

**OPTN Ad Hoc Disease Transmission Advisory Committee
PHS Revisions Workgroup
Meeting Summary
July 2, 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 07/02/2020 to discuss the following agenda items:

1. Informed Consent
2. Living Donor Specimen Storage
3. Hepatitis B Vaccination (Policy vs. Guidance)

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

1. Informed Consent

The workgroup discussed the informed consent portion of the [2020 US Public Health Service Guidelines](#).

Summary of discussion:

Concerns raised

- Providers should still have the same conversations about risks involved with organ acceptance, and that discussion is not limited to blood borne illnesses
- Focus needs to be on pre-transplant education and counseling
- Different behaviors or circumstances carry different levels of risk, ethically we should disclose the risk factor or behavior itself as well as the stats around actual disease transmissions
- Every center has different, and strong, opinions about the education and consent process

CDC input

- Feedback given was that a separate label or separate signed consent makes patients feel uncomfortable or anxious
- Didn't want to be overly prescriptive in discussions between physicians and patients
- Transplant centers should tell patients the specific risk factors of the donors
- The rationale for this change primarily came from transplant hospitals, as the terminology and separate consent process lead to an increased turn down of safe and functional organs

Proposed changes to policy

- It would be a major shift to rethink the requirements for discussion between transplant programs and patients, is it too large of a scope for this policy change?
- Will need large educational component
- Systems change for individual risk factors programmed into DonorNet?

Next steps:

UNOS Staff will begin drafting policy language for review at the next meeting.

2. 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

- Do transplant hospitals have the capacity to store these specimens for ten years? Where would they be kept?
- There is already difficulty with living donor follow ups
- Would specimen storage need to be added to the consent for living donors? Would it need to be a separate consent?
- Would the recovery facility or the transplant hospital keep these specimens? What is practical?
- Does this change the treatment of the recipient in any way?

CDC input

- This was also proposed in the 2013 PHS Guidelines, and the intent is for ten years of storage, not any shorter, as there can be infections detected much later down the road
- By the time disease is detected in a recipient, it is often too late to tell if a living donor was acutely infected at time of donation, if the donor is still alive or can be contacted

Proposed changes to policy

- Specimens to be drawn at time of donation
- Supportive of the idea, need to think through logistical concerns

Next steps:

UNOS Staff will begin drafting policy language for review at the next meeting.

3. Hepatitis B Vaccination (Policy vs. Guidance)

The workgroup discussed the Hepatitis B (HBV) vaccination portion of the [2020 US Public Health Service Guidelines](#).

Summary of discussion:

Concerns raised

- Are we requiring that a patient have their surface antigen checked, be educated about vaccination, and offer vaccination? Or are we requiring vaccination?
- What about if this is a pediatric patient and the parents are anti-vax?
- Who is responsible for giving the vaccine, the transplant hospital or the primary care physician?
 - Can be a logistical concern, especially for non-local patients

CDC input

- This was intended to be policy, not guidance

Proposed changes to policy

- All donors need to be tested for HBV surface antigen and vaccinated against HBV, with caveats so that recipients do not have to delay acceptance of either deceased donor or living donor organs

Next steps:

UNOS Staff will begin drafting policy language for review at the next meeting.

Upcoming Meetings

- July 8, 2020, 3pm EDT, Teleconference
- July 14, 2020, 2:30 pm EDT, Teleconference