IMMUNO-ONCOLOGY IN 2021:
Committed to the Cutting Edge of Care
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**THE STATE OF IMMUNO-ONCOLOGY**

**What We Learned in 2020**

Immuno-Oncology (IO) therapies have revolutionized the field of oncology, and their impact on patient outcomes cannot be overstated. Since 2011, the development of IO drugs has moved at a swift pace, transforming the treatment landscape for numerous cancers. Despite the global impact of the COVID-19 pandemic, by August 2020, there were 4,720 IO agents and 504 targets being investigated in more than 6,200 active clinical trials. This represents a 22 percent increase in actively investigated IO agents since 2019. The total number of approved immuno-therapy indications is now more than 60, a number anticipated to grow as new agents are approved to address new targets and new combinations and regimens continue to expand.

Worldwide, more than 800 trials are investigating chimeric antigen receptor (CAR) T-cell (CAR T-cell) therapy alone, which now has a total of four approvals from the U.S. Food and Drug Administration (FDA) for treating leukemia, lymphoma, and, most recently (March 2021), for multiple myeloma.

The expanding use of IO therapies is transforming the experience of cancer survivorship. Immunotherapies for cancer improve patient outcomes, and their short treatment duration enables many patients to return to their lives. IO has also changed the ways in which clinicians evaluate treatment efficacy and manage adverse events. The unique mechanisms of IO therapies, which activate the immune system to recognize and eradicate tumor cells, can contribute to a range of immune-related adverse events (irAEs). These events can be unpredictable and occur even after treatment ends, requiring more extensive collaboration between the oncology care team and a range of non-oncology sub-specialists.

Barriers remain to IO implementation in community cancer programs across the U.S., including providers’ limited familiarity with emerging agents, the impact of financial toxicity on patient access to treatment, and the lack of care coordination and communication with sub-specialists.

**2020 IO Census Survey Insights**

In summer 2020, the ACCC IO Institute conducted its fourth annual IO Census Survey to gain a better understanding of the current landscape of IO therapies in cancer care. ACCC received 39 complete responses from a representative sample of its membership. Most responses were from community cancer programs that use IO therapies to treat, on average, 21-50 patients per week.

While community-based clinicians are now very familiar with established immune checkpoint inhibitors and combination regimens that incorporate IO agents, they are less familiar with emerging IO agents, such as bispecific antibody therapies, cancer vaccines, and CAR T-cell therapies (Figure 1).

**Barriers to Treatment.** Overall, financial toxicity and coordinating and communicating with sub-specialists remain top IO-related challenges for community cancer programs. A majority found financial toxicity and communication with sub-specialists as “moderately,” “very,” or “extremely” challenging (80 percent and 87 percent, respectively). Managing patient demand, patient education, survivorship care, and operational issues were reported as less challenging.

**Top IO-Related Challenges.** In the specific context of survivorship, knowing when to stop treatment and how best to coordinate and communicate with sub-specialists ranked as a top challenge for oncology providers. Most respondents ranked these issues as “very” (81 percent) or “extremely” (77 percent) challenging. There was also a clear indication that community cancer programs want more clinical and operational support regarding the use of IO agents, including learning about associated molecular testing (78 percent), easing patient and program financial strain (63 percent), and coordinating care across sub-specialties (45 percent).
Top IO-Related Priorities. Survey responses indicated that obtaining reimbursement for appropriate off-label IO use, collecting patient-reported outcomes, and having access to IO-inclusive clinical trials are important issues for cancer programs. However, the relative importance of these priorities differed across the types of oncology providers. Medical oncologists (67 percent) prioritized having IO-specific treatment information available, whereas nurse managers (71 percent) prioritized having the ability to work directly with payers to explain the unique aspects of IO. Pharmacists (40 percent) emphasized the importance of having access to experts for consultation on clinical issues.

COVID-19. A significant number of respondents said that maintaining day-to-day operations for IO clinical trials and using telehealth or other technologies to triage or manage irAEs were “extremely” or “very challenging” issues (43 percent and 40 percent, respectively).

