Source. Belong.Life. From a study of 189 Belong.Life users. Research presented at the 5th ESO-ESMO International Consensus Conference on Advanced Breast Cancer in Lisbon.



Do Your Patients Have Easy Access to Their EHRs?

Despite healthcare providers' widespread adoption of web-based patient portals, about 1/3 of consumers report they have never used one to view their medical records, one survey found. Also, 41% say they did not receive all the records they requested from their healthcare provider.

Source. A survey conducted by DrFirst. drfirst.com.

5.4 million workers estimated to have lost their health insurance due to the coronavirus-driven recession.

Source. Stolberg SG. 5.4 million Americans have lost health insurance in coronavirus-driven recession, analysis finds. *Baltimore Sun*. Available online at baltimoresun.com/coronavirus/ct-nw-nyt-covid-health-insurance-20200714-ekkf5g5mdnftzcqd7fbhpd225y-story.html.



While telemedicine use largely remains well above pre-pandemic levels—and many still say telemedicine's popularity is here to stay—telemedicine visits accounted for just **21%** of total encounters by the middle of July, down from **69%** at the early peak of the public health crisis in April.

Source. Ross C. Telehealth grew wildly popular amid Covid-19. Now visits are plunging, forcing providers to recalibrate. STAT. statnews. com/2020/09/01 telehealth-visits-decline-covid19-hospitals.

issues

ACCC Comments on 2021 Proposed OPPS and PFS Rules

BY CHRISTIAN G. DOWNS, MHA, JD

n Oct. 5, ACCC provided comments to the Centers for Medicare & Medicaid Services (CMS) on the agency's proposed CY 2021 Outpatient Prospective Payment System (OPPS) and Physician Fee Schedule (PFS) rules. CMS is expected to release the final CY 2020 Medicare payment rules in early December. Below are highlights from these comment letters.

Specific to the proposed OPPS Rule, ACCC recommended that CMS:

- Not finalize its proposal to further reduce the payment rate for separately payable drugs acquired under the 340B Program to protect rural and underserved providers and beneficiaries. ACCC believes that the proposal to further reduce payment for 340B drugs fails to account for the numerous harmful effects it will have on patient access to care. Instead ACCC urges CMS to continue its current policy of paying average sales price minus 22.5 percent for 340B drugs.
- Finalize its proposed changes in the level of supervision of non-surgical extended duration services as long as hospitals retain the flexibility to determine how best to staff these services, with respect to both the individuals who may be providing the services and how the hospital chooses to meet the supervision requirements.
- Reverse, not extend, its requirement for prior authorization for certain outpatient department services. ACCC member

institutions continue to experience increases in unnecessary and burdensome prior authorizations, delaying patient care and increasing the administrative burden on hospitals. To protect patients, CMS should reverse its prior authorization policies finalized last year instead of extending them to additional service categories.

In its letter, ACCC supports the proposal regarding changes in the level of supervision of outpatient therapeutic services in hospitals and critical access hospitals but seeks clarification on how it will apply to chemotherapy and radiation oncology.

Specific to the proposed PFS Rule, ACCC recommended that CMS:

· Mitigate the detrimental impact of increased payment for office/outpatient evaluation and management visits, which have been offset by reductions to surgery and radiology oncology services, among others, by seeking a balanced approach to payment for all services. ACCC is deeply concerned about the impact of offset reductions on radiation oncology and surgery. The agency's own CY 2021 financial impact analysis for changes in the rule as a whole predicts a 6 percent decrease in Medicare PFS payments for radiation oncology and radiation treatment centers and an 11 percent decrease for radiology. All of the surgical specialties included in this analysis would also face a decrease in total allowed

charges if CMS's proposals are implemented.

- Not finalize its proposal to assign certain section 505(b)(2) drug products to multiple source drug codes for purposes of Part B payment, which would not lower prices for providers and would create uncertainty about reimbursement rates.
- Finalize its proposal to increase flexibilities for telehealth services and communication technology-based services, which expand access to services for patients in need. Specifically, ACCC supports CMS's proposals to allow the specific communication technology-based services codes to be billed by licensed clinical social workers and clinical psychologists, as well as physical therapists, occupational therapists, and speech-language pathologists who bill Medicare directly for their services. In addition, ACCC supports CMS's proposals to adopt two new G codes, for remote evaluation of downloadable images/recorded video and for virtual check-in, that would allow certain nonphysician practitioners who cannot independently bill for evaluation and management services to bill for these services.

Read these comment letters in their entirety at accc-cancer.org/advocacy.

Christian G. Downs, MHA, JD, is executive director, Association of Community Cancer Centers, Rockville, Md.



compliance

What Telehealth May Look Like in 2021

BY TERI BEDARD, BA, RT(R)(T), CPC

he Medicare Physician Fee Schedule (PFS) proposed rule was released on Aug. 4, 2020. The Centers for Medicare & Medicaid Services (CMS) waived the 60-day publication requirement for the final rule and replaced it with a 30-day notification so that comments on the proposed rule were due on Oct. 5. The final rule will become effective Jan. 1, 2021, although it may not be published until Dec. 1, 2020. CMS also released on Aug. 4 an executive order proposing increased flexibility for telehealth and rural healthcare in light of the COVID-19 pandemic. The 2021 PFS proposed these changes specific to telehealth.

Telehealth Services After the End of the Public Health Emergency

In response to COVID-19 and as part of the public health emergency (PHE), CMS expanded telehealth services to be more broadly accepted and applicable than these services were prior to the pandemic. As part of the waivers and expansion, CMS has allowed for telehealth services to be provided in various settings, including office settings and the patient's home. As part of the Interim Final Rule released in both March and April 2020, CMS indicated when the PHE ends, the waivers and expansions would also end and services would revert back to pre-PHE days. Health and Human Services Secretary Alex Azar extended the PHE for another 90 days effective July 25, 2020. This extended waivers and expansions through Oct. 23, 2020. On October 2, 2020, the

Secretary of HHS again extended the PHE effective October 23, 2020. The extension will be in effect for another 90 days, ending approximately January 21, 2021.

CMS recognizes that even when the PHE is declared over, the effects of COVID-19, coupled with patient reluctance to return to hospitals and clinics for care, may linger, and the agency is proposing a phased-in end to the waivers and expansions for some items rather than a hard-and-fast stop. Specifically, CMS is proposing several changes to telehealth services moving forward, which include the following:

- Creating a Category 3 level of telehealth. This would allow for the services that meet the Category 1 and 2 telehealth services criteria to be added temporarily on an interim final basis as necessary and in response to this or another PHE.
- Proposing any service added to Category 3 would remain on the Medicare telehealth services list through the calendar year in which the PHE ends.
- Proposing most of the services added during the PHE to be removed as CMS, in review of the codes, did not find they met the Category 2 criteria already established for telehealth services. In the proposed rule, CMS asked for stakeholders to comment on whether these services should be added to the Category 3 designation. For example, the agency specifically asked whether HCPCS code
 77427 (Radiation treatment management, 5 treatments) should be added as a Category 3 code.

 Proposing to amend language that when a code is deleted and replaced with a new CPT/HCPCS code that describes the same clinical services of a code currently on the Medicare telehealth services list, the new code would be considered a successor to the old code and updated accordingly.

Table 1, page 8, summarizes CMS proposals to the Medicare telehealth services list.

Telehealth Services Technology Requirements

During the PHE, CMS removed language and allowed for telehealth expanded services to be provided by "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." This allowed for providers and patients to use smartphones when communicating with audio and video capability. CMS is proposing to update the last sentence of the Medicare telehealth services regulation, which states: "prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services." The regulation that prohibits the use of telephones could be confusing when a smartphone and the capabilities for the audio and video are used for the visit. Removing this verbiage would delete outdated references to technology and potentially alleviate confusion for providers looking to bill for these telehealth services.

Communication Technology-Based Services

As part of the CY 2019 PFS Final Rule, CMS created several G-codes for services furnished via telecommunications technology. These services are not considered telehealth services but use telecommunications technology between the provider and patient. Two of the codes created include:

- G2010: Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related evaluation and management (E/M) service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment.
- G2012: Brief communication technology-based service (e.g., virtual check-in) by a physician or other qualified healthcare professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

Both codes may be billed by nonphysician practitioners. CMS is also proposing to add two new codes effective Jan. 1, 2021. These new codes would also be billable by nonphysician practitioners, consistent with their scope of practice, for those who cannot bill independently for E/M services. The value of these codes would match G2010 and G2012, respectively.

- **G20X0:** Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous seven days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
- G20X2: Brief communication technology-based service (e.g. virtual check-in) by a qualified healthcare professional who cannot report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous seven days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

Audio-Only Visits

Prior to the PHE, CMS did not provide coverage for telephone services codes, 99441-99443. In large part, this is due to the fact these services can be provided to the patient, parent, or guardian. CMS does not typically cover services (or codes) that are not directly provided to the patient. However, as part of the PHE and stakeholder feedback that most beneficiaries did not want to, know how to, or have the capabilities to use video technology for visits, CMS approved their coverage.

Telecommunication codes available prior to the PHE were only the short duration G-codes referenced above and CMS noted that, for some patients, a longer telephone visit is needed. CMS is not proposing to recognize the telephone codes under PFS after the PHE has ended. This is due to the requirement of audio/video capabilities for telehealth services once the PHE has ended. However, the agency sought comments on whether a service similar to the check-in visit should be created that covers a longer period of time for the visit. CMS also sought comments on whether the audio-only visits should remain under provisional coverage until the end of year the PHE ends or whether they should be part of the permanent PFS payment policy.

Table 1. Summary of CY 2021 Proposals for Addition of Servicesto the Medicare Telehealth Services List

TYPE OF SERVICE	SPECIFIC SERVICES AND CPT CODES
C9016	Group Psychotherapy (CPT code 90853)
C9024	Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334-99335)
C9028	Home Visits, Established Patient (CPT codes 99347-99348)
C9030	Cognitive Assessment and Care Planning Services (CPT code 99483)
C9033	Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X)
C9463	Prolonged Services (CPT code 99417)
C9464	Psychological and Neuropsychological Testing (CPT code 96121)

Physician Supervision for Telehealth Services

For the duration of the PHE, CMS has redefined direct supervision under PFS to be provided through interactive real-time audio-video telecommunication technology. This allows the physician to provide real-time assistance and direction throughout a procedure or service by allowing them to see and interact with the staff member and patient without adding any unnecessary exposure. It is important to note that the supervision adjustments are meant as a minimum requirement. There may be circumstances in which the physical presence of the physician with the patient in the same location is necessary and more appropriate; for example, administration of certain drugs or therapies. CMS stressed that in these types of scenarios the physician and facility must make the best decision given the situation, even if this means potential exposure due to the nature of the scenario.

CMS is proposing to extend direct supervision expansion under PFS to end later

in the calendar year in which the PHE ends or Dec. 31, 2021. In addition to the other waivers and extensions, this will allow an easement to the change in supervision for physicians and practices to prepare for the change back to the in-person requirement. CMS did note, if the PHE was not extended to overlap the expected date of the final rule release, supervision requirements would revert to the guidelines in place prior to March 1. 2020. Because the PHE has been extended into 2021, the changes to physician supervision will continue as established during the PHE. It is expected that the 2021 PFS final rule will provide details for how the expansion will be eased back when the PHE ends.

CMS did clarify that the use of real-time audio and video technology to provide direct supervision under the PFS does not mean the physician must be actively observing and using the technology throughout the entire procedure. Instead the supervising physician is immediately available to engage via the real-time audio and video technology (excluding audio-only) throughout the procedure.

CMS has also received requests for clarification for when a physician and patient are at the same physical location but the visit is provided using telecommunications technology and whether this can be billed as a telehealth visit. CMS did provide clarification for this in the Second Interim Final Rule released April 30, 2020. CMS states, "... If audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements." OI

Teri Bedard, BA, RT(R)(T), CPC, is executive director of corporate and client resources at Revenue Cycle Coding Strategies, LLC, Des Moines, Iowa.

tools



Approved Drugs

- On Sept. 4, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Gavreto[™] (pralsetinib) (Blueprint Medicines Corporation, blueprintmedicines.com) for adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer as detected by an FDA-approved test.
- On Aug. 20, the Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) and Amgen (amgen.com) announced that the FDA approved the expansion of the Kyprolis[®] (carfilzomib) prescribing information to include its use in combination with Darzalex[®] (daratumumab) plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.
- On Sept. 1, Bristol Myers Squibb (bms. com) announced that the FDA approved
 Onureg[®] (azacitidine) for the continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and who are not able to complete intensive curative therapy.
- On Oct. 2, the FDA approved the combination of **Opdivo®** (nivolumab) plus Yervoy[®] (ipilimumab) (Bristol-Myers Squibb, bms.com) as first-line treatment for adult patients with unresectable malignant pleural mesothelioma.

On Sept. 8, Athena Bioscience (athenabioscience.com) announced that the FDA has approved Qdolo[™] (tramadol hydrochloride) oral solution 5 mg/1 mL C-IV, an opioid agonist indicated in adults, for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Drugs in the News

- Ascentage Pharma (ascentagepharma. com) announced that the FDA has granted APG-2575, its novel Bcl-2 inhibitor, orphan drug designation for the treatment of chronic lymphocytic leukemia. The company also announced that the FDA has granted two orphan drug designations to two of the company's apoptosis-targeting assets: the MDM2-p53 inhibitor, APG-115, for the treatment of acute myeloid leukemia; and the Bcl-2/Bcl-xL inhibitor, APG-1252, for the treatment of small cell lung cancer.
- Exelixis (exelixis.com) announced the submission of supplemental new drug application (NDA) to the FDA for
 Cabometyx® (cabozantinib) in combination with Opdivo (nivolumab) for advanced renal cell carcinoma.
- CARsgen Therapeutics Co., Ltd. (carsgen. com) announced that the FDA has granted orphan drug designation to
 CT041 for the treatment of gastric and gastroesophageal junction adenocarcinoma.
- RemeGen Co., Ltd. (remegen.com) announced that the FDA has granted

breakthrough therapy designation for **disitamab vedotin (RC48)** for the second-line treatment of patients with human epidermal growth factor receptor 2-positive locally advanced or metastatic urothelial cancer who have also previously received platinum-containing chemotherapy treatment.

- Leap Therapeutics, Inc. (leaptx.com) announced that the FDA has granted fast track designation to **DKN-01** for the treatment of patients with gastric and gastroesophageal junction adenocarcinoma whose tumors express high Dickkopf-1 protein, following disease progression on or after prior fluoropyrimidine- and platinum-containing chemotherapy and, if appropriate, human epidermal receptor growth factor/ neu-targeted therapy.
- ESSA Pharma Inc. (essapharma.com) announced that the FDA granted fast track designation to EPI-7386 for the treatment of adult male patients with metastatic castration-resistant prostate cancer resistant to standard-of-care treatment.
- The FDA granted Gavreto[™] (pralsetinib) (Blueprint Medicines Corporation, blueprintmedicines.com) priority review for the treatment of people with advanced or metastatic RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer.
- Gan & Lee Pharmaceuticals Co., Ltd. (ganlee.com/en/) announced that the FDA has granted orphan drug designation to GLR2007 for the treatment of malignant glioma.

- Bristol Myers Squibb (bms.com) and bluebird bio, Inc. (bluebirdbio.com) announced that the FDA has accepted for priority review their biologics license application (BLA) for idecabtagene vicleucel (ide-cel; bb2121) for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.
- AstraZeneca (astrazeneca.com) announced that the FDA has accepted a supplemental BLA for Imfinzi[®] (durvalumab) and has also been granted priority review for a new four-week, fixed-dose regimen for treatment in the approved indications of non-small cell lung cancer and bladder cancer.
- ImmunoGen, Inc. (immunogen.com) announced that the FDA has granted breakthrough therapy designation for IMGN632 for the treatment of patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm.
- Alphamab Oncology (alphamabonc.com/ en/) announced that the FDA has granted orphan drug designation to KN046 for the treatment of thymic epithelial tumors.
- Oncopeptides (oncopeptides.se/en) announced that the FDA has granted priority review for the NDA seeking approval of melflufen (INN melphalan flufenamide) in combination with dexamethasone for the treatment of adult patients with multiple myeloma whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody.
- The FDA has awarded rare pediatric disease designation for diffuse intrinsic pontine glioma and orphan drug designation for treatment of malignant glioma to **OKN-007**, an investigational drug discovered at the Oklahoma Medical Research Foundation and being developed by Oblato, Inc.
- Athenex, Inc. (athenex.com) announced that the FDA has accepted for filing the NDA and granted priority review for **oral paclitaxel and encequidar (Oral**

Paclitaxel) for the treatment of metastatic breast cancer.

- Kazia Therapeutics Limited (kaziatherapeutics.com) announced that the FDA has awarded rare pediatric disease designation to **paxalisib (formerly GDC-0084)** for the treatment of diffuse intrinsic pontine glioma, a rare and highly aggressive childhood brain cancer.
- Kazia Therapeutics Limited (kaziatherapeutics.com) announced that the FDA has granted fast track designation to paxalisib (formerly GDC-0084) for the treatment of glioblastoma, the most common and most aggressive form of primary brain cancer.
- Precision BioSciences, Inc. (precisionbiosciences.com) announced that the FDA has granted fast track designation to **PBCAR0191**, the company's lead investigational allogeneic chimeric antigen receptor T cell therapy for the treatment of advanced B-cell precursor acute lymphoblastic leukemia.
- EMD Serono (emdgroup.com/en) announced that the FDA has accepted and granted priority review to the NDA for **tepotinib** for the treatment of adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial transition exon 14 skipping, as detected by an FDA-approved test.
- G1 Therapeutics, Inc. (g1therapeutics. com) announced that the FDA has accepted the NDA and granted priority review to **trilaciclib** for small cell lung cancer patients being treated with chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA has accepted an NDA for umbralisib (TGR-1202) as a treatment for patients with previously treated marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and follicular lymphoma who have received at least two prior systemic therapies.
- Pfizer Inc. (pfizer.com) announced that the FDA has accepted and granted priority review to the supplemental NDA for Xalkori[®] (crizotinib) for the treatment of pediatric patients with relapsed or

refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase-positive.

- Mersana Therapeutics, Inc. (mersana. com) announce that the FDA has granted fast track designation for **XMT-1536** for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received up to three prior lines of systemic therapy or patients who have received four prior lines of systemic therapy regardless of platinum status.
- Kite Pharma (kitepharma.com) announced that it has submitted a supplemental BLA to the FDA for Yescarta® (axicabtagene ciloleucel) for the treatment of relapsed or refractory follicular lymphoma and marginal zone lymphoma after two or more prior lines of systemic therapy.

Approved Genetic Tests and Assays

- The FDA approved Foundation Medicine, Inc.'s (foundationmedicine.com)
 FoundationOne[®]Liquid CDx, a comprehensive pan-tumor liquid biopsy test with multiple companion diagnostic indications for patients with advanced cancer. FDA approval includes companion diagnostic claims for Rubraca[®] (rucaparib) and three tyrosine kinase inhibitors for non-small cell lung cancer.
- Genetron Holdings Limited (en.genetronhealth.com) announced that its bloodbased next-generation sequencing test
 HCCscreen[™] has been granted breakthrough device designation by the FDA for early detection of hepatocellular carcinoma in individuals who are designated to be at high risk for hepatocellular carcinoma due to chronic hepatitis B virus infection and/or liver cirrhosis.
- The FDA has granted premarket approval to Thermo Fisher Scientific's (thermofisher.com/us/en/home.html)
 Oncomine Dx Target Test as a companion diagnostic to identify patients with RET fusion-positive metastatic non-small cell lung cancer who are candidates for Gavreto[™] (pralsetinib).

spotlight

Baptist Cancer Center Memphis, Tennessee

panning three states in the Mid-South United States, Baptist Cancer Center brings to life its mission of treating patients close to home. The cancer center is part of Baptist Memorial Health Care, a regional healthcare system that consists of 23 locations across Tennessee, Arkansas, and Mississippi, with its largest cancer center in Memphis. Physicians and staff at Baptist Cancer Center provide high-quality care in both rural and urban locations by prioritizing standardization across its network and establishing access to care for patients in need. The Baptist Cancer Center network is accredited by the National Accreditation Program for Breast Centers and the Commission on Cancer. Its network is also certified by the American Society of Clinical Oncology's Quality Oncology Practice Initiative.

