

Executive Summary

The current NMDP HLA-CT policy was developed before 2013 and implemented in 2015. In recent years, various techniques have been acquired by the HLA field in order to better characterize the exponential growth of HLA alleles. Sequencing based methods, such as NGS, have become affordable and clinically friendly with fast turnaround time and various throughput options. The new donor selection guideline, based on outcomes analysis, supports well-typed recipient and donor for better HCT outcome. In order to reflect these advancements, synchronize ASHI/EFI/CAP standards, remove policy ambiguities to enhance compliance, and incorporate best practices to improve patient HCT experience and outcome, NMDP BTM proposes to revise HLA-CT policy with the following fundamental changes:

1. Require sequencing-based typing for patients and unrelated donors.
2. Ambiguity resolution requirement is limited to Common and Infrequent alleles only. New CIWD Version 3.0.0 paper by Hurley, Dehn, et al. is close to submission. The actual table and supporting documents for the requirement will be available to all labs later this year.
3. HLA typing accuracy and identity confirmation on the recipient is essential for successful HCT outcome and will be required before the formal search process.
4. Adequate resolution on unrelated donor CT is critical for timely collection and will be required before patient conditioning for transplant or before the administration of Filgrastim to the donor, whichever occurs first.
5. To reduce the potential manual data entry error risk to patients, form 22/117 should be electronically submitted. For TCs who are submitting the forms manually, NMDP will collaborate with TCs' testing lab to achieve electronic submission.

These changes are proposed and recommended by the NMDP Histocompatibility Advisory Group. We encourage the ASHI community to provide valuable feedback during the public comment period ending October 31, 2019. After evaluating submitted comments, the new policy will be posted at NMDP and ASHI websites, along with an implementation date. In general, a 12 month implementation period will be provided.

Please email the questions/comments to neng.yu@nmdp.org