ASSOCIATION OF COMMUNITY CANCER CENTERS

THE EVOLVING IMMUNOTHERAPEUTIC LANDSCAPE IN RENAL CELL CARCINOMA

ACCC
Association of Community Cancer Centers

A Q&A with Robert A. Figlin, MD, FACP; Jocelyn Mohs, PharmD, BCOP; and Laura S. Wood, RN, MSN, OCN

As the role of immunotherapies for treating patients with renal cell carcinoma (RCC) grows, keeping up with the pace of emerging data on combination therapy regimens, effective practices for monitoring and managing immune-related adverse events (irAEs), and educating patients to empower informed decision-making can be challenging. In 2019 the Association of Community Cancer Centers developed an education program to provide all members of the multidisciplinary care team knowledge and resources to help successfully integrate immunotherapies into the treatment of patients with RCC. The program was offered in two formats: a live, on-site learning workshop and an audio-guided online course. Three cancer programs hosted half-day workshops onsite at their institutions:

- The Cancer Center at Christus St. Michael Health System, Texarkana, Texas. Live workshop held Dec. 11, 2019.
- OSF HealthCare Saint Anthony Medical Center, Patricia D. Pepe Center for Cancer Care, Rockford, Ill. Live workshop held Jan. 15, 2020.
- Hawaii Pacific Health, Honolulu, Hawaii. Live workshop canceled due to COVID-19. Virtual workshop held Sept. 29, 2020.

At these workshops, a three-member multidisciplinary expert faculty panel provided both didactic presentations and collaborative open discussion with members of the multidisciplinary care teams. Topics covered included, but were not limited to, a review of the rationale for using immunotherapies and immunotherapy combinations, optimal sequencing of therapies, patient selection criteria, and monitoring and managing irAEs in patients with metastatic RCC. Collateral issues discussed included coordination and communication within the multidisciplinary care team, coverage and reimbursement, and improving patient education and engagement. Table 1, page 3, highlights the quality improvement action plans developed by the three participating sites at these workshops.

Table 1. Action Plans Developed at the RCC Workshops

OSF Healthcare
Develop a tool to assess the knowledge level of mission partners caring for patients with RCC on immunotherapy
Survey and identify knowledge gaps of mission partners on immunotherapy
Develop and implement immunotherapy education plan for all front-line caregivers
Develop and implement patient education, tools, and resources specific to immunotherapy
Develop and implement new triage tools and resources for immunotherapies
Develop and implement immunotherapy survivorship care plan
CHRISTUS St. Michael Health System
Initiate a multidisciplinary tumor board focused on management of irAEs and include sub-specialists who can offer guidance on management of irAEs
Hawaii Pacific Health
Develop uniform staff education (system) for the management and identification of immunotherapy side effects and/or irAEs, including uniform algorithms for symptom-based immunotherapy calls
Engage pharmacy in patient education
Manage prior authorization for chemotherapeutics, biologics, immunotherapies, and oral agents
Assemble working group that could include pharmacy, registered nurse, navigation, advance practice providers, and oncology program liaison to develop patient education on symptom management for cancer oral therapies based on site-specific agents
Assemble immunotherapy working group for interdepartmental referrals and access: oncology, dermatology, rheumatology, endocrinology, pulmonary, and gastrointestinal

Oncology Issues interviewed the expert faculty panel from the live workshops. Below they share key insights on immunotherapy and patients with renal cell carcinoma.

OI. What are some of the challenges that community practitioners face when choosing an immunotherapy-inclusive regimen for their patients with RCC?

Dr. Figlin. The biggest challenge for practicing physicians is the absence of comparative effectiveness research. Physicians have multiple options for patients with RCC in the frontline setting, but they have no data with which to choose one over the other as they [treatments] were never compared. So that's the first challenge. The second challenge is recognizing that these are new classes of drugs—immunotherapy or immunotherapy combined with a target agent. Immune-related adverse events are not typical for patients with kidney cancer, and physicians must learn how to effectively manage them. The third challenge is to recognize that kidney cancer management is really what I call "a team sport," meaning that it takes a group of clinicians—physicians, nurses, subspecialists—to care for these patients because one can never know when a potentially life-threatening irAE might occur.

Dr. Mohs. It is very challenging to stay current on the new indications for immunotherapy agents and then appropriately apply their role as monotherapy or in combination with chemotherapy or oral targeted therapies. As use of immunotherapy agents expands, it is challenging to optimally sequence treatment options in each tumor type. Community practitioners must stay alert to the potential development of common and rare immune-related adverse events and not be lulled into thinking these agents are always well tolerated. It is important to become familiar with guideline-based management of less common irAEs and how

toxicities can overlap in presentation. We also need to educate patients on the signs and symptoms and typical onset of rare immune-related adverse events.

With pharmacists integrated into many multidisciplinary care teams across internal medicine and all specialties [i.e., critical care, emergency department, neurology, etc.], our program has utilized its oncology pharmacy residents to educate all pharmacy staff on irAEs through grand rounds presentations. This education helps health system pharmacists bring awareness of recognition, mitigation, and management of irAEs back to their teams as a part of patient care.

Wood. Being a member of the Oncology Nursing Society and the American Society of Clinical Oncology provides me timely updates regarding current data and safety information on immunotherapy regimens. Best practices are shared through journal club meetings, disease team meetings, and nursing meetings. Our EHR [electronic health record] provides an avenue of communication with other providers, including primary care physicians and multidisciplinary providers involved in the daily care and management of irAEs. That said, busy community practitioners who may not have ready access to all these resources may encounter issues such as:

- Lack of knowledge of, and availability to, companion diagnostics and/or diagnostic or prognostic biomarker tests for eligibility and response assessment of select immunotherapy agents.
- Care coordination challenges, including EHR limitations; for example, multiple practices and private subspecialty groups that lack a common or access to a common EHR.
- Lack of standardized local payer formularies, making immunotherapy selection difficult and/or pharmacy formularies challenging to manage.

