

ACCC Report Shows Major Growth in Immuno-Oncology Despite Pandemic

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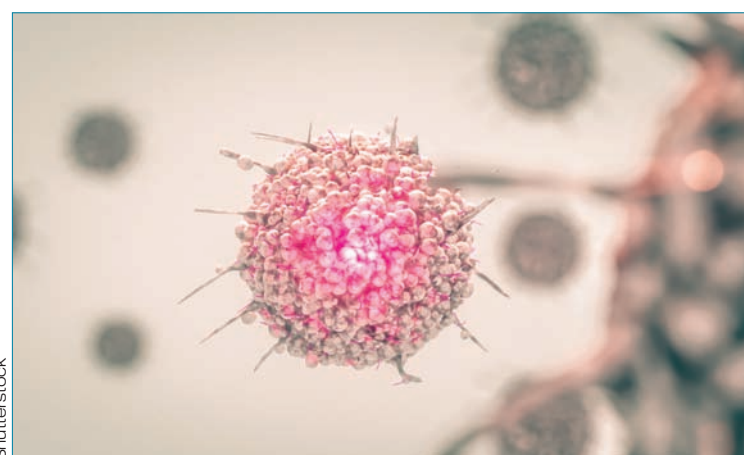
While the COVID-19 pandemic has had a number of adverse effects on oncology practice, the field of immuno-oncology (IO) continued to grow at a rapid rate despite the pandemic. A new annual IO report from the Association of Community Cancer Centers (ACCC) shows that from 2019 to mid-2020 there was a 22 percent increase in the number of IO agents under active investigation.

By August of 2020 there were 4,720 IO agents and 504 targets being investigated in more than 6,200 active clinical trials, according to the report. The total number of approved immunotherapy indications is now more than 60.

Benefits & Challenges

The new report, “Immuno-Oncology in 2021: Committed to the Cutting Edge of Care,” shows that immunotherapy has transformed the treatment landscape for many cancer patients, including extending their survival. Community oncologists are “now very familiar with established immune checkpoint inhibitors and combination regimens that incorporate IO agents.”

But the new information also shows that, because of the mechanisms of action of IO therapies, community oncologists are facing “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.”



The report also shows that about half of participants in the ACCC survey that undergirds the report—done by ACCC’s Immuno-Oncology Institute—said they are “very” or “extremely” unfamiliar with emerging therapies, such as bispecific antibodies that retrain the immune system to recognize and kill cancer cells, cancer vaccines, and chimeric antigen receptor (CAR) T-cell therapies. Globally, there are more than 800 trials investigating CAR T-cell therapy, which has been approved by the FDA for treating leukemia, lymphoma, and multiple myeloma.

In addition, survey respondents reported that their top IO challenges are financial toxicity and coordinating and communicating with sub-specialists. A majority of respondents (80%) said financial toxicity was moderately, very or extremely challenging, while 87 percent reported that communication with sub-specialists was moderately, very, or extremely challenging.

“The explosive expansion of IO therapies in community cancer programs during the past decade has engendered a tremendous learning curve in oncology,” states the report. In many cases, IO therapies have become the standard of care. Not surprisingly, community can-

cer team members are on the record as wanting more IO information and education, with

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96 percent of respondents stating that they want more education on patient access, advocacy, and the financial impact of care; 92 percent stating that they want more education on biomarkers and molecular testing; 85 percent saying they want more education on clinical applications and optimization; 73 percent saying they want more IO evidence, data, and publication updates; and 73 percent wanting more information on IO survivorship care.

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In the context of survivorship, survey participants said one of their biggest challenges was knowing when to stop treatment and the best way to coordinate with sub-specialists.

COVID & Cancer Care

As previously reported by *Oncology Times*, the ACCC’s recent annual “Trending Now in Cancer Care” report showed that COVID-19 took a heavy toll on cancer program staff. It also showed that community cancer programs rapidly adopted flexibilities such as telehealth in order to continue providing care. Flexibilities were established in clinical research which have long-term potential to reshape the design and conduct of clinical trials, including increasing access and addressing health disparities.