Multi-State Care

Baptist Cancer Center has 17 cancer treating clinics and sees approximately 7000 new patients annually. "Our catchment area



covers most of the counties in Mississippi, a large portion of western Tennessee, and eastern Arkansas," explains Nick Faris, director of thoracic oncology at Baptist Cancer Center. "The Delta Regional Authority, which is a congressionally mandated area of great socioeconomic disparities, almost completely overlaps with our catchment area for our patient population." The Delta Regional Authority is a federal-state partnership dedicated to improving the quality of life of those living in the Mississippi Delta. This wide footprint poses unique challenges to the healthcare system, such as staffing and treatment standardization. "While our hub is in Memphis, our other sites are located where patients needed us the most-close to home," explains Jon Linn, director of marketing at Baptist Cancer Center. Each clinic is operated by the hospital with which it is associated, and its clinical and non-clinical staff are employed by that hospital—all clinicians are employed by the Baptist Medical Group, which falls under the umbrella of Baptist Memorial Health Care.

> Oncology clinicians typically provide care at two or more Baptist Cancer Center locations, and non-clinical staff are permanent to their location.

Since its expansion across the Mid-South, leadership at Baptist Cancer Center has prioritized the standardization of its policies, procedures, processes, initiatives, and projects. Therefore, patients receive the same high-quality care no matter where they are treated. The health system is able to help ensure this standardization through its system directors committee, which meets monthly to make decisions that impact the network.

Staffing and Services

Each Baptist Cancer Center location is composed of a clinic and an infusion area. Patients are greeted and checked in at the front desk upon their arrival. Due to COVID-19, everyone on site is screened, new patients are tested before starting treatment, and everyone must wear personal protective equipment. In the clinic, patients have their lab work done, vital signs taken, and assays recalculated and see their physician. The clinic area is staffed by advanced practice providers, medical assistants, nurses, laboratory staff, and customer service representatives.

Registered nurses and pharmacy staff provide services in the infusion suite. Infusion nurses must go through a rigorous orientation program, and within a year of working with the cancer center, they are required to take the Oncology Nursing Society chemotherapy-immunotherapy provider course to become an oncology certified nurse. Each clinic location has an infusion-dedicated pharmacy that is staffed by a pharmacist and one or two pharmacy techs, depending on the location's size. The pharmacy staff mix and compound infusion drugs on site for nurses to administer, and the Baptist Specialty Pharmacy dispenses oral prescriptions.

The infusion suites of each Baptist Cancer Center location are set up in a similar manner. Infusion chairs encircle the perimeter of the infusion area and are separated by half-walls or curtains. A nursing station sits at the center, so all nurses have access to and a direct view of each chair. Its Memphis location has 14 chairs, and its smallest location has 8 chairs.

Baptist Cancer Center also provides surgical oncology, hematology, and radiation oncology treatments at its clinics. Through its network of clinics, Baptist Cancer Center offers a full range of high-tech radiation equipment, including a CyberKnife accelerator, linear accelerators, computed tomography and 4D simulators, and a high dose rate brachytherapy unit. If radiation services are not available at a smaller location, patients are referred to the closest radiation center to receive treatment.

The cancer center has also recently implemented intraoperative radiation therapy for patients with breast cancer, which has reduced the long-term toxicities of radiation in patients. It employs gynecology oncologists who are also surgeons, breast surgeons, a colorectal surgeon, a pancreatic surgeon, a lung surgeon, a melanoma specialist, and a sarcoma specialist to provide patients specialized care. For now, patients must travel to Memphis or a larger hospital-affiliated location within Baptist Memorial Health Care to receive surgical oncology services and these specialty provider visits. Plans are in place to regionalize surgical oncology services throughout the health system.

A Multidisciplinary Approach

Baptist Cancer Center sees high rates of lung, breast, gastrointestinal, and colon cancers. The high rate of lung cancer can be linked to the health system's central location in the Mississippi Delta region, explains Faris. Due to this need for lung cancer care, the cancer center has developed a robust thoracic program to promote early screening in local communities and provide multidisciplinary care.

As with its other screening programs, the thoracic clinic is focused on early detection using two screening programs—an incidental pulmonary nodule program and a low-dose computed tomography screening program. If a patient is identified as high-risk through one of these programs or is referred by a physician, his or her case is discussed in a multidisciplinary thoracic oncology



conference, which includes medical oncology, thoracic oncology, surgical oncology, cardiovascular, radiation oncology, genetics, pathology, and advanced practice providers. This conference—as well as ones dedicated to gastrointestinal, breast, head and neck, and brain and spine cancers—is held weekly in the Memphis location where patient treatments are discussed. Once patient cases are reviewed and discussed in the thoracic conference, they are referred to the cancer center's thoracic oncology clinic, where patients see multiple providers at once to determine their treatment plan. With this format, physicians and staff can establish care coordination and treatment plans before patients return to their communities to receive care.

To better meet the needs of its diverse patient population, Baptist Cancer Center expanded its nurse navigator program. Nurse navigators screen all patients via an intake tool before their first visit and refer them to the appropriate supportive care resources based on specific needs or requests. Support services include genetic screening and counseling, nutrition, social work, financial counseling, inpatient and outpatient rehabilitation services, and clinical trials. These services are available at each Baptist Cancer Center location, provided by the hospital with which the clinic location is affiliated, and free to all patients, who can also self-refer to services. "The nurse navigator program has been instrumental in helping us get patients to treatment and have better outcomes," explains Tori

McCurdy, director of oncology nursing at Baptist Cancer Center. Because Baptist Cancer Center provides supportive care through affiliated hospitals, patients do not have to travel to receive these services.

Access to Clinic Trials

Baptist Cancer Center strives to provide its patients the most current and ground-breaking treatment across its clinic locations. Clinical research coordinators, procurement specialists, pharmacy staff, and administration staff make up its large clinical trial department. These coordinators have oversight of all rural clinics and can see patient data to help determine which patients qualify for which clinical trial. All patients are screened for clinical trial participation and can participate wherever they are receiving treatment. Patients are also referred to a coordinator via the screening intake tool provided by a nurse navigator.

Through the cancer center's partnership with the National Cancer Institute, Baptist Cancer Center receives research study grants that enable it to conduct an array of cooperative group trials and partners with industry to provide sponsored trials.

"I think the one area we really shine, maybe potentially over our competition, is that we do provide rural-based care. Patients are not a number here. It's very personal," says McCurdy.

Paving the Way for APPs in Clinical Research



A Q&A with Christa Braun-Inglis

ith more than 25 years of oncology nursing experience and more than 18 years as an oncology nurse practitioner, Christa Braun-Inglis, MS, APRN-Rx, FNP-BC, AOCNP, has a wealth of clinical expertise. The trajectory of her career has given Braun-Inglis a unique perspective on oncology care. For one thing, she practices in Hawaii, a state that consists of 1.42 million people spread out over eight islands and speaking more than 100 languages. In Hawaii, patients may reside on small rural islands that do not have a local cancer clinic or full-time oncologist. Thus, the availability of translators and airplanes is a common consideration Braun-Inglis must consider when treating her patients.

Braun-Inglis, a native of Buffalo, N.Y., earned her degree in nursing from the University of Hawai'i and returned five years later to earn her masters and become a nurse practitioner (NP). After graduating, she moved to California, where she worked in a cancer practice in San Francisco. There she met Randall A. Oyer, MD, (current president of the Association of Community Cancer Centers [ACCC]), who cultivated Braun-Inglis's interest in medical oncology as an advanced practice provider (APP). She soon learned that she was blazing a new path in Hawaii as the only advanced oncology certified nurse practitioner in the entire state. Her clinical work with patients made her excel in matching the patients she knew so well with the trials she believed were most likely to benefit them.

Braun-Inglis believes that how APPs are onboarded when first joining a new cancer program or practice is crucial to their longterm success. "When I first came on, I was mentored by physicians and nurse practitioners to live up to my potential as a clinician," recalls Braun-Inglis.



University of Hawai'i Cancer Center.



Ko'olau Mountains in Windward, Oahu.

When she left San Francisco and returned to Hawaii to join a large private medical oncology practice, Braun-Inglis used her training with Dr. Oyer to demonstrate to her new employer how her clinical skills could add value to the practice overall. She soon learned that she was blazing a new path in Hawaii as the only advanced oncology certified nurse practitioner in the entire state. Her clinical work with patients made her excel in matching the patients she knew so well with the trials she believed were most likely to benefit them. In time, she became recognized as a researcher in her own right.

In 2018, Braun-Inglis left full-time clinical onology practice to become an NP/assistant researcher at the University of Hawai'i Cancer Center and a clinical faculty member at the University of Hawai'i School of Nursing and Dental Hygiene. "I have a hybrid position, in which I am a part-time clinician working with breast cancer patients and a part-time faculty member supporting clinical research," says Braun-Inglis.

Braun-Inglis knew that she was entering a line of work uncommon in her profession. "The common belief was that opening clinical research to APPs would take work away from physicians," she explains. Braun-Inglis would go on to prove that there is plenty of research to go around, and bringing more clinical trials into community cancer centers not only benefits patients, but also enables all clinicians to work at the top of their license.

In her current role, Braun-Inglis is positioned to help bring down the barriers that often stand in the way of other oncology APPs who want to assist with clinical research. "When I joined the University of Hawai'i, I wanted to get more APPs involved in research across the community," says Braun-Inglis. "I have mentored and helped train 10 oncology APPs in clinical research, and they are all now registered as non-physician investigators through the National Cancer Institute [NCI]. We recognize Hawaii's top accruers to trials each year, and in 2019 that honor went to an APP." Below, we ask Braun-Inglis for her insight into the role of APPs in clinical research.

Q. How did mentoring pave the way for your work on clinical trials?

A. I took the grounding that Dr. Oyer gave me in medical oncology and applied it to my work in Hawaii. One oncologist, Dr. Jonathan Cho, with whom I worked in my practice, was very engaged in clinical research. He worked with the NCI Community Oncology Research Program (NCORP) at the University of Hawai'i Cancer Center. NCORP brings cancer clinical trials and care delivery studies to people in local communities. Dr. Cho fostered my love of clinical research and instructed me in the conduct of clinical trials. Our patient base is very different from that of the majority of the country.

We became a team. He saw patients in consultation, and I saw them for chemotherapy counseling. We established a workflow in which we identified appropriate trials for our patients and recruited them. In identifying trials, I started working with the University of Hawai'i, and they began to invest in me and send me to research meetings.



University of Hawai'i Cancer Center.

When I attended those meetings, I noticed that I was the only APP there. I typically saw medical oncologists, PhD researchers, clinical research nurses, clinical research professionals, and PhD nursing researchers—but they are all different from APPs. I wanted to know why there were no APPs there, since we are the ones who are typically working most directly with patients.

Q. Mentorship and coaching played important roles in shaping your career. How can other APPs get the training they need to support their interests?

A. When you are a new APP, it can be difficult to get experience on the job. There is only so much you can learn in school. The roles and responsibilities of an APP are very different from that of an RN (registered nurse). What you do day in and day out is not the same. You need to start thinking in a different way and make autonomous decisions. If you are not mentored appropriately by another experienced APP or oncologist, you end up limiting your abilities and scope and not living up to your full potential. Today, the skills of many APPs are wasted because they are not being mentored appropriately.

I've seen how important onboarding is to professional development. When new APPs walk into a busy clinic on their first day, many doctors assume that because they are APPs, they must know what they are doing, and they do not take time to mentor them. They push work on new APPs without giving them direction. So when they make a mistake, they are dismissed as not knowing what they are doing. But the fact is that these professionals cannot take on new tasks without proper training. It becomes a game of *Survivor*; whoever manages to survive grows into their role over time. This situation is slowly improving, but in many programs and practices it is still sink or swim.

In oncology, APPs typically work in a blended model in which they see patients jointly with oncologists. Knowing what your oncologist wants and how he or she practices is important to your success. To set up new APPs to succeed, my recommendation is to pair them with a physician or other experienced APP who acts as a mentor or coach. Develop an onboarding plan for six months with clear measures to meet. Make sure that the mentor to whom you assign your APP has adequate time to dedicate to training.

Q. What are the barriers to APPs working in clinical research?

A. Primarily, it's the workload of APPs that hinders them from doing research. Poor workflow can also work against them. Even if a practice is very busy, if you have an efficient workflow, your APPs can be fully involved in research. APPs often say to me, "I



University of Hawai'i Cancer Center Faculty staff: Nate Ramos, Sasha Madenn, Shirley Higa, Diana Martin, Jenai Umetsu, Dr. Jami Fukui, Christa Braun-Inglis, Kate Bryant-Greenwood

have too many patients to do research." Well, yes and no. It depends on how you set up your practice's workflow.

When you have different silos for research and medical oncology departments, it's virtually impossible to build an efficient workflow for conducting clinical trials. If a practice integrates patient treatment with clinical research and individual roles and responsibilities are clear to everyone, even a busy practice can host clinical trials.

To achieve a model in which APPs are active in conducting trials, it is very important to have a physician champion. I have had many champions over the years, and they have helped me establish my role as a clinical researcher. I think more APPs would be conducting clinical trials if this were the case for everyone.

Restrictions on the roles APPs can play in conducting clinical trials are another barrier. For example, the NCI does not permit APPs to prescribe drugs in clinical trials. Because that means APPs must track down physicians to sign prescriptions, processes can slow down and interfere with efficient workflow. This lessens the appeal of using APPs in clinical trials, since their scope of practice is limited.

For trials that do not involve medication—such as quality of life or care delivery studies—APPs can be very effective at accruing patients to trials (separate from an oncologist), given their knowledge of the patients they care for. However, because most community APPs are not engaged with the research community, they are often unaware of these trials.

When I joined the University of Hawai'i Cancer Center as an NP/assistant researcher in 2018, I wanted to get more APPs involved in oncology research across the community. I have worked to recruit the 10 oncology APPs in Hawaii to be registered as non-physician investigators through the NCI, which enables them to enroll patients in clinical trials. I mentor them, educate them, and help get them registered with the NCI.

Q. What roles should community cancer centers play in the conduct of clinical trials?

A. Community cancer centers treat about 85 percent of all cancer patients. When clinical trials are conducted solely in academic or research-specific settings, how generalizable are those results to the entire population? The patient populations of community cancer centers and large research institutions are very different. Their socioeconomic status is different, and their ethnicities vary. Conducting studies within local communities makes it much easier to apply findings to the populations most affected by cancer.

For example, if you give patients a dose of a drug found effective for people in a large city on the mainland, it may not be an appropriate dose for patients in Hawaii. A small Asian woman



Christa Braun-Inglis with a patient at Kapiolani Women's Cancer Center, a UHCC Consortium community practice site.

is not going to metabolize a drug in the same way as a group of Caucasian men in a clinical trial in New York City. In Hawaii, there are unique geographical and economic considerations that may pose transportation and financial challenges that patients on the mainland do not experience. When we conduct trials in our own communities, we better understand how different drugs affect a variety of people in ways that are not typically considered.

It is also vital that non-pharmaceutical trials that study quality of life and care delivery are conducted in local community cancer centers. As our patients live longer due to new drugs, quality of life and survivorship become bigger issues. We need these types of trials just as much as we need treatment trials.

I do think the movement of some trials to community cancer centers is accelerating, but we still have a long way to go. I would like to see more pharmaceutical industry and NCI-sponsored trials in local communities. Right now, it's difficult for community cancer centers to participate in pharma trials. They don't have the infrastructure to launch trials as quickly as larger academic and tertiary cancer centers.

I would love to see NCORP grow. As the role of APPs expand in community cancer centers, it makes sense to allow us to participate in more oncology trials. Many times, APPs are the closest to patients, and they know their specific needs. They are uniquely suited to identify the patients most suited to participate in individual trials.

Q. What are the demographics and specific needs of the patients you serve?

A. I see everyone, from the affluent to the very poor. I even have one patient who is homeless right now. Honolulu is very metropolitan. Our patients are Caucasian, Asian, Pacific Islanders, and many mixed-race individuals from our local populations. I see patients, counsel them, order chemotherapy, do follow-up visits, and manage symptoms.



UHCC Director Dr. Randall Holcombe presents the UHCC Award for Most Non-Therapeutic Accruals to Oncology Clinical Trials to the first APP recipient, Ashley Springer, MS, APRN, AGPCNP-BC.

Hawaii is home to many different cultures and languages. For our patients who do not speak English, we often use in-person translators. However, at times that can be a barrier, depending on the culture of the person we are treating. For example, for certain Pacific Island cultures, there may be only male translators available. Sometimes that male-female dynamic between translator and patient can be uncomfortable for a patient who has breast cancer.

Nevertheless, as patients come into the clinic for treatment repeatedly, they become better and better at communicating in English. In addition, we often develop an unspoken language in which patients can indicate whether they are comfortable discussing something in front of a translator. In general, we do prefer in-person translators. When they are not available, we have a video conferencing system that provides translation services for our patients.

I have one patient who speaks a native language so rare that there is no translator available. Unless she comes in with her cousin, I cannot communicate with her. She is from Micronesia, a nation that consists of several islands in the Pacific. Hawaii is the closest state to Micronesia, so the people who live there often come here for treatment. Micronesians speak a variety of native languages. They make up probably 10 percent of our patients. Sometimes we get patients from very remote areas and there is no translator available. It's a special population that we treat in Hawaii. We have a huge immigrant population in general. It's so diverse: 20 percent Caucasian, 20 percent native Hawaiian, 20 percent Filipino, 15 percent Japanese, 5 percent Chinese, 10 percent other Asian, 5 percent other Pacific Islander, and 5 percent other. There are so many mixed-race people here; I would say most of the people in Hawaii are of mixed race.

The multiple languages and cultures we encounter can create barriers to clinical trials. Perhaps the consent form or other paperwork is printed in English or Spanish, neither of which some of our patients speak. The language and cultural barriers we experience are not like those in other states. Our immigrants are very different from the majority of the country's immigrants.

Q. Does Hawaii's unique geography pose barriers to the delivery of cancer care?

A. Hawaii's unique geography and population can make it difficult to access healthcare here. In Honolulu, we have very good transportation resources, so patients can generally get to the treatment they need. But when you expand to the outer islands, it gets more difficult. We have approximately one million residents on Oahu and approximately 400,000 residents on the other islands that make up the state.

Every island outside of Oahu is considered rural. It's a challenge to retain oncologists on the outer islands; we have a lot of turnover. Patients there who need cancer care cannot always drive to their local clinic. If there is no one to treat them where they are, they must get on a plane.

We have oncologists who continually travel among the islands to provide care to patients where they live. In some practices, traveling to other islands a few days a week is the norm. At one of the practices at which I worked in Honolulu, we routinely flew to Hawaii Island to see patients there. That island did have a stable oncology clinic, but it's very difficult to keep oncologists long term, and we constantly struggled with that.

Q. Tell me about your research on the role of APPs in clinical trials.

A. When I joined the University of Hawai'i Cancer Center two years ago as nursing faculty supporting clinical research, I wanted to increase the involvement of APPs in clinical trials, especially in the community. (The University of Hawai'i Cancer Center does not have its own clinical space, so all of our practice is in the community.) I tried to research the role of APPs conducting research in community cancer centers, but I found nothing in the literature. One article addressed the potential role of NPs in research, but there was a lack of data on the topic that surprised me. So I began to develop a survey to determine if there were others like me and, if not, why?

I worked with ACCC to develop a survey for APPs and pharmacists, and I piloted it in Hawaii. I added pharmacists because they, too, can add value to clinical trials, as they are integral in reviewing protocols and medications. I gave the survey to 20 practitioners in Hawaii and then led a focus group to further refine the survey. I took it to the ACCC Clinical Affairs Committee and asked the members for feedback to ensure the survey reflected a national audience.

