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Clarifying the HOPE Act landscape: The challenge of donors with false-positive HIV results

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To the Editor:

We represent a group of investigators funded by the National Institutes of Health (R01AI120938, U01AI134591, U01AI138897) to conduct a prospective multicenter study of the landscape of HIV-infected (HIV+) donors and two prospective multicenter trials comparing outcomes between HIV+ recipients of HIV+ and non-HIV+ donor kidneys and livers. These clinical trials are ongoing ([NCT02602262](#), [NCT03500315](#), [NCT03734393](#)).

We read with interest the Brief Communication entitled “National landscape of HIV+ to HIV+ kidney and liver transplantation in the United States” by Wilk *et al* of the United Network for Organ Sharing (UNOS).¹ The study utilized data from the Organ Procurement and Transplantation Network (OPTN) database managed by UNOS under a federal contract. The authors concluded that one-year patient and graft survival in HIV+ recipients of HIV+ donors did not deviate from that observed in non-HIV+ donor recipients.

As acknowledged by Wilk *et al*, an important limitation of the study is the inability of OPTN data to accurately identify donors with HIV infection. In their report, HIV+ donors were defined by any report of a positive HIV antibody (Ab), nucleic acid test (NAT), or antigen/antibody combination assay (Ab/Ag).¹ These assays have a low false-positive rate (0.1–0.5%); however, given the number of deceased donors screened annually, we have estimated there should be 50–100 donors with false-positive HIV tests annually in the United States.² Confirmatory testing is not routinely done or reported by the OPTN.

As such, the number of donors that are incorrectly identified as HIV+ in the UNOS cohort is significant.³ Of the 56 donors with organs recovered for transplant under the HOPE Act between March 2016 and December 2018,¹ there were 27 HIV+ kidney donors versus 23 non-HIV+ donors with false-positive HIV test results (46%). Similarly, there were 21 HIV+ liver donors versus 11 non-HIV+ liver donors with false-positive HIV testing (34%). Importantly, according to our data, there were actually no transplants using HIV+ donor organs donated after circulatory death.

Since approximately 40% of the donors labeled as HIV+ by Wilk *et al* were not actually infected with HIV, the comparisons of patient and graft survival between HIV- and HIV+ donor to HIV+ recipient transplantation are inaccurate. Providing transplant outcomes stratified by true HIV+ donor designation is outside the scope of this letter, but it is the primary goal of the NIH-funded HOPE in Action clinical trials, which our group will report on when the appropriate amount of data has been collected.

The Wilk study highlights the need for UNOS to address the issue of donors with false-positive HIV screens, both from a practical and scientific standpoint. OPTN policy requires all increased risk donors have an HIV NAT in combination with either an HIV Ab or HIV

Ag/Ab combination testing.⁴ In practice, all donors regardless of risk designation are currently tested in this way. HIV Ab assays have higher false-positive rates and are no longer recommended by the CDC as first line in diagnostic algorithms. Thus, UNOS might consider eliminating the use of HIV Ab assays or requiring confirmatory testing. The transplant community would also benefit from further guidance on cases where HIV infection is excluded with confirmatory testing prior to organ recovery and whether organs including hearts, lungs, and pancreases from these donors could be allocated outside of HOPE studies. Finally, from a scientific standpoint in order to ensure accurate future analyses, the OPTN should consider adding data elements to identify donors with false-positive HIV test results.

In the current era, all people living with HIV who develop end-stage organ disease should be considered for solid organ transplantation as standard practice. We would emphasize that long-term outcomes of HIV+ transplant recipients have been demonstrated to be comparable to those without HIV.⁵ As the HOPE Act continues to open the door to more potential donors for this patient population, we also hope that it decreases HIV-related stigma in the both transplant and broader community.

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