Leveraging New Virtual Infrastructures

telemedicine and Virtual irAE Tumor Boards. COVID-19 has radically altered the landscape of telemedicine and virtual communication. Many cancer programs pivoted toward telemedicine in 2020, especially following the suspension of previous regulations imposed by the Centers for Medicare & Medicaid Services (CMS) concerning reimbursement requirements, interstate medical licensing, synchronous videoconferencing, confidentiality, compliance, and patient physical location. Support for many of these temporary policy changes is strong among both providers and the public. Although it remains unclear which telemedicine regulations will be reinstated in a post-pandemic world, the rapid expansion and uptake of telemedicine in oncology during COVID-19 have revealed its potential to effectively monitor and manage patients being treated with IO therapies.

Several bills have been introduced in Congress to address reimbursement issues concerning the timing, type, and location of telehealth services, including the Telehealth Modernization Act of 2021 and the Ensuring Parity in MA and PACE for Audio-Only Telehealth Act, which are key legislative priorities for ACCC. ACCC is continuing to spotlight practices and programs that have used telehealth to better serve patients during the pandemic. For example, the IO Institute’s Virtual Toxicity Team Spotlights highlight cancer programs that have developed best practices for delivering telehealth services to patients being treated with IO therapies.

Project ECHO®. In 2021, the ACCC IO Institute, in partnership with Virginia Commonwealth University Massey Cancer Center, launched the Immuno-Oncology Project ECHO program. Project ECHO (Extension for Community Healthcare Outcomes) uses a hub-and-spoke model to share specialist expertise and build capacity in community care teams. During a six-month period, expert teams (hubs) in Immuno-Oncology Project ECHO sessions will mentor providers in the community (spokes) and lead virtual clinics in which participants review de-identified patient cases from their own practices. The Project ECHO model is designed to empower community cancer providers to use immunotherapies, and it has the potential to expand patient access to the latest care and reduce disparities in care. Project ECHO mentoring sessions will address a range of IO topics, and highlights from the sessions will be shared with ACCC’s broader membership throughout the year.

Immuno-Oncology Project ECHO®

Mentoring Sessions Topics

- The IO landscape: Approvals, Indications, and Clinical Trials
- Novel IO therapies: CAR T-cell therapies, bi-specific antibodies, and cancer vaccines
- Cancer Biomarkers in Immuno-Oncology
- Communication & Coordination in IO Patient Care
- Financial Navigation & Financial Toxicity
- Redefining Survivorship in Immuno-Oncology
### Figure 1. IO IO-Related Challenges, Therapeutic Familiarity, and Priorities

#### IO-Related Challenges (%)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>NOT AT ALL CHALLENGING</th>
<th>SLIGHTLY CHALLENGING</th>
<th>SOMEWHAT CHALLENGING</th>
<th>VERY CHALLENGING</th>
<th>EXTREMELY CHALLENGING</th>
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</thead>
<tbody>
<tr>
<td>Financial Toxicity</td>
<td>5</td>
<td>15</td>
<td>21</td>
<td>31</td>
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<tr>
<td>Coordinating and Communicating with Sub-Specialists</td>
<td>3</td>
<td>8</td>
<td>41</td>
<td>31</td>
<td>18</td>
</tr>
<tr>
<td>Coverage and Reimbursement Issues</td>
<td>3</td>
<td>21</td>
<td>38</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>Education and Training of Practice Staff on IO Administration</td>
<td>3</td>
<td>13</td>
<td>31</td>
<td>44</td>
<td>10</td>
</tr>
<tr>
<td>Survivorship Care</td>
<td>10</td>
<td>21</td>
<td>46</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Expansion of Indications for IO Agents</td>
<td>2</td>
<td>15</td>
<td>42</td>
<td>35</td>
<td>6</td>
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<tr>
<td>Practice Operations Issues</td>
<td>3</td>
<td>28</td>
<td>51</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>Use of IO Agents in Combination with Other Drugs/Biologics</td>
<td>10</td>
<td>18</td>
<td>51</td>
<td>18</td>
<td>3</td>
</tr>
<tr>
<td>Identifying and Managing Immune-Related Adverse Events</td>
<td>3</td>
<td>18</td>
<td>49</td>
<td>28</td>
<td>3</td>
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<tr>
<td>Managing Patient Demand and Expectations</td>
<td>13</td>
<td>23</td>
<td>38</td>
<td>23</td>
<td>3</td>
</tr>
<tr>
<td>Patient Education</td>
<td>6</td>
<td>27</td>
<td>44</td>
<td>21</td>
<td>2</td>
</tr>
</tbody>
</table>
### Challenges Related to Survivorship Care Planning in IO (%)

