

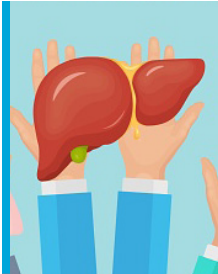
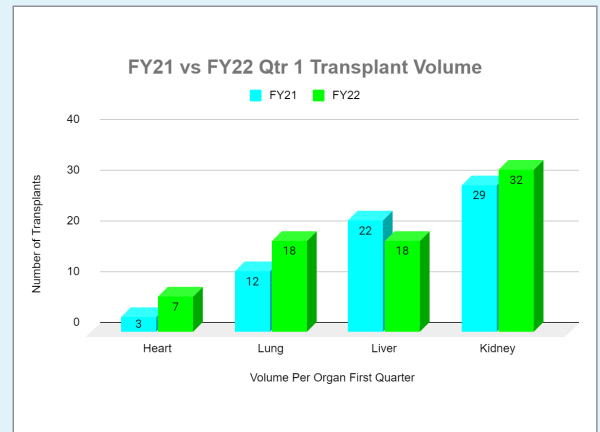


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Transplant by the Numbers

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Transplant Hot Topics

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Due to the shortage in supply of donor liver organs, thousands of patients with advanced liver disease die each year waiting for liver transplant. As a transplant community, we continue to look for innovative ways to improve access for our patients needing liver transplant. Organs infected with hepatitis C virus (HCV) were previously discarded because of the high risk for reactivation causing graft failure after transplant. However, recent advancements in HCV treatment has provided hope with a cure for those with chronic HCV infection and advanced liver disease.

These direct acting antiviral therapy for HCV have also shown to be safe and effective after transplant as well. With the rise in drug overdose deaths from the opioid epidemic, there has been an increase in young, otherwise healthy organs with HCV infection. Increasing use of young viremic donors can provide many patients with access to life-saving treatment with liver transplantation. Early direct acting antiviral therapy within the first month after liver transplant has shown to avoid recurrence or complications related to HCV infection after transplant. In addition, our team at Baylor St. Luke's has shown that patients awaiting transplant who accepted a viremic, otherwise healthy HCV positive organ had comparable or better outcomes than other organs. We have had a successful experience using HCV positive organs at Baylor St. Luke's, providing many patients who would not have access to transplant, the opportunity to have life-saving treatment. Over the last few years, we have also seen a similar shift in expanding donor organs for other solid organ transplants, including kidney, heart and lung transplant.

References:

- Cholankeril et al. Increasing Trends in Transplantation of HCV-Positive Livers into Uninfected Recipients. *Clinical Gastroenterology and Hepatology*. 2018.
- Cholankeril et al. Expanding Donor Pool for Liver Transplantation by Utilizing Hepatitis C Virus-Infected Donors for Uninfected Recipients. *Hepatology*. 2018
- Cholankeril et al. Direct-Acting Antiviral Therapy and Improvement in Graft Survival of Hepatitis C Liver Transplant Recipients.



