

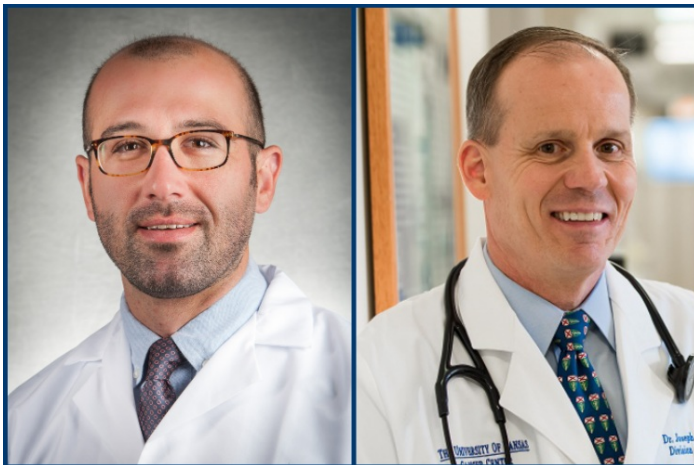
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AACI

# Commentary

## AACI Initiative at the Forefront of Cellular Therapeutics Revolution

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### Commentary Overview

- Recognizing rapid advances in the field of immunotherapy, AACI has expanded the focus of its CAR T Initiative, renaming it the Cellular Therapy Initiative (CTI).
- Although we have made significant progress since CAR T therapies were approved in 2017, challenges remain, including treatment resistance and toxicity and barriers to access.
- Through collaborations with like-minded organizations, AACI is working to reduce barriers to referrals and improve patient outcomes.
- In the coming years, we anticipate approvals of cellular therapies for more malignancy subtypes, in earlier lines of therapy, and outside of oncology.

Recent advances in the field of immunotherapy have helped to firmly establish this treatment approach as the “fifth pillar” of cancer care, alongside surgery, chemotherapy, radiation, and targeted therapy. Immunotherapy gained significant attention when James Allison, PhD, an immunologist at The University of Texas MD Anderson Cancer Center, jointly received the 2018 Nobel Prize in Physiology or Medicine with Tasuku Honjo, MD, PhD, of Kyoto University in Japan, for advancing the study of checkpoint inhibitors.

Chimeric antigen receptor (CAR) T-cell therapy is a form of adoptive immunotherapy that

engineers a patient's own T cells to identify and attack specific cancer cells. Two CAR T-cell therapies were approved by the U.S. Food and Drug Administration (FDA) in 2017 and by the beginning of 2018, nearly half of AACI member cancer centers were approved to provide these therapies. That year, AACI spearheaded the CAR T Initiative to establish best practices for these emerging treatments. Since 2018 the indications for CAR T-cell therapy have greatly expanded, including current approvals in various subtypes of B-cell non-Hodgkin lymphoma, B-cell acute lymphoblastic leukemia, chronic lymphocytic leukemia, and multiple myeloma. Unprecedented clinical responses to CAR T-cell therapy have driven further expansion into earlier lines of therapy in both large B cell lymphoma and multiple myeloma.

Our knowledge of these therapies and their application continues to grow and recently we saw the critical expansion of cellular therapeutics to encompass the treatment of solid tumors. Tumor-infiltrating lymphocyte (TIL) therapy has shown great promise, with lifileucel (Amtagvi) approved in February 2024 for the treatment of melanoma. Acknowledging the continued development and expansion of novel cellular therapeutics, AACI recently renamed its CAR T Initiative the **Cellular Therapy Initiative** (CTI). The mission of the CTI is to provide a forum for cellular therapy experts at AACI cancer centers to collect, evaluate, and share best practices that promote the efficient and effective operation of cellular therapy programs.

## Challenges and Opportunities Ahead

As we look forward to continued advancements, we recognize the need to tackle existing limitations. Although CAR T therapies have been transformative for patients with a range of hematologic malignancies, the majority of patients receiving these therapies either do not respond or suffer subsequent disease progression. On a global scale, scientists are working to unravel the basis for resistance and toxicity with these therapies, and this research is helping to inform our next generation of novel therapies. Strategies currently under investigation include alternative tumor antigen targeting, utilizing high-fidelity gene editing, and putting CAR machinery on third-party allogeneic T or NK cells.