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Not at All Challenging</th>
<th>Slightly Challenging</th>
<th>Somewhat Challenging</th>
<th>Very Challenging</th>
<th>Extremely Challenging</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Standard Recommendations</td>
<td>15</td>
<td>31</td>
<td>38</td>
<td>13</td>
<td>5</td>
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<tr>
<td>Keeping up-to-date with IO Drug-Specific Side Effects</td>
<td>18</td>
<td>31</td>
<td>36</td>
<td>13</td>
<td>10</td>
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<tr>
<td>Coordinating and Communicating with Sub-Specialists</td>
<td>15</td>
<td>33</td>
<td>41</td>
<td>10</td>
<td>8</td>
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<tr>
<td>Difficulty identifying when to stop treatment</td>
<td>13</td>
<td>33</td>
<td>44</td>
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<td>8</td>
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<tr>
<td>Educating the patient on immune-related adverse events</td>
<td>28</td>
<td>38</td>
<td>26</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Differentiating chemotherapy side effects from immunotherapy side effects</td>
<td>15</td>
<td>54</td>
<td>21</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Identifying immune-related adverse events</td>
<td>15</td>
<td>25</td>
<td>36</td>
<td>31</td>
<td>5</td>
</tr>
</tbody>
</table>

### Familiarity with IO Therapeutic Topics (%)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Not at All Familiar</th>
<th>Slightly Familiar</th>
<th>Somewhat Familiar</th>
<th>Very Familiar</th>
<th>Extremely Familiar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune checkpoint inhibitors (ICIs)</td>
<td>15</td>
<td>26</td>
<td>54</td>
<td></td>
<td></td>
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<tr>
<td>Combination regimens that incorporate IO agents</td>
<td>18</td>
<td>36</td>
<td>38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic, prognostic, and therapeutic biomarkers</td>
<td>10</td>
<td>41</td>
<td>41</td>
<td>23</td>
<td>18</td>
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<tr>
<td>Bispecific antibody therapies</td>
<td>15</td>
<td>41</td>
<td>23</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>Cancer vaccines</td>
<td>10</td>
<td>41</td>
<td>21</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>CAR T-cell therapies</td>
<td>5</td>
<td>41</td>
<td>28</td>
<td>15</td>
<td>10</td>
</tr>
</tbody>
</table>

### IO-Related Priorities (%)

<table>
<thead>
<tr>
<th>Priority</th>
<th>Not at All Important</th>
<th>Low Importance</th>
<th>Neutral</th>
<th>Very Important</th>
<th>Extremely Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ability to work directly with payers to explain unique aspects of IO</td>
<td>8</td>
<td>46</td>
<td>44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collecting patient-reported outcomes</td>
<td>8</td>
<td>21</td>
<td>36</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Having IO-specific treatment information available</td>
<td>23</td>
<td>36</td>
<td>33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Having access to experts for consultation on clinical issues</td>
<td>8</td>
<td>56</td>
<td>33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Access to IO-inclusive clinical trials</td>
<td>13</td>
<td>59</td>
<td>21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting reimbursed for appropriate off-label IO use</td>
<td>10</td>
<td>28</td>
<td>41</td>
<td>18</td>
<td></td>
</tr>
</tbody>
</table>
Survivorship

Given the expansion of indications for IO agents in the U.S., increasing numbers of people with cancer now have access to treatment with checkpoint inhibitors, improving outcomes for many. More and more IO patients with metastatic disease are transitioning into post-treatment, long-term remission, or survivorship. In 2020, approximately 36 percent of patients with cancer in the U.S. were estimated to be eligible for checkpoint inhibitor therapy. In 2020, there were almost 17 million cancer survivors, a number that is likely to grow to more than 22 million by 2030.