RESEARCH

RESEARCH NEWS: THE IMPLANTABLE BIOARTIFICIAL KIDNEY

N. THAO N. GALVÁN MD, MPH, FACS

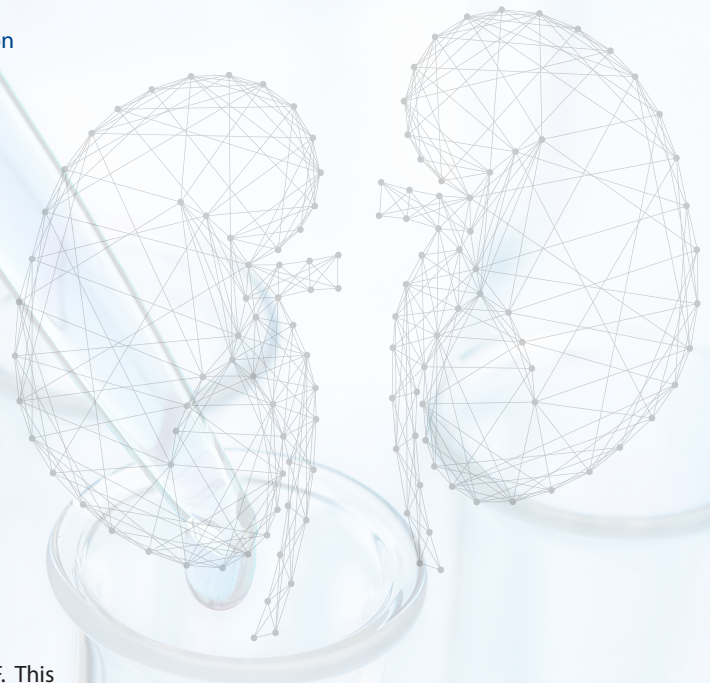
Assistant Professor of Surgery, Division of Abdominal Transplantation
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End stage renal disease is one of the top ten leading causes of death in the world according to the World Health Organization. It affects 37 million people in the US alone. Kidney transplantation is the gold standard in treatment, and yet there are never enough organs to treat the number of patients on the waitlist. As of this submission, over 90,000 patients are on the waitlist for a kidney transplant in the US. In an effort to address this profound mismatch in organs available for patients waiting, our attention focuses on a more immediate solution.

Researchers at UCSF have developed an implantable artificial kidney with silicon nanotechnology and living kidney cells that will be powered by a patient's own heart.

An implantable, dialysate-free bioartificial kidney is undergoing preclinical safety trials necessary before testing in humans. This will take place in part at Baylor College of Medicine under the direction of Dr. N. Thao Galvan in collaboration with UCSF. This innovation is remarkable in the barriers it overcomes. Dialysis as it stands requires a large filter within massive machinery, power for energy-intensive pumps, water, and liters of dialysate for each session. The implantable bioartificial kidney is compact using membranes that mimic the slit-shaped pores of podocytes and relies on the cardiovascular system pressure to filter its own blood. It pushes this blood through living renal tubule cells in the biochamber that provide cellular metabolism and filtration. If successful, this device may effectively treat end stage renal disease and/or bridge to kidney transplantation.

Our collaboration will involve in vivo studies to be implemented over two phases, a preclinical and a clinical phase, with the goal of seeing the implantable bioartificial kidney as a bridge to transplantation or destination therapy for those patients ineligible for kidney transplant. This will be trialed under expanded access through the FDA as a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical device.



PREGNANCY IN ORGAN TRANSPLANTATION

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Organ transplantation has now become the standard of care treatment for patients with end stage organ disease, and transplant recipients have benefited from improving survival over time. In 2020, there were over 39,000 transplants performed in the United States and approximately 37% were women. During the five year time period of 2015-2020, there were over 8000 females of child bearing age (18-45) who received organ transplants. For many of these women, their end-organ disease would have played a role in anovulation and infertility. Organ transplantation, especially in liver transplantation, can help to restore hormone production and in many cases ovulation and fertility in women.

Pregnancy is possible in patients who are post-transplant, but it is not without risks to both the mother and the fetus. In all women of child bearing age, counseling should be done at the time of transplant evaluation as a pregnancy early after transplant would pose high risks for rejection, organ failure and death to the mothers. We often refer our transplant recipients to Gynecology for a discussion on birth control options shortly after transplant. In most women, IUD's are safe though many options exist. Family planning and counseling should be part of the discussions with the patients and their doctors to ensure timing that is safest for both the mother and infant.

The first successful pregnancy in an organ transplant recipient was in 1958 in a patient after renal transplant. Since that time more and more women have had successful pregnancies after all types of organ transplants including liver, kidney, heart and lung transplant recipients. The pregnancies must be carefully planned with consultations involving the transplant team, high risk maternal-fetal medicine specialists, and other disciplines based on the medical history of the patient. This may involve changing immunosuppression medications that would potentially be harmful to the fetus. With careful planning and monitoring, successful pregnancies are possible. Studies have shown the best chance for a successful pregnancy is with healthy allograft function and usually stable doses of immunosuppression medications for at least 1 year post transplant.

