

# Comprehensive pediatric CAR T guidelines developed

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Almost one year after the U.S. Food and Drug Administration (FDA) approval of chimeric antigen receptor (CAR) T-cell therapy for children with acute lymphoblastic leukemia (ALL), researchers at The University of Texas MD Anderson Cancer Center and the Pediatric Acute Lung Injury and Sepsis Investigators Network (PALISI) today published treatment guidelines for managing the treatment in the online issue of Nature Reviews Clinical Oncology. These guidelines outline lessons learned by leading experts in various fields to identify early signs and symptoms of treatment-related toxicity and detail ways in which to manage it.

CAR T-cell therapy involves removing patient T cells, re-engineering them, and introducing them back into the body, where they attack cancer cells. The FDA approved the first CAR T-cell therapy for children and young adults with ALL last year. Ongoing research aims to expand its use for other cancers.

"CAR T-cell therapy has been associated with remarkable response rates for children and young adults with ALL, yet this innovative form of cellular immunotherapy has resulted in unique and severe toxicities which can lead to rapid cardiorespiratory and/or neurological deterioration," said Kris Mahadeo, M.D., associate professor of Pediatrics and Chief of Stem Cell Transplant and Cellular Therapy at MD Anderson. "This novel therapy requires the medical vigilance of a diverse multi-disciplinary team and associated clinical infrastructure to ensure optimal patient outcomes."

As CAR T-cell therapy becomes more widely used, treatment guidelines, comprehensive training of multi-disciplinary staff, and other measures should facilitate the appropriate management of toxicities that may occur following this new treatment, added Mahadeo.

MD Anderson's CAR T-cell-therapy-associated Toxicity (CARTOX) program collaborated with PALISI and its Hematopoietic Stem Cell Transplantation (HSCT) sub-group in creating the comprehensive guidelines for treating children with cancer receiving CAR T-cell therapy. By bringing together experts from many areas, including pediatric intensivists, pharmacy, neurology, and translational immunotherapy research, the guidelines offer key learnings to providers and aim to help improve the patient experience and outcome.

"CARTOX, which oversees care for MD Anderson CAR T-cell therapy patients, is the first stand-alone immune effector [cellular therapy](#) program to earn accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT)," said Elizabeth Shpall, M.D., professor of Stem Cell Transplantation and Cellular Therapy and one of the senior authors on the Nature Reviews Clinical Oncology paper. "The program provides oversight for more than 20 active immune effector cell research protocols and two approved standard of care therapies at MD Anderson, and it is clear these new guidelines will serve as an important new model for care of CAR T-cell patients."

In 2017, MD Anderson's CARTOX Program published guidelines in Nature Reviews Clinical Oncology on management of adult patients receiving CAR T-cell [therapy](#). However, early signs and symptoms of toxicity in children brought attention to pediatric-specific monitoring including escalation of care based on parent and caregiver concerns.

Some examples of the recommendations include:

\* Monitoring for cytokine release syndrome (CRS) using pediatric normal ranges for organ function.

\* Promptly addressing parent and/or caregiver concerns as early signs or symptoms of CRS can be subtle and best recognized by those who know the child best.

Provided by University of Texas M. D. Anderson Cancer Center

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