However, in addition to the known (and relatively unmet) needs of cancer survivors in general, patients treated with IO therapies have additional, unique survivorship needs, including the potential for late physical and psychosocial effects of treatment (Figure 2). All of these experiences can negatively impact patient quality of life.

**FIGURE 2. THE POTENTIAL IMPACT OF LONG-TERM AND LATE EFFECTS OF TREATMENT ON CANCER SURVIVORS**

- **PAIN**
- **FATIGUE**
- **ECONOMIC PROBLEMS**
- **FEAR OF RECURRENCE**
- **LOSS OR CHANGE IN EMPLOYMENT STATUS**
- **SLEEP PROBLEMS**
- **PSYCHOSOCIAL ISSUES**
- **SOCIAL ISOLATION**
- **ROLE DISRUPTION**
- **PSYCHOLOGICAL ISSUES**
- **STUGGLE FOR MEANING**
- **SPIRITUAL ISSUES**
- **OSTEOPOROSIS**
- **HOT FLUSHES**
- **LYMPHEDEMA**
- **PERIPHERAL NEUROPATHY**
- **SEXUAL DYSFUNCTION**
- **COGNITIVE IMPAIRMENT**
- **SEXUAL DYSFUNCTION**
In 2020, ACCC directed its efforts to support providers who care for the growing population of IO survivors by developing resources to promote effective communication and coordination among care team members and address the psychosocial and physical well-being of IO survivors. These resources include:

- **Webinars** to educate care team members about the importance of carefully transferring patients from oncology care to primary care post-treatment.

- **Tools to support care transitions after treatment**, including an IO Treatment Summary and an IO Care Transition Summary.

- **A guide for managing patients being treated with IO** that offers tips for setting personal goals with patients, managing patient symptoms and irAEs, supporting psychosocial/physical well-being and sexual health, screening for financial distress, and planning for transitions of care.

- **A compendium of resources for survivor support.**

## Multispecialty Coordination

Multispecialty coordination between oncologists and a growing range of sub-specialists was a key education priority for ACCC in 2020. The ACCC IO Institute created multi-channel education materials for community cancer providers to enable them to share their perspectives and real-world strategies for effective multispecialty care coordination, including e-learning webinars, the Immuno-Oncology Subspecialty Insights Series, and ACCC’s cross-disciplinary podcast, CANCER BUZZ.

### Emergency Department Providers

Emergency departments (EDs) serve as front-line care facilities for many patients with cancer. Among the estimated 4.5 million adult ED visits in the U.S. per year, approximately 4 percent are made by patients with a cancer diagnosis. Many of these visits (10 percent to 12 percent) are treatment-related or related to an uncontrolled symptom burden. This makes ED providers vital partners in the care of patients being treated with IO therapies. Jason Bischof, MD, emergency medicine physician, at the Ohio State University Wexner Medical Center, presented a webinar for ED providers as part of an IO Institute education program designed to raise awareness about triaging and managing irAEs in the ED and emphasize the importance of engaging with oncologists to develop collaborative treatment plans.

### Working with Rheumatologists

Rheumatologists evaluate and treat patients experiencing a wide range of irAEs, including inflammatory arthritis, sicca syndrome, polymyalgia rheumatica, myositis, vasculitis, and scleroderma. Rheumatic irAEs are under-recognized, but they can have a significant negative impact on activities of daily life and may persist after immune checkpoint inhibitor (ICI) cessation.