The National Transplantation Pregnancy Registry, was established in 1991 at Thomas Jefferson University in Philadelphia, and is an ongoing research study focused on the effects of pregnancy on transplant recipients and the effects of immunosuppressive medication on fertility and pregnancy outcomes. In 2016, the registry expanded to include worldwide participation and was renamed Transplant Pregnancy Registry International (TPRI). In the 2019 TPRI Annual Report, the live birth rates in both kidney and liver transplant recipients ranged from 70-75%. The heart and lung transplant recipients live birth rates were lower, ranging from 60-70%. Notably, most of the infants were born small at less than 3000 g, born prematurely at less than 38 weeks, with 40-50% delivered by C section, with a high rate of maternal and fetal ICU admissions. The organ rejection rates were low, ranging from 2-14% with the highest rates in the heart and lung transplant recipients. The pregnancies frequently had complications of diabetes, hypertension and pre-eclampsia warranting close follow up by the medical teams. Organ failure within 2 years of delivery for all organs ranged from 2-7.5% with the highest loss seen in lung transplant recipients. The average age of the maternal death ranged from 7.5 years post-delivery in the lung transplant recipients, up to 17.5 years in the kidney transplant recipients. More than half of these women have chosen to breast feed their infants based on data from the registry. Of note, pregnancies fathered by male organ transplant recipients had similar outcomes overall when compared to non-transplant pregnancies, with infants born at greater than 38.7 weeks with slightly larger infants and a birth defect incidence of 2.4 to 3.8%.

Having your own family after transplant is possible. Because of the high risks involved for both the mother and the infant, transplant recipients who seek pregnancy need consultations with high risk maternal-fetal medicine specialists, transplant specialists and other medical specialists. With careful planning and specialized care, successful pregnancies are possible.

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Quality Corner: UNOS RISK LABS AND TRANSPLANTATION

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The US Public Health Service (PHS) issued new Guidelines in June, 2020 about donor behaviors associated with risk of exposure to infectious disease. Since 2013, transplant centers have been required to identify donors with certain behaviors as “increased risk” donors. Because of today’s very sophisticated testing, the Centers for Disease Control (CDC) have found that there is less than 1 chance in 1,000,000 that a donor could have an infectious disease that went undetected. As a result, the CDC recommended that transplant centers stop using the term “increased risk”, as it tended to unduly frighten candidates and had the potential to contribute to discard of functionally sound organs, and increase the possibility of a candidate’s death while waiting for another organ. The Organ Procurement and Transplantation Network (OPTN) updated its requirements in March, 2021 to correspond with the PHS Guidance. Previously, post-transplant infectious disease testing was mandated only for recipients who received organs from donors who exhibited specific behaviors. After March, 2021, transplant centers are now required by policy to perform infectious disease testing on ALL recipients after they arrive at the hospital for their transplant, but before the first stitch of their new organ. The testing includes multiple tests for Hepatitis B (HBV), Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV). In addition, at about one month after transplant, ALL recipients must be tested again for HBV, HCV, and HIV (the testing must occur between 28 - 56 days after transplant). Liver transplant recipients must be tested once again for HBV at one year.