I then conducted a national pilot, surveying 28 NPs, physician assistants, and pharmacists to validate the survey on a national level. In January 2020, we (ACCC and Harborside) sent the final survey to more than 14,000 email addresses. Over a period of six weeks, we received more than 400 responses. We are now in the process of analyzing those data, and we have submitted an abstract to the American Society of Clinical Oncology. Ultimately, I hope to use my data and conclusions to advocate on behalf of oncology APPs and pharmacists who want to assist with clinical trials on the local level.

I particularly want to provide evidence that counters policies that prevent APPs from prescribing medications and thus fully participating in clinical trials. APPs cannot prescribe any drug in an NCI-sponsored clinical trial, whether they are primary treatment (e.g., chemotherapy) or supportive (e.g., anti-nausea) drugs. These tasks are the very essence of what oncologists rely on APPs to do.

APPs also cannot enroll patients in NCI trials that have medications as independent providers; we must enroll under a physician. This is also the case for non-treatment trials. While these trials may not be top of mind for physicians, they are for many



Iconic Diamond Head, Waikiki Beach, Honolulu, Oahu, Hawaii.

APPs, and they allow us to improve quality of life for our patients who are living longer. Good news, however: NCI is in the process of changing their guidelines. There are also barriers in pharmaceutical trials. Many clinical research protocols are not updated with an APP scope of practice.

Q. Can you share any preliminary results from your study?

A. Yes, we've found that approximately 90 percent of APPs believe there should be a role in clinical research for us, and more than 75 percent want to become more involved. More than 66 percent of the respondents practice in community cancer centers, where more research should be taking place. We identified several barriers to APPs playing a more active role in research, including under-representation on research committees, heavy workloads, and a general lack of knowledge about the trials that are out there. Only about 50 percent of respondents knew if they were part of an NCORP. Until these factors are addressed and APPs are embraced as partners in clinical research, I believe it is a huge miss for the community cancer centers.

On the plus side, I see more APPs becoming energized about this issue. Like me, they are identifying the barriers that exist and are addressing them. The bottom line is that little will change if APPs are not aware of trials and how they work. We should be aware, if for no other reason than we are the ones most familiar with the needs of individual patients, which makes us uniquely suited to match patients with the trials most likely to benefit them. APPs add value to patient care in so many ways, from managing symptoms, to coordinating care, to helping patients maintain a good quality of life. Research is an area in which they could also have a significant impact, ultimately resulting in better patient care.

Barbara A. Gabriel, MA, is the senior writer/editor at ACCC and an associate editor of Oncology Issues.

Telehealth at Its Best









Transitioning a comprehensive psychosocial program to a virtual format



ife with Cancer, a program of the Inova Schar Cancer Institute, is a national model for cancer education, psychological health, nutrition, and wellness. Each month, it offers about 200 programs at five locations throughout Northern Virginia. A variety of classes, integrative therapies, wellness programs, individual counseling, and support groups are available to patients (adult and children) who are in treatment or survivorship. Family members and friends of patients are also welcome at many of these programs. Life with Cancer programs are evidence based and reflect standards set by the American Society of Clinical Oncology, National Institutes of Health, National Comprehensive Cancer Network, Oncology Nursing Society, Society of Integrative Oncology, Oncology Dietitian Practice Group, and the American Institute for Cancer Research. Programs are designed to help individuals and the community understand cancer, its treatment and side effects, how to maintain physical and psychological health, and how to navigate illness and survivorship. Due to generous donations from the community and the commitment of the Inova Schar Cancer Institute that anyone impacted by cancer should have access to the tools they need to live better with cancer, all programs, except for psychiatry, are provided at no cost-regardless of where people receive treatment. For a comprehensive look at the Life with Cancer program, we refer readers to this article in the March/April 2018 Oncology Issues: accc-cancer.org/LifeWithCancer.

Global Pandemic Requires a Call to Action

Due to the COVID-19 pandemic and its associated risks for patients with cancer, all Life with Cancer programming was cancelled on Mar. 12, 2020. Staff, struggling with their own Remarkably, between Apr. 1 and Apr. 30, 2020, Life with Cancer successfully transitioned more than 100 classes and groups to a virtual telehealth format, as well as all individual counseling and nutrition and educational consult sessions in which 3,025 patients and family members participated.

anxiety over personal safety, quickly went into action on how best to continue to meet the psychological and educational needs of patients and families. Although Life with Cancer had offered virtual one-on-one patient sessions for three years through Vidyo, a Health Insurance Portability and Accountability Act-compliant telehealth platform, patient reception had been tepid and services were only used by those who were too ill to travel or those who lived far from a Life with Cancer location. After COVID-19, requests for individual counseling, education, and nutritional telehealth consults increased significantly.

During the last two weeks of March, staff researched appropriate technology platforms, state regulations, suitable classes to transition to a virtual platform, and how best to market. Due to the group-style nature of Life with Cancer programing, Inova Health System ensured that clinicians had access to the Health Insurance Portability and Accountability Act-compliant telehealth platform, Zoom Pro. One of the first steps was then to determine the state's Department of Health telehealth regulations. Fortunately, many prior restrictions specific to licensure and accessibility were temporarily lifted due to the pandemic. The next step was to develop a policy for online etiquette that addressed privacy and security concerns for participants. The policy the team developed included the following:

- Participants must enroll for all Life with Cancer classes and programs through the Life with Cancer website registration page.
- Twenty-four hours before a class, registration is closed and a copy of the Zoom invitation is sent to all registrants.
- All curriculum materials are emailed to participants prior to the start of a class.
- To protect the privacy of personal emails (Zoom does not allow for blind-copy sending of a Zoom invitation), program facilitators create, copy, and then send the invitation to participants through their Inova Outlook blind copy function.
- Life with Cancer administrative staff are included in the email, so they can send invitations to accommodate late phone registrations.
- Participants are encouraged to create a Zoom sign-in using only their first name.
- Facilitators use the waiting room option and cross-check names against the list of invitees.
- The class is locked down once the group begins.
- Facilitators disable the screen sharing option for participants.
- For support programs, where information is shared among participants, all participants are asked to activate their cameras, although for several reasons, such as challenges with technology, some participants are unable to comply with this request.
- Participants are asked to ensure that they are in a private space, so no one else can hear or see the session; however, Life with Cancer is clear that privacy cannot be guaranteed.
- Participants are also advised that there is no recording or photos taken of sessions.
- Participant feedback is collected through Survey Monkey after the session ends.

Initially, staff was anxious as Life with Cancer made the huge pivot to telehealth and wondered how this new therapeutic realm would affect best practices. Our experienced clinicians use visual cues—body language, breathing, muscle tension, and facial expressions—to direct support and interventions. Many worried how to remain attuned to these important aspects of care through a computer screen.

There was a sense of urgency for clinicians to learn how to navigate the features and functionality of the Zoom platform. Staff was keenly aware of their accountability to patients and families who were experiencing even higher levels of distress during the public health emergency. Our therapists, nurses, and dietitians familiarized themselves with Zoom Pro as quickly as possible, so that they, in turn, could act as Zoom experts for patients and families. Our staff held countless practice sessions to work through any challenges—on both their office and home networks, because most staff were now working off-site. With class location no longer a consideration, schedules were adjusted. For example, five caregiver groups offered throughout the system were condensed to three groups.

Though many team members described themselves as "technologically challenged" long before COVID-19, our clinicians learned from each other, supported each other, and faced fears and technological learning curves together—recognizing that it was all in an effort to continue to provide access and support to patients during this unprecedented time.

Remarkably, between Apr. 1 and Apr. 30, 2020, Life with Cancer successfully transitioned more than 100 classes and groups to a virtual telehealth format, as well as all individual counseling and nutrition and educational consult sessions in which 3,025 patients and family members participated. As of Sept. 1, 2020, in just five months, more than 7,200 individuals had participated in just the fitness classes.

Lessons Learned

Fitness Classes

Some of the first classes that were made available virtually were fitness related. Prior to going live in this virtual space, Life with Cancer offered more than 100 fitness programs each month ranging from cardio drumming, chair-based exercise, yoga, Tai Chi, Zumba, circuit training, and much more. It was a challenge to understand how these programs would work virtually—especially because the original format offered the in-person experience of improved health through movement and the bond that comes with being in a community of others who have shared experiences.

Because fitness classes were held at five different locations, many offered by contractors, moving these classes online posed several challenges for Life with Cancer.

Susan Gilmore, MS, ACSM-CET, program manager of fitness shared, "The transition from personalized, on-site training to streaming exercise instruction required a technically tricky changeover to re-orient program resources and technology. We moved from fitness training in a controlled environment with music, student cueing, and on-site equipment to instructing our patients in their home environment."

Our instructors assessed class curriculums to determine how each could be adapted for live streaming, working out challenges with streaming simultaneous music and verbal cuing. Because instructors could no longer see and offer corrections, each class began with written and oral safety reminders and release waivers that participants had to sign prior to class.

Life with Cancer offered 52 virtual fitness classes within the first month. Response to the online format was amazingly favorable. Participation in fitness classes continues to grow as patients welcome the convenience and accessibility of at-home workouts. In fact, Life with Cancer has had almost twice as many students with fewer classes. "One reason live streaming caught on so quickly and has been so successful has been the ability of our patients and instructors to adapt to the new platform," shared Gilmore. "The live streaming allows our patients to continue to feel part of the Life with Cancer community. They can reach out to one another after class. Life with Cancer has virtual check-ins to encourage and support students in this 'new-normal' environment."

Perhaps, this comment from one couple sums it all up, "Thank you for all you have done with the fitness program online! The life-affirming connections, the support from you and the teachers, the guided healing, is so greatly appreciated. I'm sure we all share this feeling!"

Brain Fog Psychoeducational Program

An education program addressing cancer-related cognitive impairment, also known as brain fog, was scheduled to start the week Life with Cancer was told it could no longer safely hold in-person classes. This four-week program:

- Presents the state of the research on cancer-related cognitive impairment.
- Discusses contributing factors such as anxiety, depression, and insomnia.
- Focuses on evidenced-based strategies to manage the effects of brain fog using compensatory strategies, lifestyle factors (exercise and nutrition), and psychological strategies and contemplative strategies, such as cognitive behavioral therapy and mindfulness.

The program is designed so that each participant completes an individualized brain fog plan at the end of the program. Due to this individualized component and the use of scales as part of the brain fog curriculum, staff required significant time to transition the class to an online format. Typically, one therapist supports the group through all four presentations, but for virtual classes, two therapists were needed to launch the program online.

From a program delivery standpoint, there was also a learning curve. In an in-person group, welcoming participants to the group is easily managed; with the move to Zoom, more attention is required for this once simple task. In the program's first meeting, an oncology nurse navigator shared background information and the current state of research on cancer-related cognitive impairment. Seven of the 10 registered participants signed on to the Zoom meeting. Some signed on with their name as "iPad" or "iPhone." For security reasons, the moderator verified participants' names by offering a private chat with the moderator. Participants who did not respond to these requests were removed from the group. Though this action was intended to safeguard participants' privacy, the moderator wondered whether removing people from the group might negatively impact the open and inviting environment.

The nurse navigator then delivered her lecture of educationally dense and potentially emotionally charged material. Although she encouraged questions and offered the group a break, more and more participants turned off their cameras as the class went on. This experienced facilitator was concerned about aspects of



Susan A. Gilmore, MS, ACSM-CET, Program Manager – Fitness, teaching a cardio drumming fitness class via Zoom.

brain fog that could make virtual learning difficult; for example, executive function changes that affect emotional regulation, concentration, and attention. Was this the right group for this virtual platform? Without participant feedback, it was difficult to come to any conclusions. The navigator also commented that lack of visual cues from participants, which normally helped pace and target her talk, left her feeling exasperated and she only imagined that the participants shared a similar feeling. This first virtual class did not look like a success.

Armed with this information, the oncology clinical therapist who led the second session emailed participants prior to the start of the session and asked them to share their video. This request was an effort to increase social interaction and facilitate concentration, learning, and physiological and emotional regulation based on the polyvagal theory by Stephen Porges.¹ Though one group member would not share their video due to security concerns, other group members complied. The facilitator also increased the number of times the group entered discussions, meaning that the slide deck was "closed" and the group returned to a format where all participants were seen on the screen. Although less content was delivered due to this approach, engagement seemed higher. One participant said that after the second session she felt "less defective and understood the brain better, how it was affected by emotions, and what was going on in the body." Though the facilitator shared that there was still a preference for an in-person group, it was helpful to have participants share their video and have more planned discussions.

Integrative Psychosocial Oncology Program

Life with Cancer has developed a novel, four-program curriculum designed to build emotional coping skills and resilience from cognitive, mindfulness-based, and contemplative perspectives called the Integrative Psycho-Oncology Program. Each program



The Life with Cancer team.

in the curriculum is five to eight weeks long for a total of roughly eight months. The curriculum focuses on the different strategies of emotional regulation, including cognitive, mindfulness, compassion, and meaning making. One program in the curriculum, "Mind Over Matter," was developed by Life with Cancer, and the other three, Mindfulness-Based Cancer Recovery, Compassion Cultivation Training, and Meaning-Centered Psychotherapy, were created by institutions such as the University of Calgary, the Stanford Center for Compassion and Altruism Research and Education, and Memorial Sloan Kettering. The programs are designed to be taken in order because the skills learned in earlier programs build a foundation for the experiences and skills learned in the later programs.

At the onset of COVID-related restrictions, one cohort had just finished Compassion Cultivation Training and was scheduled

to start Meaning-Centered Psychotherapy. Another cohort had completed the orientation for Mindfulness-Based Cancer Recovery but had not started on program content. Lastly, we offered a monthly drop-in group for anyone who completed the second program in the curriculum, Mindfulness-Based Cancer Recovery. This drop-in group was the easiest to conceptualize in an online format. There were no new skills being introduced, and many of the regular group members knew each other and were familiar with the meditation and mindfulness content. The drop-in group was designed to maintain connection and offer a more formal opportunity to practice. Members of this group shared their appreciation for the opportunity to connect and meditate together, including one participant who said, "I feel that I had special training for this situation." She shared that the Integrative Psycho-Oncology Program programs, collectively, had taught her coping skills and that she could trust those skills and her ability to manage uncertainty and fear—the feelings that COVID-19 brought up in her. The drop-in group often closes with a loving kindness meditation and did so in the virtual format as well, promoting shared feelings of connection, gratitude, and satisfaction.

Offering an eight-week experiential program like Mindfulness-Based Cancer Recovery in an online format was more challenging. These groups had met only once in person before making the switch to the virtual environment. Each session had a discussion component, but most session time is spent in meditation or in other mindfulness practices, such as mindful movement, yoga, or walking a labyrinth. The labyrinth is a walking meditation that offers participants more time for silence and to focus on one intention. It is a different form of movement meditation that provides the opportunity for a spiritual connection or connection to an entity larger than the self. How does one walk a labyrinth virtually? Our team members began to explore alternate possibilities. One facilitator gave his participants two different Zoom links for the labyrinth session. One link, he explained, was for the first part of the session-the opening meditation and discussion-and he encouraged patients to use video. The second link was to call in by phone only, so that participants could be mobile and hands free. He invited participants to place the call while outside for a walking meditation in their own outdoor environment. The facilitator was then able to craft the meditation to hold all of the components of the original experience of walking the labyrinth by relying on the exploration of the senses and walking for structure, rather than the structure and intent of walking a labyrinth. Group members shared their enjoyment of this experience and said that they have done similar practices on their own after participating in the group.

Unlike the other Integrative Psycho-Oncology Program classes, the Meaning-Centered Psychotherapy group was intended to be initiated in an online format. Luckily, some participants in the program had also participated in the Mindfulness-Based Cancer Recovery drop-in group. The potential challenge of this group is that the content is often deeply personal and shared very early in the group formation process. Facilitators worked, as usual, to create connection and a sense of safety but felt challenged by the virtual setting. The group is led by two experienced facilitators who noted that they had to work harder to stay connected to each other and to the participants in the group because they realized much of their communication, and therefore coordination, was nonverbal.

The first two of the eight Meaning-Centered Psychotherapy sessions were challenging. In the third session, the facilitators focused on their experiences with this group and invited conversation on what was and what was not working. Finally, the group began to coalesce. Many factors may be at work here—a slightly smaller group attended the third session, the content of the session may have been easier to connect to, or, three sessions in, the group was naturally forming.

"I do think participating in a virtual group does change the dynamics. Physical presence allows for more easily shared compassion," wrote one participant. Another wrote, "Virtual participation also makes it difficult to realize when to speak. When physically present you see others' expressions and readiness to speak and you can gauge when to jump in." However, the overall response to the Meaning-Centered Psychotherapy sessions was positive.

Support and Networking Groups

Three Life with Cancer support groups were held virtually even before the pandemic: The Lung Cancer Group, Weight Management for Women Who are Survivors of Breast Cancer, and Young Women with Breast Cancer. Interestingly, the Young Women with Breast Cancer group, which had been held in person at one location for many years, had been cancelled for several months due to low registration numbers. When Life with Cancer offered the support group online, nine women signed up for the first virtual session and requested that the group continue to use this format going forward. Participants shared that their busy schedules and the needs of young children had prevented them from being able to attend an in-person group.

During the first virtual meeting of Weight Management for Women Who are Survivors of Breast Cancer, one participant commented, "It was a bit awkward at first as I was inexperienced with Zoom." Another wrote, "Conversation lagged initially as there were several new members to the group but got better as the 90 minutes passed. The Life with Cancer staff was very good (as usual!) with providing info and answers to questions. I plan on trying the group again if it's still online next month. Thank you so much for the continued support!"

The first virtual Lung Cancer Group meeting had 19 participants, who offered many grateful comments. "It was great to be able to connect with everyone in a safe environment. I think the facilitators did a wonderful job of making sure everyone had a chance to share and not talk over others. For a first run, it was fantastic!"

Educational Groups

Life with Cancer offers several pre-surgical classes for patients, as well as rehabilitation classes that focus on survivorship needs. The virtual pre-surgical classes were significantly smaller than the usual in-person group largely due to the number of surgeries scheduled, which decreased due to COVID-19. Patients welcomed the information and interactions. As with other programming, classes worked better when participants left their videos on. Setting this expectation up front and including it in the class description increased patient participation and engagement. The oncology nurse navigator who facilitates the class reported that the level of comfort and engagement among patients was the same as in the in-person classes. Facilitators strove to provide an open atmosphere and found that participants also engaged with each other, which reflected a similar tone to the in-person classes. Some participants mentioned that it was much easier to involve their caregivers in the virtual process because they did not have to coordinate logistics and schedules. A few participants were very appreciative of the virtual pre-surgical class because they would not have felt comfortable attending one in person and risking exposure to COVID-19.

The new online format did pose challenges and necessary changes. Traditionally, facilitators distributed informational material during class and offered hands-on demonstrations to participants. As a work-around, facilitators emailed information the day before the class, including PowerPoint slides, a drain record, and other basic information. Sending the information prior to the virtual session allowed facilitators time to help participants who had trouble opening or accessing materials. For information and supplies that were unable to be sent electronically, facilitators created pre-op kits (educational booklets, drain belt, Hibiclens, and/or Ensure) that the patients picked up from their surgeon's office, the hospital front desk, or by driving up to the front of the Life with Cancer Family Center so the package could be handed off into a car window. It was also important that facilitators had a good grasp of Zoom functions because they needed to switch between sharing PowerPoint slides and fullscreen demonstrations of teachings, such as drain or ostomy care, throughout the class.

Virtual Support of Children and Adolescents Impacted by Cancer

Life with Cancer's Child and Adolescent Program offers psychoeducation, parent consultations, individual counseling, group therapy, resources, and other programs to support children and adolescents impacted by cancer (e.g., those diagnosed with cancer or whose family members are diagnosed with cancer) and their parents and caregivers. Our licensed clinical oncology therapists provide evidence-based therapies to help with adjustment, anxiety, mood and behavioral changes, grief and loss, and more.