Rheumatic irAEs can have a larger effect on patients compared to other IO-related irAEs. Laura C. Cappelli, MD, MHS, a rheumatologist and assistant professor of medicine and oncology at the Johns Hopkins School of Medicine, authored an IO Insight in which she gives guidance to the oncology care team on the importance of referring patients being treated with IO therapies to rheumatologists and integrating rheumatologists into the IO care team.

### Transitioning to Primary Care

As patients being treated with IO transition into survivorship, primary care providers are becoming increasingly important members of the IO care team. Although primary care clinicians are willing to manage the long-term care of cancer survivors, most feel ill-equipped to do so. Regina Jacob MD, MSCE, FACP, associate professor of medicine at the Lewis Katz School of Medicine at Temple University in Philadelphia, addressed this issue by authoring an IO Insight about the importance of effective communication between the oncology care team and primary care clinicians.

### IO and Mental Health

There are many unknowns associated with IO treatment, including the extent to which patients’ anxiety about their care can negatively affect their mental health. On a 2020 CANCER BUZZ podcast, Jessica Vanderlan, PhD, manager of siteman psychology service at Siteman Cancer Center and Linda Bohannon, RN, BSN, MSM, president of Cancer Support Community, discussed how cancer care providers can better integrate awareness about mental health issues into the IO care continuum.

### IO and Dermatology

For patients undergoing treatment with cancer immunotherapies, irAEs most often present on the skin, and lesions can be so severe, some patients opt to discontinue treatment. On a recent CANCER BUZZ podcast, Joshua Arbesman, MD, a dermatologist at the Cleveland Clinic, reviewed dermatology’s role in the cancer care continuum and discussed how cancer teams can better integrate dermatology into the immunotherapy care process.
Expanding the IO Care Team

Non-Oncology Sub-specialists as Members of the IO Care Team.
The optimal care of patients receiving IO therapies requires close coordination among providers in a variety of medical sub-specialties. Despite the clinical benefit of IO therapies for many patients, immunotherapy for cancer is associated with a variety of organ-specific irAEs that vary by type of therapy and can be unpredictable or delayed in presentation. Clinical practice guidelines increasingly emphasize the importance of establishing a multidisciplinary approach to managing irAEs via collaboration between the oncology care team and multiple sub-specialists (Figure 4).

Although providers in a range of non-oncology sub-specialties are becoming increasingly familiar with IO therapies, considerable scope for education remains.

In 2021, the ACCC IO Institute will expand its efforts to reach and educate non-oncology sub-specialists about irAEs and convene a range of sub-specialists and oncology teams virtually or in person to discuss care coordination, irAE management, communication, and other relevant topics. Summits and individual workshops will aim to better define the roles of sub-specialists in the management of irAEs and establish care coordination strategies among relevant care providers.

Real-World Evidence and Big Data in IO
Cancer Biomarkers and Predictive Analytics. The identification and development of predictive biomarkers in IO continue to garner research attention. In addition to identifying PD-L1 expression and tumor mutational burden, there is considerable research dedicated to discovering and validating biomarkers to detect killer T-cell expression, tumor-associated proteins...
(e.g., HER2), and microbiome characteristics. Researchers’ analysis of real-world evidence (RWE) from patient data beyond the clinical trial setting, such as health records, cancer registries, and population health databases, also has the potential to further revolutionize cancer care.

RWE uses bioinformatics, large-scale quantitative data mining, and deep analytics to draw conclusions. The ability to search and retrieve real-world data in real time could better link clinical research with clinical care and give oncology care teams valuable insights into treatments and their outcomes (particularly for patients with molecular abnormalities in tumor types, for whom IO regimens are not yet approved). The potential usefulness of real-world data relies on using machine learning to identify and explain patterns in patients, diseases, treatments, and outcomes (e.g., why some patients respond to treatments and others do not) and construct prediction and decision models and algorithms.\(^\text{17}\)

