



Biology of Blood and Marrow Transplantation

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ASBMT Notes

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ASBMT RELEASES PAPER ON CONSENSUS GRADING FOR IEC TOXICITIES

ASBMT always strives to be a leader in our field – and that includes tackling issues in an ever-changing landscape. That's why ASBMT leadership is proud to announce the publication of our paper on consensus grading for IEC toxicities, "ASBMT Consensus Grading for Cytokine Release Syndrome and Neurological Toxicity Associated with Immune Effector Cells."

Published in this very journal, the paper is authored by some of the best minds from around the world. Its inception began after CAR-T cell therapy started becoming one of the most encouraging forms of therapy for hematological malignancies. In recent years, there have been several different CAR-T products approved in the U.S. and Europe, including immunotherapies that use cell- and bi-specific antibody-based approaches.

They were highly successful too: Tisagenlecleucel was approved last year in the U.S. and Europe, and is designed to treat multiply relapsed or refractory B-cell acute lymphoblastic leukemia in patients up to age 25.

And while these therapies have promising results, they are associated with unique toxicities of cytokine release syndrome (CRS) and neurological toxicity. Some of these toxicities were serious. The symptoms clinicians were seeing with a few therapies were similar to a study published in the *New England Journal of Medicine* in 2006, where six young, male volunteers were given a low dose of TGN1412, a superagonist monoclonal antibody to CD28. They all required critical care for the rapid onset of multiorgan failure, fever, hypotension, respiratory failure, and more.

ASBMT leaders saw that the assessment and grading of these toxicities greatly varied in clinical trials. This made it hard to figure out the effectiveness and the safety of the therapies. More importantly,

it proved difficult for clinicians to develop strategies to treat and manage the toxicities. There was also no benchmark to differentiate the effects of neurological toxicities on children or for hospitalized adult CAR-T patients, some of whom are bedridden for related co-morbidities.

ASBMT wanted to come together and create our own system, something that could create a more unified understanding and grading system for CRS. Experts from around the field of cellular transplantation met last summer to workshop definitions and grading for CRS and neurotoxicity. Some of the key goals included:

- Provide a uniform consensus grading system for CRS and neurotoxicity associated with effector cell therapies for use across clinical trials and in the post-approval clinical setting
- Create a system that is objective, easy to use and that accurately categorizes the severity of toxicities

In June 2018, 49 experts from all aspects of the field met. ASBMT, along with representatives from the Center for International Blood and Marrow Transplant Research (CIBMTR), the American Society of Hematology (ASH), and the National Cancer Institute (NCI), among many others, began proposing new definitions and grading for immune effector cell-associated CRS and neurotoxicity.

We're incredibly proud of the teamwork and camaraderie of this group. This paper is an important step forward in understanding and regulating cellular therapies, allowing them to become more widespread. The more we learn about these therapies, the more lives we can potentially save in the future.

ASBMT leadership, along with the incredibly talented authors of this paper, hope you take the time to read it and access our findings for yourself.

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ASSOCIATION NEWS AND UPDATES

What's New with ASBMT

Get the Materials from ASBMT's Latest Town Hall

Miss ASBMT's latest town hall? In December, ASBMT officials touched on some important topics, including inpatient Medicare payment and advocacy, perspectives on the final rules, outpatient hospital SCT and CAR-T updates and Medicare Physician Fee Schedule Updates. If you would like to review the materials presented, please visit asbmt.org.

Consider Attending Beyond Fundamentals at the TCT Meetings

Attending the 2019 TCT | Transplantation & Cellular Therapy Meetings of ASBMT and CIBMTR? Add the Beyond Fundamentals of Hematopoietic Cell Transplantation (HCT) Course to your agenda. Join the Beyond the Fundamentals of HCT group February 20-21 for an extensive training program designed to provide practitioners with the skills required to care for patients undergoing HCT.

We look forward to seeing you in Houston in February! For questions related to the Beyond Fundamentals of HCT Course, please email Anna Hawkhead at ahawkhead@asbmt.org.

Fill Out Your Application for the 2019 Cell Therapy Training Course

The International Society of Cell & Gene Therapy (ISCT) is now accepting applications for the 2019 Cell Therapy Training Course. This educational opportunity is a joint effort between ASBMT and ISCT. Twelve scholars are selected from the applicants, and given hands-on training in cell therapy from some of the best minds in the field. This five-day intensive workshop helps junior cell therapy researchers take their research project from bench to bedside. The biennial event is an all-expenses paid experience for those chosen to attend. Participants are competitively selected,

and preference is given to fellows and faculty with no more than two years of BMT and cellular therapy experience following training or a faculty appointment. Next year's event will take place from Oct. 21, 2019 to Oct. 25, 2019, in Philadelphia, Penn. Beth Sage, MBBS, PhD, attended the 2015 inaugural Cell

Therapy Training Course. In a post for ISCT, she wrote how valuable the experience was for her research. "This was without a doubt one of the best courses I have attended," she said. "The chance to talk to so many experts who have really been the trail blazers of cell therapies was invaluable, and although the road

ahead is still a challenging one, it seems less scary to navigate with the new supporters we have found. As is so often the case feedback comes down to 'how likely are you to recommend us to a friend.' My answer? Extremely likely." Visit ISCT's website for more information, and to apply.