OPTN Ad Hoc Disease Transmission Advisory Committee
PHS Revisions Workgroup
Meeting Summary
July 8, 2020
Conference Call

Ricardo La Hoz, MD, FACP, FAST, FIDSA, Chair
Lara Danziger-Isakov, MD, MPH, Vice Chair

Introduction

The PHS Revisions Workgroup met via Citrix GoToMeeting teleconference on 07/08/2020 to discuss the following agenda items:

1. Living Donor Specimen Storage
2. Universal Testing Post-Transplant
3. Hepatitis B (HBV) Vaccination
4. Terminology

The following is a summary of the Workgroup's discussions.

1. Living Donor Specimen Storage

The Workgroup discussed the living donor specimen storage portion of the 2020 US Public Health Service Guidelines.

Summary of discussion:

Concerns raised

- This would increase cost of living donor transplant surgeries, which already have very tight margins
- We would need to develop a guidance document on how to store these samples
- Obtaining the specimen would not be difficult, this is already happening for donor-specific antibody (DSA) checks for living donor kidney donation, with the plasma being discarded
- Specimens would only need to be stored for 1-2 years to detect HIV/HBV/HCV, those will be detected long before the 10 years recommended in the guidelines.
- Since living donors only have one recipient, isn't this more academic in terms of finding out if the disease is donor-derived? It won't impact treatment of other recipients as it does with deceased donors
    - OPOs still store specimens for 10 years even if there is only one recipient from a deceased donor

CDC input

- Samples should be stored for 10 years, we have seen the usefulness in emerging diseases and new technology in the past, such as with HIV. Even if this is a longer timeframe than needed for HIV/HBV/HCV, this guideline is intended to reduce risk and increase early detection of all blood borne pathogens
- This was also written into the 2013 PHS guidelines

- This guideline is a significant change in donor screening practices, we're shortening the timeframe for behaviors as well as the number of behaviors, we want to make sure we have archived samples for later testing if needed

Next steps:

UNOS staff will begin drafting policy language for workgroup review.

2. Universal Testing Post-Transplant

The Workgroup discussed the universal testing post-transplant portion of the 2020 US Public Health Service Guidelines.

Summary of discussion:

Concerns raised

- There are now early interventions that can prevent acute infection and graft damage/failure, so early detection is even more important
- Logistical concerns about a short timeframe for recipient follow up, especially 1-year follow up, recommended a broader timeframe in case appointments are rescheduled or outpatient labs are run incorrectly
- Should there be exceptions to 1-year HBV testing for liver recipients if they are surface antibody immune pre-transplant?
    - Antibody levels decrease for the first year or two post-transplant, HBV testing should still be required
- Should we require testing for HBV core and NAT, or just NAT?
    - NAT testing will be more accurate

CDC input

- 4 weeks is the definite minimum in order to reliably detect HBV, and 6 weeks would be the preferred maximum to limit secondary transmission and detect HCV in the acute phase

Proposed changes to policy

- Required universal testing for HIV/HBV/HCV at 4-8 weeks after transplant
- Required HBV testing at 11-13 months after transplant for liver recipients

Next steps:

UNOS staff will begin drafting policy language for workgroup review.

3. Hepatitis B (HBV) Vaccination

The Workgroup discussed the HBV vaccination portion of the 2020 US Public Health Service Guidelines.

Summary of discussion:

Concerns raised

- Policy language needs to be flexible enough to allow patients to receive organ offers even if they have not completed vaccine series
- Some patients don't develop antibodies, and it's especially common if patients are on dialysis
- Information on dosage, frequency, and antibody levels should be in guidance, not policy

- Can be a logistical challenge, especially at larger centers where patients can come from across the country. The center shouldn't be mandated to give the vaccine themselves, just ensure that the patients receive them
- Some dialysis centers don't like programs giving patients vaccines since they can have a positive surface antigen result for a short period of time
- This is not the first preventative treatment with logistical challenges to overcome, and that does not take away from the strong patient health impact

CDC input

- This should be policy, not guidance, it needs to have more strength behind it. This is already a recommended practice

Proposed changes to policy

- Including HBV surface antibody testing in transplant candidate requirements
- Require HBV vaccination, with caveats so that patients are still able to receive organ offers before completing the full series

Next steps:

UNOS staff will begin drafting policy language for workgroup review.

4. Terminology

The Workgroup discussed the terminology portion of the 2020 US Public Health Service Guidelines.

Summary of discussion:

Concerns raised

- The term "increased risk donor" has caused a lot of concern and fear
- Transplant programs still need to tell candidates the risks of accepting a particular organ
- Having a specific term makes communication between OPOs and transplant programs, as well as transplant programs and patients, much easier
    - PAC representative recommended instead having a handout, similar to vaccination handouts, at each transplant evaluation that a patient could be offered a donor associated with certain factors, and that these factors would be disclosed to the patients at time of transplant
    - There are other risks associated with organ donation that we don't have a neat term for, that providers have learned how to contextualize risks associated with donors with lower kidney function
    - OPOs and transplant programs are communicating the individual risk factors already
- Research has shown the label itself leads to a decline in organ acceptance and increase in patient mortality, and we need to shift away from trying to have one term that encompasses many different behaviors or risk factors

CDC input

- The CDC is already developing an informational sheet for patients, and is also looking into creating a video

Proposed changes to policy

- Remove all references to "increased risk donor" in policy language

- Recommend a contextualized discussion between providers and patients, focusing on education around all aspects of end-organ disease and organ donation, not just blood borne pathogens

Next steps:

UNOS staff will begin drafting policy language for workgroup review.

Upcoming Meeting

- July 14, 2020, 2:30 pm EDT, teleconference

Attendance

- **Workgroup Members**
  - Catherine Kling
  - Elisa Gordon
  - Emily Blumberg
  - Gwen McNatt
  - Lara Danziger-Isakov
  - Marian Michaels
  - Nahel Elias
  - Nicole Theodoropoulos
  - R Patrick Wood
  - Regino Gonzalez-Peralta
  - Ricardo La Hoz
  - Sarah Koohmaraie
  - Sridhar Basavaraju
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Courtney Jett
  - Craig Connors
  - Darby Harris
  - Emily Ward
  - Kristine Althaus
  - Leah Slife
  - Michelle Rabold
  - Peter Sokol
  - Shannon Edwards
  - Susan Tlusty
  - Tamika Qualls