**Big Data in IO.** In oncology, as in many other specialties, RWE is increasingly recognized as an opportunity to reduce disparities in healthcare, contribute to regulatory approval, and establish a foundation for research on the role of biomarkers for patient selection and irAE prediction.\(^\text{16}\) In November 2020, the ACCC IO Institute hosted the virtual workshop, “Big Data in Immuno-Oncology.” Research experts and cancer program leaders discussed the practical applications of combining the rapidly expanding evidence base on IO therapies with real-world clinical insights for an audience of physicians, nurses, administrators, and researchers. Participants learned about the role of companion diagnostics, the potential for linking claims data with molecular platforms, and the importance of incorporating and standardizing patient-reported outcomes (PROs) in the IO setting.

Outcomes from this workshop will inform a 2021 education series on different types of data and their applications in IO research that may include digital platforms, publications, and in-person or virtual events.

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**Highlights from Big Data in IO**

In this virtual workshop, Eliezer Van Allen, MD, associate professor of medicine at Dana-Farber Cancer Institute, described the Metastatic Prostate Cancer Project, which is using big data to engage patients in clinical trials via a direct-to-patient research model. This patient-partnered initiative focuses on exploring why patients respond differently to treatments and identifies new genetic targets. To date, this internet-driven project has enrolled 687 men with prostate cancer and is sharing data among the global biomedical community.

Another participant in the workshop, Matthew Hellman, MD, medical oncologist at Memorial Sloan Kettering Cancer Center, reviewed machine learning solutions to the challenge of determining treatment-specific outcomes. Deep-learning RECIST is a model that can estimate outcomes using text reports from routine scans and may offer a tool to determine outcomes at scale in real-world evidence studies.

Insights gained from the workshop included:

- As the use and approval of IO agents expand, there is a growing need to leverage existing registries or data networks to disseminate and integrate real-world evidence regarding therapeutic outcomes and irAEs.
- The cancer care team requires additional education regarding the application of patient-reported outcomes (PROs), as these will be a critical data point in managing long-term immunotherapy treatment and irAEs.
- Immune pathways and tumor biomarkers will play an increasing role not only in the use of IO agents, but also in predictive analytics of both treatment outcomes and adverse events.

Through case-based breakouts and a brainstorming session, participants in the workshop explored granular applications of real-world data, addressing topics such as how aggregated PRO data—perhaps in irAE registries—could support irAE monitoring. Participants also explored how repository data on steroid response could provide important data points to support rechallenge therapy strategies for which there is currently limited evidence-based guidance.

The ACCC IO Institute will keep community oncology providers apprised of innovative ways to capture and leverage data to ensure community cancer programs are equipped with relevant information to support irAE management and incorporate PROs into treatment decisions.
Managing irAEs. The ACCC IO Institute continued to support cancer programs in their efforts to manage irAEs in 2020 and 2021. In July, ACCC updated its Immunotherapy Wallet Card for patients being treated with IO therapies in the event of an emergency department visit. Details on the card help support clear communication between oncologists and ED providers treating the same patient.

CANCER BUZZ. In addition to episodes on mental health and dermatology, the CANCER BUZZ podcast, launched in 2019, featured episodes on patient perspectives on IO and CAR T-cell therapy, including:

- Journalist Mary Elizabeth Williams, a featured speaker at ACCC’s 36th National Oncology Conference, spoke about her experience as one of the first patients with Stage 4 melanoma to receive combination immunotherapy in a clinical trial. Williams views patients as active contributors to knowledge production rather than passive recipients of treatment. She discussed the many avenues of opportunity that exist to improve the patient experience of clinical trials, including bridging communication gaps among patients, doctors, and researchers.

Healthcare can be an echo chamber of experts talking to experts. Most of us don’t understand. Patients are coming to treatment under extreme emotional distress, and if the person sitting in front of you says they understand what you’re saying, maybe they don’t because they are scared, and blindsided, and distracted. They are experiencing the trauma of the moment. Make sure patients know that it’s okay to be inquisitive, it’s okay to have questions, it’s okay to take notes. Approach this through the eyes of the patient, who is experiencing this for the first time.

