Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN

OPTN Histocompatibility Committee

Purpose of Proposal

- Require reporting of critical discrepancies in Human Leukocyte Antigen (HLA) to gain insight about root cause and develop prevention strategies to reduce the number of these cases
- Update the definition of critical discrepancies to focus required reporting of what is most immunologically significant and align with the required HLA typing resolution.

Proposal

- Require HLA critical discrepancy reporting to the OPTN Patient Safety Reporting Portal within 24 hours of discovery
- Update the definition of HLA critical discrepancy
- Require reporting of incorrect specimens or typings used for physical or virtual crossmatch

Rationale

- Critical discrepancies are *voluntarily* reported to the OPTN
  - Reported events may lead to root cause analyses (RCA) and corrective action plan (CAP) to prevent errors from recurring
  - Histocompatibility labs are required to report critical discrepancies to OPOs and transplant programs
- Required reporting would provide system-wide information to inform future policy and prevention efforts
  - When caught after transplant, they are a patient safety concern due to their potential to have an immunologic reaction in the recipient(s)
  - Reducing HLA critical discrepancies would increase patient safety and increase system efficiency

Rationale

- Current critical discrepancy definition includes discrepancies within the same split antigen group.
  - The proposed definition excludes discrepancies within the same split antigen group
  - Proposed changes intend to reduce required reports to what's most immunologically significant and align with the required HLA typing resolution
- Potential for incorrect donor or recipient samples to be used in a physical or virtual crossmatch
  - This error could cause a potential immunologic reaction between the recipient and potential donor to go undetected and should be a required report

Member Actions

- Histocompatibility Labs
  - Will be required to report critical discrepancies to the OPTN within 24 hours of discovery
  - Upon review of the reported incident, this may involve performing root cause analyses to determine the cause of the HLA critical discrepancy and implementing corrective action plans as needed

What do you think?

- Should the discovering lab or the lab that had the error be responsible for reporting critical HLA discrepancies to the OPTN?
- Is 24 hours an appropriate time frame for the initial report of a critical HLA discrepancy to the OPTN?
- Do you agree with the modified definition of a critical HLA discrepancy?
- Should incorrect donor or recipient samples used for crossmatch be included in required reports?
- Should incorrect donor HLA typings or incorrect candidate HLA antibody test used for virtual crossmatch be included in required reports?

Additional Questions?

- Please Contact Courtney Jett at Courtney.Jett@unos.org

Provide Feedback

Submit public comments on the OPTN website:

- July 31, 2024 – September 24, 2024
- **optn.transplant.hrsa.gov**