Similarly, this new report on IO shows that cancer program staff adapted during the pandemic to keep treating patients.

“While this year’s report is different because of the impact of COVID-19 on all areas of cancer care, what we found to be encouraging about immuno-oncology is how the pandemic actually revealed strategies that will forever change care,” said Sigrun Hallmeyer, MD, Chair of the ACCC Immuno-Oncology Institute Executive Committee.

“For example, the rapid utilization of telemedicine revealed the potential for effectively monitoring patients under IO treatment. An incredibly tragic pandemic did not slow down the speed of development, approval, or adoption of immunotherapy,” added Hallmeyer, who is Director of the Cancer Institute and Medical Director of the Cancer Survivorship Program at Advocate Lutheran General Hospital in Park Ridge, IL.

While community cancer staff treating patients with IO on clinical trials adopted flexibilities to cope during the pandemic, 43 percent of survey respondents said maintaining day-to-day operations for IO clinical trials was extremely or very challenging. Some 40 percent said using telehealth and technology triage for irAEs was extremely or very challenging.

The new report notes that many cancer programs pivoted toward telemedicine and virtual irAE tumor boards, especially after the easing of regulations on telemedicine imposed by the Centers for Medicare & Medicaid Services governing reimbursement.

“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

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potential to effectively monitor and manage patients being treated with IO therapies,” states the new report.

Future Directions

Insights from the new ACCC report on IO include the following.

- As the use and approval of IO therapies 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, since these will be a critical data point to manage long-term 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.
- The clinical success of checkpoint inhibitors has fostered the development of new T-cell immunomodulators, modulators of other immune cells, and cell therapies.
- Research continues to explore the response of cancerous tumors that have not been recognized and infiltrated by killer T-cells, such as pancreatic cancer and glioblastoma, by using methods such as combining checkpoint inhibitors with agents that target macrophages and dendritic cells.
- Advances in T-cell engineering, gene editing, and cell manufacturing may enhance the accessibility of cell therapies in solid tumors.

This year, the ACCC IO Institute, in a partnership with the Massey Cancer Center at Virginia Commonwealth University, launched

the Immuno-Oncology Project ECHO (Extension for Community Healthcare Outcomes) Program, which shares specialist expertise with community cancer care teams.

The program includes mentorship and virtual clinics with de-identified case studies to empower community cancer providers to use IO. Mentoring session topics include the following: the IO landscape: approvals, indications and clinical trials; novel IO therapies: CAR T-cell therapies, bispecific antibodies, and cancer vaccines; cancer biomarkers in IO; communication and coordination in IO patient care; financial navigation and financial toxicity; and redefining survivorship in IO.

The ACCC IO Institute will also develop educational resources on emerging cellular therapies and the unique irAEs associated with them, such as cytokine release syndrome. In 2020, ACCC launched an educational program to prepare community cancer programs for bispecific antibodies, which combine the specificities of two antibodies and simultaneously address different antigens or epitopes. Bispecific antibodies can interfere with multiple surface receptors or ligands associated, for example, with cancer, proliferation, or inflammation. Bispecific antibody-based immunotherapies have gained research momentum following the 2018 FDA approval of the T-cell redirecting antibody blinatumomab.

And this year the ACCC launched an educational program on CAR T-cell therapies to help community cancer practices 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 where patients live. As part of this program, the ACCC plans to conduct a series of focus groups and publish an effective practices guide to identifying patient candidates for CAR T-cell therapy and coordinating their care.

The need for more IO education is only going to increase as new therapies are approved and new combinations and treatment regimens expand. “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,” states the new ACCC report. **OT**

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Learning Objectives for This Month's Activity:

After participating in this activity, readers should be better able to: 1. Describe new IO treatment options, determined by the ACCC's Immuno-Oncology Institute's survey. 2. Summarize insights from the ACCC report regarding future directions in IO.

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