

EDUCATION CORNER

HIV AND ORGAN DONATION & TRANSPLANTATION

Current Situation

- 10-30% of the human immunodeficiency virus (HIV) infected population, develop chronic kidney disease (CKD) (Lucas et al, 2014).
- This population accounts for about 1.5% of the dialysis population.
- There was a 14-fold increase in prevalence between 1999 and 2010.

The Development of the HOPE Act

- With the ongoing organ shortage, novel donor sources are needed.
- In 1984 & 1988, the National Organ Transplant Act, made the following provision: 42 U.S.C. 274(b) Sect 372(b):
 "...requires the OPTN to adopt and use standards for preventing the acquisition of organs from individuals known to be infected with HIV."
- Based on a study in 2011 (Boyarsky/Segev), it is estimated there is a potential of 500-600 HIV-infected (HIV+) organ donors per year.
- The HIV Organ Policy Equity (HOPE Act) was conceived (Boyarsky/Segev) to revise the National Organ Transplant Act and was supported by dozens of professional medical, transplant, and patient organizations.
- In 2013, president Obama signed the HOPE Act.

Mandates of the HOPE Act

- The Secretary will revise the current regulations, specifically 42 Code of Federal Regulations (CFR) 121.6.
- The Secretary will publish the research criteria for HIV+ to HIV+ transplant.
- The OPTN will revise the standards for the acquisition and transportation of donated HIV infected organs.
- Those regulatory revisions were to be made within two years by November 21, 2015.
- On June 8, 2015, the Final Rule was published with the following regulatory amendment:
 "..., this regulation includes new requirements that organs from individuals infected with HIV may be transplanted only into individuals who are infected with HIV and who are participating in clinical research approved by an institutional review board...in accordance with the research **criteria to be published by the Secretary.**

Requirements for HOPE Act Research Studies

- In November 2015, guidelines were released allowing any center* with an IRB-approved protocol to perform HIV to HIV transplants.
- Several transplant programs plan to conduct studies.
- These scientific studies will be evaluated for standards of quality.

*John Hopkins is NIH funded and is running a national multi-center program of HIV-to-HIV transplants.



References:

- Boyarsky B.J., et al. (2011) Estimating the potential pool of HIV-infected deceased organ donors in the U.S. *American Journal of Transplantation* 11: 1209-1217.
- Boyarsky BJ & Segev DL (2015) From Bench to Bill: How a transplant nuance became one of only 57 laws passed in 2013. *Ann Surg*, Nov 2. [Epub ahead of print]
- Health & Human Services Department, Final Rule (2015) <https://www.federalregister.gov/articles/2015/05/08/2015-11048/organ-procurement-and-transplantation-implementation-of-the-hiv-organ-policy-equity-act>
- Lucas G.M., et al. (2014). Clinical practice guideline for the management of chronic kidney disease in patients Infected with HIV: 2014 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis* 59(9): e96-138.
- National Organ Transplant Act: <https://history.nih.gov/research/downloads/PL98-507.pdf>
- Scientific Registry for Transplant Recipients (SRTR) - www.srtr.org

This inservice is also available on The Alliance blog:

<http://organdonationalliance.org/hiv-organ-donation-transplantation/>

Taken from a webinar presentation by Christine Durand, MD and Dorry Segev, MD (Johns Hopkins Hospital). A special thanks to Dr. Durand and Dr. Segev for their contributions in this inservice.

For info on how to get involved or for resources, please contact [Dr. Durand](#) or [Dr. Segev](#). Phone no. provided on blog.