Prior to the COVID-19 pandemic, services were offered in several locations including the outpatient Life with Cancer Family Center, Inova Schar Cancer Institute pediatric oncology clinic, and the Inova Children's Hospital pediatric oncology inpatient unit. As a result of necessary social distancing regulations, national stay at home orders, and changes to clinic and inpatient policies, Life with Cancer leadership quickly embraced new models of service delivery, like telehealth, to continue providing the highest level of care in this rapidly changing environment.

Converting to telehealth brought unique challenges to our pediatric providers, because virtual formats were not feasible for some of our previous models and modalities of care. For example, we made the difficult decision to suspend our in-person Touchstone Grief Group, a six-week psychoeducational group for children six to twelve years old who have lost a loved one to cancer. There are few evidence-based guidelines for conducting group teletherapy to school-aged children and most of the existing program curriculum involved hands-on activities. As an alternative, Amanda Thompson, PhD, the chief of Pediatric Psychology at Life with Cancer prepared and recorded two educational webinars: 1) the typical emotional and behavioral reactions that are common among grieving children and 2) strategies for supporting children as they grieve. Both videos were immediately made available to parents via the Life with Cancer website. One benefit to this format was that all caregivers of grieving children could access the videos-not just those who had planned to attend the grief group, which typically includes six to eight families. Parents of grieving children are offered individual parent consultation sessions through Zoom, and older children and adolescents can receive one-on-one grief counseling online. This transition has proven successful, as illustrated through the words of a grateful grandmother, who is now the guardian of her 17-year-old grandson after he lost his mother to cervical cancer prior to the pandemic: "He always seems a bit lighter after he speaks with you. He isn't much of a talker with anyone else, and it's a challenge for me to gauge how he's doing. Thank you for finding an alternative way to continue working with him. I always notice a little more pep from him after you meet. He is a difficult one to get to open up at all, so I'm truly grateful for you, especially during this pandemic."

As with other groups, COVID-19 and the conversion to telehealth required us to alter our approach to individual counseling for children. Dr. Thompson explains, "While adolescents generally have great comfort and familiarity with technology and easily made the transition to the virtual format, we knew it was going to be much more difficult for younger children to stay engaged via telehealth. This is especially true for children who struggle with attention or hyperactivity."

In addition, child-focused approaches like play therapy do not translate well online, and we do not have sufficient evidence to support its effectiveness in the virtual format. As a result, for our younger children, we have largely switched to offering parental consultations for managing child anxiety, stress, grief, and behavior problems—challenges that have been exacerbated by the required quarantine, school closures and cancellations of major milestones and/or events, and societal focus on illness and collective loss.

"Our goal is to support parents, normalize these challenges, and empower them with evidence-based skills that they can use to coach their children through these difficult times," Dr. Thompson explains. She describes the success of telehealth in working with the young mother of a five-year-old girl, who lost her father just prior to the pandemic and was struggling with more frequent and intense tantrums and difficulty sleeping alone at night. "After five virtual sessions, where I provided this overwhelmed and grieving (yet very motivated) wife and mother some concrete and evidence-based behavioral management strategies, this young girl is sleeping through the night in her bed and hasn't had a tantrum in two weeks," says Dr. Thompson.

Because the children and adolescents we work with are among the most vulnerable, Dr. Thompson notes that there are important considerations for providing telehealth services to children and adolescents, including:

- Thoughtfully considering and/or evaluating whether the child can participate meaningfully in telehealth, which may vary by maturity, presenting issue, physical limitations, attention/concentration, and hyperactivity.
- Ensuring parental presence in the home and/or availability during a session in case of crisis, particularly for adolescents

who generally choose to meet without a caregiver present.

- Having a clear plan for addressing safety issues that may arise during a session.
- Being flexible (e.g., adjusting your expectations, like the length of sessions if you are having a hard time keeping the child engaged).
- Taking time to build rapport in the virtual environment.

Regarding the latter, Dr. Thompson shares, "Even if you've met previously in person, it's important to take the time to make sure the child feels comfortable in this new environment. Evidence shows that kids who are initially anxious about telehealth tend to feel less distressed after 10 to 15 minutes."

Oncology therapists have used a number of approaches that take advantage of the virtual platform to promote rapport building, including asking participants to show off their room or preferred toys and belongings, having the child color or draw and then share their picture, using the whiteboard feature of Zoom to play tic-tac-toe or other games, and/or playing virtual Uno while talking.

As the COVID-19 crisis continues, Life with Cancer will look for new ways to support children and families impacted by cancer by leveraging technology and virtual platforms. Therapists are now piloting a support group for parents of pediatric oncology patients and will be launching another support group for adolescents currently in treatment for cancer. The team is learning from their successes, while understanding the limitations within pediatrics, and maintaining a growth mindset to be well positioned to care for children and families in the post-COVID healthcare landscape.

Receiving an email from a patient who has taken the time to craft a heartfelt thank-you that acknowledges the importance of the program and continued connection during what feels like an entirely disconnected time right now validates every effort that was made by Life with Cancer along the way.

Need for Self-Care

Staff quickly determined that though doable, virtual sessions required additional energy and focus and said that they often felt depleted afterwards. The larger virtual groups added additional variables and required steps for both facilitators and participants. Individual virtual counseling required a thoughtfulness toward body language usage because therapists often speak or gesture with their hands and at times hands were below the camera for video visuals. The Life with Cancer team initially scheduled daily meetings to discuss challenges, brainstorm, and problem solve. There was a mutual feeling of "one team," because all facilitators were learning and implementing virtual programs at the same time. We quickly recognized a continued need for increased patience and flexibility. As a result of all of these new stressors related to virtual programming, it became critical to renew a focus on staff self-care. We heard from some of our clinicians, who are mental health and healthcare experts, that it was hard for them to ask for help. We tried to create intentional spaces through large group and smaller team meetings for Life with

Cancer team members to discuss the challenges this new virtual environment brought, in addition to the added stress and fear from the unknowns of the COVID-19 pandemic. We set up a buddy system, pairing staff one on one; organized regular team lunches that are optional; and held after-hours fun, Zoom sessions to play Pictionary and other games. All of these strategies had varying successes. Some of the challenges staff were experiencing (i.e., exhaustion, disconnection, and isolation) are inherent to communicating over video and simply could not be resolved with more video time. We continue to work on supporting our staff as they provide support to patients and families and as we all adjust to this new normal. Given that our traditional ways of coming together as a team in person are not feasible ways to find connections and small successes within work, identifying creative ways outside of work has become even more important.

Looking Toward the Future

Like many organizations, the COVID-19 pandemic forced Life with Cancer into a virtual space much quicker than anticipated. Luckily, our staff have been contemplating this move for several years now. Keenly aware of the therapeutic value of personal connection, closeness, and community building that comes from sharing physical space, the team was surprised to learn the extent to which online programming can meet some of these needs while also eliminating barriers. Given that the pandemic has no end in sight and the immunocompromised nature of oncology patients, it is likely that in-person groups will not be possible for some time and virtual groups will continue to be a viable option to meet the psychological, educational, and physical health needs of patients. For some, offering counseling sessions over Zoom is more favorable than the current in-person alternative where facilitators and patients both don masks, especially when considering the important nuances of body language and facial expressions. The learning curve has been steep and continues to grow at an exponential speed. Fortunately, telehealth can help overcome access issues related to time and travel for staff and patients and other issues, like a limited amount of physical space for classes. As Life with Cancer moves forward, the team will thoughtfully consider what programs can remain online, what new programs are needed, and what challenges will occur when virtual care is transitioned back to in-person care. One thing is certain-Life with Cancer has been changed forever as an organization and will continue to provide programing virtually because it is in the best interest of our patients and families.

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Confronting Cyber Threats to Your Practice

How to prepare for—and respond to—a potential catastrophe

yberattacks can take place against any entity on any scale, striking both individuals and multinational companies with consequences big and small. As we have seen repeatedly, not even the largest companies with the most sophisticated security resources at their disposal are immune from security breaches.

The healthcare industry is particularly vulnerable to attack because medical practices typically house their most valuable data on the web. The severity of an attack and its impact on a practice can vary dramatically. Attacks can range from relatively benign actions, such as installing simple adware, to threatening a whole practice by compromising an entire network.

Even if you have not experienced a malicious cyberattack, it is critical to have a plan in place to prepare for the possibility of a security breach. Often something as simple as an employee opening a phishing email can escalate into a device compromise that can disrupt, delay, or shut down business operations entirely, impacting your ability to care for patients. That might sound dramatic, but it is an entirely plausible scenario of what can occur if an attacker is given an easy opening into and throughout your network with little to no resistance. Those of us who work in the cybersecurity defense industry all echo the same adage to our clients: Hackers can attack as often as they like; they only need to be successful once. This scenario puts on the onus on practices to always be on alert.

Unfortunately, it is not realistic to expect your practice to be able to successfully ward off every attempted attack in perpetuity. There are far too many variables, including your clinicians and staff, your third-party vendors and service providers, new technologies and systems, and ever-evolving attack tactics. Because Careful preparation should be the first element of your incident response plan. Responses to cyberattacks should not be an entirely reactionary function; careful planning, preparation, and training can serve as significant risk mitigators.

maintaining a 100 percent prevention rate is impossible, it is crucial to have a plan in place for response, mitigation, and recovery.

Responses to cyber incidents should follow a playbook. Regardless of the size of your practice or where you are located, your cyber security procedures should be the same. The following is an outline of what a cyber incident prevention and response plan should look like, the questions you should ask of yourself and your information technology (IT) or security team, and what you should do in the event of a worst-case cyberattack scenario. In general, an ideal cybersecurity incident response plan should:

- Assemble an incident response team.
- Detect and analyze potential security threats.
- Disclose incidents when they occur.
- Contain any damage.
- Eradicate identified vulnerabilities.
- Conduct a post-incident analysis.

Prioritize Your Threats

The types of events that may trigger an incident response protocol can vary greatly, and you should take all of them seriously. Your team should not only respond to perceived catastrophic events. For example, within a hospital network or clinic, thousands of indicators of potential security incidents may appear each day. An organization typically logs these events, and they can provide an abundance of data that companies can mine for prevention purposes. These data can be filtered using automated techniques, yielding valuable information that IT staff can use to identify whether a security incident has occurred.

Incidents should be prioritized based on their functional impact and the time and resources needed to recover, not dissimilar from the triage approaches used by healthcare providers. If you are unsure which incidents you should prioritize in your organization, you may want to start by performing a business impact assessment to identify your most pressing security concerns. Classify the types of adverse situations your practice may encounter into three separate categories:

- 1. Events
- 2. Security incidents
- 3. Breaches.

These categories should dictate your team's response. For example, a compromised endpoint, such as a phishing email that was clicked on a laptop, should be classified as a security incident. Should the phishing malware take hold of critical systems, such as your electronic health record or billing software, that occurrence should be classified as a breach.

The term *breach* is often considered a four-letter word. As with most words, though, its true meaning is rooted in context. For example, although you might not have a *Health Insurance Portability and Accountability Act (HIPAA) breach*, you could still have a *contractual breach*. You should attempt to use uniform nomenclature in your internal documentation for the sake of clarity, particularly regarding your information security policy and incident response plan. Review the language in your contracts to ensure terms are consistent and mutually understood.

In any instance of a security compromise, taking the following steps can provide a standardized roadmap for organizations to address the cyber risks that threaten them and respond appropriately with established incident response plans.

Be Proactive

Careful preparation should be the first element of your incident response plan. Responses to cyberattacks should not be an entirely reactionary function; careful planning, preparation, and training can serve as significant risk mitigators.

In the early steps of incident response, it helps to have ready access to continually updated information about your personnel, assets, and processes, including items such as contact information for team members, network diagrams, computer inventories, templates for documenting security events, spare computers for gathering evidence and analyzing forensic information, and an incident reporting mechanism through which employees can proactively report suspected attacks. Organizations should take proactive measures to address potential disruptions in business operations, including:

- Performing risk assessments. HIPAA security rules mandate that organizations undergo risk assessments annually. We recommend risk assessments that include an exhaustive vulnerability analysis of technical resources to get a full picture of your risk landscape.
- Ensuring endpoint security. "Endpoints," such as servers, laptops, and workstations, should be appropriately secured, incorporating permissions controls according to individual job tasks and implementing configurations in accordance with HIPAA technical controls. We recommend forgoing traditional antivirus software in favor of next-generation antivirus products that are inclusive of response functionality.
- Enforcing network security. Firewalls, virtual private network activity, and connections to vendor resources should be configured, produce log reports, and be reviewed regularly.
- Conducting security awareness training. HIPAA requires annual security awareness training, which should be expanded to include conducting simulated phishing attacks and providing employees access to additional resources to foster a security and safety-first culture.

Assemble an Incident Response Team

A cyberattack can unleash a flurry of activity. For many of us, our first instinct is to try to reset everything back to the way it was. Unfortunately, when an attack of unknown significance occurs, even the most seasoned of practice administrators, healthcare professionals, IT professionals, and others may be tempted to opt for the "pretend nothing happened and hope for the best" approach—which is the absolute worst way to react to an adverse event.

Even if backups are readily available, the best practice is not to "sweep things under the rug" and revert to a backup immediately. Why? Because reverting to a backup will remove the crucial clues and evidence of what has happened. If you destroy the traces of what the hostile entity did, you will have a much more difficult time figuring out what needs to be repaired, dealt with, and remedied to ward off future attacks. The best course of action is to remain calm and follow the incident response procedures you have established.

Assembling an incident response team should be your first action toward creating an effective response plan that you can mobilize in the case of a security incident or breach. Your team should include IT management, security personnel, the appropriate representatives of senior management, and, in the case of a breach, representatives from the affected departments. Depending on the nature of the attack, the team should also include representatives who manage affected or essential systems, such as electronic health records, medical imaging equipment, payment software, claims management, and others, as necessary.

Outsourced resources can be helpful in performing the skilled portions of incident response work, such as security assessments and forensic investigations. Off-site managed security services providers can provide ongoing monitoring of endpoint protection, cloud applications, firewalls, and other security devices. These organizations can help temporarily or permanently augment staff to fill gaps in security-specific knowledge or specialized software. These vendors can also provide economies of scale to lend assistance when additional security resources are needed.

Detect and Analyze Potential Security Threats

After creating an incident response team, your next step to help ward off cyberattacks is to detect and analyze potential security threats. This step will help you understand what may attack your organization and the implications of any potential attack. Gaining visibility into your systems and their weaknesses in this preparation phase can help you lay a foundation for knowing where to look for potential security incidents, how to manage alerts, and how to determine the extent of any damage caused by an attack.

Security incidents can occur in a seemingly infinite number of ways, and coming up with strategies to combat each one individually is not feasible. However, cyberattacks in the healthcare industry take fairly predictable forms: phishing, unpatched vulnerabilities, insider threats, network attacks, and web application weaknesses.

Developing visibility adequate to accurately detect whether a system has been compromised takes time. Sometimes it can take years of detection to accurately understand a given network and adjust logging and alerting processes to be able to provide actionable information in the event of a cyberattack. If you believe that your program or practice is entirely free of adverse programs, such as malware, it may just take a closer look to uncover it.

Detection can be enhanced by focusing on some of the more obvious indicators of compromise, including firewalls, traffic going in and out, antivirus software, and server logs. One of the easiest ways to gain visibility into a potential issue is to ask your clinicians and staff to report suspicious network behaviors, through either a support system, email inbox, or informal questions. It is important for incident responders to address both big and small issues with care, because simple network pings traveling outside the United States can lead to discovery of entirely compromised systems.

Analyzing suspicious indicators once they are detected can be a daunting task, and it often comes down to experience and judgment. Due to an abundance of false positives, system malfunctions due to configuration issues, and human errors, detection can become a full-time job. Some incidents—such as ransomware or a defaced website—are easier to detect than others, but often the ones we should be looking for are hidden in logged data. Whether you are actively responding to a security incident or creating the foundation for an evidentiary logging structure, it is important to rely on security professionals to set processes up correctly.

When a security incident occurs, your documentation of the event should detail:

- The source or initial suspicious behavior noticed.
- The summary of the incident as it continues to transpire.
- Log data.

- Specific dates and times.
- Actions taken by staff.
- Steps intended to remedy the issue.

When properly documented, detection and analysis become the catalysts for information sharing, incident prioritization, and understanding the technical impact and material risk to the organization. We recommend retaining a firm that specializes in breach response and then establishing a retainer with the vendor. Often, a baseline relationship can be established without cost to avoid slowdowns in analysis, which may be hindered by legal negotiation and contracts.

Disclose Incidents When They Occur

During the course of detecting and responding to a security incident or breach, the question of how and when to communicate the event to others—partners, vendors, clinicians and staff, law enforcement, patients, regulatory organizations, insurers, and more—will arise. The appropriateness and nature of these disclosures should be considered carefully and ethically and evaluated with your legal counsel. Your counsel can also provide information about the necessity of disclosing the event to your patients based on Health and Human Services and Office for Civil Rights requirements.

Contacting law enforcement officials is typically a necessary step, although engaging with them incorrectly, or too early, may reduce their efficacy. For a variety of reasons—including a lack of law enforcement personnel resources, poor investigative capacity, and the abundance of attacks outside the United States—the apprehension and conviction of cyber criminals is not what we would hope or expect. Law enforcement may be able to give you some guidelines on how to provide digital forensic information to them after you have activated your response plan. It is important to engage with law enforcement after an attack, especially if you are seeking a legal remedy or making a cyber insurance claim.

Contain Any Damage

Containment strategies—including quarantining machines, locking down a network, or simply turning machines off—should be determined based on the type of cyberattack you sustain. Containment operations may even be automated to some extent if you are leveraging advanced products to protect your endpoints. Most incidents require some level of containment, and this measure can be critical in preventing damage spreading to additional systems. Containment strategies should include considerations for potentially lost or stolen devices, evidence gathering and preservation, how much of a system to contain, and estimated time to recovery.

In previous security incidents, we have had to temporarily shut down entire elements of a medical practice to give ourselves time to determine how we should proceed in the aftermath of an attack. This pause took down medical device functionality for a short period of time, but it allowed us to make network configuration changes, gather evidence, and address concerns from a compromised vendor with little impact on patient care.

Eradicate Potential Vulnerabilities

Too often, eradication and recovery are prioritized during the security incident response process. These steps should only begin after the preceding steps—detection, analysis, disclosure, containment—have taken place. Though continuing patient care and avoiding disruptions to a practice are truly high priorities, mishandling an incident response process and not learning from it can have a severe impact on your entire healthcare organization down the road should another compromise occur. It is essential to first understand the nature of a given attack and its full impact to determine what the next appropriate steps should be. Moving forward too quickly with a backup could cause you to miss persistent mechanisms that may have been put into place by the entity seeking to harm your practice, potentially re-infecting the devices restored by your backups.

For many medical practices, it can take months to identify and mitigate all of the vulnerabilities exploited in a cyberattack, return systems to normal operation, and confirm that affected systems are now functioning correctly. When responding to an incident, we often leverage forensic and incident response tooling to protect systems while they are being patched, removed of malware, and otherwise secured to a greater degree. This process is not always simple, and we have clients that are still challenged with defining a "new normal" even a year after a breach has been contained.

Conduct a Post-incident Analysis

You may be tempted to break out the champagne after the "successful" resolution of a security incident. We tend to rationalize our mistakes and then simply move on. But identifying lessons learned after a cyberattack is a critical piece of the incident response process, although something that is often skipped. If you do not measure, reflect, and grow from a cyberattack, you are likely doomed to repeat any mistakes again. Conducting a post-mortem to uncover what you could have done better is essential. Doing so will help you better understand the full scope of what happened, how your staff performed, what information you could have benefited from sooner, and any actions taken that may have inhibited the successful recovery of your organization.

This is also the time to deploy your evidence gathering and retention plan. Often we do not fully understand the scope of an incident that has occurred, so housing evidence to give to an external security team, industry regulator, or legal team is a helpful step in ensuring that you are not destroying evidence that may be helpful in the future.

There are many reasons why cybersecurity concerns are not prioritized in medical practices and other organizations. Whether due to the daily demands of treating patients and keeping a practice running smoothly or uncertainty over what you should do to protect yourself from cyberattacks or respond to one should it occur, the worst thing for your practice is to do nothing.