PRE-TRANSPLANT

- 1) HIV using a CDC recommended laboratory HIV testing algorithm ((HIV 1Ag 1 / 2 AB)
- 2) Hepatitis B surface antigen (HBsAg)
- 3) Hepatitis B core antibody (total anti-HBc)
- 4) Hepatitis B surface antibody (HBsAb)
- 5) Hepatitis C antibody (anti-HCV)
- 6) Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)

POST TRANSPLANT TESTING AT 28-56 DAYS

	1 month (28 – 56 days)	12 months (335 days but no later than 395 days post-transplant)
HIV ribonucleic acid (RNA) by nucleic acid test (NAT)	X	
HCV ribonucleic acid (RNA) by nucleic acid test (NAT)	X	
HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT)	X	X Liver recipients only

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Staff Spotlight: Shannon Cook, RN, BSN, CCTC



I am Shannon Cook and I am a pre-transplant Liver Transplant Coordinator with the Division of Abdominal Transplant at Baylor St. Luke's Medical Center.

As a pre-transplant Liver Transplant Coordinator, I assist the patient from the time he or she is referred for transplant until the day the patient receives their life saving liver transplant. I have been a transplant coordinator since 2000. Seeing a very sick patient receive a transplant and become healthy again has been extremely fulfilling for me. The liver transplant team is exceptional and I am very fortunate to be a part of such a great group.

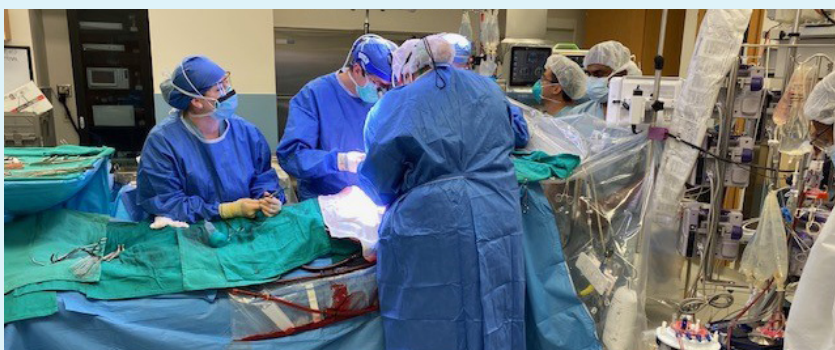
I chose to become a transplant coordinator because I also received a life saving transplant and I have personally seen the impact a transplant can have on a person's life. I received a kidney transplant over 30 years ago from my sister after being on dialysis for approximately three years. I have lived a fairly normal life since receiving my transplant and was able to become a mom to my amazing son.

I am so thankful to my sister (pictured, on left), as well as all donors and donor families for the amazing gift of a transplant and a new beginning. Transplant would not be possible without them. Outside of work, I enjoy traveling, boating, and spending time with my husband, son, and pets (a Corgi and 4 rescue cats).

Patient Spotlight: A Word from Our Patients

COVID-19 PATIENT WITH IRREVERSIBLE LUNG DAMAGE RECOVERS AFTER DOUBLE LUNG TRANSPLANT

Read about it here: <https://www.stlukeshealth.org/newsroom/covid-19-patient-irreversible-lung-damage-recovers-after-double-lung-transplant>



Save the Date

Transplant Clinical Practice Council Hepatology & Liver Transplant

NOVEMBER 16, 2021
5:30 - 6:30 PM VIA ZOOM

- Overview of Cirrhosis and current medical indications for referral for liver transplant
- Acute Chronic Liver Disease and High Risk for Mortality
- Hepatocellular carcinoma, criteria for surgical resection vs. liver transplantation
- Use of increased risk donors to maximize the organ pool

Registration Information to come at a later date.
Please share with your medical staff, nurses and APPs

Upcoming Events

▶ **Transplant Round Up**
MARCH 23, 2022

▶ **Transplant Grand Rounds**
MONTHLY

[https://CommonSpirit-VirtualCareAnywhere.zoom.us/meeting/register/tJAtceCspjMjHtHIVjPjUinsN-3M1m8EpZfdss](https://CommonSpirit-VirtualCareAnywhere.zoom.us/join/https://CommonSpirit-VirtualCareAnywhere.zoom.us/meeting/register/tJAtceCspjMjHtHIVjPjUinsN-3M1m8EpZfdss)

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