Enhanced resource utilization, reduced waste, and expedited transplantation through real-time donor screening for infectious disease

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The decision to donate the organs and tissues of a loved one is a very powerful and personal experience for donor families. It is the responsibility of all organ procurement organizations (OPOs) to facilitate the organ and tissue donation process and ensure stewardship of the donors' gifts. A key step to determining organ/tissue viability is the required screening of potential donors for communicable diseases including human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). Screening is done using the U.S. Food and Drug Administration (FDA) licensed, approved or cleared donor screening tests according to the Organ Procurement and Transplantation Network (OPTN) policy and FDA regulations.

Previously, at Mid America Transplant, screening of tissue donors for infectious diseases was performed in batches using manual testing methods with an average turn-around time of 18 hours 22 minutes. Because tissue procurement must take place within 24 hours of donor death, timing of testing is critical. Historically, and due to time constraints, screening results from infectious disease testing were not available until after tissue procurement had been completed. This workflow was not ideal, resulting in unnecessary utilization of resources, excess waste, and procurement procedures on donors later determined to be ineligible.

Recognizing an opportunity to improve the donor screening process, a cross-functional team at Mid America Transplant implemented a fully automated donor serology testing platform. The FDA approved test system enables real-time screening for the qualitative detection of HBV surface antigen (HBsAg), HBV core antibody (anti-HBc), HCV (anti-HCV), HIV p24 antigen and antibody to HIV-1/HIV-2 (HIV Ag/Ab Combo), and antibody to Human T-Lymphotropic Virus Type I and II (anti-HTLV), on both pre- and post-mortem specimens.

Following implementation of the new testing system, workflow no longer needed batch analysis, improving efficiency by 94.7% with an average turnaround time of 58 minutes from laboratory receipt of specimens to clinical results reporting. Given this remarkably shortened workflow, serology results are now available prior to procurement, significantly transforming the tissue donation process. This includes the ability to only move forward with donation on donors with non-reactive serologies (i.e., identification of infectious diseases that disqualify them as donors). This new process has also been transformative to the organ and tissue donation landscape by opening opportunities for additional organ placement in cases when time can be a limiting factor. This new initiative has increased satisfaction from stakeholders including the donor families, tissue/eye processors and OPO staff. Finally, the new workflow helps to optimize allocation of resources and utilization of tissue/eye donation, as well as laboratory operations.

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