By anticipating and preparing for a potential cyberattack, you can proactively mitigate any damage that hostile actors may be able to do to your network, your data, and your patients' personal information. Creating a thorough incident response plan will give you the peace of mind that comes with knowing that you and your team will know what to do if something happens.

Sean Hall is the CEO and Adam Rebhuhn is the COO of Firm Guardian, Inc., with offices in Austin, Tex., and Madison, Wisc.

Eight Simple Steps to Create a More Secure Practice

- Practice good cyber hygiene. It is important to address the IT basics, such as backups, automated updates, limited user privileges, and multifactor authentication.
- 2. Segment your networks. This makes it hard for hackers to move around and infect multiple systems. It may be a challenge for healthcare providers with multiple small clinics, but it can be accomplished when properly prioritized.
- 3. Look into automating processes and outsourcing elements of your security and IT. The scope of information technology is so vast that specialized and well-trained employees are often a necessity.
- **4. Increase the amount and retention of critical logs.** Evaluate which of your areas are logging properly and where improvements can be made. Nothing makes a response process more difficult than having little to no information to start the investigation.

- 5. Plan incident coordination with external parties in advance. Organize relationships with security pro-fessionals, cybersecurity lawyers, cyber insurance companies, and law enforcement entities.
- 6. Evaluate changing your antivirus software. If you are still using a traditional antivirus, there are much better options that are significantly more effective and provide incident response capabilities.
- 7. Perform a risk assessment. Risk assessments should include an exhaustive evaluation of your vulnerabilities that address your quantifiable risk with a focus on adherence to HIPAA controls.
- 8. Review or create an incident response plan, disaster recovery, and business continuity policy. Let the frameworks and processes you develop take the lead in creating a standard that supports your healthcare organization.
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All It Takes Is One

Securing your practice against cybercriminals

Il it takes is one. One person, one email, one click, to grant cybercriminals access to your confidential files, your applications, and your patients' protected health information. But the damage that can result from a cybercrime can often be prevented by adequately safeguarding the information entrusted to your practice. The adage, "an ounce of prevention is worth a pound of cure," holds true.

It is important to understand why healthcare breaches are so valuable to cybercriminals. The healthcare industry is entrusted with some of the most sensitive information about individuals, and adequately protecting that information requires enforcing physical, clinical, and digital safeguards. Upholding patient trust is essential to the foundation of the provider and patient relationship. The information provided by a patient should be held in confidence and safeguarded by that patient's entire care team. Given that patient information is typically stored in any one of a variety of electronic documents, applications, and systems, protecting that information is not always straightforward.

Cybercriminals understand how vital the preservation of patient trust is to healthcare systems, and they seek to exploit that. Each year, the cost to healthcare systems resulting from cybercriminal activity totals in the billions, approximately \$408 per compromised patient chart. Breaches affect both public and private organizations, with between 5,000 and 25 million patient charts affected in each incident.¹ Cybercriminals are equal opportunity offenders; the nature or size of your practice is immaterial to them. Responding to cybercrime has less to do with employing countermeasures should your data become compromised and more to do with instituting a culture that makes those countermeasures unnecessary.

A Different Type of Crime

On June 19, 2017, Oncology Consultants, a physician-owned oncology practice with multiple clinic locations across the city of Houston, suffered a ransomware attack that disabled the servers that hosted our email system, information systems (including billing), and shared drives. Without access to email, we immediately lost one of our primary methods of communication. We were suddenly unable to process claims or access practice management systems, spreadsheets, or documents.

As the practice administrator, I recall receiving a text that day at approximately 7:00 am from one of our managers, who indicated that our email and billing systems would not open. I assumed that it was a minor network connectivity issue that perhaps Cybersecurity is not about how many thousands of dollars you spend to create a digitally secure working environment; it is about how you incorporate good digital hygiene into your daily operations.

required a server re-start. But when I arrived at the practice, I was presented with the hacker's message, demanding money in the form of bitcoin in return for the decryption keys necessary to retrieve our encrypted data.

When faced with a significant criminal act, the first reaction of many people is to call 911 and await the arrival of police officers to inspect for ongoing danger and damage and collect any evidence of the crime. Video monitoring systems, fingerprints, license plates, eyewitnesses, and other evidence can provide clues with which to identify the perpetrator and lead to their apprehension.

Unfortunately, cybercrime is unique, and none of these remedies are likely to track down the culprit. Unlike a crime that leaves physical evidence, the nature and extent of a cybercrime may not be immediately apparent. When you cannot access a desired document or program, your first attempt at a remedy is often to power your computer off and on again. If the problem does not go away, you may escalate it to your local information technology (IT) resources. Unlike in the aftermath of a physical crime, there is yet no indication that any crime has been committed. You have not yet made a connection between your lack of access to your files and a criminal action that may have significant consequences to your practice. In the meantime, the cybercriminal is left to roam freely through your encrypted databases, picking and choosing what information they want to steal from your digital space.

A Culture of Security

Responding to cybercrime has less to do with employing countermeasures should your data become compromised and more to do with instituting a culture that makes those countermeasures unnecessary.

Your organizational culture encompasses both the mundane and the essential. What you wear to work, the hours you keep, the level of professionalism among staff, and organizational hierarchy all reflect the unique culture of a workplace. So, too, do your practice's mission, values, and vision. All of these variables affect not only the morale and professional satisfaction of your staff but also how your patients feel about your practice and their treatment there.

Culture does not have a distinct moment of conception or of termination. Rather, it evolves organically and can change over time. The attitudes and behaviors of a practice's management staff are often reflected—for good or for bad—in the demeanor of front-line practitioners, administrators, and staff. Organizational culture is the common denominator of all of your operations. As such, culture is incorporated into your organization's approach to maintaining and promoting a safe digital environment for your practice and your patients.

Your practice's culture should promote the understanding among staff that cybersecurity is everyone's responsibility. Each employee should have a baseline understanding of what cybersecurity is and why it is essential. Everyone should know how to maintain a secure digital environment and how to detect potential hacking attempts. This effort requires a continual conversation between management and staff so that everyone fully understands their role in preventing and heading off potential attacks. Cybersecurity is not about how many thousands of dollars you spend to create a digitally secure working environment; it is about how you incorporate good digital hygiene into your daily operations.

Four simple policies are foundational to creating an effective cybersecurity awareness culture in any practice.

Policy 1. Beware the Suspicious Email

Email is the lifeblood of communication in the modern-day workplace, and cybercriminals have become sophisticated in using emails to dupe employees into unwittingly granting them access to sensitive information. In their efforts to trick employees into clicking links that enable unauthorized access to information, cybercriminals will disguise the origin of emails and use language that indicates that immediate action is required to resolve a claim, ensure a shipment, or pay an invoice.

More sophisticated cybercriminals will impersonate the identities of upper management to convince staff that an email is an urgent request from a supervisor. Such messages can evoke an emotional response from the receiver, who may unthinkingly do what they are told, enabling a potentially disastrous security breach.

But proactively heading off such attempts can be effectively accomplished by teaching staff how to quickly spot dubious emails and determine the sender's true identity. Staff can be easily taught to determine whether a given email is questionable and how to check the identity of the source of a message. If staff are even remotely suspicious of the true intent of an email, they should be directed to put safety first and delete the message or report it to the appropriate IT resource for review.

Policy 2. Resist Surfing

Cybercriminals well understand the siren song of the internet. Having the world at your fingertips has brought much good into the world. But it has also heralded an insidious—and lucrative form of crime. There are many available tools that can block web browsing and help your staff steer clear of malicious websites. But these tools cannot always keep pace with the rate at which new malicious sites are launched or new ways of bypassing security measures are created. Ultimately, unless you completely disable internet access across your organization, you cannot be completely protected. The best prevention remains having your staff limit their use of the internet to workplace needs only. Doing so can significantly reduce the surface area on which a cybercriminal can gain footing.

Policy 3. Practice Password Hygiene

The healthcare industry, more so than others, is required to use different systems for multiple reporting, invoicing, and storage purposes. There is no magical application that does everything. With multiple systems comes the challenge of creating and remembering multiple passwords to gain access. For many, the natural tendency is to use the same password for multiple systems or to create a simple password such as "12345" or "password." Cybercriminals look to exploit these shortcuts. They know that in many cases, obtaining one password will grant access to additional applications that use the same password.

It is essential to require all staff to create alphanumeric passwords that incorporate at least seven characters and change their passwords regularly. Modern-day applications are configured with minimum password requirements and the ability to prompt users to change their passwords at a specific frequency. Another popular method of maintaining password security is to employ two-factor authentication, in which users must authenticate their access to an application with both a password and a secondary method, such as a text, telephone call, authentication service, or a physical security USB key inserted into a computer.

Policy 4. Log Off and Turn Off

When a cybercriminal attempts to access your digital environment, there may be indicators that an attack is in process, such as slowed performance or unexpected malfunctions. But just as burglars know that their chance of a successful robbery is improved when you are not in your home, cybercriminals understand that afterhours break-ins are less likely to be detected.

When your staff leave the office at the end of a day or over a weekend, workstations are unattended and fewer eyes are guarding your data. This is the ideal time for an attacker to attempt to access your systems. The most straightforward way to protect your assets when your office is empty is to require employees to log off any applications and shut down their computers when they are away.

Organizational Safeguards

In addition to creating an organizational culture that emphasizes the responsibility of individuals to maintain digital security, there are foundational components to securing your digital assets. No matter how proactive you are in teaching your staff to safeguard their computer access, all it takes is one person to make an honest mistake and the door to cybercriminals is open.

Each of the four safeguards detailed below incorporate people, processes, and technologies that together can build organizational protection against cybercrime.

Safeguard 1. Develop Vendor Security Assessments

The healthcare industry, like any business, relies on multiple information systems to maintain operational areas, including To continually maintain robust cybersecurity measures, healthcare organizations should assemble a multidisciplinary, interdepartmental information security committee.

compliance, clinical, finance, and accounting. These systems must be able to communicate with one another to exchange and update relevant information. Both protected health information and personally identifiable information may be stored and exchanged among your systems, increasing opportunities for cybercriminals to gain access to sensitive data.

A vendor security assessment is a document with a mix of checklist-style and narrative-based questions designed to assess the security elements of the applications you currently have or desire to have in the future. These assessments are designed by security and legal professionals to help you understand both the technical and legal risks associated with working with a digital vendor and/or service provider. Before working with a potential vendor, you can use vendor security assessments as part of your due diligence process of vetting your vendor's security protocols. This can help you more fully understand the vendor's cybersecurity protections and response procedures. In the event of a cybersecurity breach, these assessments can determine the respective liability of each party involved. Vendor security assessments should be updated at a specific frequency (i.e., annually) or when the nature of a business relationship or services change.

Safeguard 2. Create an Information Security Committee

To continually maintain robust cybersecurity measures, healthcare organizations should assemble a multidisciplinary, interdepartmental information security committee. These committees meet regularly to ensure that an organization's information security objectives concerning networks, software, hardware, and data flow are being met. The extensive nature of organizational cybersecurity requires information security committees to define their scope in terms of team members, meeting frequency, purpose, tasks, budget, and goals.

Committee members should represent the various levels of functions in a given organization, including direct decision makers, managers, subject matter experts, and daily users. It is advisable to maintain a set of core members who meet regularly and an ad hoc group that attends depending on the issues being discussed or the projects being reviewed.

An essential function of an information security committee is to translate operational objectives into training and, ultimately, the culture of how users interact with information systems. Committee members should translate the technical jargon associated with information security into identifiable goals by communicating practical examples of how to engage with systems and the consequences of inadequate cybersecurity hygiene.

Because failure is often inevitable in this realm, it should be treated as a valuable lesson. The information security committee should develop post-failure mitigation strategies to limit the scope of the potential damage that can be done to an organization in the case of a cybersecurity breach.

Safeguard 3. Encrypt Sensitive Data

Protected health information and personally identifiable information are coveted items for cybercriminals. Often, these data reside in multiple places, because many staff members may need access to perform their jobs. Analysts may need to store information on their local workstations or laptops to turn patient data into information. Many of the tools of data analysis, such as Excel spreadsheets, require data to be stored on local drives, creating a risk in the event that a laptop is compromised via theft or unauthorized access.

One effective measure to prevent sensitive data from being compromised is to protect workstation hard drives with encryption technology, which makes it much more difficult to access data. Due to the technical nature of encryption, it is essential to consult with IT security professionals to learn about the various types of encryption technology available and the pros and cons of each.

Safeguard 4. Obtain Cyber Liability Insurance

Cyber liability insurance provides a safety net against the extensive costs that may be incurred in the event of a cybersecurity breach. Depending on the structure of the coverage purchased, covered costs may include expenses incurred for hardware replacement, regulatory defense, network assets, cyber extortion, and disciplinary fines. As is the case with all insurance, it is best to be proactive and obtain this insurance as a preventive measure rather than purchase it after a breach has occurred.

Adopting good cybersecurity practices lies at the intersection of user policies and organizational initiatives. Just as the practice of medicine hones clinical skills, provides experience, and ultimately improves patient outcomes, continually practicing good cybersecurity protects the digital health of your organization.

A proactive cybersecurity strategy is most effective when there is collective buy-in from the top of the organizational structure to the front lines. Assigning a budget to cybersecurity protocols is secondary to developing and implementing the rules that guide our work in the digital sphere. Consistently adhering to those rules is crucial, because cybercriminals are relentless, knowing that all it takes is one person, one email, or one click to gain access to your most sensitive information.

A Look Ahead

A few months after the ransomware incident at Oncology Consultants, the attackers ceased communications with our practice. At the onset of the incident, we used a forensics firm to review our network, server, and workstation environment to ensure that the invisible criminals had been removed. Upon completing a forensics report, we reported the incident to the Office of Inspector General and then completed a network security audit and improvement process with the aid of a cybersecurity firm. We retained that firm to provide 24/7 monitoring of our network. We now run annual exercises and hold educational sessions within our organization to maintain continual vigilance of potential cyberattacks.

In 2020, the advent of COVID-19 has led to a rapid expansion of telemedicine, creating more opportunities for cybercriminals to exploit. Though companies can exercise control over their own cybersecurity, patients may not have similar protections in place. More work is required to create security barriers, especially as healthcare moves to a hybrid model of digital and face-to-face interactions.

In the long term, healthcare will continue to move from a referral-based transaction to a consumer-driven one that more resembles industries such as retail, automotive, and air travel. Such convenience will require heavy investment to keep secure a proliferation of technologies in the form of apps, digital wearables, and mobile diagnostic tools. As consumer-driven healthcare becomes more commonplace, we must stay vigilant to growing cybersecurity threats looking to exploit any doors left open in our digital homes.

Alti Rahman, MHA, MBA, CSSBB, is practice administrator, Oncology Consultants, an oncology practice with multiple clinic locations across the city of Houston.

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Cold Cap Therapy: 101



A supportive care option to prevent hair loss for women—and men undergoing chemotherapy

The hose of us who work in the field of oncology understand that retaining some measure of control is important to our patients. For most patients, shared decision making around treatment, symptom management, survivorship, and/or end-of-life care affords that sense of being "in control." For others, this measure of control can be achieved through something as specific as the choice to undergo treatment to stop hair loss during chemotherapy. Methods to help patients with cancer maintain hair during treatment have existed for quite some time. This article offers information about one specific method: cold cap therapy, also known as scalp cooling.

Most chemotherapy-induced hair loss occurs from treatment with anti-cancer drugs like Adriamycin, methotrexate, Cytoxan, and Taxol, which damage hair follicles as the drugs act to target and kill cancer cells.

Scalp cooling technology reduces the temperature of the scalp a few degrees before, during, and after chemotherapy treatment. This cooling causes blood vessel vasoconstriction in the scalp, which reduces blood flow and, therefore, reduces the number of chemotherapy agents that reach the hair follicles. Since 2019, the National Comprehensive Cancer Network has recommended scalp cooling in its breast and ovarian cancer guidelines.¹ Given the chemotherapy agents that cause hair loss and the patient population most emotionally affected by this side effect, much of the focus on scalp cooling has been on those being treated for breast cancer. A new generation of cold cap treatment now exists, featuring self-contained units that are clean, easier to use, and standardized for consistent treatment. This technology has led to more stable treatment temperatures and the ability to provide better outcome studies.

In the Beginning

The earliest method to cool the scalp and prevent chemotherapyinduced hair loss—still used by some today—is the use of caps like those worn by swimmers. These caps are cooled to very low temperatures by dry ice, placed on the head of the patient during chemotherapy, and replaced repeatedly before, during, and after treatment. Though this method has some success in hair retention, it comes with its challenges. For example, the initial temperatures, the timing of cap replacement, and cap temperature changes are not stable variables across all patients or treatments. This variability makes the practice of cold capping challenging to evaluate



Infusion nurse Amy Anderson (left) adjusts the cold cap on patient Tonya Cooper.



Amy Anderson, RN, starts cooling process for patient Tonya Cooper.

and document in terms of clinical outcomes. Therefore, most cold capping "successes" are demonstrated through anecdotal patient stories. Cold capping, particularly during treatment, can be quite painful for patients due to the extreme coldness on the scalp. Cold capping is also labor intensive because patients need assistance removing and replacing the cap during treatment. Sometimes infusion nurses take on this role even though they should be focused on infusion patients' treatment.

A Modern Approach

A new generation of cold cap treatment now exists, featuring self-contained units that are clean, easier to use, and standardized for consistent treatment. This technology has led to more stable treatment temperatures and the ability to provide better outcome studies.^{2,3} This new-generation technology is much easier to use and does not require the time and resources of infusion room nurses. However, this new technology comes at a cost to both institutions wanting to offer this service to their patients and to patients themselves because the service is not covered by payers. For patients who cannot afford this treatment, many cancer programs work with internal and external foundations, as well

as other fundraising sources, to assist with or completely cover the cost of this treatment.

Developm't and Implementation

When Mercy Health Lourdes Hospital in Paducah, Ky., began developing its cold caps program, we started by outlining our primary goals. Specifically, we wanted to partner with a vendor that:

- Utilized the most modern technology available.
- Had strong clinical studies that backed up the use of the technology.
- Had superior marketing materials that we could brand to our hospital and cancer program.
- Would guide our team members and patients every step of the way by providing ongoing support.

Eventually, our research led us to Paxman (paxmanusa.com). From initial contact with Paxman to installation of its equipment in our infusion suite, the process took around six weeks. The vendor's technical and user support for staff and patients exceeded our expectations.



Cap being adjusted for patient Tonya Cooper during cooling process.

Today, our cold caps program operations start with a personalized visit with a registered nurse at Mercy Health Outpatient Infusion. While present, the patient will be properly fitted to receive his or her own silicone cooling cap and neoprene cover. Proper fitting will help ensure success of the treatment. The patient will then be given Paxman literature and tips for success, which are quite expansive and useful to patients. Each patient is also encouraged to join Paxman on social media, with support from both the company and past and current patients utilizing the service. The social media groups offer a wide diversity of women and men who are experiencing or have experienced scalp cooling, and this support is helpful for success. Paxman will contact the patient directly and the patient will receive his or her own cooling kit in the mail prior to infusion. This kit includes everything the patient needs for each treatment.

Many patients will feel overwhelmed at their first treatment. Our infusion staff is very aware of this sensitive time in their treatment and are available to continue providing needed reassurance to patients. Time in the cold cap depends on the patient's treatment plan, but on average 2 hours and 30 minutes is spent in cooling. Patients are encouraged to bring a warming blanket from home for added comfort while in treatment. Most patients Recognize that cold cap therapy is not for every patient. Decisions about which patients will benefit from cold cap therapy must be based on the treatment regimen and approved by the attending physician.

describe the first 15 minutes as the hardest to cope with but find the remaining time as completely manageable. Treatment time consists of pre-infusion (30-45 minutes), treatment infusion (60-90 minutes), and, lastly, postinfusion (20-90 minutes). Patients always feel relieved after the first treatment and find that future treatments go much easier.