OI. On the topic of coverage and reimbursement of immunotherapies, did RCC workshop attendees share specific challenges; for example, issues obtaining pre-certifications and/or prior authorizations? Any solutions to share with our readers?

Dr. Figlin. The biggest challenge they [workshop participants] shared is one we all face: Immunotherapy drugs and treatments are hugely expensive, and they're being scrutinized heavily by payers. Oftentimes there is an unfortunate delay in therapy between the time that the patient and the physician agree on a treatment plan and when payers finally agree to cover that treatment. When a patient with RCC is being treated with immunotherapy, those delays are not in the best interest of the patient. [These types of payer challenges] were articulated by the RCC workshop participants. So, the biggest barrier is access to care for these expensive, potentially effective therapies.

Dr. Mohs. Having a vigorous prior authorization process on the front end of starting immunotherapy treatment can prevent many reimbursement issues. Staff dedicated to completing all pre-certifications or prior authorizations can be very efficient, especially if they have a background in coding and reimbursement. Pharmacists or even experienced pharmacy technicians can help lead the prior authorization process, as well as assist with submitting denial appeals on behalf of providers. One challenge in the realm of prior authorization and reimbursement is the lag in payer coverage for immunotherapy agents with new data showing positive outcomes in a unique treatment setting.

Wood. Our cancer program has reimbursement specialists who complete the prior authorization for all oncolytics prior to initiation of treatment. These reimbursement specialists received additional training on the immunotherapy medications, indications, and combination regimens. Oral oncolytics are sent to our specialty pharmacy, which completes the prior authorization and any patient assistance applications.

OI. At the Hawaii workshop, attendees shared that many patients with RCC must travel to other islands to receive treatment.

Dr. Figlin. Hawaii is a unique state in that the islands are separated by water, but certainly across the United States many patients with RCC must travel long distances to receive immunotherapy treatment. These are complicated therapies with potential serious side effects that need be managed by an experienced care team. Excessive travel presents challenges and risks, and clinicians must be mindful of those.

OI. In terms of the actual administration and monitoring for irAEs and having experienced staff available to do both, do you see any specific challenges?

Dr. Figlin. Oncology staff are very familiar with intravenous transfusions and starting people on oral medications, so the administration of immunotherapy agents is not the challenge. The challenge is that irAEs can occur at any time and how are they going to be managed? If a patient with RCC who is being treated with immunotherapy presents at the emergency department [ED], are the ED clinicians aware of the toxicities associated with these treatments? Is somebody available 24/7 to make sure that if something occurs in the middle of the night, the patient doesn't have to wait until the next day to have their issues resolved? So, the challenge and the barriers to care are really education and access. From workshop discussions, it's clear that practicing oncologists are so busy they have little time to educate their colleagues about irAEs. That must be something we improve and potentially a future education program: practical strategies to help oncologists educate their community colleagues on immunotherapy and, specifically, irAEs.

Wood. In addition to renal cell carcinoma, immunotherapy is now used to treat multiple malignancies, so training of staff has become much more comprehensive. Telling patients and caregivers to communicate to their primary care provider and emergency department staff that the patient is being treated with immunotherapy—not chemotherapy—continues to be a major component of patient education. At our cancer program, patients on immunotherapy clinical trials are given an additional copy of the informed consent to take with them to every medical visit. All patients are also given copies of the immunotherapy education sheet and the NCCN [National Comprehensive Cancer Network] irAE infographic to take to provider appointments.

Challenges experienced by some community oncology programs or those in rural locations include:

- The need for specialty trained staff to provide comprehensive immunotherapy patient education.
- Patients who must travel long distances to receive treatment.
- Availability of emergency services.
- Lack of familiarity with guideline-based management of irAEs, including standardized, early toxicity intervention.
- Administration of routine lab testing and standard monitoring of organ function (i.e., thyroid, skin) and staff trained and/or available to conduct these assessments (e.g., APPs [advanced practice providers], nurses, pharmacists).
- Radiologists and other imaging specialists with a sufficient level of experience to interpret inter-treatment scans; for example, pseudo-progression.

OI. Dr. Figlin called the care of patients with RCC being treated with immunotherapy "a team sport." From what you heard from your colleagues at the workshops, do you see any kind of care coordination challenges between oncology and the other sub-specialties?

Dr. Figlin. I think that all community practitioners are on the learning curve with regards to immunotherapy and RCC. Often, the oncologist is more knowledgeable about the treatment regimens and the subspecialists—endocrinologists, gastroenterologists, and pulmonary physicians—are less familiar with this class of drugs. I think it will take some time before they fully understand the complexities of the immunotherapy treatments we [oncology] give.

Wood. [On the topic of care coordination] our cancer program collaborates directly with a team of multidisciplinary providers. We host an irAE tumor board that many of our collaborating specialists participate in. Standardized testing and treatment algorithms were developed during the irAE tumor board meetings and are shared at staff meetings, grand rounds, and ED and hospitalist meetings.

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A publication from the ACCC education program, "Renal Cell Carcinoma Immunotherapeutic Landscape." **Learn more at accc-cancer.org/RCC-Landscape or scan this QR code.**

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. F or more information, 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.

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