– Mary Elizabeth Williams, CANCER BUZZ podcast guest

- Firas El Chaer, MD, assistant professor of medicine at the University of Virginia Emily Couric Clinical Cancer Center, discussed the promise that CAR T-cell therapies and bispecific antibodies (or bispecific T-cell engagers [BiTE®]) hold for treating cancer. Dr. El Chaer addressed the challenges that community programs face in offering these treatments, such as high costs, lack of patient and provider education, and a limited ability to administer select agents.

New IO Insights. Installments in the Immuno-Oncology Insights Series are authored by members of the ACCC IO Institute Working Groups to highlight real-world perspectives and strategies for tackling challenges to safely and effectively delivering immunotherapies for cancer. IO Insights in 2020 explored the parameters of predictive modeling, the expansion of telemedicine in a post-pandemic world, and survivorship care.

Scientific Abstracts. The ACCC IO Institute presented four scientific abstracts in 2020:

- “Exploring Online Access of an Immuno-Oncology Wallet Card Among Oncology Providers” – Presented at the ASCO-SITC Clinical Immuno-Oncology Symposium, February 6–8, Orlando, Florida.
- “Identifying Obstacles to Optimal Integration of Cancer Immunotherapies in the Community Setting” – Presented at the ASCO-SITC Clinical Immuno-Oncology Symposium, February 6–8, Orlando, Florida.
- “Assessing Educational Gains and Gaps for Advanced Practice Providers in Immuno-Oncology: 2017-2020” – Presented at the JADPRO Live Virtual meeting, October 15.

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

- Fever (oral temperature greater than 102.2°F)
- New or worsening cough, chest pain, or tightness of breath
- New or worsening fatigue or activity intolerance with or without palpitations
- Diarrhea (five or more bowel movements per day)
- Anorexia
- Abdominal pain and/or blood in stools
- Numbness or tingling in hands and/or feet
- Unusual weakness or pain in legs, arms, or face
- Diarrhea (loose stools) or more bowel movements than usual
- Dark urine (tea-colored) and/or change in urination frequency
- Unusual headaches
- New or worsening symptoms

*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.*
COVID-19 Resources

ACCC Immuno-Oncology Institute 2020 Census. COVID-19 presented numerous challenges in 2020 that the ACCC IO Institute captured via the online annual IO Census Survey described above. Many cancer programs ranked maintaining day-to-day operations for IO clinical trials and using telehealth or technology to triage or manage irAEs as “very” or “extremely” challenging during the COVID-19 pandemic (Figure 3). Thirteen percent of respondents found decision-making about permitting patient clinic visits and adjusting treatment regimens “slightly” challenging (10 percent) or “not at all” challenging (3 percent).

The Impact of COVID-19 on IO Clinical Trials. Community cancer programs continued to operate and support IO clinical trials with unshakable commitment in 2020. However, the COVID-19 pandemic made the continuation of IO clinical trials difficult for many reasons, including travel restrictions and new demands placed on program staff. Many trials were paused, postponed, or cancelled. Joanne Riemer, RN, BSN, a research oncology nurse at Sidney Kimmel Comprehensive Cancer Center (SKCC) at Johns Hopkins Hospital in Baltimore, described in a CANCER BUZZ podcast how SKCC drew on guidance from its COVID Command Center to determine whether to delay patient participation in studies or pause them. Riemer and her colleagues revised protocol language for screening to support recruitment for future trials, optimized telemedicine and electronic chart messaging to ensure seamless communication with patients, and introduced COVID-19 policies to ensure safety for patients and staff onsite during open trials.