Funding

Our next step was to find a way to make this service free to all clinically qualified patients. It soon became evident that this was not normal practice at other cancer programs. Many cancer programs offered assistance to help defray the costs of cold cap therapy, but we found none that would cover the complete costs of this treatment. Typically, the cost of a full course of cold cap therapy is between \$1,800 and \$2,500. We worked with the hospital's foundation, Mercy Health Foundation Lourdes, to identify and create ongoing funding sources that will pay the vendor directly for cold cap therapy costs normally incurred out of pocket by patients. This fund was put together rather quicklyin about 30 days-because we have such a great and responsive foundation. Though this funding is regularly procured to replenish the account from multiple sources, we have been lucky to have found multiple grants and fundraising efforts, nationally and locally, to help defray these costs. Demand for this service has increased as the program has gotten more visibility, which has also helped gain fundraising for the program. Patient success stories in our outreach materials have been successful and helped our fundraising efforts.

Keys to a Successful Cold Cap Program

For cancer programs looking to offer cold cap therapy, we offer these lessons learned:

• *Partner with a vendor that uses the newest cold cap technology and equipment.* The vendor should also have a strong focus on patient and staff support. Before signing with a vendor, check with other cancer programs that currently partner with the vendor to better understand how they operate. Look for a vendor that has the tools and resources to help you market this new service to your patients and your community.



Patient Marie Gray (left) with her sister Jaqueline Wilkerson.

- *Recognize that cold cap therapy is not for every patient*. Decisions about which patients will benefit from cold cap therapy must be based on the treatment regimen and approved by the attending physician. It is also important to note that some patients do not want this service and can feel very strongly about it; for example, patients who view their hair loss as battle scars of chemotherapy. Educate patients about this service, but do not do a hard sell. Even though technology has evolved since the days of dry ice, cold cap therapy can still be painful for patients and may cause some to cease treatment, which must be calculated into vendor agreements.
- Know the operational changes required for implementation of this new service. Though these state-of-the-art units mostly run themselves during treatment, cold cap therapy will add to treatment times—both prior to and after chemotherapy administration. This time should be considered in infusion budgeting and scheduling. Additionally, infusion center staff must be trained on this new technology and know how to run the equipment.
- Understand the costs and how you are going to pay for this service prior to implementation. It is difficult to offer a service

that is out of the financial reach of patients who would like to use it. Fortunately, it has been our experience that raising funds for this type of supportive care is easier compared to other services and/or programs. And because cold cap treatment is not currently reimbursed by the Centers for Medicare & Medicaid Services or private payers, you do not need to worry about violations of inducement rules.

- *Identify champions for this new technology*. Referral champions are needed to educate patients about cold cap therapy so that patients are prepared, fitted for a cap, and trained by the vendor prior to starting their chemotherapy. At our program, champions in breast surgery and medical oncology discuss this option with patients who will benefit from cold cap therapy and help enroll qualified patients into the program as a part of their normal care. Infusion center champions become the "go to" for all cold cap operational questions and act as a guide for those patients receiving the service.
- Recognize that continuous improvement is needed to main*tain and improve a cold cap therapy program.* We found the initial vendor training simple and quick, but true expertise requires commitment from the infusion team. We carefully tracked our patients receiving this service to collect data, evaluate success from both the patient and staff perspectives, and monitor patient comfort levels and pain. We then used these data to improve the service and gain a better understanding of which patients benefited the most from cold cap therapy. In doing so we learned that cold cap therapy has a more subjective level of success than what we are used to seeing in healthcare. For example, from our perspective some patients had little hair loss, yet saw cold cap therapy as a failure based on the time they invested or how they personally felt about their hair loss. Other patients had a great deal of hair loss, except on the sides of their head, and still felt that cold cap therapy was a success because they could wear a hat or scarf and still feel they had not lost their all of their hair. Simply put, cold cap therapy is a personal choice and a personal service, which is reflected in patient feedback. Be ready to monitor your cold cap therapy program, collect data, and make changes to ensure the success of program.

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First Person Perspective

BY CHRISTIE MANGIR

Being diagnosed with breast cancer at age 30 and learning I needed chemotherapy was devastating. I did not feel like I had a choice. If I wanted to live, I had to complete an intense regimen of chemotherapies and targeted therapies. Cancer patients do not have many choices, but one of the only things I felt like I could do was to preserve my hair during chemo. I still lost about 50 percent of my hair while cold capping, but I would do it all over again because it gave a sliver of normalcy and confidence when my body and my life felt it had been ripped apart. When I looked in the mirror after losing 20 pounds and having my breasts amputated, my hair was the only thing that allowed me to recognize myself.

Fifty percent of female patients consider hair loss the most traumatic part of chemo, and 8 percent would decline treatment due to potential hair loss.¹ There are many reasons patients choose to preserve their hair: to have a sense of normalcy for their children, to support their selfesteem and mental health, to have control over when and with whom they share their health struggles, and to avoid the looks of pity and discomfort that cancer patients often receive.

I chose to receive treatment at George Washington Cancer Center in Washington, D.C., because my care team thoughtfully engaged me in shared-decision making and were supportive of my desire to preserve my hair. I was one of the first patients to cold cap at my infusion center in 2016, before the newer generation of U.S. Food and Drug Administrationcleared scalp cooling devices became more widespread. Using manual caps meant that my husband had to take time off from work to carry large coolers of dry ice into the infusion center and change my cold cap every 30 minutes for a total of eight hours. It cost us more than \$2,000 because the technology is not covered by insurance. This time commitment and financial burden is not feasible for many patients.

Hair preservation can ease a variety of patient concerns and improve their quality of life, but awareness, affordability, and access continue to be significant barriers. In 2017, my friend and fellow survivor Liz Lord decided to take action to help remove these barriers for patients with cancer in the Washington, D.C., area. Several other survivors and I joined Liz in forming the Cold Capital Fund, a nonprofit that empowers patients across the District of Columbia, Maryland, and northern Virginia to have the option to preserve their hair.

To improve affordability, the Cold Capital Fund provides financial assistance to people who would not otherwise be able to afford cold capping—



as of August 2020 we have supported more than 100 patients. We work with local cancer programs to educate care team members about cold capping and our resources, as well advocate for the installation of U.S. Food and Drug Administration-cleared scalp cooling systems in infusion centers to make cold capping more accessible for their patients.

For too long, hair loss was an unavoidable and distressing side effect of cancer treatment. Now that there is a reasonable therapy to mitigate this side effect, we must work to level the playing field to make it available to all eligible patients. Though hair preservation may not be the right choice for everyone, our mission at Cold Capital Fund is to make it an *option* for all patients who would be candidates for this therapy. Learn more about our efforts at coldcapitalfund.org.

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Expanding Patient Access to Cancer Care Services



Key results from a national survey show a range of new initiatives

P atient need for cancer care services is growing. At the same time, cancer programs face a confluence of dynamics that impact their ability to meet patient demand, including an increasing number of new cancers, an exponential volume of cancer survivors requiring follow-up care, and a looming oncology physician shortage. Most recently, longstanding patient access challenges have been exacerbated by the COVID-19 crisis.

Many cancer programs saw a temporary reduction in patient volumes and a dramatic increase in virtual visits as a result of COVID-19 as they shut down routine cancer screening, deferred treatments (when safe to do so), and altered approaches to care to minimize risk for this vulnerable patient population. With screenings, diagnostics, and other care restarted and postponed services (re)scheduled, there is even greater need for cancer centers to expand access to meet pent up demand.

In October 2019, prior to the COVID-19 public health emergency, The Chartis Group (chartis.com) conducted a national survey of 14 academic medical cancer programs, five community-based cancer programs, and two freestanding, independent cancer centers. Participating organizations answered 23 standard questions about organizational background, patient access goals and metrics, scheduling and registration systems, use of virtual care and telehealth, care team staffing models, and referral management, among others. Follow-up discussions focused on specific challenges and performance optimization initiatives being implemented to improve patient access to care. Though survey respondents reported significant utilization of advanced practice providers (APPs) to expand capacity, how these APPs are utilized—either through shared visits with physicians or independent visits—differed by program and often by disease-based clinic within a single program.

Survey findings suggest that, though efforts are underway to improve patient access to cancer care, many academic- and community-based cancer programs continue to struggle to meet the growing demand for services. Cancer programs are implementing a variety of new models to increase patient access and capacity, demonstrating their commitment to patient-centered care, while acknowledging that newly diagnosed patients with cancer may go elsewhere if they cannot quickly access services. Some strategies include implementation or expansion of "tried and true" approaches, such as expanding capacity by growing the workforce or increasing productivity expectations. Others are more novel, such as creating new sites of care to support specific patient populations (e.g., urgi-care centers, survivorship clinics). Through survey questions and follow-up conversations, survey participants shared data on efforts to improve access, accomplishments and frustrations, and future plans.

Patient Access to Cancer Care: Current State

The goal for most cancer programs surveyed is to see newly diagnosed cancer patients within five to seven days (Figure 1a, right). A few cancer programs in more competitive markets set a stricter goal of three days or less, which aligns with The Chartis Group's leading practice of two to three days. Ensuring that patients are seen by an oncologist within this time frame helps to reduce patient stress and anxiety, maximize speed to intervention and treatment to optimize outcomes, and attract and retain patients. For benign hematology patients, the goal in most cancer programs is to see patients within 14 days (Figure 1b, right). Longer lag times for both newly diagnosed patients with cancer and benign hematologic disorders are often associated with higher cancelation and no-show rates—along with higher levels of patient and referring physician frustration.

The ability of organizations to achieve their goals varies. Most respondents indicate that performance against goal is specialty specific, because some disease-specific programs and clinics are more successful than others. Only two respondents reported that "all patients are offered an appointment within our target time frame," suggesting that delay in accessing needed services remains a significant concern for most of the participating cancer programs.

Scheduling Model: Centralized vs. Decentralized

More than half of cancer programs surveyed (53 percent) provide centralized scheduling for cancer (and other) services (Figure 2, right). The rest rely on either a hybrid or primarily decentralized model requiring new and existing patients to contact individual clinics or departments to schedule services and treatment. These models can be frustrating and time-consuming for patients who need to coordinate and schedule multiple visits for different services.

Overall satisfaction with centralized scheduling varies. One organization reported a 70 percent turnover rate for centralized staff and expressed a need to "reimagine" the objectives, roles, and training of centralized staff with an added focus on care coordination. Another organization described an extremely effective (leading) practice that includes robust training of contact center personnel, in-person introductions of new providers during onboarding, and weekly in-person meetings with call center and clinic physician and administrative leadership. In our experience, this leading practice does not happen nearly as often as it could or should.

Of the cancer programs with a centralized scheduling model, the majority offer new and existing scheduling, appointment reminders, patient registration/intake, and records collection (Figure 3, page 52). Very few offered Find-a-Doc services, Figure 1. Days to Schedule Initial Visits^{*}

A. What is your organizational goal for newly diagnosed cancer patients or patients with suspicion of cancer to be scheduled and undergo an initial visit?



B. What is your goal for benign hematology patients to be scheduled and undergo an initial visit in your cancer center?



*Percentages total more than 100% due to rounding.

Figure 2. Scheduling Systems^{*}

What best describes the scheduling systems at your cancer center?



*Percentages total more than 100% due to rounding.

centralized template management, or support of online scheduling.

Only 33 percent of cancer programs surveyed will schedule patient visits without records, and the rest will not schedule patient appointments for all or select patient populations until they collect all patient records (Figure 4, page 52). The primary reasons for collecting the records in advance of scheduling are provider preference and ensuring that the visits are maximally productive (i.e., scheduled with the right provider at the appropriate time and based on patient needs). Yet, this practice frequently causes delays in scheduling and significant patient and referring provider frustration. The Chartis Group experience suggests that appropriate processes can be put in place to ensure that records are obtained prior to the visit and scheduling adjustments can be made when records indicate a required change. These processes can include partnering with referring providers to send records electronically or outsourcing to a third party for records collection. Outsourcing is an expensive proposition, but

one academic medical center surveyed credits the move to thirdparty record collection with reducing days to appointment for new surgical patients from seven to eight days to three to four days.

Cancer Program Metrics Tracked

Most surveyed cancer programs track an array of patient access metrics, establishing a baseline for continuous measurement and monitoring that can inform process improvement initiatives (Figure 5a, page 53). Far fewer track operational metrics or set operational targets to ensure they have the space and resources to support their access goals (Figure 5b, page 53).

One academic medical center that participated in the survey is using a third-party customer experience platform to survey patients on whether they would recommend their physician and/or the organization through a text that is sent within four hours of the patient leaving the facility. This immediate feedback loop allows managers to assess and resolve—in real time—issues around wait times, care coordination, etc.

Patient Access and the Patient Experience

Survey responses revealed several innovative solutions being employed to expand organizational capacity and improve access. Select findings and examples are highlighted below.

The Use of Advanced Practice Providers

Though survey respondents reported significant utilization of advanced practice providers (APPs) to expand capacity, how these APPs are utilized—either through shared visits with physicians or independent visits—differed by program and often by disease-based clinic within a single program (Figure 6, page 54).

APPs at one organization independently see established visits, survivorship visits, and same-day and urgent care visits in the clinic and support consults and discharge planning in the inpatient setting while also supporting remote symptom management through virtual visits. The relationship between the APPs and the physicians is described as a "very strong partnership" due to careful recruitment, thorough orientation, and a multi-month training program with physician colleagues. The Chartis Group recognized this model as a leading practice that increases clinic capacity and streamlines access to care; unfortunately, this type of leading practice is rare.

Navigation Services

In follow-up conversations with survey respondents, many indicated that their navigation services are critical to helping patients understand how best to access care along their care journey. When access questions or issues arise, navigators act as internal advocates for the patient, working with schedulers and clinicians to create an efficient schedule that ensures that the patient receives all required treatments and services.

Dedicated Oncology Urgi-Care Centers

Nearly half of survey respondents (48 percent) have a dedicated oncology urgi-care center with extended hours to offer patients expedited treatment and care for common cancer-related com-(continued on page 53)



Figure 3. Services Provided by Centralized Scheduling Systems

Note: Data only includes the cancer centers that have some level of centralized scheduling services. Data only includes services that were provided by at least 5/16 cancer centers.

Figure 4. Scheduling Patient Appointments



Do you collect all patient records prior to scheduling appointment?

Figure 5. (A) Patient Access and (B) Operational Metrics.

A. What access metrics does your leadership team actively track and follow?



B. What operational standards do you have in place to ensure you have the resources and space to support your access goals?



(continued from page 51)

plications, including infections, shortness of breath, nausea and vomiting, and neutropenic fevers (Figure 7, page 54). An additional 19 percent have design and build plans underway. The greatest benefits of urgi-care centers are improved patient experience and reduction of avoidable hospitalizations and emergency department visits.

Virtual Care Visits

At the time of the survey (October 2019), most respondents reported using virtual care visits, either across or within select sub-specialties, or were planning to roll them out within the next year for patients who do not require a physical exam or procedure (e.g., symptom checks, return visits, navigation visits). However, a notable 38 percent of respondents were not offering and had no plans to offer virtual care within the next year. This delivery model is one of the most highly impacted by the COVID-19 pandemic, because virtual care services quickly accelerated across the healthcare industry to meet patients' needs during this crisis.

There are many benefits realized through virtual care visits. For patients and their caregivers, virtual visits remove the hassle of travel and parking and limit exposure to pathogens such as COVID-19. For cancer programs, virtual visits extend the reach of providers and free up space and resources within the clinic to open additional new patient appointment capacity.

COVID-19 provided the impetus for rapid expansion of virtual visits at many cancer programs. Accordingly, virtual visits will likely continue to be an important care delivery model given the many benefits to both patients and providers, as well as the continued risks specific to COVID-19.

Figure 6. Use of APPs^{*}

How do you use Advanced Practice Providers within your ambulatory clinics?



*Only includes centers that use APPs within their ambulatory clinics.

Figure 7. Availability of Urgi-Care Centers



Second Opinion Programs

In some cancer programs, a significant portion of new patient visits are second opinions, though many of these patients may not continue with treatment at the institution. Only seven survey respondents provide a formal Second Opinion Program where patients can come on-site to see a provider (Figure 8, page 55). Of these, three also provide patients with a virtual second opinion option.

The Chartis Group has seen a growing number of organizations partner with an external vendor to offer second opinions. The third party acts as the primary interface between the patient and the cancer program, collecting patient records, working with a select group from within the cancer center to evaluate records and gather patient results, and educating the patient about treatment options.

Survivorship Programs

There are currently 16.9 million cancer survivors in the United States, and estimates suggest that by 2030 the population of cancer survivors will increase to more than 22.1 million.¹ Most cancer programs surveyed (86 percent) have a formal survivorship program, either embedded within specialty-specific clinics or supported by an independent clinic (Figure 9, page 55). Though the format and location of the survivorship programs differ, most

have a shared goal: to provide access to patients to meet their physical and emotional needs after treatment and free up provider capacity for new patients and those undergoing treatment.

Improving Patient Access

Doubling down on ambulatory patient access is more critical than ever for cancer programs striving to attract patients in the post-COVID environment and retain and serve a growing patient population. The Chartis Group recommends these four foundational and more advanced strategies to cancer programs looking to improve patient access.

Strategy 1. Optimize Patient Service

- Assess scheduling and other pre-visit processes from the patient's perspective; that is, how easy versus how difficult and/or time consuming is it to schedule multiple services in different departments? How much do internal processes (e.g., record collection, insurance processes) delay scheduling?
- Establish appropriately aggressive patient access goals to set expectations and raise performance levels.
- Offer navigation services with initial intake and support to assist patients with accessing services across different departments.
- Evaluate current records collection processes to identify ways to streamline the process.

Figure 8. Second Opinion Programs

What best describes your second opinion program?



We do have a formal second opinion program where patients come on site to see a provider in person; 3 out of the 7 respondents also offer video visits to patients and/or referring providers.

Figure 9. Survivorship Programs

Availability of Survivorship Program



Strategy 2. Maximize Existing Capacity

- Integrate APPs appropriately into the care model to support physicians and increase access. Effective use of APPs can allow physicians to conduct more new patient visits.
- Develop a survivorship program to more efficiently support existing patients and increase ability to accommodate newly diagnosed patients.
- Focus on cancelation and bump rate reduction; employ provider template optimization to increase capacity for new and existing patients.

Strategy 3. Expand Visit Pathways

- Employ and expand new modalities (i.e., virtual provider visits, remote monitoring, and case management) to make it easier and more convenient for patients to access needed information and services.
- Establish an urgi-care center or extended hours clinic to make accessing care more convenient for patients.
- Develop a remote second opinion program that efficiently provides a needed service, while also "saving" on-site appointment slots for patients who likely require treatment at the cancer center.

Strategy 4. Establish Structure and Leadership to Support Patient Access Goals

- Routinely monitor a comprehensive set of patient access metrics to understand current performance and gaps against goals.
- Establish a leadership structure—inclusive of physician leaders—to monitor access performance, actively address issues, and oversee access initiatives.
- Establish expectations for provider time to expand capacity and optimize utilization of provider time.

Even before COVID-19, the need for expanded patient access was well documented. Post-pandemic, to be able to accommodate patients who put off screening and follow-up visits during the public health emergency, cancer programs will need to purposefully and intentionally improve patient access to establish, continue, and/or complete cancer treatment.

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After the Outbreak: Preparing for the Return of Cancer Cases



In Brief

Cancer programs are facing multiple challenges related to treating patients in a COVID-19 environment. First, centers must design and implement systems and processes to ensure the health and safety of both patients and caregivers. Second, given the widespread disruptions in health care services experienced between mid-March and mid-May, it is anticipated that nationally there is a large backlog of new cancer patients. Therefore, cancer programs need to also deploy systems and processes to help navigate these patients into the healthcare system and to work through this backlog as quickly as possible within existing resources.

hile shelter-in-place orders limited many people across the United States from leaving their homes to do more than buy groceries, cancer patients faced a more daunting challenge—how to continue their treatment, potentially in different ways than they had planned (e.g., telehealth appointments). Others have experienced the initial symptoms of a new cancer (such as a new source of pain or discomfort) but, due to closures and restrictions for healthcare services, were unable to initiate care.