Prolonged cytopenias and associated infectious complications remain the second most common cause of morbidity and mortality following CAR T therapy, with progression of disease being the lead cause. Secondary cancers, some due to prior chemotherapy exposure, including lymphodepleting chemotherapy, as well as insertional mutagenesis, have been brought to the forefront of discussions with patients regarding the risks of immunotherapy treatment. Through a combination of translational, prospective, and retrospective studies we will ideally better decipher toxicity patterns and optimal mitigation and management strategies to continuously improve the safety of these therapies.

We also continue to see suboptimal access to cellular therapy for a variety of reasons, including knowledge gaps regarding indications, expected toxicities and outcomes along with financial and caregiver concerns. These challenges can often be magnified in socioeconomically disadvantaged and underrepresented populations. This lack of access is underscored by data indicating that only 30-35 percent of patients with diffuse large B-cell lymphoma who should be eligible for CAR T therapy in the second- or third-line setting actually receive the therapy. While there are many ways to address these issues, cost of therapy must notably decrease to avail all potentially eligible patients of treatment. Novel strategies being explored to mitigate cost include the use of allogeneic "off-the-shelf" CAR products and on-site manufacturing techniques.

## Addressing Barriers to Cellular Therapy

To address common barriers to referrals, AACI collaborated with the **American Society for Transplantation and Cellular Therapy** (ASTCT) and the **Association of Cancer Care Centers** (ACCC) on the **RECUR initiative**, which aims to empower oncologists, health care professionals, and patients with an understanding of the factors necessary for successful CAR T therapy, including early and timely referral for consultation with a center with expertise. By streamlining the efficiency of the referral process and fostering collaboration among medical experts, this initiative seeks to enhance patient outcomes and expand access to life-saving treatments. One important outcome of this partnership was the publication of a commentary outlining these goals in **Transplantation and Cellular Therapy**.

Ongoing collaborations with ASTCT, ACCC, the **American Association for Cancer Research** (AACR), and AACI **Corporate Roundtable** members include participation on ACCC's CAR T education advisory committee and an upcoming webinar series on the "nuts and bolts" of CAR T therapy and its current applications for a community oncology audience. Additional activities of the AACI CTI may include surveys and other collaborative efforts with like-minded organizations

to deepen our understanding of and improve cellular therapy programs at AACI cancer centers.

## Looking Ahead

In the coming years, we anticipate additional approvals of cellular therapies for more malignancy subtypes and in earlier lines of therapy. We also envision expansion outside of oncology, as clinical trials are currently underway for lupus and other autoimmune diseases. This growth offers an opportunity for AACI cancer centers and cellular therapy experts to collaborate with an increasing number of subspecialty experts and further expand the number of patients who may benefit from these therapies.

As the field continues to evolve, AACI and the Cellular Therapy Initiative Steering Committee are committed to supporting the growth of cancer centers' cellular therapy programs. Cancer centers will need to expand infrastructure and operations to seamlessly provide multidisciplinary care to patients receiving TIL therapy and to ensure sustained growth of the field and the success of our patients.

With members spanning North America, AACI is well-positioned to serve as a hub of knowledge on cellular therapies, a facilitator of communication on new developments in the field, and an advocate for continued robust investment in these life-saving treatments.

We live in an extraordinarily hopeful time for cancer therapeutics. Though CAR T and similar therapies have been explored for decades, we are still in the very early stages of an ongoing revolution in cellular therapeutics, with untapped potential on the horizon. The future is very bright for our patients, their families, and our communities.

## Our Mission

The Association of American Cancer Institutes (AACI) represents over 100 premier academic and freestanding cancer centers in the United States and Canada. AACI is accelerating progress against cancer by enhancing the impact of academic cancer centers and promoting cancer health equity.

## About AACI Commentary

To promote the work of its members, AACI publishes *Commentary*, a monthly editorial series focusing on major issues of common interest to North American cancer centers, authored by cancer center leaders and subject matter experts.

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