The Risks of COVID-19 for Patients Receiving IO Therapies. Ryan M. Weight, DO, MS, a medical oncologist in Denver, Colorado, who specializes in treating patients with cutaneous melanoma, summarized data on the risks of COVID-19 for patients with a cancer diagnosis who are being treated with IO therapies. In an IO Insight, Dr. Weight specifically addressed the question of whether the heightened state of immune awareness during checkpoint inhibitor treatment protects patients against viruses such as SARS-CoV-2, and he summarized data from three retrospective cohort studies regarding the clinical impact of COVID-19 on patients with cancer. Although the proportion of patients in these studies receiving IO therapies was small, they did not show increased risk for hospitalization or mortality.18,20

FIGURE 3. MOST- AND LEAST-RANKED CHALLENGES RELATED TO IO DURING THE COVID-19 PANDEMIC

- MAINTAINING DAY-TO-DAY OPERATIONS FOR CLINICAL TRIALS: 43%
- DECISION-MAKING/ADJUSTING TREATMENT REGIMENS: 13%
- TELEHEALTH/TECHNOLOGY TRIAGE FOR irAEs: 40%
Staying on the Cutting Edge of Care

The explosive expansion of IO therapies in community cancer programs during the past decade has engendered a tremendous learning curve in oncology. In many cases, IO therapies have become the standard of care. Oncology providers have worked ceaselessly to understand these therapies, integrate them into clinical practice, and expand access to more patients. Remarkably, the world of IO is shifting once again in ways that will demand ongoing education to ensure providers stay on the cutting edge of care.

Immune Pathways and the Power of T Cells. The clinical success of checkpoint inhibitors has encouraged the development of new T-cell immunomodulators, modulators of other immune cells, and cell therapies.\(^1\) Research also continues to explore the response of tumors that have not been recognized and infiltrated by killer T cells (e.g., pancreatic cancer, glioblastoma) by using methods such as combining checkpoint immunotherapy with agents that target macrophages and dendritic cells.\(^2\) There has also been an explosion of interest in cellular therapies that reengineer the immune system via synthetic biology (e.g., with CAR T-cell therapy) or retrain the immune system to recognize and kill cancer cells (e.g., with bispecific antibodies).

These therapies offer the potential of lengthier survival rates and better outcomes for patients with hematologic malignancies because they reduce toxic chemotherapy as the mainstay of treatment, eliminate measurable residual disease positivity, and overcome resistance through immunotherapy combinations. Advances in T-cell engineering, gene editing, and cell manufacturing may enhance the accessibility of cell therapies in solid tumors.\(^2\)

Moving forward, the ACCC IO Institute will develop education efforts on emerging cellular therapies to teach community oncology providers about different types of CAR T-cell and BiTE\(^\text{®}\) therapies and the unique adverse events associated with them (e.g., cytokine release syndrome). In 2020, ACCC launched an education program, Preparing Community Providers for Bispecific Antibodies, to identify and address barriers to the awareness, preparedness, adoption, and use of bispecific antibodies. As part of this program, ACCC conducted a survey of providers across the U.S. to obtain a baseline understanding of emerging bispecific antibody therapies in cancer care, understand how new treatments are being integrated into cancer care settings, and identify potential and ongoing barriers to adoption and patient access to these emerging therapies.

In 2021, ACCC launched the education program, Bringing CAR T-Cell Therapies to Community Oncology, to help community cancer programs and practices obtain the education and tools necessary to identify their patients who may be eligible for CAR T-cell therapy and coordinate with local cancer centers that can deliver that care close to patients’ homes. As part of this program, ACCC will be conducting a series of focus groups and publishing an effective practices guide and additional resources related to identifying patient candidates for CAR T-cell therapy and coordinating their care.

The ACCC IO Institute remains the only initiative dedicated to helping multidisciplinary cancer care teams go beyond a clinical understanding of IO and tackle real-world implementation issues. With the care of patients on immunotherapies now extending beyond the cancer team, the ACCC IO Institute is at the forefront of developing critical education tools and resources to empower healthcare professionals across multiple care delivery settings.
REFERENCES


A publication from the ACCC Immuno-Oncology Institute. Learn more at accc-cancer.org/immunotherapy.

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 28,000 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. Follow us on social media; read our ACCCBuzz blog; 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.

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