Preliminary data from Harvard University researchers and Phreesia indicate a precipitous drop in outpatient volumes over a two-week period in mid-March.¹ Oncology providers saw, on average, a 47 percent decline in outpatient visits during this period.² Given the widespread disruption to healthcare services and the U.S. economy, these data are not surprising. It is estimated that more than 1.8 million new cancer cases will be diagnosed in 2020² (an average of 150,000 new cancer cases per month). The surge in patient volume after the pandemic will depend on the magnitude and duration of the disruption to clinical care, because patient volume will be driven by the number of patients who had to delay care. For some cancer programs, the increase may be considerable—as much as 30 percent above average—and will potentially last through the end of 2020. Leading cancer programs are planning to maintain telehealth as a core service delivery tool, anticipating that 25 to 50 percent of office visits will be provided remotely.

With the precipitous drop in outpatient visits due to COVID-19, it is likely that many of these new cancer patients were unable to initiate care. Data from Flatiron Health validate this assumption, reflecting an approximate 40 percent decline in new patient visits from early March to early April.³ Similar to the outpatient visit data shown above, the rate of new patient visits stabilized in April at a baseline level for the pandemic period. With service disruptions for cancer programs lasting at least two months (mid-March to mid-May), and extrapolating from the data above, it is estimated that there is a backlog nationally of approximately 120,000 new cancer patients. Accordingly, cancer programs operating in the new COVID-19 environment must account for how they will work through this backlog.

ECG recently spoke with leaders from National Cancer Institute (NCI)-designated cancer centers across the country to learn how COVID-19 is impacting their programs during the pandemic and how they are preparing for recovery. The interviews we conducted show that every cancer program's decline in clinical volumes is unique, as is the nature of their recovery. Because the COVID-19 pandemic is a dynamic situation, local trends may change over time and require a more—or less—aggressive response by cancer providers. The surge in patient volume after the pandemic will depend on the magnitude and duration of the disruption to clinical care, because patient volume will be driven by the number of patients who had to delay care. For some cancer programs, the increase may be considerable—as much as 30 percent above average—and will potentially last through the end of 2020.

Planning for a volume surge following COVID-19 requires a comprehensive approach across six domains affected by the pandemic: clinical operations, financial performance, quality and safety, workforce, facilities, and research. All of these areas are likely to be affected. Below we will explore key strategies for each of these areas. To help guide their cancer programs through a successful recovery, physician and administrative leaders should:

- 1. Prepare your clinical operations to accommodate an increase in patient demand while ensuring patient and staff safety.
- 2. Deploy financial management systems to maximize your revenue.
- 3. Develop or maintain strict safety protocols to ensure the safety of patients.

- 4. Prepare the clinical and nonclinical workforce to respond to increases in demand.
- 5. Update the physical environment to meet current social distancing requirements, while at the same time accommodating additional patient volumes.
- 6. Thoughtfully resume clinical research efforts.
- 7. Improve communication with patients, allaying their fears while also educating them about the risks inherent with delaying treatment.

In the remainder of this article, we explore key strategies for each of the six domains identified above.

Domain 1. Clinical Operations

Over the last two to three years, many cancer programs began experiencing the combined effects of an aging facility, a growing community, the integration of acquired practices, or the addition of newly recruited providers. Though the COVID-19 public health emergency may provide temporary relief from the overcrowding experienced just a few months ago, this will last only until the recovery begins. It will be important, in preparation for recovery, for many cancer programs to deploy strategies to increase their capacity.

Telehealth

Most cancer programs rapidly implemented or expanded their use of telehealth during the COVID-19 pandemic. Oncology leaders told ECG that they saw a 100-fold to 1,000-fold increase in use of the telehealth platform in March 2020. For many cancer programs, the adoption of telehealth services led to a redesign of clinical workflows (e.g., no longer requiring a physician visit before chemotherapy). Telehealth was embraced by many patients and providers and is a logical tool for managing routine follow-up and survivor visits. Leading cancer programs are planning to maintain telehealth as a core service delivery tool, anticipating that 25 to 50 percent of office visits will be provided remotely. Telehealth services offer both near- and long-term benefits, including:

- Increasing capacity by allowing providers to see more in-person patients at the physical care location while also offering care remotely.
- Improving social distancing by reducing the number of patients physically in the cancer center.
- Creating market differentiation, as early results from both patients and providers indicate positive feedback of virtual visits.

Cancer programs should look for opportunities to extend telehealth services, particularly related to survivorship clinics, social work support, and clinical pharmacist follow-up visits for medication management.

Operational Debulking

Cancer programs should carefully evaluate clinical practices across the organization to identify opportunities to further reduce the number of on-site clinical encounters, such as:

- Eliminating unnecessary encounters (e.g., physician consultations before each chemotherapy procedure)
- Transitioning encounters to alternate care settings (e.g., oral oncoloytics or in-home infusions)
- Reducing the number of encounters required (e.g., hypofractionation for patients undergoing radiation therapy).

Surgical Alternatives

Facilitate discussions with medical staff leadership to develop or update clinical protocols regarding the use of radioembolization, radio frequency ablation, and cryoablation as alternatives to surgical procedures.

Addressing Bottlenecks

Identify operational bottlenecks in the system (both in the cancer center and in upstream/diagnostic service areas) and develop solutions to improve capacity (e.g., extended operating hours, increased staffing).

Operating Hours

Of the NCI-designated cancer center leaders ECG interviewed, most are planning to extend operating hours to increase their capacity. Cancer programs should develop a clear plan that addresses factors such as when to implement extended hours, how to staff the clinic, etc.

Decanting to Smaller Centers

Many NCI-designated cancer centers are looking to use their community-based network to decant volume out of the main center. Doing so requires a staffing plan, clinical algorithms regarding the appropriate care locations, and the potential use of telehealth services to augment the provider services in community clinics. Centers that have begun implementing this strategy report increased patient satisfaction in being able to receive care closer to home.

Testing

COVID-19 testing protocols for patients and staff are a key concern for NCI-designated cancer centers. All recommended developing a set of policies governing the routine testing of asymptomatic patients and staff. The frequency of testing will evolve, based on the availability and turnaround time for tests; however, the following steps were recommended:

- Test all patients before initiating treatment.
- Test patients receiving therapy every two to four weeks.
- Develop protocols for staff testing, although there was no consensus regarding the frequency of this testing.

Visitor Policy

All NCI-designated cancer centers had implemented a strict no visitor policy. Though these policies are viewed as being in the patients' best interests, it was acknowledged that they take an emotional toll and are not very patient friendly. Although these policies are currently necessary, cancer programs must evaluate alternative models to support visitors, such as COVID-19 testing, required use of personal protective equipment (PPE), or other strategies. The phasing back in of visitors will also need to be

gated with the pace of recovery and the incidence rate in the community. Nonetheless, cancer programs should monitor this policy vigilantly to ensure that they provide an optimal healing environment.

Social Distancing

Policies have been enacted across all NCI-designated cancer centers to increase social distancing. Examples include:

- Not collecting copays to minimize the number of patients at reception.
- Conducting virtual scheduling of new patients, including collecting all necessary financial information.
- Reducing the number of infusion chairs in operation to increase the distance between patients.

Domain 2. Financial Performance

One of the most significant challenges of COVID-19 is the financial strain it places on cancer programs. During the height of the pandemic, many cancer programs operated at reduced revenue levels. This will be followed by periods of volume growth, although the payer mix will likely be less favorable than before. Many patients are transitioning to public payer plans (Medicare or Medicaid) or an exchange product or have no insurance after losing private insurance that was tied to their job.

Cancer programs need to develop a holistic financial improvement plan, complete with scenario modeling and quantification of potential tactics, as soon as possible to understand available tactics, their financial impact, and potential strategic implications. Strategies to include in such a financial improvement playbook are below.

Payer Strategy

Begin key conversations with payers early; NCI-designated cancer centers indicate that most have yet to begin these efforts. Cancer programs can start by:

- Identifying alternative payment constructs that support changes to the care delivery model discussed above (e.g., shorter course therapy, oral chemotherapy).
- Exploring potential development of value-based payment models that may generate additional income for the cancer program.
- Identifying potential areas of payer assistance (e.g., accelerated or advanced payments) and enrolling patients in these programs.
- Toughening the negotiation strategies (if possible) for contracts that are currently being negotiated. Take advantage of the fact that payers are likely to be in a favorable financial position.
- Negotiating with payers to extend or expand telehealth coverage models that were implemented during the pandemic. Specifically, seek to preserve telemedicine rate parity with facility-based services.

Financial Navigation

Recognizing the financial challenges that many patients may be facing, develop or expand your financial navigation program by increasing the number of dedicated FTEs.

Accounts Receivable

The irregular distribution of patients in calendar year 2020 will create unique challenges from a cash flow and accounts receivable perspective. In preparation for the recovery surge, add support for accounts receivable functions, either by staffing up in this department or by seeking short-term vendor support. Given the potential competition for limited skilled resources, develop a solution early, before costs increase.

Expense Management

Look for creative ways to reduce costs and eliminate waste, such as the consolidation of regional programs or termination of underperforming programs or services. Given the potential lead time to implement these strategies and the expense management efforts already under way, this is unlikely to be a primary strategy for most programs.

Capital Investments

Operational decanting and debulking strategies should create considerable capacity that will likely endure beyond COVID-19. Cancer programs may find that this virtual capacity enables them to delay potential capital investments that would otherwise have been required to expand physical capacity.

Domain 3. Quality and Safety

Now, more than ever, quality and safety issues are of paramount importance. Cancer programs will simultaneously seek to adopt new care models and refine operational practices to improve patient access and ensure patient safety. However, change creates disruption and must be carefully monitored to avoid adverse impacts on patients. Start by looking at these areas:

- *Infection Control.* Many cancer programs adopted a variety of infection control policies during the pandemic, such as requiring patients to pass a COVID-19 screening, restricting visitors, limiting vendor access, and mandating use of PPE by patients and employees. Extend these policies for the foreseeable future to ensure a safe, healing environment for cancer patients.
- *Guideline Relaxation.* With an eye to the future, establish the criteria and policies that will be used to determine when to relax COVID-19 infection control measures.
- Triage Criteria. Anticipating periods during the recovery surge when the cancer program is overwhelmed by patient demand, develop (or adopt) a set of triage protocols that govern access to services. The triage protocols published by the American Society of Clinical Oncology⁴ and the American College of Surgeons⁵ to guide patient management through the pandemic may provide a baseline from which to begin.

Domain 4. Workforce

The post-outbreak period presents several workforce challenges. Cancer programs will need to balance staffing to meet patient demands with efforts to prevent burnout among the workforce. Though specific challenges will likely vary by location, employee category, and the specific needs of the cancer program, specific areas to consider include capacity, staffing, and compensation.

Increase Capacity

Develop plans to scale up staffing, as appropriate, to meet increased patient demands. Given the physical limitations of each facility, many could find that this involves moving to extended hours of operation, as most of the NCI-designated cancer programs we interviewed are planning to do. Begin by surveying staff to understand their preferences and/or flexibility for alternative work schedules. With limited day care options, younger parents may favor work schedules that allow them to balance childcare with their significant other. At the same time, evaluate your compensation policies to ensure that staff are fairly paid and incentivized to provide much-needed services.

Provider Staffing

Evaluate your provider (physician and advanced practice provider) staffing model soon. Stress-test the model to determine how much additional capacity it can absorb and then begin looking for additional resources to fill any gaps. In addition, consider potential changes in the provider mix and roles (e.g., more advanced practice providers working at the top of their license to manage follow-up and survivorship visits). Cancer programs with a clinical affiliation partner may be able to tap into additional resources to provide in-person care or to support telemedicine visits.

Provider Compensation

During the pandemic, some cancer programs offered guarantees or subsidies to providers on production-based compensation plans. It is important to address how these guarantees will be treated going forward. Many cancer programs are extending the compensation plan's reconciliation period to look at the full year of 2020, rather than doing a midyear reconciliation. If providers can meet the demands of the recovery surge, they should be able to make up the guarantees that were extended during the pandemic period. However, it is important to have clear communication with providers about what to expect for 2020 from a compensation perspective.

Domain 5. Facilities

Preparing cancer programs for the post-outbreak volume recovery involves readiness for an increase in patient volume while also ensuring patients' health and safety. Start by looking at these key areas.

Maintain Distancing Measures

Until a vaccine is widely distributed, plan on continuing key safety measures that were implemented during the pandemic, such as physical barriers for reception, decreased seating capacity in waiting areas, screening stations at entrances, and similar measures. Distinct egress and circulation for patients and staff should be defined to minimize risk within the building if possible. Doing so will help to prevent the spread of COVID-19 through the center and reassure patients that their health and safety is of paramount importance.

Adjust the Air Pressure Environment

An updated air pressure environment will help supplement the distancing measures already in place. Establish a positive air environment to better protect patients from COVID-19 entering their room (or zone). For patients who have tested positive for COVID-19, a negative pressure environment should be established, or measures put in place, to filter air in exiting rooms or zones housing those patients. These spaces should be developed by first assessing current conditions, installing room pressure monitors, and then updating operations of the centralized HVAC system. In general, establishing positive pressure zones is a low-cost measure that can be accomplished with most existing HVAC systems. Establishing negative pressurization usually requires more costly modifications or adjustments to existing systems.

Off-Site Operations

Consider relocating non-clinical and non-essential staff and operations off site from the cancer center. Doing so will reduce the density of people in the building and support efforts to create spatial distancing. This practice will free up additional office space for clinicians or provide an area for positive pressure zone(s).

Additional Space

The combined effect of social distancing and patient volume increases may mean that additional office space must be found for consultations. Begin identifying nearby options now, potentially in the offices of other specialists or clinics that are not projected to experience a surge in volume. In identifying additional clinical space, it is important to ensure that spatial and/or temporal distancing from the non-oncology patients can be achieved and that the spaces will be cleaned and maintained in a manner that is similar to the primary oncology spaces.

Telehealth Space

Given the increase in digital and telehealth care in the industry, additional space for telemedicine clinicians should be made available. Using existing clinical offices on site, and with support of the main oncology staff, could prove valuable.

Alternative Waiting Spaces

Evaluate alternative options for check-in and patient waiting to avoid large groups of patients in waiting areas. For example, consider a pager system that allows patients to wait in their car until the provider is ready. Another alternative is to install temporary structures (e.g., modular trailers) outside, adjacent to the main building egress point.

Parking

The surge of patient volume may be more than the site's parking was originally planned to accommodate. Give top priority to patients needing access close to the building's egress point(s). Short-term solutions that could be implemented quickly include implementing or expanding shuttle service, leasing additional space, and/or rezoning staff or physician spaces near the center. Research participants are hesitant to travel to their health systems for care. This has forced research teams to implement and expand telehealth, mobile nursing, and other remote monitoring tools throughout the pandemic.

Domain 6. Research

In early May, only 10 percent of clinical research sites remained open to enrollment, because most research programs halted screening and enrolling participants. For ongoing trials, research teams have struggled with protocol adherence due to fewer patients and research staff. The good news is that a significant backlog of trials is planned. Cancer programs will be able to continue to serve their patients with novel treatments; this will be balanced against the need to conduct research in a new, post-outbreak environment. It is vital that research efforts be coordinated with previously discussed processes, especially around PPE distribution, infection control, and facilities management. Consideration and planning should be given to the following issues.

Federal Guidelines

Cancer programs must continue to follow announcements from the U.S. Food and Drug Administration, NCI, National Institutes of Health, and other federal agencies related to the management of covered clinical studies. Clinical research leadership should monitor the respective websites for updates and provide this information to investigators and study teams as new guidance is released or organizational protocols shift.

Virtual Studies

Research participants are hesitant to travel to their health systems for care. This has forced research teams to implement and expand telehealth, mobile nursing, and other remote monitoring tools throughout the pandemic. Though there are few clinical oncology studies that can be fully managed in a virtual format, investigators and research teams should continue to embrace remote consent, telehealth, remote patient care, and mobile nursing visits with research participants.

Sponsor Management

Our clients report continued challenges with protocol modifications due to the pandemic that are starting to lighten up as the entire industry adapts to the need for flexibility in contracting, site visits, and drug distribution. Clinical research administration must document, by sponsor, their respective protocol modifications and make this information available to study teams.

Study Management

Protocol deviations will continue to be a concern, because research participants may be reluctant to fully comply with their scheduled visits. Research teams must continue to fully document whether these constitute minor or major protocol deviations, with any major deviations being reported per organizational protocol to the appropriate institutional review boards.

Research Staff

Cancer programs need to continually monitor the workload of the respective study teams. Some may consider centralizing their clinical research staff to better manage study deployment, and others may create dedicated backup teams to manage any staff shortages.

Blood and Tissue Samples

Many organizations stopped collecting biospecimens for all patients in the early stages of the pandemic. Coordinate with infection control to document handling precautions for COVID-19-infected and noninfected patients. There are typically no additional handling precautions for noninfected samples; however, biospecimens from COVID-19 patients should have clearly documented procedures around collection, processing, and disposal.

Domain 7. Communication

Communication with patients is vitally important—now more than ever. For months, patients have seen images on television of overwhelmed hospitals, and many are avoiding healthcare services for fear of being at an increased risk of exposure to COVID-19. However, for cancer patients, these fears may place them in greater danger of an unfavorable outcome from their disease. Now is the time for cancer programs to proactively begin a dialogue with their patients around:

- *Education.* Providers should educate patients about local developments in the community and how these impact their treatment.
- *Safety*. Patients need to understand that providers are taking their safety seriously. Communication to patients should clearly identify the various safeguards put in place to protect them.
- *Risks.* Providers also need to make certain that patients fully understand the risks inherent with treatment delays. For patients with cancer, this is a key concern—delays in treatment may result in a more advanced disease and/or may affect the type of therapy they receive.
- *Compassion.* Cancer is a scary and emotional journey for patients. Providers should seek to engage with patients to understand their fears and concerns as a treatment plan is being formulated. In certain cases, the care team may consider alternative treatment pathways, such as the use of neoadjuvant therapy, to navigate these challenges. By empowering patients to have a role in establishing their treatment plan, providers can better address patients' psychological needs while treating their physical needs, thereby keeping them engaged with their therapy.

COVID-19-Positive Patients

Interviews with NCI-designated cancer centers highlighted the need to develop a plan to care for COVID-19-positive patients with cancer. The prevalence of this patient population will trend with the COVID-19 incidence, but it is possible that any community may encounter these patients. The cancer program leaders we interviewed stressed the importance of physical distancing this patient population from other patients. For instance, one cancer program asks COVID-19-positive patients with cancer to use a separate entrance to the facility and manages these patients in an area that is isolated from the rest of the patient population. Many of the facility planning issues discussed above may be applied to improve segregation of this patient population (e.g., physical barriers, airflow), and many operational precautions will also apply. In addition, cancer programs may choose to have dedicated staff supporting these patients either full time or on a rotational basis. Doing so reduces the use of PPE by staff moving in and out of the "hot zone."

The Imperative for Planning

Regardless of your organization's or your community's current circumstances, now is the time to begin planning or refining strategies to support the recovery of the cancer program. A recovery plan will ensure that the necessary resources are in place to maintain support for the expected surge in cancer patients who need care. The recovery plan needs to be comprehensive encompassing the care delivery model, operational requirements, financial implications, and near- and long-term strategic considerations. When such a plan is carefully developed and vetted with program and health system leadership, it will be ready for implementation when it is needed.

Matthew Sturm, MBA, and Jessica Turgon, MBA, are principals at ECG Management Consultants, Arlington, Va.

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Help patients find the financial assistance they need.



Find the latest patient assistance information, including the addition of a table of contents that organizes medications by their administration type and an encompassing list of all oncology-related medications.

Download the most up-to-date version at accc-cancer.org/PatientAssistanceGuide

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 25,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit **accc-cancer.org** or call 301.984.9496. Join our social media communities; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.



