|  |
| --- |
| **PROCEDURE TITLE:** The use of hepatitis C positive donor kidney and/or pancreas in hepatitis C negative recipients |
| **APPLICABLE FACILITIES:**[ ] EHC [ ] EDH [ ] EHH [ ] EHI [ ] EHN [ ] EJCH [ ] ELTAC [ ] ESJH[x] EUH [x] EUHM [ ] EUHS [ ] EUOSH [ ] EWWH [ ] RJV-ERH [ ] RJV-ESOP [ ] TEC/ESA |
| **EFFECTIVE DATE:** 01/15/2020 | **ORIGINATION DATE:** 12/18/2019 |

**SCOPE:** The Emory Transplant Center Kidney and Pancreas Transplant program and patients eligible to receive HCV positive donor kidney and/or pancreas organs

**PURPOSE:** To ensure appropriate identification, education and consenting of patients to receive kidney and/or pancreas organs from a Hepatitis C positive organ donor

**PROCEDURE:**

***New evaluation patients on Day 1 will proceed as per current procedures with the following exception:***

1) *New evaluation patients or currently listed patients in* ***outreach clinics*** may receive education and informed consent during the new consultation or follow up visit. The informed consent would cover receiving a kidney and/or a pancreas from a donor with hepatitis C and then receiving hepatitis C treatment after transplant including the risk of treatment failure.

2) The transplant staff can provide patients the consent forms for signature.

3) Transplant physician may document in the medical record that the patient was given education and informed consent regarding receiving a kidney and/or a pancreas from a donor with hepatitis C and its treatment.

***Day 2 operations will have the following changes:***

1) Patients may receive education and informed consent during the surgical consultation. The informed consent would cover receiving a kidney and/or a pancreas from a donor with hepatitis C and then receiving hepatitis C treatment after transplant including the risk of treatment failure.

2) The transplant staff can provide patients the consent forms for signature (as is the current practice for other Day 2 consent forms, and the current hepatitis C video should not be shown until a new video has been created).

3) Transplant surgeons may document in the surgery consult note that the patient was given education and informed consent regarding receiving a kidney and/or a pancreas from a donor with hepatitis C and its treatment.

***Selection conference will have the following changes:***

1) The transplant physician will document in the conference note that the patient has received education and whether or not after the patient consents to undergo transplantation and treatment for a hepatitis C positive donor kidney and/or a pancreas.

 ***Transplant nephrology waitlist re-evaluation will have the following changes:***

1) Patients may receive education and informed consent during the waitlist re-evaluation visit. The informed consent would cover receiving a kidney and/or a pancreas from a donor with hepatitis C and then receiving hepatitis C treatment after transplant including the risk of treatment failure.

2) The transplant nephrologist may document in the waitlist re-evaluation note that the patient was given education and informed consent regarding receiving a kidney and/or pancreas from a donor with hepatitis C and its treatment.

3) The transplant nephrologist and/or transplant team member can provide patients the consent forms for signature.

4) A waitlist team member may enter the patient preference for hepatitis C donors in UNET based on the patient’s consent form.

5) Waitlist patients who have not yet undergone education and consent for hepatitis C positive kidney and/or pancreas will not be offered hepatitis C positive organs.

***The Organ Procurement Program changes:***

1) The coordinator for the OPP will read the Public Health Service (PHS) presumed infected script currently in use for any patient offered a hepatitis C positive kidney and/or pancreas.

***Transplant Operative Note changes:***

1) Surgeons will document in the operative note that the patient will almost certainly contract hepatitis C by accepting a kidney and/or a pancreas from an HCV positive donor, that treatment will be given and that there is a risk of treatment failure.

***Post-transplant management changes:***

1) Post-transplant management will follow the guidelines of the hepatitis C positive organ protocol.

2) The post-transplant coordinator will order PHS increased risk labs per current protocol.

**RELATED DOCUMENTS AND LINKS:** Hepatitis C protocol, Hepatitis B protocol, Kidney and Pancreas Recipient Evaluation Procedure, HCV kidney/pancreas education pamphlet, HCV Positive Organ to Negative Recipient Consent,

**DEFINITIONS:**

**REFERENCES AND SOURCES OF EVIDENCE:**

Mavyret [package insert]. Chicago, IL: AbbVie; 2018.

Epclusa [package insert]. Foster City, CA: Gilead; 2017.

La Hoz et al. AJT 2019;19:3058-70.

Durand et al. AJT 2019;19:2969-70.

De Vera et al. AJT 2019;18:2451-6.

Livitsky et al.AJT 2017; 17: 2790–2802.

Colombo M et al. Ann Intern Med. 2017;166:109-117.

**KEY WORDS:** Hepatitis C, kidney transplant, pancreas transplant, HCV NAT positive