ASSOCIATION OF COMMUNITY CANCER CENTERS

I M M U N O -ONCOLOGY I N S T I T U T E

Education Interventions Improve Management of irAEs, Study Shows

Since the approval of the programmed death-1 (PD-1) inhibitors pembrolizumab and nivolumab for the treatment of metastatic melanoma in 2014, the oncology community has seen a tidal wave of new approvals and indications for immunotherapies to treat cancer. This paradigm shift has been led by monoclonal antibodies targeting both sides of the PD-1 pathway, with six drugs approved by the Food and Drug Administration across dozens of indications. As PD-1 pathway blockade releases anergic T-cells to mount a robust immune response, class-specific toxicity results from autoimmune attack of self-antigens that can occur in any organ. Dubbed immune-related adverse events (irAEs), these effects have forced oncologists to learn how to optimally manage an entirely new spectrum of toxicity. Unusual and potentially serious side effects include conditions such as:

- Pneumonitis, inflammation of the lungs
- Myocarditis, inflammation of the heart muscle
- Hypophysitis, inflammation of the pituitary gland or pituitary stalk
- Guillain-Barre syndrome, a rare disorder in which your body's immune system attacks your nerves
- Myasthenia gravis, a chronic autoimmune, neuromuscular disease,
- And many others.

Treatment of irAEs often require diverse resources and expert consultation from subspecialists from all corners of the medical field.

Managing irAEs in the Community Setting

Community cancer programs have been particularly susceptible to challenges in managing irAEs, as they may have variable access to subspecialist care, limited resources compared to larger academic institutions, and/or less practice experience using anti-PD-1 pathway agents. Thus, the Association of Community Cancer Centers (ACCC) embarked on a quality improvement (QI) research study to identify barriers to optimal care of patients receiving PD-1 pathway inhibitors in community cancer programs and assess the impact of a comprehensive multidisciplinary immunotherapy educational intervention.

The project intended to assess the needs of community cancer programs administering immunotherapies, with a focus on minimizing irAE morbidity and mortality and barriers to optimal care delivery. Then, targeted educational programs were provided to faculty and staff in various formats (live and online) to educate patient-facing team members about irAE management, patient education, and care coordination strategies. The end goal was to demonstrate that targeted educational interventions offered to community oncology professionals were feasible and could improve management of irAEs.



Interested cancer programs applied for inclusion in the research study and completed a detailed questionnaire outlining specifics about their clinical practice and experience with immune checkpoint inhibitors. ACCC formed an Advisory Committee composed of two medical oncologists, an oncology nurse, and an oncology pharmacist to help select the sites included in the study, direct the project, and develop the educational materials. Site selection criteria included: adequate numbers of patients treated with checkpoint inhibitors overall and in predetermined tumor types, presence of an onsite QI or data informatics staff, and site participation in value-based payment models.

QI Methodology

The two sites selected for the project were Centra Health Alan B. Pearson Cancer Center in Lynchburg, Virginia, and Cancer and Hematology Centers of Western Michigan, in Grand Rapids, Michigan, Baseline data (see Figure 1, below) were collected from 98 patients initiating immuno-oncology (IO) therapy between December 2017 and April 2018 at both community cancer programs, including information on comorbidities, irAE development, laboratory values, emergency room visits and hospitalizations, presence or absence of patient education on said immunotherapy agent(s), and treatment adherence.

The clinicians also completed surveys designed to help understand varying immunotherapy practice patterns at each site. Some of the pertinent findings at baseline included that a majority of patients at both sites treated with IO drugs had multiple non-cancer medical co-morbidities, only 5 percent of patients had treatment-emergent irAEs graded on a standard grading system, and the majority of clinicians assessed did not feel confident managing irAEs. The advisory committee analyzed the baseline data and designed targeted educational interventions for cancer center faculty and staff to address specific gaps identified.

The participants received ACCC immunotherapy wallet cards (see Figure 2, page 66) for patient distribution and National Comprehensive Cancer Network (NCCN) pocket guides on management of irAEs as a clinician resource. In addition, members of the advisory committee held on-site educational workshops that included didactic presentations focusing on irAE





Figure 2. ACCC Immunotherapy Wallet Card

Contact your oncology provider's office if you experience any of these symptoms:

- Fever (oral temperature greater than 100.4F)
- New or worsening cough, chest pain, or shortness of breath
- New or worsening fatigue or activity intolerance with or without palpitations
 Diarrhea (loose stools) or more bowel
- movements than usual
- Abdominal pain and/or blood in stools
 Skin rash, with or without itching
- Blurry vision, double vision, or other vision problems
- Numbness or tingling in hands and/or feet
- Unusual weakness or pain of legs, arms, or face
- Dark urine (tea-colored) and/or change in urination frequency
- Headaches that will not go away or unusual headaches
- Any new or worsening symptoms

Acc

IMMUNOTHERAPY WALLET ID CARD

PATIENT NAME:
EMERGENCY CONTACT NAME & TEL.:
ONCOLOGY TEAM PRIMARY CONTACT:
CANCER DIAGNOSIS:
NAME OF IO AGENT(S):
ONCOLOGY PROVIDER NAME:
PROVIDER HOURS: MON. THRU FRI AM to PM
TEL AFTER-HOURS TEL
This patient is receiving IMMUNOTHERAPY for cancer treatment. Side effects may differ from

standard chemotherapy but with PROMPT recognition and management, most side effects are treatable. Please contact the oncology provider's office for assistance in managing immune-related adverse events.

Figure 3. Impact of IO Wallet Card on Hospitalization Rates at One Participating Site



management within the context of case scenarios and an open discussion period intended to uncover institution-specific challenges to implementing irAE management and provide strategies to improve care. Live discussions were attended by clinicians as well as nurses, pharmacists, advanced practice providers, and other team members.

During the open discussion sections, the site participants and Advisory Committee members had an opportunity to discuss specific barriers encountered that they felt affected irAE management and worked with the Advisory Committee members for guidance. A common refrain was lack of subspecialty support and understanding of irAEs. The clinicians also reported inadquate training in diagnosing irAEs, as well as insufficient standardized guidelines on management. The Advisory Committee members provided information on up-to-date practice resources, as well as reviewed their experiences in engaging and involving subspecialists in complex cases. In addition to the live events, the cancer care teams were also included in four webinars designed and led by the Advisory Committee members:

- 1. Clinical Advances in Immunotherapy
- 2. Rare irAEs
- 3. Common irAEs
- 4. Challenges with Implementing Immunotherapy.

Study Findings

Following the live workshops and online webinars, ACCC surveyed the participating sites at three and six months to assess the status of their progress and patient outcomes. Data was collected from 100 patients initiating IO therapy between January 2019 and April 2019 and compared to baseline using Fisher's exact test. Surveys were also performed before and after participating in the live and online workshops to understand clinician perspectives of the value of these educational programs.

Results of the study were presented in abstract form at the 2020 ASCO-SITC Clinical Immuno-Oncology Symposium. The study found that the educational interventions were, in fact, feasible and well-received by faculty and staff, with pre- and post-surveys revealing perceived improvements in several areas. Clinicians from both sites reported handing out more patient-centered education materials after the workshops, although only one site utilized the immunotherapy wallet card provided by ACCC. Clinician participants also reported improved understanding of how to manage specific irAEs. Notably, there was consistent reporting of improvements in care coordination and communication both among inter-office team members, as well as with outside specialists. Although these were not statistically significant (primarily due to the overall total numbers of respondents among only two sites), there did appear to be a trend toward perceived care improvements owing to the workshops.

As noted above, one institution elected to utilize the ACCCdesigned immunotherapy wallet card while the other did not. There was a statistically significantly lower rate of hospitalization among IO-treated patients at the cancer program that adopted the wallet card in comparison to the site that did not (19% vs 35%, p = 0.0024; Figure 3, left). While many factors could have contributed to this difference in the hospitalization rate, these data are hypothesis-generating and lends credence to the idea that simple educational initiatives have the potential to dramatically impact patient outcomes.

Cancer programs and practices that want to use this education tool with their IO patients can download a print-ready PDF of the IO Wallet Card at accc-cancer.org/io-walletcard. Limited print quantities are available. Please contact Janelle Schrag, Senior Program Manager, at jschrag@accc-cancer.org for these and other inquiries.

In summary, this ACCC-initiated QI research study successfully provided educational materials and targeted learning to faculty and staff at two community cancer programs and demonstrated clearly that this approach was feasible and valued by faculty and staff alike. The study design utilized relatively little time or resources to provide educational interventions, thus it would likely be possible to design a similar enduring program that would be portable and provide perceived value at other community cancer programs. The finding of a marked decline in hospitalizations at the site that adopted the ACCC IO wallet card for patients suggests the possibility that this intervention could have tangible value but requires further research to confirm its significance.

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Bristol-Myers Squibb





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visit accc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn; read our blog, ACCCBuzz; and tune in to our podcast, CANCER BUZZ.

The ACCC Immuno-Oncology Institute is the leader in optimizing the delivery of cancer immunotherapies for patients by providing clinical education, advocacy, research, and practice management solutions for cancer care teams across all healthcare settings. Access all ACCC IO Institute resources online at accc-cancer.org/immunotherapy.

ASSOCIATION OF COMMUNITY CANCER CENTERS

action

ACCC Welcomes Its Newest Members

Inova Schar Cancer Institute-Alexandria Alexandria, Va. Delegate Rep: Nancy Bowles RN, MHA Website: inova.org/our-services/inova-schar-cancer-institute

Jupiter Medical Center

Jupiter, Fla. Delegate Rep: Angelia Palahunik MHA Website: jupitermed.com/services/cancer-care

A Reminder from ACCC's Bylaws Committee

Dec. 1 is the deadline for submission of any proposed amendments to the ACCC Bylaws. Recommendations should be sent to bspruill@accc-cancer.org. ACCC's Bylaws are available online at accc-cancer.org/bylaws.

It's a Wrap! The 37th [Virtual] National Oncology Conference

As the COVID-19 pandemic hit full force in the spring, ACCC adapted its conference format to meet the needs of its members, while prioritizing the safety of its staff and speakers. This led the Association to launch its first fully virtual National Oncology Conference that took place Sept. 14-18. With the new format, ACCC members across the nation tuned in from anywhere and everywhere to learn how to lead through adversity and how adversity actually spurs innovation as the oncology and greater healthcare community develop solutions to meet these challenging times.

The conference opened with a keynote address on building resiliency among staff to drive positive change. Greg Hiebert, leadership educator, coach, and consultant at leadership*Forward*, shared with viewers that building resiliency is a journey shaped by our own circumstances. "We don't see things as they are; we see them as we are," said Hiebert. "Everything we see is filtered through our experience of gender, race, class, and other factors." As individuals move from the Fear Zone into the Learning Zone, they can emerge from a challenge with leadership strategies that will enable them to rise above their self-interests and take into account the needs of the entire community within what he calls the Contribution Zone. This inspiring talk set the stage for the 2020 ACCC Innovator Award Winner presentations.

Four of the eight 2020 ACCC Innovator presentations were released on demand on Sept. 15; the other four were released on-demand on Sept. 16. National Oncology Conference attendees viewed the innovator presentations on their own time and reconvened on Sept. 18 for a live Q&A to learn how each innovator received buy-in from key physician and administrator leaders, as well as the role this champion played in the development and implementation of the innovation.

The ACCC [Virtual] National Oncology Conference closed with a frank conversation between ACCC President-Elect Krista Nelson, MSW, LCSW, OSW-C, BCD, and ACCC Board of Trustees Member Nadine J. Barrett, PhD, MA, MS, about their experiences as a woman and a woman of color in oncology and how these affected their leadership opportunities in their given careers. Both women shared with viewers how blatant sexism and calculated microaggressions played a role in attempting to keep them from reaching their full potential in achieving and fulfilling a leadership role. At the conclusion of this thought-provoking discussion, they introduced the closing keynote on the LIVESTRONG Cancer Institutes' Summer Healthcare Experience (SHE). The SHE program invites juniors and seniors attending Title I high schools who identify as female to participate in a two-week-long immersion program that introduces them to cancer biology, research, and care and promotes the importance of mentorship to these young women. "The lack of women department chairs and deans results in a lack of mentorship and leadership opportunities for female students," said Nick Smith-Stanley, MBA. "SHE strives to provide these opportunities to young women who would not otherwise have them." To learn more about this innovative program, listen to Cancer Buzz Episode 20 (accc-cancer.org/podcast-episode-20) where Kristen E. Wynn, senior administrative program coordinator, Livestrong Cancer Institutes, and Ximena Cruz and Korena Martinez, two SHE participants, share their insights and experiences.

If you missed this innovative and exciting meeting, sessions are available on demand for continuing education credit. Learn more and register today at courses.accc-cancer.org/p/ACCCNOC.

A New ACCC Online Experience!

Your accc-cancer.org experience is now more seamless, intuitive, and engaging!

You can now sign into our website, eLearning platform, and register for meetings with the same login information. Go to https://accc.force.com/login to start. Click on "Reset Password" to activate your account, then go to your "My Profile" page to update your personal information and indicate your Areas of Concentration. If your institution has strict firewalls, please provide your personal email address.



ACCCeXchange now has a new look! While things may feel a little different, we are pleased to continue to offer a virtual community for ACCC members to share knowledge, address tough questions, and get real-time feedback and solutions from colleagues. When logged in, navigate to "Groups" in the top right-hand corner of the page, then click on ACCCeXchange to share a post or ask a question.



Access multidisciplinary education and resources that support the delivery of quality cancer care. With a variety of flexible online formats that fit individual learning preferences, you can take your professional development to the next level through in-depth courses or gain quick knowledge in shorter learning formats. Get started at http://courses.accc-cancer.org/.

If you have any questions or feedback, please reach out to ACCC at membership@accc-cancer.org.

views

Helping Patients Access Free Mobile Phones and Cell Service

BY AMY ELGIN



I have been the patient resource coordinator at AnMed Health Cancer Center for almost five years now, and the best part of my job is being able to help patients and obtaining financial and other resource assistance that so many don't even know is available. I am able to be a part of the patient's journey from start to finish and feel like I have helped to ease some of the burdens they faced in the beginning; that feeling is just amazing!

In the Beginning

In 2015, when I was still very new to my position, we began treating a newly diagnosed patient with cancer who required an "all hands on deck" approach. The patient was homeless, unemployed, and uninsured, and we had no way of directly contacting him. Our only means of contact was through his friend who lived near the abandoned house the patient stayed in and who could take his phone to the patient if needed. After a quick search online, I found two websites that offered cell phones to low-income patients at little to no cost to them, including the Federal Communications Commission's (FCC) Lifeline program (lifelinesupport.org).

When I was asked to write this article, I did some research on this federal program. It was an eye-opener for me because I had no idea that the Lifeline program has been around for as long as it has. With the increasing number of patents struggling to afford their cancer treatment and the current economic downturn due to COVID-19, the resources below may help.

Technology Creates Need for Universal Access

The FCC established the Lifeline program in 1985 to make communications easier and more affordable for low-income individuals.¹ At that time, the Lifeline program provided landline phone service at a discount. It is now part of the Universal Service Fund, which was created by the FCC in 1997 to promote universal access of all telecommunication services.² In 1997 the FCC also made changes to the program under its Universal Service Order that included the following updates:

- Lifeline was now available to eligible households in all states, common-wealths, and territories of the United States.
- It became more affordable for low-income households.
- The order increased the federal support amount to Lifeline.



• The order also included operator services, directory assistance, and emergency services at no extra charge.

Later, in 2005 the FCC made Lifeline benefits available for pre-paid wireless service plans. This allowed wireless phone service providers to offer free mobile phone services to low-income households. Some wireless service providers would also include a free cell phone for users. To reduce waste, modernize Lifeline, and fight fraud, such as not being able to confirm that enrolled customers were eligible for the program to begin with, the FCC overhauled the program in 2012 and enacted the following reforms:

- The National Lifeline Accountability Database was created to reduce duplicate enrollments to the program by the same customer.
- Fully automated eligibility databases were used to ensure that only applications from qualified customers were processed, and the verification process was made easier for customers and providers.
- The program adopted the rule of one per household.
- Households were re-defined to be "economic units," which allowed low-income families who lived at the same address to sign up for the program.

To qualify for the Lifeline program, applicants' income must be at or below 135 percent of the federal poverty guidelines, or they (or someone in their household) must be a participant in one of the following programs:

- Medicaid
- Supplemental Nutrition Assistance Program (SNAP)
- Supplemental Security Income
- Federal Public Housing Assistance
- Veterans Pension and Survivors Benefit
- Tribal Programs (and live on a federally recognized Tribal lands).

Applicants must show proof of participation via a card, letter, or official document when applying. Most service providers will use the same eligibility requirements, but some do vary by state. Be sure to check your local providers' guidelines when applying.

Since my first encounter five years ago with this homeless patient, my cancer center has treated other patients who needed access to a device to communicate easily with our care team. If you are facing the same situation, know that there are multiple service providers in the Lifeline program and three different ways to apply for Lifeline support:

- Print and submit a paper application via mail with proof of applicant's eligibility.
- Apply online at nationalverifier.servicenowservices.com/lifeline.
- Use the Lifeline National Verifier online tool to identify a participating phone and/or Internet provider in your area.

Lifeline also has its own rules and rights to ensure that the program is providing fair, high-quality service to its customers, including:

- Proof of eligibility.
- Only one discount per household.
- One must recertify/renew every year. This must be done within 60 days of the provider requesting a recertification, or Lifeline eligibility will be lost.
- Use it or lose it. If receiving free service from Lifeline, patients must use their benefits at least once every 30 days or service may be turned off.
- Keep your service provider up to date. If the patient's address changes, he or she no longer meets eligibility requirements, or another member of the household gets Lifeline, the providing company must be notified within 30 days.

 Be honest if applying for Lifeline. It is against the law to be fraudulent on any forms or questionnaires when applying to the program.

If applicants meet program eligibility, Lifeline guarantees the following rights:

- Minimum service standards. Currently patients who are eligible for cell phone service receive at least 1000 minutes.
- Choice of a hotspot-enabled device.
- Choice of which service (e.g., voice or Internet) is a Lifeline benefit. (Lifeline cannot provide both Internet and voice services at no cost, so applicants can have their benefit applied to one and pay for the other.)
- Opportunity to change service provider at any time.
- Answers and help. If a service provider is unresponsive or refuses to help, customers can contact their state's public utility regulator, Universal Service Administrative Company, or the FCC to submit a complaint.

Other Companies That Can Help

In addition to Lifeline, other companies provide similar services to eligible cancer patents.

The first free cell phone I obtained for our homeless patient was through SafeLink Wireless (safelinkwireless.com), which offers an easy online application process. The patient was a SNAP recipient, so I completed the online application and scanned a copy of his SNAP card to upload with the application as proof of participation. Within 10 to 14 business days, the patient had received his mobile phone in the mail. Because the patient was homeless, we mailed it to a close friend of his and he ensured that the patient received it.

Once patients receive their SafeLink wireless phone, it must be activated online, which is also very easy to do. Qualified recipients receive a SIM card, about 350 voice minutes, and three gigabits of data every month for free, along with features like unlimited texting, voicemail, caller identification, 911 access, 411 directory assistance, and 4G LTE capable coverage. With this program, patients can also use their own smartphone if it is compatible with the program or unlocked.

The simple act of finding and applying to SafeLink for this patient helped our entire cancer center because we could now reach the patient at any time. The patient's quality of life drastically improved, too, because the cell phone gave him a sense of freedom he did not previously have. No longer did our patient have to rely on his friend to come and get him when his doctor or navigator needed to speak with him. Most important, if our patient had an emergency, he could get in contact with 911.

Since that first patient, I have also used Lifeline Wireless and Access Wireless (accesswireless.com). With Access Wireless, applicants receive about 250 voice minutes, unlimited texting, and three gigabits of data for free each month.

Putting Patients' Needs First

Connecting qualifying patients with these services has made them feel more independent and improved their access to care. In turn this has also improved patient compliance. I have been able to help several patients from this one Internet search, and I am sharing this knowledge with others who may be able to help their eligible cancer patients in this time of great need.

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